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NATIONAL INSTITUTE ON AGING
INTRAMURAL RESEARCH PROGRAM



**Healthy Aging in Neighborhoods of Diversity across the Life Span
(HANDLS)**

Wave 3 Protocol

Principal Investigator

Michele K. Evans, MD

Lead Associate Investigator

Alan B. Zonderman, PhD

National Institute on Aging
Laboratory of Epidemiology & Population Sciences
Health Disparities Research Section
NIH Biomedical Research Center
251 Bayview Boulevard
Baltimore, MD 21224

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1.0.0 HANDLS Study Staff Roster

Medical Advisory Investigator: Michele K. Evans, MD
Lead Associate Investigator: Alan B. Zonderman, PhD

Associate Investigator(s):

Deidra C. Crews, MD – Johns Hopkins Hospital, Division of Nephrology
1830 East Monument Street, 4th Floor
Baltimore, MD 21205
Phone: 410-955-5268

Ngozi Ejiogu, MD – NIH-NIA-LEPS
Biomedical Research Center NIA, 251 Bayview Blvd
Baltimore, MD 21224
Phone: 410-558-8627

Marie T. Fanelli Kuczmarski, PhD, R.D., L.D.N.
University of Delaware, Department of Health, Nutrition and Exercise Sciences
303E Willard Hall
Newark, DE 19716
Phone: 410-995-3639

Michael Nalls, PhD – NIH-NIA-LNG
35 Convent Dr
Bethesda, MD 20892
Phone: 301-451-3831

HANDLS Sub-studies Collaborating Institutions:

HANDLS Scan Sub-study
University of Maryland Baltimore – FWA00007145

PI: Leslie Katzel, MD, PhD
Associate Professor, Department of Medicine
University of Maryland Medical Center
22 S. Greene St.
Baltimore, MD 21201-1595
Email: lkatzel@grecc.umaryland.edu
Phone: 410-605-7185

University of Maryland Baltimore County – FWA00000069

PI: Shari Waldstein, PhD
Professor, Department of Psychology
University of Maryland, Baltimore County

Adjunct Professor of Medicine
University of Maryland School of Medicine
Affiliated Research Scientist
Geriatric Research Education & Clinical Center
Department of Psychology
University of Maryland, Baltimore County
1000 Hilltop Circle
Baltimore, MD 21250
Email: waldstei@umbc.edu
Phone: 410-455-2374

Subjective Experience of Diabetes Sub-study
University of Maryland Baltimore County – FWA00000069

PI: J. Kevin Eckert, PhD
Professor and Chair, Department of Sociology and Anthropology
Adjunct Professor, Epidemiology and Preventive Medicine
1000 Hilltop Circle
Baltimore, MD 21250
Email: Eckert@umbc.edu
Phone: 410-455-5698

Circadian Rhythm Sub-study
Rensselaer Polytechnic Institute – FWA00009470

PI: Mariana Figueiro, PhD
Program Director
Associate Professor
Rensselaer Polytechnic Institute
Lighting Research Center
Troy, NY 12180
Email: figuem@rpi.edu
Phone: 518-687-7142

Other Collaborating Institutions:

Johns Hopkins Medical Institutions - FWA00005752

PI: Deidra Crews – Listed above under Associate Investigator

PI: Lee Peterlin, MD
Associate Professor of Neurology
Director of Headache Research
The Johns Hopkins Bayview Medical Ctr
301 Bldg, Suite 2100

4940 Eastern Avenue
Baltimore, MD 21224
Email: lpeterlin@jhmi.edu
Phone: 410-550-2243

PI: Roland Thorpe, PhD
Associate Scientist
Department of Health Policy and Management
624 N. Broadway Suite 309
Email: rthorpe@jhsph.edu
Phone: 443-287-5297

Massachusetts General Hospital - FWA00003136

PI: Ravi Thadhani, MD, PhD
Professor of Medicine
Division of Nephrology
55 Fruit Street, Bulfinch 127
Boston, MA 02114
Email: thadhani.ravi@mgh.harvard.edu
Phone: 617-724-1207

US Department of Housing and Urban Development

PI: Ron E. Wilson
Social Science Analyst
Office of Policy Development and Research
Department of Housing and Urban Development
451 7th Street SW, Room 8126
Washington, DC 20410
Email: Ronald.E.Wilson@hud.gov
Phone: 202-402-5848

University of Delaware - FWA00004379

PI: Marie T. Fanelli Kuczmarski, PhD, R.D., L.D.N.
Associate Investigator - HANDLS (listed above)
Professor, Behavioral Health & Nutrition
University of Delaware, Department of Health, Nutrition and Exercise Sciences 303E Willard Hall Newark, DE 19716
Email: MFK@udel.edu
Phone: 410-995-3639

Contractual Arrangements – University of Delaware

1. Type of Contract/ Agreement:	2. Sources of funding:
<p>Agreement Type:</p> <p><input checked="" type="checkbox"/> Contract</p> <p><input type="checkbox"/> Subcontract</p> <p><input type="checkbox"/> Technology Transfer Agreement</p> <p><input type="checkbox"/> Data Use Agreement (DUA)</p> <p><input type="checkbox"/> Material Transfer Agreement (MTA)</p> <p><input type="checkbox"/> Cooperative Research and Development Agreement (CRADA)</p> <p><input type="checkbox"/> Memorandum of Understanding (MOU)</p> <p><input type="checkbox"/> Memorandum of Agreement (MOA)</p> <p><input type="checkbox"/> Letter of Agreement</p> <p><input type="checkbox"/> Confidential Disclosure Agreement</p> <p><input type="checkbox"/> If other; then specify: <u>IRB Authorization Agreement</u></p> <p>Agreement Start Date: 2005</p> <p>Agreement Expiration Date: upon completion of project</p> <p>Have funds been awarded?</p> <p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> Pending <input type="checkbox"/> No</p>	<p><input checked="" type="checkbox"/> Institute/Department/Program Funds</p> <p><input type="checkbox"/> Another NIH Institute</p> <p><input type="checkbox"/> Another Federal Agency</p> <p><input type="checkbox"/> Foundation for the National Institutes of Health (FNIH)</p> <p><input type="checkbox"/> Industry</p> <p><input type="checkbox"/> Other Private Entity</p> <p><input type="checkbox"/> Other, specify: _____</p> <p>Name of Funder/s and/ or Sponsor/s: _____ _____ _____</p>

2.0.0 Statement of Compliance

The HANDLS study will be conducted in accordance with the design and specific provisions of this IRB-approved protocol, in accordance with the ethical principles that have their origin in the Declaration of Helsinki, the requirements set forth in the US code of Federal Regulation applicable to clinical studies (45 CFR 46, parts A through D) concerning informed consent and IRB regulations; and in compliance with the International Conference on Harmonization's guidelines for Good Clinical Practices (ICH GCP). The Principal Investigator will assure that no deviation from, or changes to the protocol will take place without prior agreement from the sponsor and documented approval from the IRB, except where necessary to eliminate an immediate hazard(s) to the study participants. The Principal Investigator will promptly report to the IRB and the sponsor any changes in research activity and all unanticipated problems involving risk to human subjects, or others.

3.0.0 List of Abbreviations

HANDLS.....	Healthy Aging in Neighborhoods of Diversity across the Life Span
MRVs.....	Medical Research Vehicles
SES	socioeconomic status
MRI	magnetic resonance imaging
DXA.....	Dual-energy X-ray absorptiometry
DNA	deoxyribonucleic acid
AA	African American
DTI.....	diffusion tensor imaging
ADC	apparent diffusion coefficient
LRC	Lighting Research Center at Rensselaer Polytechnic Institute
SOP	Standard Operating Procedures
SSB	single strand breaks
DRC.....	DNA repair capacity
SNP	single nucleotide polymorphism
GWAS.....	genome wide association study
COGENT	Continental Origins and Genetic Epidemiology Network
CARe.....	Candidate gene Association Resource consortium
NHANES.....	The National Health and Nutrition Examination Survey
CKD	chronic kidney disease
ESRD.....	end stage renal disease
KIM	1 kidney injury molecule-1
ASPIRES	Assessment of Spirituality and Religious Sentiments
FA.....	fractional anisotropy
GM	gray matter
WM	white matter
T2DM.....	Type 2 Diabetes Mellitus
UMBC	University of Maryland Baltimore County
MINI	McGill Illness Narrative Interview
HIV.....	human immunodeficiency virus
FTA.....	fast technology for analysis
mRNA	messenger ribonucleic acid
AMPM.....	Automated Multiple Pass Method
BVRT	Benton Visual Retention Test
REALM	Rapid Estimate of Adult Literacy
TOFHLA	Test of Functional Health Literacy in Adults
WRAT	Wide Range Achievement Test
IVA	Instant Vertebral Assessment
mrem	millirem
ATM	automated teller machine
FDA.....	Food and Drug Administration
NIA.....	National Institute on Aging
NIH	National Institutes of Health
OHRP.....	Office of Human Research Protection

4.0.0 Protocol Summary

Healthy Aging in Neighborhoods of Diversity across the Life Span (HANDLS) – Wave 3

Short Title: HANDLS

Conducted by: National Institute on Aging, Intramural Research Program,
Laboratory of Epidemiology and Population Sciences,
Health Disparities Research Section

Principal Investigator: Michele K. Evans, M.D.
p: 410-558-8573 email: EvansM@grc.nia.nih.gov

Lead Associate Investigator: Alan B. Zonderman, Ph.D
p: 410-558-8280 email: zondermana@mail.nih.gov

Study Coordinator: Jennifer H. Norbeck, MSW, CCRC
p: 410-558-8622 email: norbeckj@mail.nih.gov

Associate Investigators: Deidra C. Crews, MD – Johns Hopkins Hospital, Division of
Nephrology 1830 East Monument Street, 4th Floor Baltimore,
MD 21205 Phone: 410-955-5268

Ngozi Ejiogu, MD – NIH-NIA-LEPS, 5600 Nathan Shock Dr.,
Box 6 Baltimore, MD 21224 Phone: 410-558-8627

Marie T. Fanelli Kuczmarski, PhD, R.D., L.D.N. – University
of Delaware, Department of Health, Nutrition and Exercise
Sciences 303E Willard Hall Newark, DE 19716
Phone: 410-995-3639

Michael Nalls, PhD – NIH-NIA-LNG, 35 Convent Dr.,
Bethesda, MD 20892 Phone: 301-451-3831

Sample Size: 3720

Accrual Ceiling: 4000

Study Population: The baseline HANDLS sample consists of 3720 community-dwelling African American and white adults aged 30-64. Participants were drawn from 13 neighborhoods (groups of contiguous census tracts) in Baltimore City, sampling

representatively across a wide range of socioeconomic and income circumstances.

Accrual Period: 2004-2009

Study Design: The heuristic study design is a factorial cross of four factors: age, sex, race, and SES with approximately equal numbers of subjects per “cell” (Figure 2 on page 23). HANDLS is planned as a 20-year longitudinal study of the 3720 individuals accrued (Figure 3 on page 23). Using our mobile medical research vehicles, we are revisiting each census tract for 2-3 months over the next 3 years.

Study Duration: Start Date: 2004; End Date: 2024

Primary Objective: The primary objective of HANDLS is to conduct a longitudinal study of minority health, aging, and health disparities focused on investigating the differential influences of race and socioeconomic status on health in an urban population.

5.0.0 Précis

The Healthy Aging in Neighborhoods of Diversity across the Life Span (HANDLS) study is an interdisciplinary, community-based, prospective longitudinal epidemiologic study examining the influences of race and socioeconomic status (SES) on the development of age-related health disparities among socioeconomically diverse African Americans and whites in Baltimore. This study investigates whether health disparities develop or persist due to differences in SES, differences in race, or their interaction. Planned as a 20-year longitudinal study, HANDLS is unique because it assesses physical parameters as well as evaluating genetic, biologic, demographic, and psychosocial parameters of African American and white participants over a wide range of socioeconomic statuses. HANDLS also employs novel research tools, mobile medical research vehicles, in hopes of improving participation rates and retention among non-traditional research participants. The domains of the HANDLS study include: nutrition, cognition, biologic biomarkers, body composition and bone quality, physical function and performance, psychology, genomics, neighborhood environment and cardiovascular disease. Utilizing data from these study domains will facilitate an understanding of selected underlying factors of persistent black-white health disparities in overall longevity, cardiovascular disease, and cognitive decline.

HANDLS recruited a fixed cohort as an area probability sample of Baltimore City from August 2004 through November 2009 as Wave 1 (Figure 1). HANDLS Wave 2 entitled *The*

Association of Personality and Socioeconomic status with Health Status – An Interim Follow-up Study began in June 2006 under a separate protocol. It was designed as a follow-up telephone interview approximately 18 months after the initial examination (Wave 1) was complete. Wave 2 provided interim contact with study participants, and important interim information regarding their health. The current protocol outlines Wave 3, the first follow-up examination and participants' second visit to our mobile Medical Research Vehicles (MRVs). Planned as a follow-up after 3-4 years, Wave 3 consists of health examinations, a telephone dietary-recall interview, renal function assessments, and optional studies of circadian rhythm, structural MRIs, and an evaluation of the subjective experience of diabetes mellitus.

6.0.0 Background and Scientific Rationale

There are well-documented differences in health status among groups defined by age, race, ethnicity, and socioeconomic status (SES). Over the past decade or so, evidence from cross-sectional studies and nationally representative follow-ups suggests that there are persistent disparities among African Americans and other minority groups compared to Whites in morbidity¹⁻¹⁶ and mortality.^{15,17-21} This is particularly evident in the steadily growing divide between well-educated white men and women and less educated African Americans.²² Double jeopardy describes the constellation of health disparities conferred by old age and membership in a minority group.²³ Evidence suggests that there are unique disadvantages conferred by the combination of old age and minority status,^{1-7,9,11-19,23-27} but the extent to which minority status is a direct cause of the disadvantage is unknown. Race, ethnicity, and SES are inextricably confounded in many studies. Membership in a minority group may be an indicator of the combinations of other effects such as low income, poor education, environmental exposure to toxic compounds, and lack of occupational opportunities.

Independent of the effects of race and ethnicity, SES accounts for differences in the functional status associated with chronic disease, but has only a small role in predicting prevalence of chronic disease.¹⁶ Further complicating this relationship, physicians' assessments and treatment differ by race and sex.^{24,28} Addressing these disparities in health status requires data about the differences in risks for chronic disease associated with race, ethnicity, and SES in all groups regardless of their majority or minority standing.

The scientific objectives of HANDLS are to establish a single-site prospective longitudinal epidemiologic study of health disparities in socioeconomically diverse African Americans and whites residing in the city of Baltimore. Specifically, we designed HANDLS to disentangle the effects of race and SES on risk factors for morbidity and mortality, to examine the incidence and progression of pre-clinical disease, and to follow-up the development and persistence of health disparities, longitudinal health status, and health risks. The mechanisms or biologic and molecular pathways through which the health and longevity trajectories of individuals in American society are influenced are unknown at this time.

The present protocol focuses on predictors of change in cardiovascular function and fitness, risks for cerebrovascular conditions such as stroke, vascular dementia, and carotid

stenosis, renal function, and pathological cognitive decline. We chose these specific areas as representing the health issues that are among the most prevalent, but least understood, in African Americans and low SES urban dwelling whites who have health burdens similar to African Americans. Specifically, we will measure heart function by echocardiogram, muscle strength by grip strength, chair stand and single leg stand exercises, body composition by dual photon x-ray absorptiometry (DXA), cognitive performance with cognitive and neuropsychological tests, and neuroimaging parameters by structural MRI.

We assess each of these areas by separate procedures for which we will investigate cross-sectional differences and longitudinal change within this sample and by comparison with other samples, particularly the National Health and Nutrition Examination Studies and other studies with which this study shares many procedures and tests. We will combine these measures in various ways to examine the risks for pathological outcomes such as stroke, dementia, and loss of functional independence.

7.0.0 Study Objectives

The primary objective of HANDLS is to conduct a longitudinal study of minority health and health disparities focused on investigating the differential influences of race and socioeconomic status on health in an urban population.

The scientific research questions for this interdisciplinary epidemiologic study of minority health and health disparities are:

- Do race and SES influence health disparities independently or do they interact with several factors (race, environmental or biologic factors, and cultural or lifestyle practices)?
- What is the influence of SES and race on age-related declines in function in an urban population?
- What is the influence of SES and race on the incidence and natural history of age-related disease?
- Are there early biomarkers of age-related health disparities that may enhance our ability to prevent or ameliorate the severity of these diseases?

For specific systems we will test the following hypotheses during Wave 3 of HANDLS:

Cardiovascular

- There will be significantly greater decline in cardiovascular health status as a function of SES and race independent of the effects of age in both men and women
- For example, left ventricular mass, an important cardiac risk factor, is greater in African Americans than whites and is greater in African Americans of lower SES as compared to age-matched African Americans with higher SES, in both men and women

Body Composition and Bone Quality – Compared to white adults of comparable age, African Americans have:

- A higher proportion of fat to lean mass of the total body, trunk and extremities, and greater odds of meeting DXA-defined criteria for sarcopenia and sarcopenic obesity
- Faster loss of lean mass, greater accumulation of fat mass and greater increase in the proportion of fat to lean mass of the total body, trunk and extremities, and greater risk of transition to sarcopenia and sarcopenic obesity
- Faster and earlier decline in bone density
- These associations are correlated with, and perhaps mediated by, differences in health habits such as nutrition, physical activity, and alcohol consumption

Cognition – The rates of decline of various cognitive abilities will be the same in all groups regardless of race, ethnicity, or SES.

Muscle Strength

- African Americans have the same trajectory of muscle loss as other ethnic or racial groups after accounting for differences in occupational history, nutrition, and body mass and composition
- All ethnic and racial groups will show the same relationships among changes in muscle strength, physical activity, and cardiovascular fitness regardless of socioeconomic factors, nutrition, and comorbid conditions such as diabetes
- The greater strength reductions at older ages among lower SES individuals will be attributable to their greater severity of chronic diseases

Covariates. Other variables such as nutrition, environment and neighborhood effects, genetic make-up, family history, activity level, access to health care, prevalent medical, dental, psychiatric conditions, caregiving status, renal function oxidative stress, and DNA repair capacity may modulate the effects of SES and race on cardiovascular, musculoskeletal, and cognitive functioning. For example:

- *Nutritional intake assessed by two 24-hour dietary recalls* will examine the effects of race socioeconomic status (SES) on nutritional status and identify nutritional factors that may contribute to health disparity in cardiovascular and cerebrovascular health and cognitive function

Oxidative stress and inflammatory state. As a translational research study, HANDLS permits investigation of health disparities in terms of socioeconomic, socio-cultural, and psychosocial parameters. HANDLS allows us to define a medical/biologic phenotype that may be amenable to dissection by bench scientists examining the molecular aspects of aging, disease and disability. The early appearance and increased severity of age-associated disease among African Americans and low SES individuals suggests that the factors contributing to the emergence of health disparities may also induce a phenotype of 'accelerated aging'. While others have attributed this to racism and other socio-cultural factors, we seek to understand the underlying biologic, genetic, and environmental factors that may result in this phenotype that ultimately contributes to the disparate life expectancies for low-SES and minority sub-populations. The health disparities induced phenotype of accelerated aging may be biologically similar to heritable 'progeroid' syndromes whose manifestations include increased susceptibility to oxidative stress, premature accumulation of oxidative DNA damage, defects in DNA repair and higher levels of biomarkers of oxidative stress

and inflammation. While genetic background, environmental and behavioral factors influence health outcomes in all populations over the lifespan, health disparities may be the end product of an accelerated trajectory of dysfunctional interactions of these factors in populations at high risk or with high levels of risk exposure. Every day, cells are faced with damage to their DNA, the most common form of oxidative, which includes single strand breaks (SSB) and oxidative base damage. Normally, cells repair oxidative DNA damage through various repair mechanisms. Unrepaired DNA damage can cause mutations that can lead to age-related diseases, aging, and death. Oxidative DNA damage includes single strand breaks (SSBs) and oxidative base damage. An increased baseline level of oxidative DNA damage is associated with several age-related diseases including: cardiovascular disease²⁹, diabetes mellitus,³⁰ cancer,³¹ neurodegenerative disease,³² and end-stage renal disease.³³ The level of oxidative DNA damage depends on a variety of factors. They may include age,³¹ environmental exposure to genotoxic factors,³⁴ smoking,³⁵ ethanol intake,³⁴ and intracellular and extracellular metabolism.³⁶

HANDLS examines this hypothesis by measuring biomarkers of oxidative stress and inflammation, assessing levels of the most widely studied oxidative DNA adducts, and measuring DNA repair capacity (DRC) in study participants. In addition, other important biomarkers of oxidative stress are being evaluated. These include glutathione levels, fluorescent heme degradation products, and plasma carbonyl levels. Measures of inflammatory states include the pro-inflammatory cytokines such as IL-17, MCP-1, IL-23, and C-reactive protein. Prospectively measuring biomarkers of oxidative stress in a longitudinal study may clarify whether oxidative stress plays a pivotal role in aging and in the development and or progression of age associated disease. It may also provide insights into the different trajectories of aging observed in individuals. Genetics. Current technological advances in genotyping permit high throughput whole genome single nucleotide polymorphism (SNP) genotyping to proceed with the overall goal of examining the genetic contributions to the development of multi-gene complex clinical disorders. Of equal importance is the contribution this new knowledge will provide in furthering the examination of the genetics behind the differences in medicinal drug responses frequently seen in individuals as well as to the discovery of new drug targets for a range of diseases with persistently high morbidity and mortality. Our primary aim is to identify the genetic factors that are associated with age-associated health disparities. We hypothesize that the prevalence and severity of age-associated disease in minority populations is related to in some cases genetic susceptibility factors. Genotyping will focus on identifying specific SNPs that may be related to disease susceptibility and or the severity of disease states and metabolic conditions that disproportionately affect this longitudinal cohort over the next 20 years. Examining the prevalence of these genetic polymorphisms is critical to understanding not only the association between the polymorphism and the disease but the molecular and biological functional outcome of these polymorphisms. Although race itself is not a definitive biologic factor but largely a proxy for social, cultural behavioral and environmental factors it is critically important for us to attempt to understand the role of genetic susceptibility to specific age-related heath disparities and clinical characteristics. The first step to gaining this understanding is to identify risk alleles for common diseases through genome wide association studies (GWAS). However, most of the early GWAS analyses failed to include diverse cohorts enriched for sub-populations at greatest risk. Therefore inclusion of diverse population groups will hopefully enhance understanding of the effects of various genetic variants in different groups who may have different environmental exposures.

Whole genome SNP genotyping using the Illumina Infinium II platform for the first 1000 participants has been completed. Planned work will proceed in conjunction with GWAS consortia including: the Continental Origins and Genetic Epidemiology Network (COGENT) and the Candidate-gene Association Resource consortium (CARe). Initial areas of research focus on renal, metabolic, hematologic, and cardiovascular characteristics or conditions. Analysis of the data set is underway to determine genetic associations with hypertension, renal disease, cardiovascular disease, stroke and other age associated health disparities. In addition, other GWAS studies underway are focused on height, platelet count, water balance, and serum sodium concentration.

- *Epigenetics.* The disproportionate incidence and mortality from age-associated disease may also result from epigenetic mechanisms such as DNA methylation. One theory of aging focuses on the role of genes and the epigenome in the development of the aging phenotype. We will examine the hypothesis that human disease and disability may result from DNA modifications that are not the result of changes in the coding sequence of genes. The clinical relevance of DNA methylation states in the development of age-related disease has yet to be understood on a population basis. There is variation in methylation states from individual to individual. This may be related to age, gender, environmental exposure, and other genetic factors. Is it possible that our hypothesized phenotype of accelerated aging phenotype seen in low SES and minority communities is related to epigenetic factors such as methylation? We will examine methylation states within this longitudinal cohort to attempt to understand whether methylation states are associated with the premature development of age-associated disease. Because there is limited information about methylation status of lymphoid cells, we have chosen to employ DNA isolated from the buccal cells for this study. This is also likely the best source of DNA in our urban based cohort at higher risk for environmental exposures from air pollution and because of the prevalence of tobacco and alcohol use within this cohort at higher risk for the development of aerodigestive cancers of the lung and esophagus. Our investigations will focus on identifying DNA methylation patterns factors that are associated with the development of health disparities and with changes in human DNA repair capacity. These studies will examine the gene promoter methylation status in buccal mucosa cell DNA from HANDLS participants. Assessing this at baseline and longitudinally may permit us to identify molecular markers of disease susceptibility especially for aerodigestive malignancies that are characterized by disproportionate incidence and mortality rates in African Americans.
- *Renal function.* The National Health and Nutrition Examination Survey (NHANES) reports that while chronic kidney disease (CKD) prevalence among Americans older than 20 years of age was 16.8%, rates for non-Hispanic Blacks and Mexican Americans were higher (19.9% and 18.7% respectively. This disparity is significantly highlighted when assessing the prevalence of stage 1 CKD. Prevalence of CKD 1 among non-Hispanics whites is 4.2% compared with 10.2% for Mexican Americans and 9.4% among non-Hispanic Blacks. The statistics for End-Stage Renal Disease (ESRD) mirror these disparities; African Americans have a 3.6 fold higher rate than whites and

Hispanics have a 1.5 times higher prevalence rates than the U.S. non-Hispanic white population.³⁷

The risk factors for CKD are multifaceted and difficult to dissect; they include: hypertension, diabetes mellitus, smoking, race, age, obesity and heart disease³⁸. However, it is clear that other etiologic factors may also play a role including behavior, genetics, and the physical and sociologic environment as has been shown for ESRD³⁹⁻⁴¹. Because of the complexity of the factors that influence the development of chronic kidney disease and the significant impact CKD and ESRD have on quality of life, disability and life expectancy³⁹⁻⁴³, we set out to examine predictive factors for CKD, including poverty, genetics, food security, diet, and race. In hopes of providing early identification of participants with CKD, to improve outcomes and awareness of CKD among participants, serum Cystatin C levels and urinary kidney injury molecule-1 (KIM-1) will be measured in each participant. Cystatin C has been selected because the literature suggests that it may provide a more accurate estimate of GFR, especially when GFR is only mildly depressed.⁴⁴ Additionally, Cystatin C has been found to be a better predictor of cardiovascular mortality than creatinine among persons with mild CKD. Urinary KIM-1 has recently been shown to be increased in patients with non-diabetic CKD and may be an important target for treating CKD.

- *Caregiving.* Health disparities may result from various forms of stress including psychological stress. Many studies have linked caregiving with significant levels of chronic stress for caregivers. This chronic stress is moderated by socioeconomic status, the condition and disabilities of the individual for whom care is provided, social support, and the age of the caregiver. Although depression is a well studied health outcome among caregivers, other studies have shown that overall health, compliance with appropriate health related behaviors, and diet are all negatively influenced by caregiving. There are a few studies that have examined the effects of accumulated multiple social roles (i.e. caregiver, spouse/partner, parent, and employment, and volunteer) and role combination (e.g., elder care, only; child care only; elder care and child care).⁴⁵⁻⁵⁰ This body of literature supports either the *scarcity hypothesis*, occupancy of more than one role is associated with poor well-being (e.g. Hong & Seltzer⁴⁶); while others support the *enhancement hypothesis*, occupancy of more than one role is associated with positive outcomes (e.g., Adelmann⁵¹). Most of this research sampled primarily white caregivers. There remains a lack of research focused on middle and older aged, African-American women who are in multiple caregiving roles. To examine the influence of multiple caregiving roles (i.e., occupancy of more than one caregiving role) on the physical and mental health outcomes of HANDLS participants with specific focus on grandmother caregivers. This aim is to gain greater understanding about the relation between multiple caregiving roles (i.e., occupancy of more than one caregiving role), and health status (physical and mental) among HANDLS participants. This proposed study could extend the caregiving literature in several ways. First, it will assess the influence of multiple caregiving roles on health status of caregivers, across race/ethnicity, class and gender. Previous studies lacked sample diversity and primarily focused on low-income, African Americans, or grandmothers. Inclusion of a diverse sample will allow the researcher to

examine intra and inter variations based on caregivers' age, race and ethnicity, sex and education. Second, it will assess the influence of role combination, (e.g. elder care, only; grandchild care only; elder care and grandchild care). Several researchers found that role combination may have a greater influence on health outcomes than simply the number of roles.⁴⁶

- *Spirituality.* We will examine the role of spirituality in health disparities. Spirituality is the sentiment or emotional tendency to associate oneself with and value ritual practices and social traditions that may transcend physical reality in favor of identifying with a broader purpose or eternal being. We will assess spirituality using the *Assessment of Spirituality and Religious Sentiments* (ASPIRES),⁵² a 12-item inventory that measures two broad scales, Religious Sentiments and Spiritual Transcendence. Scores on these scales are associated with interpersonal style, coping ability, sexual attitudes, psychological maturity, and well-being.^{53,54}
- *Health literacy.* Examination of the underlying factors of health disparities requires investigation of health literacy among populations at risk. Health literacy is defined as "the degree to which individuals can obtain, process, and understand the basic information and services they need to make appropriate health decisions..."⁵⁵ In 2004, the IOM estimated that almost 90 US adults million adults had low levels of health literacy.⁵⁶ Work by multiple groups has linked health disparities to low levels of literacy and these disparities are not solely linked to income level, race or education levels.⁵⁷⁻⁵⁹ Older adults are also more likely to have low levels of health literacy as well as those with multiple chronic illnesses or co-morbid conditions.⁶⁰⁻⁶³ Reading and numerical skills are required to function effectively in health care environment. Inadequate health literacy affects several factors that may influence health disparities as well as severity of age-related conditions such as preventive care, medical compliance, and health care expenditures. Health literacy may also influence the recruitment and retention of low SES and minority individuals in clinical research. One of the gaps in our knowledge about reducing health disparities is how to modulate associated factors like health literacy to promote the reduction of health disparities. As many suggest, it is essential to integrate health literacy assessments in disparities research.⁶⁴

We will assess health literacy in Wave 3 of HANDLS to examine its and to investigate the influence of race, sex, age, income, education and reading level on health literacy. We will also assess the associations of health literacy with chronic medical conditions, multiple co-morbidities, cognition, and symptoms of depression and other psychological factors. It provides an adequate evaluation of an individual's ability to read and understand health materials. Perhaps most significantly, we will use the health literacy data to develop appropriate HANDLS research study materials as well as health education messages tailored to our study population. Although we now assess all participant study materials for culturally competent and proficient communication as well as for readability using the Flesh-Kincaid Readability formula, it is likely that this additional information about health literacy levels will better inform our material preparation and review process. Given the very high smoking rates in

our population, it is clear the standard health education messaging has not been effective. We hope that by evaluating health literacy in our population we can add to the literature information that will improve health education messages for vulnerable, at risk populations.

- *Mobile Health.* HANDLS will test the feasibility of providing cellular phones or small internet ready devices to determine whether the device will help to improve compliance with HANDLS physician recommended healthcare follow-up stemming from their HANDLS medical examination. We will send electronic reminders to participants about physician's treatment recommendations explaining the risks for further complications should their healthcare needs go untreated. For difficult to track participants, we will test whether providing the device will assist in maintaining contact between study visits and whether providing appointment reminders improves retention rates among the most difficult to track HANDLS participants.

7.1.0 Sub-studies Objectives

7.1.1 Neuroimaging Sub-study (HANDLS Scan)

Structural neuroimaging. There are pronounced health disparities associated with race and socioeconomic status (SES) in various brain health endpoints including stroke, dementia, cognitive decline, and functional disability.^{65,66} Particularly potent race disparities in stroke incidence are apparent at strikingly young ages, with a four-fold increased risk of stroke mortality among 45-59 year old African Americans (AA).⁶⁷ Efforts are needed at disentangling the respective influences of race and SES in brain health, particularly early and subtle markers of brain pathology that predict future stroke, dementia, or cognitive and functional decline. Measures of subclinical or covert cerebrovascular disease assessed by magnetic resonance imaging (MRI), including gray matter and white matter volumes and white matter microstructure, offer such proven associations.^{68,69} Identifying multi-level mediators of the relations of race and SES to subtle brain pathology is also crucial. Biomedical, behavioral, psychological, social, and environmental factors have been implicated as potential mediators of the relations of race and SES to a multitude of physical health outcomes,^{70,71} but little is known about these pathways for brain health endpoints.^{71,72} Recent quantitative MRI data in older adults revealed larger brain volumes, but greater white matter hyper-intensities in African Americans than whites.⁷³ The most pronounced relations of vascular disease to brain atrophy and white matter hyper-intensities were found in African Americans. MRI indices of subtle brain pathology have been associated with lower levels of cognitive and physical function and cognitive decline,^{74,75} and may mediate relations of race and SES to these endpoints.

This protocol is an sub-study linked to the ongoing HANDLS study. In a subset of 500 HANDLS participants, we will assess total and regional gray matter and white matter volumes and white matter microstructure in 500 stroke- and dementia-free HANDLS participants (250 African American, 250 white; 50% women; ages 30-64 at baseline) over the full range of socioeconomic status using quantitative MRI data, including volumetrics and diffusion

tensor imaging (DTI). Please see appendix – Protocol for HANDLS Neuroimaging Study for specific study procedures.

We will address the following aims and hypotheses:

Specific Aim 1. Examine race- and SES-related health disparities in MRI-assessed measures predictive of future stroke, dementia, or cognitive decline, and evaluate whether these relations differ by sex and age. The primary outcome measures will include total and regional gray matter and white matter volumes quantified by voxel-based morphometry, ischemic lesion volumes, and total and regional fractional anisotropy (FA) and the apparent diffusion coefficient (ADC) estimated by DTI.

Hypothesis 1. There will be significant interactive relations of race and SES with respect to MRI indexes of gray matter and white matter volumes, ischemic lesion volumes, and white matter microstructure such that lower SES African Americans will display the most extensive brain pathology, particularly in prefrontal regions. Moderated mediation by age and sex (i.e., that age and sex may moderate the mediational paths by which race and SES relate to brain outcomes) will be explored.

Specific Aim 2. Examine multi-level mediators of the relations of race and SES to brain MRI outcomes; potential mediators (i.e., vulnerability or resilience factors) include biomedical (e.g., cardiovascular risk factors, subclinical vascular disease, cardiovascular comorbidities), behavioral (e.g., diet, smoking, alcohol, physical activity), psychological (e.g., depression, vigilance, anger, stress, spirituality), social (e.g., social support and networks, racial discrimination), and environmental (e.g., neighborhood deprivation, access to health care) factors.

Hypothesis 2. The multi-level mediators of MRI-based measures of GM and WM will differ as a function of race and SES. For example, select psychological factors such as racial discrimination may be prominent influences in high SES African Americans (as per pilot data), whereas behavioral, social, and environmental factors may be the most prominent influences in low SES African Americans. Moderated mediation by age and sex will be explored.

Specific Aim 3. To examine whether MRI indexes of gray matter and white matter are proximal mediators of the relations of race and SES to cognitive and physical function.

Hypothesis 3. Lesser white matter integrity and lesser white matter and gray matter volumes, and higher ischemic lesion volumes will be associated with lower levels of cognitive (particularly executive) function and physical function. These associations will be most pronounced among lower SES African Americans. Moderated mediation by age and sex will be explored.

7.1.2 Circadian Rhythm Sub-study

Ecological measurement of circadian entrainment. African Americans in Baltimore are statistically more likely to exhibit higher rates of mortality and morbidity than age-matched whites. Disruption of circadian rhythms has been linked to a wide range of maladies from

diabetes to cancer. To our knowledge no formal study of circadian disruption in African American populations has been undertaken, particularly in a natural setting.^{76,77} The HANDLS cohort is an ideal population to compare circadian disruption among sub-populations in Baltimore. If shown that this population is in fact disrupted, non-pharmacological interventions can be then developed to increase circadian entrainment, and possibly, reduce risks in this population.

Circadian rhythms are a fundamental part of life. All species on Earth exhibit 24-patterns at behavioral, physiological, and cellular levels. Circadian disruption associated with a lot of maladies.^{78,79} Light is the primary zeitgeber (time-giver) for the circadian system. Disruption of a regular, 24-hour pattern of light and dark leads to circadian disruption. The Lighting Research Center at Rensselaer Polytechnic Institute (LRC) has developed personal light exposure devices (e.g., the Daysimeter12) for deployment in natural settings.^{76,77} The LRC has also pioneered analytical methods for quantifying circadian disruption in humans and in other species, including nocturnal rodents, called phasor analysis.⁸⁰ Phasor analysis is based upon the functional relationship between two periodic cycles. The Daysimeter12 measures actual light-dark cycles together with activity- rest cycles, and based upon phasor analysis circadian disruption can be measured. From the Nurse's Health Study our collaborators were able to quantitatively compare circadian disruption in dayshift and in rotating-shift nurses, the latter population being at higher risk of breast cancer than the former. Disease and mortality are exhibited differentially in subpopulations within the city of Baltimore. A totally unexplored area is the quantification of circadian disruption through ecological measurements of patterns of light-dark and activity-rest in these subpopulations to determine whether there is an association between circadian disruption and disease and mortality. This is an entirely plausible line of research because (a) circadian rhythms are essential for life, (b) circadian disruption is associated with a wide spectrum of maladies, including increased risk for cancer, diabetes, obesity, cardiovascular disease, and seasonal depression and (c) the ecological approach proposed here has been successfully demonstrated in several populations including, nurses, submariners, teens, young adults, and those with dementia.

This protocol is an ancillary project linked to the ongoing HANDLS study. In a subset of 100 HANDLS participants we will collect rest/activity and dark/light data using the Daysimeter12. Please see appendix entitled Ancillary Study - Circadian Rhythm Protocol for specific study procedures.

Aim 1: Collect rest/activity and dark/light data using the Daysimeter12 from participants in the HANDLS cohort using the Daysimeter12. It is hypothesized that those sub-populations with greater incidence of mortality and morbidity will exhibit greater levels of circadian disruption as determined by phasor analysis, based on the measured rest/activity and dark/light profiles, compared to those with lower incidence.

7.1.3 Subjective Experience of Diabetes Sub-study

Subjective Experience of Diabetes. Diabetes is the seventh leading cause of death in the United States.⁸¹ Type 2 diabetes (T2DM) accounts for 90-95% of diagnosed diabetes and is

predicted to nearly double over the next 15 years.⁸² Diabetes disproportionately affects older adults, people of color, and individuals within urban environments,^{82,83} with both African-American and women's diabetes mortality rates in particular increasing over the past several decades.^{81,84} African-Americans and women also experience more diabetes-related complications.⁸⁵ These secondary conditions such as cardiovascular disease, stroke, dementia, diabetic neuropathy, amputations, renal failure and blindness compound what has grown into a public health crisis. Diabetes-related health care costs consume approximately 20% of US total health care expenditures and are expected to nearly triple by 2034.^{81,86} Notably, 91% of these costs are associated with persons aged ≥45.⁸³ Addressing diabetes prevention and treatment, then, is a leading US public health priority.⁸⁷

As with the prevalence of diabetes, urban, race, and gender disparities are found in diabetes treatment and self-management. With respect to geographic differences, medication adherence and self-management can be particularly challenging in urban environments with variable health care, transportation, food, and exercise opportunities.⁸⁸⁻⁹² Overall, African-Americans with diabetes are less likely to meet national exercise recommendations than whites.⁹³ Similarly, women are less likely to engage in diabetes self-management than men,⁹⁴ with older adult diabetic women in particular being less likely to meet national exercise recommendations.⁹³ Women also report high levels of self-blame regarding their illness,^{95,96} numerous barriers to self-care,⁹⁷ and high rates of stress in managing care-giving responsibilities in addition to their own diabetes self-care.⁹⁸

To address race and gender disparities, many diabetes control efforts call for "cultural sensitivity" and for the creation of programs that recognize the cultural context of high-risk populations.⁹⁹⁻¹⁰³ With very few exceptions,¹⁰⁴⁻¹⁰⁸ however, previous studies have not explored how persons with diabetes define and conceptualize their illness and illness management. Extant ethnographic research generally is limited to understanding diabetes in terms of the health beliefs of specific ethnic groups such as Latino, Native American, and Bangladeshi,^{105,109-117} and may presuppose a belief system based upon group affinity. Furthermore, while research grounded in theories regarding cumulative disadvantage,¹¹⁸ social ecology,¹¹⁹ and stress,^{107,111,120} have sought to explain race and gender differences in chronic conditions like diabetes with respect to broader political and economic disparities, few studies have examined how subjective understandings of diabetes and treatment vary both across and within male and female African-American and white groups.^{121,122}

Finally, there is growing acknowledgement that decades of education and behavior change interventions have had mixed success in creating sustained diabetes self-management,^{123,124} and renewed attention to patient-centered approaches to diabetes management is needed.¹²⁵ It is our premise that real progress in controlling diabetes cannot be made until we take seriously the individual's personal ideas about diabetes, such as the nature, definition, progression, priority and treatment of diabetes. Providers in particular need a deeper understanding of patients' subjective diabetes worlds. Through attention to the subjectivity of diabetes, providers can promote clinical encounters that not only diagnose and educate, but that help patients to negotiate the beliefs and contexts that play a role in self-management.

The study, using ethnographic interviewing, will examine subjective conceptualizations of diabetes and self-management among male and female, African-American and white older adults in an urban environment. The study will provide critical information on the ways in which subjective definitions, subjective experiences, shared and idiosyncratic illness models and varied social contexts underlie participants' construction of and self-management of their diabetes. We will address the gap in understanding of the subjective experience of diabetes and the operation of cultural processes among male and female African American and whites with diabetes.

This sub-study involves a unique partnership between the NIA IRP Healthy Aging in Neighborhoods of Diversity across the Lifespan (HANDLS) study, and the University of Maryland Baltimore County (UMBC), Department of Sociology and Anthropology, Center for Aging Studies.

Objectives. The 36-month study investigates the subjective construction of diabetes among African-American and white older adults, age ≥ 50 , with T2DM, living in Baltimore City ($n=80$). We will use the McGill Illness Narrative Interview (MINI), a semi-structured ethnographic interview guide that we have modified for this study.¹²⁶ We seek to identify how local social, cultural, and material contexts inform participants' conceptions of their diabetes, perceptions of its risk factors and comorbidities, and their approach to managing their illness.

This study will address four specific aims:

Specific Aim 1. Identify participants' subjective accounts of their diabetes, including perceptions of the etiology, risk factors, symptoms, secondary conditions, and short and long term outcomes of their diabetes;

Specific Aim 2. Elicit participants' diabetes management practices, including perceptions and use of biomedical and lay (popular or folk) health care resources and self-management activities;

Specific Aim 3. Explore participants' accounts of the social context within which their diabetes is embedded, including how participants manage their diabetes with respect to other responsibilities and constraints, such as family care taking, job constraints, transportation, finances, time commitments, or other illnesses; and

Specific Aim 4. Determine the race and gender variations in participants' subjective understanding of their diabetes, their diabetes management strategies, if any, and the social contexts surrounding their diabetes.

Together, addressing these specific aims will provide rich, detailed insight into the subjective definition and construction of diabetes and diabetes management among urban older adults, and the race and gender variation in these constructions. We believe these aims will offer providers a better understanding of the subjective arenas in patients' lives that must

be taken into account when working conjointly with patients to develop self-management plans.

Please see appendix entitled *Subjective Experience of Diabetes Protocol* for specific study procedures.

8.0.0 Expected Risks and Benefits

There is very little risk to participants in this observational study. The exposure to low dose radiation from the analysis of bone density and body composition by the densitometer and the risks associated with having blood drawn are the minimal risks.

The potential benefits to the participants include access to a full medical evaluation including screening for pathology in which early detection is advantageous. If the study doctor discovers any condition or problem, the information is provided to the participant immediately and their primary care doctor, with their permission. If the participant does not have a physician, efforts will be made to refer them for care. Participants will be reimbursed for time and inconvenience.

The potential benefits to society relate to improvement of overall health in a vulnerable population that currently bears a disproportionate burden of disease and disability in this country. Healthy People 2010, the nation's disease prevention agenda, have defined two national goals to reduce preventable threats to the nation's health.¹²⁷ The first is to increase the quality and years of healthy life and the second is to eliminate health disparities. However, in order to achieve this second goal it is critical to develop research initiatives that provide new insights into the relationship between psychosocial factors and health status by (1) incorporating biological measures into large scale epidemiologic health and survey research projects and (2) the development and inclusion of a diverse panel of biomarkers or biologic measures that evaluate biologic pathways that may be involved in the causal relationship between SES and health.¹²⁸ This is what HANDLS attempts to accomplish. If successful, HANDLS will provide unique information that will hopefully uncover findings that will provide a basis for the development of appropriate prevention and intervention strategies to reduce health disparities.

9.0.0 Eligibility

In this study we are examining age related disorders in a target population of African Americans and whites in a representative sample of Baltimore City residents.

Inclusion criteria:

- Verified HANDLS participants (age 30-64 at baseline recruitment)
- Able to give informed consent
- Must have valid picture identification

Exclusion criteria:

- Pregnancy*
- Within 6 months of active treatment of cancer (chemotherapy, biologic, radiation)

* For the examination visit and the HANDLS Scan sub- study a urine pregnancy test is performed with women of child bearing potential during the medical screening prior to any testing or procedures. If positive, participant will not be eligible for the examination visit until they are no longer pregnant. Participants with a positive pregnancy test will be invited to return for examination visit and/or the HANDLS Scan once pregnancy is resolved (pregnancy testing is repeated at each encounter, if indicated). The Diabetes sub-study protocol does not pose increased risk so pregnancy status is not required or obtained.

10.0.0 Subject Enrollment

Plan to re-contact participants for Wave 3. The HANDLS study has recruited a representative sample of 3720 whites and African Americans between 30 and 64 years old from 13 neighborhoods in Baltimore city in both low and high socioeconomic strata as a fixed cohort following the overall design. We have used several methods to remain in contact with our participants since they initially enrolled in HANDLS. Specific examples include sending regular mailings such as newsletters, holiday and birthday cards to the addresses we have on file, participation in the wave 2 interim study, mailing study updates and reminders with change of address cards, and periodic reviews of the Baltimore city judicial system public records and the National Death Index database. While this does allow us to remain in contact with many of our participants, there still exists a sub-set of participants for whom traditional methods will not be successful.

For Wave 3 we have employed a tracing and tracking specialist whose primary responsibility is to focus on conducting investigative fieldwork and extensive tracing & tracking procedures to locate missing participants. This requires (a) physically driving through all identified HANDLS study neighborhoods in Baltimore City to previously known addresses for missing participants, communicating with current residents (and or neighbors) of identified households to assist in locating participants; (b) contacting participant's family or friends identified by the participant as persons to be reached if participant cannot be located (c) using search engines on the internet, Baltimore City judicial system public records, National Death Index, Division of Vital Records, and similar methods to locate current residence or to verify status of missing participants; and, (d) other tracing and tracking methods developed over time and with experience.

Including this strategy will allow us to make every possible effort to locate as many of our participants as possible. It is particularly crucial in this first follow-up re-examination phase of the study.

11.0.0 Study Design and Procedures

The HANDLS study is an interdisciplinary, prospective epidemiologic longitudinal study examining the influences and interaction of race and SES on the development of cardiovascular and cerebrovascular health disparities among minority and lower SES subgroups.

The baseline HANDLS sample consists of 3720 community-dwelling African American and white adults aged 30-64. Participants were drawn from 13 neighborhoods (groups of contiguous census tracts) in Baltimore City, sampling representatively across a wide range of socioeconomic and income circumstances. The heuristic study design is a factorial cross of four factors: age, sex, race, and SES with approximately equal numbers of subjects per “cell” (Figure 2). HANDLS is planned as a 20-year longitudinal study of the 3720 individuals accrued (Figure 3). Using our mobile medical research vehicles, we are revisiting each census tract for 2-3 months over the next 3 years.

The 13 neighborhoods identified were selected because they were likely to yield representative distributions of individuals between 30 and 64 years old who are African Americans and whites, men and women, and lower and higher SES.

Study sample. The study recruited an area probability sample of whites and African Americans between 30 and 64 years old from 13 neighborhoods in Baltimore City in both low and high socioeconomic strata as a fixed cohort following the overall design. By collecting a baseline assessment and 5 follow-up triennial assessments over approximately 20 years, there will be sufficient power ($>.80$) with 30 participants per group (race by SES by sex by age group) remaining after 20 years. There will also be sufficient power ($>.80$) to compare rates of change among groups after the baseline assessment.

Procedures. The study data for wave 3 is collected in three phases. We collect the first phase of the participant examination data on the medical research vehicles. These data include an interim medical history and physical examination since the baseline examination; dietary

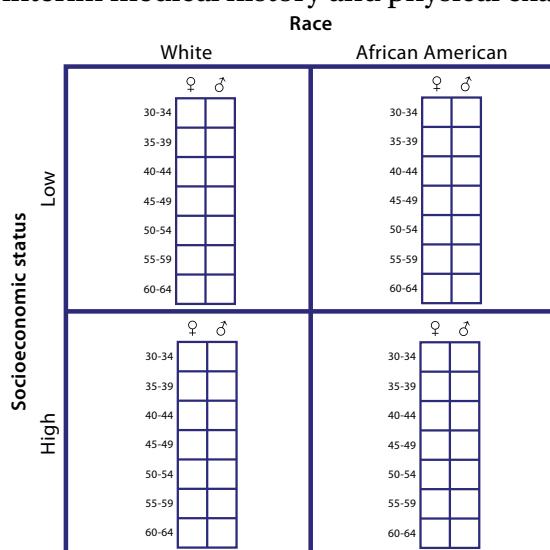


Figure 2. HANDLS sampling design

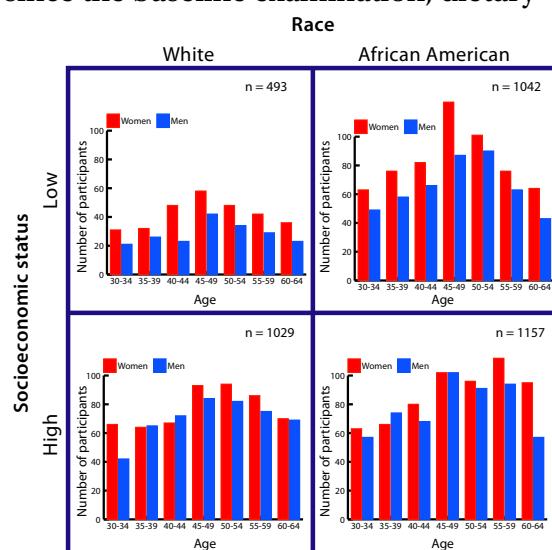


Figure 3. HANDLS baseline accrual

recall; cognitive evaluation; echocardiography; assessments of muscle strength and bone density; laboratory measurements (blood chemistries, hematology, biomaterials for genetic studies); an evaluation of health literacy; and, an audio-administered questionnaire. For those participants who have difficulty ambulating independently, we recommend they complete the HANDLS home visit for wave 3 - phase 1 (see phase 1A table of procedures below).

We collect the second phase of HANDLS wave 3 as a telephone survey. It includes a repeated dietary recall interview and use of dietary supplement questionnaire.

A selected subset of participants is invited to participate in one or more of the optional studies that comprise the third phase of wave 3, the circadian rhythm ancillary study, the neuroimaging sub-study, or the diabetes sub-study. We conduct the circadian rhythm study on the MRVs. We conduct the neuroimaging study at University of Maryland School of Medicine and the Subjective Experience of Diabetes study is conducted in the field, at the participants home or at a place of the participants choosing.

12.0.0 Procedure Description

Fasting blood samples for clinical tests, banking plasma, serum, and DNA. As a part of the medical evaluation, blood tests are performed to look for anemia and other blood disorders, diabetes mellitus, thyroid disease, hepatitis, prostate disease, HIV disease and kidney disease. We are also using some blood samples to study genes that may play a role in age-related diseases like Alzheimer's disease, heart failure, high blood pressure, and cancer. The total amount of blood drawn from each participant is about 71.5 milliliters (~5 tablespoons).

Phase 1: Medical Research Vehicle Examination

Measure or Procedure	Estimated Duration	Location
Consent	20 minutes	MRV 3
Specimen Collection (Urine, Blood, Buccal Smear)	20 minutes	MRV 3
Anthropometrics & EKG	5 minutes	MRV 1
Interim Medical History	20 minutes	MRV 1
Interim Physical Exam	20 minutes	MRV 1
Dietary Recall I	30 minutes	MRV 2
Cognition	40 minutes	MRV 2
Physical Performance	15 minutes	MRV 1
Echocardiogram	20 minutes	MRV 1
Questionnaire – Audio/Health Literacy	35 minutes	MRV 2
Body Composition/Bone Densitometry	30 minutes	MRV 1

Phase 1A: Home Visit

Measure or Procedure	Estimated Duration
Consent (completed by phone or in-person)	20 minutes
Specimen Collection, Vitals and EKG	45 minutes
Cognition	60 minutes
Interim Medical History	30 minutes
Interim Physical Exam	45 minutes
Hand Grip	10 minutes
Questionnaires	15 minutes

Phase 2 – Post-examination Telephone Survey

Measure or Procedure	Estimated Duration	Location
Dietary Recall II & Supplement Questionnaire	30 minutes	Telephone

Phase 3 – HANDLS Wave 3 Sub-studies

Measure or Procedure	Estimated Duration	Location
Circadian Rhythm Study	30 minutes	MRV
Neuroimaging Study	90 minutes	UMB
Subjective Experience of Diabetes Study	90 minutes	Field

Risks. There are some risks from having blood drawn. There is a risk of an infection from the needle puncture. There is also a risk of a black and blue mark, and the participant may feel faint. It is common to have a small black and blue mark, but it disappears after a day or so. Some people may begin to perspire or feel nauseated. These risks are very small. Our medical staff is well trained and has drawn blood many times.

Buccal Cell Collection. As part of the medical evaluation buccal mucosa cells are collected from saliva samples using the Genotek Oragene DNA self collection kit from each consenting participant. Participants are asked to spit into a DNA collection system (a small sample cup) to collect buccal mucosal cells. The extracted DNA will be used for epigenetic analysis as well as human mRNA expression profiling.

Risks. This is a completely non-invasive self-collection system. There are no known physical risks.

Alternative Buccal Cell Collection Method. The Whatman FTA collection system will be used as a back-up buccal cell collection method. This system collects buccal cells using a foam tipped applicator which is placed into the mouth and rubbed on the inside of both cheeks for 30 seconds by the participant. The sample obtained is then transferred to the Indicating FTA cards. The extracted DNA will be used for epigenetic analysis.

Risks. Buccal mucosa smear risks include irritation of the inside of the cheek and/or gum line by the foam tipped swab used to collect cells and saliva.

Resting Electrocardiogram (EKG). We place electrodes on the participant's skin to record their heartbeats. By looking at the electrical pulse of their heart we examine the heart rate and rhythm, and check if they have had a heart attack.

Risks. None.

Anthropometrics. We measure the height and weight of each participant.

Risks. None.

Medical History and Physical Examination. A physician or nurse practitioner performs an interim physical examination and medical history. The purpose of the physical examination and medical history is to document as unambiguously as possible any diagnosable conditions, to record medications and their frequencies and dosages, and to assess disabilities that might limit independent functional activities, that have developed or occurred since their last examination on the MRVs. In addition, we will examine subjects to insure that they do not meet exclusionary criteria for any subsequent tests such as the DXA.

Risks. None.

Dietary Recall.

Dietary Recall Interview. This measure is administered in both the first and second phases of data collection. We will ask participants to recall all of the foods and beverages they consumed during the previous 24 hours. An interviewer records the dietary recall using methods developed by the USDA called the Automated Multiple Pass Method (AMPM) that is supplemented by measurement aids and illustrations to assist in estimating accurate quantities consumed.

Nutrition Supplement Questionnaire. We ask participants to report all of the types and quantities of nutritional supplements they took during the previous 24 hours following the dietary recall. An interviewer also records usual supplement practices.

Risks. None.

Cognitive testing. We administer a battery of cognitive tests assessing memory, executive function, verbal fluency and knowledge, and spatial ability. In addition to dementia screening using the Mini-Mental State Examination¹²⁹, we administer the Benton Visual Retention Test (BVRT),¹³⁰ California Verbal Learning Test,¹³¹ Card Rotations, Prospective Memory, Wechsler Adult Intelligence Scale Digit Span Forward and Backward,¹³² Identical Pictures, Clock Drawing, Brief Test of Attention, Wide Rage Achievement Test, Trail Making A and B, animal fluency. We assess baseline personality and symptoms of depression using the CES-D. These tests are given in a private, quiet room with an experienced tester.

Risks. None.

Physical Performance Measures

Age-associated strength loss (Grip Strength Test). Handgrip strength in both hands, measured using an adjustable, hand-held, hydraulic grip strength dynamometer, is used as an overall assessment of physical strength and skeletal muscle function. Repeated measurement of grip strength over the follow-up visits will permit an estimate of strength loss over time. Grip strength is a commonly used indicator of health status and physical frailty and mid-life grip strength has been shown to be a strong predictor of early mortality.

The examination is done with the participant in the sitting position with the arm to be tested resting on the table and the elbow held at approximately a right angle. The dynamometer is held in the hand to be tested and is resting on a mouse pad. The participant is instructed to grip the two bars of the dynamometer in their hand, and to slowly squeeze the bars as hard as they can. The test is repeated on the other hand. This test is performed 3 times on each hand.

Exclusions. Participants who have had fusion, arthroplasty, tendon repair, synovectomy, or other related surgery of the upper extremity in the past 3 months will not be tested on the affected hand.

Age-associated functional decline

Sit-to-Stand Test. A commonly used performance-based test of physical function, the sit-to-stand test (also termed repeated chair stands), is used to assess functional status at study inception and to track loss of functional capacity over time. Using a standard armless chair placed securely against a wall, the participant is first instructed to rise from the chair without using arms and return to a seated position. If this is done successfully, the participant is then asked to repeat that movement 10 times. Performance, both whether 10 stands are completed and time to perform 5 or 10 stands has been strongly associated with onset of functional limitation, physical disability, institutionalization, and mortality.

Exclusions. There are no formal exclusions from attempting the single chair stand; inability to rise from a chair without using arms excludes participants from doing repeated chair stands.

Single Leg Stand Test. The single leg stand test should be performed with the participant standing a little less than an arm's length from a wall to provide an additional source of support if a loss of balance does occur. This test requires the participant to stand on one leg with the other leg flexed at the knee and held about two inches from the floor. The participant is asked to hold the position for as long as they can, up to 30 seconds. The single leg stand has been found to be a sensitive test of standing balance for middle age and older adults and has been used in numerous epidemiologic studies of well elderly without mishap.^{133,134}

Risks. There are very minimal risks associated with the Physical Performance Measures. The only risks are that there is a slight risk of falling and the participant may feel tired after these tests.

Echocardiogram. Echocardiography is an ultrasound test that is the preferred exam for the non-invasive assessment of the structure and function of the heart. We measure the dimensions of the chambers of the heart, the thickness of the walls, and the systolic and diastolic function of the chambers. We also examine the structure and function of the valves. This test does not involve radiation and there are no exclusions.

Risks. Rare irritation from electrode placements.

Audio-administered Questionnaires. We assess risk of poor mental health and questions about food security and income with an audio-administered (using a computer and headphones) questionnaire. Assistance is provided to the participants, if for example they have trouble seeing or reading the questions or are uncomfortable with using a computer.

Risks. None.

Health Literacy. To assess health literacy in our population we employ two measures, the Rapid Estimate of Adult Literacy in medicine (REALM) and the Test of Functional Health Literacy in Adults (TOFHLA). The REALM assesses reading level through scoring pronunciation of 66 health care related terms by participants. It correlates with other measures of reading literacy and health literacy. The TOFHLA measures reading comprehension and numeracy and correlates well with the REALM and the WRAT. It provides an adequate evaluation of an individual's ability to read and understand health materials.

Risks. None.

Bone Density and Body Composition. We perform dual energy X-ray absorptiometry (DXA) on total body, lumbar spine, the hip and the Instant Vertebral Assessment (IVA) using a Discovery QDR series (Hologic, Bedford MA). DEXA delivers a small amount of radiation through an X-ray source while you lay on the scanner bed. Site-specific scans of the lumbar spine and right hip provide information on bone area (cm^2), and bone mineral density (g/cm^2). Total body scan measures both body composition and bone mineral density, including bone mineral content (g), bone area (cm^2), bone mineral density (g/cm^2), total body tissue (g), fat mass (g), lean mass (g), lean mass plus bone mineral content (g), and percent total fat (%). The IVA provides an assessment of vertebral fractures. Results of

the total body scan are presented for the body as a whole as well as for the arms, legs, trunk, head, pelvis, and spine.

Exclusions. DXA studies are not administered to pregnant women or individuals weighing greater than 450 pounds due to the densitometer's limitations.

Risks. The NIH Radiation Safety Committee has reviewed the use of radiation in this research study and has approved this use as involving minimal risk and necessary to obtain the research information desired. Although each organ receives a different dose, the amount of radiation exposure participants receive from these procedures is equal to a uniform whole-body exposure of less than 1 millirem. This calculated value is known as the "effective dose" and is used to relate the dose received by each organ to a single value. The amount of radiation received in this study is within the dose guideline established by the NIH Radiation Safety Committee for research subjects. The guideline is an effective dose of 5 rem (or 5,000 mrem) received per year (Table 6).

Table 6. Radiation associated with DXA studies on spine, femur, vertebrae and whole body.

Scans	Millirems
Anterior-posterior spine, DXA	0.7
Anterior-posterior femur, DXA	0.7
Lateral Scan for IVA	7.0
Total body scan, DXA	1.0

The NIH Radiation Safety Branch monitors equipment and technique used in this study.

13.0.0 Collection and Storing of Human Sample Specimens and Data

Intended Use of the Samples, Specimens, and Data. Samples and data collected under this protocol may be used to study the differential influences of race and socioeconomic status on health in an urban population. Genetic testing will be performed.

Labeling of Stored Samples. Subjects' stored samples will be labeled with HANDLS identification numbers that only the study team can link to participants. Any identifying information about participants will be kept confidential to the extent permitted by law.

How Samples, Specimens, and Data will be tracked? Samples are tracked using the NIA Biological Sample Inventory system following NIH guidelines.

Storage and Release of Samples. Samples of the participant's blood are kept in a research laboratory at the National Institutes of Aging, NIH or one of our contract facilities. The subject's samples are tested immediately, or they may be frozen and used later. Informed consent allows subjects to determine future use and use for genomic projects. The subject's samples are stored with a confidential code. Samples may be kept until no cells remain or

until the investigators decide to destroy them. If the participant gives us permission some samples are released to other doctors and scientists who are not associated with this institute. The Clinical Director and the Principal Investigators on this protocol will decide which researchers may receive samples. The subject's samples may be used in their research only if the research has been approved by an Institutional Review Board (IRB) and is related to the original research questions association with this protocol or for other research purposes as indicated below. Access to the samples will be limited by storing samples in a locked room.

What will happen to the Samples, Specimens, and Data at the Completion of the Protocol?
The stored material will be used only for research and will not be sold.

What Circumstances would prompt the PI to Report to the IRB Loss or Destruction of Samples/Specimens/Data? We will report any loss of samples (e.g., freezer malfunction to the IRB according to NIA protocol violation policy. In addition we will report to the IRB any loss of unanticipated destruction of samples or data.

Subjects may decide at any point not to have their samples stored. In this case, the principal investigator will destroy all known remaining samples and report what was done to both the subject and the IRB. This decision may not affect the subject's participation in this protocol or any other protocols at NIH.

14.0.0 Data Collection and Management Procedures

HANDLS data are collected electronically or manually on the MRVs, over the telephone and in participant's homes. Data are kept in medical charts in locked file cabinets. All clinical research forms are filed in locked file cabinets. These materials are kept within a locked medical record room. Access to all study data is limited to HANDLS staff and investigators. Data are coded and entered by ID number only. Collaborators receive ID numbers only. No other identifying information is provided with the data unless there is a data use or materials transfer agreement in place, consent has been obtained from the HANDLS participant and the collaborators have obtained required IRB approval.

Data Analysis. The study employs a standard statistic software package depending on the independent and dependent variables being analyzed. Data analyses include logistic regression and mixed effects modeling.

Data sharing agreement. Data generated by the HANDLS study is available through several mechanisms including publications, presentation of results at national scientific meetings, and via a proposal review mechanism routed through the HANDLS principal and co-investigators working group.

The HANDLS Study web site contains a data dictionary for each of the study domains outlining available data sets. This website also describes the proposal submission process for investigators who would like to use HANDLS data or biomaterials. Proposers are required to submit an electronic HANDLS concept sheet detailing the hypotheses and specific aims

of the proposals as well as the required data sets and/or biomaterials. These proposals are reviewed by the HANDLS Working Group. Meritorious proposals are assigned a HANDLS Investigator to serve as liaison and collaborator working with the successful proposer facilitating the completion of the NIA and NIH data transfer and/or material transfer agreements required by federal regulations and to access and use the data set(s) and/or biomaterials required for the approved proposal. Proposals not completed and submitted for publication within the time frame stipulated in the proposal will be re-negotiated or terminated.

Data Safety and Monitoring. No data or safety monitoring board is required. The Principal Investigator will monitor and evaluate the progress of the study, including periodic assessment of data quality and timeliness, participant recruitment, accrual and retention, participant risk versus benefit, performance of contractors and other factors that can affect study outcome. This monitoring will also consider factors external to the study when interpreting the data, such as scientific or therapeutic developments that may have an impact on the safety of the participants or the ethics of the study.

15.0.0 Quality Control

All data for the HANDLS study is collected by following detailed Standard Operating Procedures (SOPs) as outlined in the HANDLS Operations Manual. The majority of data is collected electronically, in real time, and is monitored at regular intervals for accuracy and adherence to the protocol by HANDLS computer programmers and information technology specialists. Manually collected data are stored in the research medical record and are reviewed for accuracy and completion daily by the HANDLS Medical Records Specialist. The HANDLS Nurse Practitioner selects medical records at random for monthly audits.

16.0.0 Statistical Considerations

Power analysis. Initial estimates based on the 2000 census data indicate that we needed to visit approximately 35% of the households in each census tract to collect the required 333 individuals. The initial sample of 3,500-4,000 participants is based on power analyses and assumptions about attrition over 20 years. For a power of 80% (the likelihood of finding an effect if it is really present), we can identify moderate effects (magnitude of the differences between groups) for various outcomes with as few as 30 participants per group at the end of the study. Working backwards by assuming 20% attrition after the baseline assessment and 15% attrition between subsequent assessments, we need approximately 3,500-4,000 participants at baseline to yield 1,680 after 20 years.

The study employs standard statistical software depending on the independent and dependent variables being analyzed. Data analyses include parametric and nonparametric statistics for cross-sectional comparisons applying logistic regression and mixed effects modeling as appropriate for the data. Longitudinal analyses will typically require either mixed-effects models, survival analyses, or proportional hazards depending on the data and specific outcome under study.

17.0.0 Regulatory Requirements

17.1.0 Informed Consent

HANDLS Wave 3 Phase 1& 2. There are three phases to the Wave 3 study. The first phase occurs in the field, at the medical research vehicles (MRVs) or in the participant's home, if they have limited mobility. If the participant has been identified as a home visit participant, consent may be obtained in the home or over the telephone. Among the preparations for their examinations on the medical research vehicles, participants are provided copies of the informed consent documents and are asked to read them. Participants are then instructed to view a consent film about the HANDLS study that explains the purpose of the study and all procedures they have previously reviewed in the informed consent documents. The HANDLS study consenter then reviews each documents with participants a final time, page by page stopping to ask if they have any questions to ensure the participant has a clear understanding of the study, the degree of risk, potential benefits, and alternatives and then provides the participant with an opportunity to ask any further questions and to consider their decision to participate in this next wave of the HANDLS study. If participants agree to take part, signatures will be obtained using an IRB approved hard copy of the informed consent document or electronically using a PC tablet. HANDLS staff provides participants with printed copies for their records and a copy is placed in the research medical record. HANDLS staff sends participants copies of all signed informed consent documents with the results from their examinations.

Alternate Home Visit Consent Procedures. This consent will be done as an oral consent, when participants are consented over the telephone. The consent form will be read to the participant verbatim. The participants will have their own copy available to review as the consenter reads it. All elements required by 45 CFR 46.116 are included, as well as required documentation of the oral consenting process using the following:

Oral documentation.

I have read the above informed consent over the phone to (print name of person being consented) _____ and s/he has agreed to answer the questions and participate in this research study.

*Signature recorded on last page

Print name of person reading this consent_____

Print name of witness who observed: _____

Is there anything you would like me to repeat? (Responded) Yes No

Have you understood everything I have told you? (Responded) Yes No

Do you have any questions? (Responded) Yes No

Do you agree to participate? (Responded) Yes No

Date _____ Time: _____

HANDLS Wave 3 - Optional Studies. Informed consent for the Circadian Rhythm Study will take place on the MRVs using in-person procedures. Informed consent for the Neuro-imaging Study will take place at the UMD following guidelines set forth by their IRB and Informed consent for the Diabetes study will take place in the community and will follow procedures set forth by the University of Maryland Baltimore County IRB.

17.2.0 Compensation

The amount of payment to research volunteers is guided by the National Institutes of Health policies. In general, participants are not paid for taking part in research studies at the National Institutes of Health. Reimbursement of travel and subsistence will be offered consistent with NIH guidelines.

Participants may be reimbursed up to a total of \$360.00 for participating in the HANDLS - wave 3 study. They may be paid up to \$200 for participating in phase 1 (\$160) and 2 (\$40) of this study. If they participate in phase 3A (Ecological measurement of circadian entrainment pilot study) they will be compensated an additional \$60.00. If they participate in phase 3B (Neuroimaging study) they will be compensated an additional \$50.00. Finally, if a participant decides to enroll in the "Subjective Experience of Diabetes" study they will receive \$50.00.

If a participant is unable to complete all of the tests they may receive a portion of that payment. They will receive payment in the form of an ATM debit card at the end of each phase. In most cases, the ATM card will be activated by the end of the study visit day. The participant will be instructed to take the card to an ATM machine of their choosing to withdraw payment. Written instructions regarding how to access payments will be provided. Occasionally participants are not able to complete all testing in one visit to the MRVs or some tests require repeating if there are questionable or abnormal results. We would like to be able to offer additional compensation for time and travel to return to the MRVs for return visits. The amount of compensation will vary between \$20.00 and \$80.00 depending on the length of time spent on the MRVs. We anticipate the return visits to be between 1- 4 hours. This would include participants who never had a baseline evaluation.

17.3.0 Subject Confidentiality

HANDLS participants' confidentiality will be maintained by informing them of the following:

When results of an NIH research study are reported in medical journals or at scientific meetings, the participants will not be named and/or identified. In most cases, the NIH will not release any information about participant's research involvement without their written permission. However, if they sign a release of information form, for example for an insurance company, the HANDLS Medical Records Specialist will give the insurance company information from the medical records. Participants are informed this information might affect (either favorably or unfavorably) the willingness of the insurance company to sell them insurance.

The participant's are informed that the Privacy Act protects the confidentiality of their medical record. However, the Act allows release of some information from the medical record without permission, for example, if the Food and Drug Administration (FDA), members of Congress, law enforcement officials, or authorized hospital accreditation organizations, require it.

HANDLS participants are asked to sign a Health Insurance Portability and Accountability Act (HIPAA), consent document that allows the investigator and sponsors, and certain other people, agencies or entities to look at and review the records related to this study including personal health information (PHI) and the information discovered during this study.

To help us protect privacy, we have obtained a Department of Health and Human Services Certificate of Confidentiality issued by the National Institutes of Health. With this certificate the researchers cannot be forced to disclose information that may identify participants, even by court subpoena, in any federal, state, or local civil, criminal, administrative, legislative or other proceedings. The researchers will use the certificate to resist any demands for information that would identify them, except as explained below. The Certificate cannot be used to resist a demand for information from personnel of the U.S. Department of Health and Human Services that is used for auditing or program evaluation or for information that must be disclosed in order to meet federal regulations. A Certificate of Confidentiality does not prevent participants or a member of their family from voluntarily releasing information about themselves or their involvement in this research. If an insurer, employer, or other person obtains written consent to receive research information, then the researcher may not use the Certificate to withhold that information. The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without participants consent, information that would identify them as a participant in the research project under the following conditions: It does not apply to state requirements to report certain communicable diseases. In addition, the study clinician may be required to report certain cases of abuse, neglect, or suicidal or homicidal intent to the appropriate authorities.

Information regarding who will have access to the data and use of personally identifiable data or private health information (PHI) are described in further detail in sections 7 (data collection and management procedures) and 8 (data analysis) of this protocol.

18.0.0 Adverse Events and Unanticipated Problem Reporting

Adverse events associated with HANDLS study procedures are expected to occur very infrequently. Most of the potential risks associated with study procedures (see Section 1.2) are limited to mild, transient discomforts of no clinical significance. Only clinically significant adverse events will be reported to the IRB.

A clinically significant adverse event will be reported as a serious adverse event if it is life threatening, causes persistent or significant disability, leads to death, or requires medical or surgical intervention to prevent one of these outcomes.

HANDLS staff is trained to detect and respond to clinically significant adverse events. They are expected to report clinically significant adverse events to the Principal Investigator immediately or as soon as is practical. The Principal Investigators for the HANDLS Scan and the Subjective Experience of Diabetes sub-studies are also expected to report clinically significant adverse events immediately to the NIA Principal Investigators and to follow the adverse event reporting policies of their institutions. The HANDLS principal investigator will be responsible for reporting all clinically significant adverse events to the NIEHS IRB within 72 hours of receiving notification that an event occurred.

Serious or unexpected adverse events and unanticipated problems as defined by NIH and NIA policies and the OHRP guidance document (<http://www.hhs.gov/ohrp/policy/ad-vevntguid.html#Q4>); will be reported to the NIEHS IRB orally as soon as possible and in writing within 7 days if life-threatening and within 15 days otherwise. Expected or non-serious adverse events will be reported at the time of continuing review.

The investigator will report unanticipated problems to the IRB within 72 hours of identifying such an occurrence. Unanticipated problems are defined as any incident, experience, or outcome that meets **all** of the following criteria:

- unexpected in terms of nature, severity, or frequency given (a) the research procedures that are in protocol and informed consent and (b) the characteristics of the subject population being studied;
- related or possibly related to participation in the research;
- suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

19.0.0 Site and Clinical Safety Monitoring Plan

The NIA Clinical Research Protocol Office will perform routine visits to the HANDLS research site to ensure the safety and conduct of the study complies with 45 CFR 46 and NIA

guidelines. Audits are performed to assure that clinical research is in compliance with FDA, DHHS domestic regulations, Clinical Practice Guidelines (GCP), and local and federal human subjects standards. An audit may be performed following an adverse event, protocol deviation or at the time of annual renewal. The Clinical Protocol Coordinator of the Clinical Research Protocol Office determines the frequency of monitoring visits. Participant records are randomly selected from the protocol to be audited. Targeted audits may also be carried out when there is specific concern regarding patient safety or data integrity. The principal investigator and clinical research coordinator of the study are notified at least three weeks in advance of the audit, and are asked to supply all research records and patient medical records for the audit.

The NIA Clinical Research Protocol Office (CRPO) staff and the Clinical Protocol Coordinator of the Clinical Research Protocol Office (CRPO) carry out the audits. Audit format follows the NCI guidelines for national cooperative group audits. Following intensive review of the research and medical records, a formal written report of the audit findings is sent to the principal investigator and the NIA Clinical Director. The site visits will be recorded in a visit log, by the monitor, and kept at the HANDLS research site.

The monitor will review various aspects of the study including, but not limited to:

- Compliance to the protocol
- Review of written informed consent forms for participants enrolled
- Comparison of clinic records (source documentation) to data recorded on case report forms to assure the completeness and accuracy of data collected
- Continued acceptability of facilities and staff
- Assessment of proper sample accountability, transfer and storage

During the scheduled monitoring visits, source documentation will be made available to the monitor to substantiate proper informed consent procedures, adherence to protocol procedures, adequate reporting and follow-up of AEs. The Investigator (and as appropriate the research study staff) must be available to meet with the study monitor to discuss the findings from this review of CRFs and source documents, make necessary corrections to case report form entries, respond to data clarification requests and respond to any other study-related inquiries of the monitor.

The principal investigator will be notified of any planned visit and a date will be set that is mutually agreeable. A report will be written to document all findings, solutions and discussions. The report or a follow-up letter summarizing the contents of the report will be sent to the principal investigator. Additional follow-up will be conducted by email and telephone as needed.

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Appendix 1.1: Retention materials – Wave 3 lead letter



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Dear _____ :

National Institutes of Health
National Institute on Aging
5600 Nathan Shock Drive
Baltimore, Maryland 21224-6825

The National Institute on Aging is conducting a study of age-related health disparities in Baltimore called ***Healthy Aging in Neighborhoods of Diversity across the Life Span (HANDLS)***. We are contacting you now to see if you are interested in participating in the next wave of the study. You will be asked to visit our mobile Medical Research Vehicles (MRVs) for a medical evaluation and to participate in a telephone survey shortly after your MRV visit.

You may recall that we visited you in your home and you agreed to participate in the ***Healthy Aging in Neighborhoods of Diversity across the Life Span (HANDLS) study***. Following the home visit, you participated in the medical evaluation on our mobile Medical Research Vehicles. Thank you for taking part in the first wave of the HANDLS study. By inviting our field staff into your home, you successfully completed the household and dietary recall interviews. By participating in the visit to our MRVs, you also completed the first of several medical evaluations we plan to conduct over the next twenty years. **Your participation in the next wave of the study is very important.**

HANDLS is looking at health issues, problems, and concerns in communities all over Baltimore. The purpose of the study is to understand some of the diseases related to aging in African Americans and whites in Baltimore. We want to discover why some people are healthier than others as they get older. It will help us learn about changes in health over time. Ultimately, this will be a long-term observational study in which participants will have state-of-the-art medical evaluations every three years over the next two decades. We are doing this study using two mobile medical research vehicles. These vehicles serve as community-based platforms for clinical research. The vehicles will bring the study to you as participants in the community. We hope this will make it possible for more people to participate than in traditional hospital-based studies.

In the next several weeks, HANDLS staff will be calling and /or knocking on doors of HANDLS participants to invite you to participate in your next visit to the MRVs. They will provide information about the study and schedule appointments for study participants. You may also call for your appointment, at your convenience. Please call Bridget Cromwell at 410-558-8404 or 443-250-1403.

On the back of this letter are answers to questions that participants ask most often about the study. You may also learn more about the study by logging onto our website at handls.nih.gov.



410-558-8622

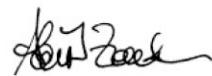
Fax 410-558-8067



Sincerely,



Michele K. Evans, M.D.
Principal Investigator



Alan B. Zonderman, Ph.D.
Principal Investigator

Frequently Asked Questions

1. How can I or my friends and family become a participant?

HANDLS participants were selected through a statistical process using the most current Census information for Baltimore. This means that anyone who did not participate in any part of the HANDLS study between 2004-2009 will not be eligible to participate in the study. We can only schedule individuals who have already been selected. However, if you did not complete your study visit when initially selected, we will be able to schedule your visit to the MRVs at this time.

2. What are the benefits of being a study participant?

If you agree to take part in this study, there may or may not be direct medical benefits to you. We hope the information learned from this study will benefit others in the future. You may benefit by learning more about your health, or possibly from learning that you have a condition or problem that you were unaware of. This is a chance for you to gain additional health information about yourself at no cost to you. Many of the tests performed on the MRV's are not commonly done at physician's offices during routine physical exams. You will receive a Participant Report Package in the mail with results of your blood and urine test, EKG and bone scan.

3. How much time is involved and will I be compensated?

There are two parts of the HANDLS wave 3 study. The first part takes place on the MRVs. A staff member will call you or come to your home to talk to you about the study and ask you to participate. If you agree to participate, you will receive an appointment to come to the mobile MRV's for a full day of testing. During your visit to the MRV's, you will receive a thorough medical evaluation, as well as other testing. At the end of the MRV visit you will be scheduled for the second part, a telephone interview that will last about an hour. You will be compensated a maximum of \$200 if you participate in both parts. If you are unable to complete all of testing you may receive a portion of the payment. More information regarding payment is available in the informed consent documents that accompany this letter.

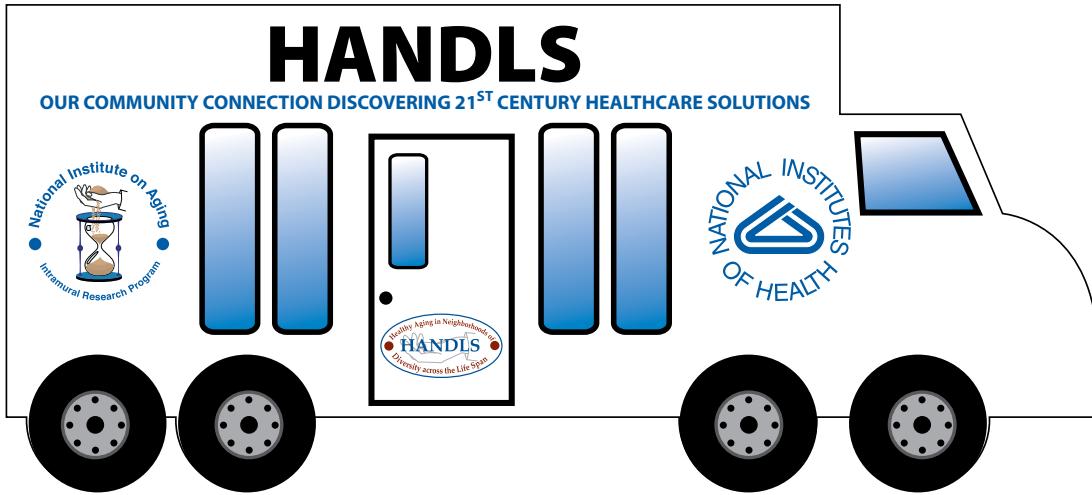
4. Are there any risks in participating in this study?

The risks for this study are minimal. The bone and body scan uses small amounts of X-ray radiation to take measurements of our body. The risks from the radiation are no greater than what you are exposed to by sunlight. There is a very small risk to having blood drawn. Possible risks include infection from the needle puncture; light bruising and some people also feel faint. These risks are very small and occur only rarely. Please review the informed consent booklet for more information regarding risks.

5. What about confidentiality? Public laws keep all information participants give confidential. Federal

Law: the Public Health Service Act (42 USC 242K) authorizes collection and section 308(d) of that law (42 USC 242m) and Privacy Act of 1974 (5 USC 552A) prohibits us from giving out information about you or your family without your consent. We hold all data collected in strictest confidence. Medical records of research study participants are stored and used according to legal guidelines. Your personal information will not be identified in any reports or publications resulting from this study. We assign code numbers in place of names or other facts that could identify you. A Certificate of Confidentiality has been obtained from the Department of Health and Human Services (DHHS). This certificate will protect the investigators from being forced to release any research data in which you are identified, even under court order or subpoena.

Appendix 1.2: Retention materials – Participant flyer



The Healthy Aging in Neighborhoods of Diversity across the Life Span study is coming back. Look for our medical vehicles in your neighborhood.

All aboard... next stop South Hilton...

COMPENSATION
Breakfast & lunch provided

Appointments will begin January, 2013

We thank you for contributing to the success of HANDLS!

Your participation in this groundbreaking study was instrumental in reaching our goal.

It is now time for your next examination!



Look to hear from us soon!

Call **1-877-677-9538** with your questions or to make an appointment.

Appendix 1.3: Retention materials – Follow-up recontact letter



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute on Aging
Intramural Research Program
Biomedical Research Building
251 Bayview Blvd
Baltimore, Maryland 21224-2816

Dear ,

In 2008 you met with the HANDLS Research Study and had a complete physical on our Medical Research Vehicle. We would love the opportunity to see you again and to provide you with this great opportunity. **Please call us to set up an appointment at 877-677-9538.** We are currently at 5504 Key Avenue, Baltimore, MD 21215. We provide transportation to and from your appointment, breakfast and lunch and up to \$200.00 compensation for your time.

If you reside outside of Baltimore, please feel free to call. We will try to make arrangements to see you for an appointment.

The HANDLS study is a research study and we do not provide medical work-ups or treatment of health problems. All tests are done for research purposes only and will be used to describe the health status of men and women who are taking part in the study. These tests are not done to replace any tests that might be ordered to check for health problems. We hope this information is useful to you and your doctor.

Thank you for being a participant in the National Institute on Aging's Healthy Aging in Neighborhoods of Diversity across the Life Span (HANDLS).

Sincerely,

Monique A. Brown

Monique A. Brown
Administrative Assistant
HANDLS
877-677-9538
410-558-8029



Appendix 2: Social media URLs

HANDLS Social Media

Website: <http://handls.nih.gov>

Youtube page: <http://www.youtube.com/user/niashandls>

Facebook page: <http://www.facebook.com/pages/Handls/155105291219820>

Appendix 3.1: Informed consent documents – Wave 3 exam consent

HEALTH DISPARITIES RESEARCH SECTION
LABORATORY OF EPIDEMIOLOGY AND POPULATION SCIENCES
NATIONAL INSTITUTE ON AGING, INTRAMURAL RESEARCH PROGRAM
NATIONAL INSTITUTES OF HEALTH
DEPARTMENT OF HEALTH AND HUMAN SERVICES

INFORMED CONSENT FOR RESEARCH WITH HUMAN SUBJECTS

Study: Healthy Aging in Neighborhoods of Diversity across the Life Span (HANDLS) – Wave 3

Principal Investigator: Michele K. Evans, M.D.

Lead Associate Investigator: Alan B. Zonderman, Ph.D.

Associate Investigators: Deidra C. Crews, MD; Ngozi Ejiogu, MD; Marie T. Fanelli Kuczmarski, PhD, RD, LDN; Michael Nalls, PhD

Medical Advisory Investigator: Michele K. Evans, M.D.

Study Number: 09-AG-N248

INTRODUCTION

We invite you to take part in the next phase of a National Institute on Aging (NIA) research study called Healthy Aging in Neighborhoods of Diversity across the Life Span (HANDLS). You were selected as a participant in this study because when we were looking for residents from 30 and 64 years old in your neighborhood, you decided you wanted to take part in the study. It is time for us to return to your neighborhood for the first follow-up examination. You now have an opportunity to decide whether you would like to participate in the next phase of HANDLS. You will notice that some of the tests are the same as the last time we saw you. We have added some different tests and questionnaires that you might not be familiar with. Please take your time to read this form. Be sure to ask any questions you may have before making your decision. We encourage you to discuss your decision with your family, friends and your doctor(s).

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to learn about changes in health over time in an urban group of African-American and white men and women residing in Baltimore city. Our goal is to study health change, as people grow older. We plan to do this by studying many people in different neighborhoods and the same people over many years. This gives us the information we want about how peoples' bodies change over time.

We also want to study why some people are healthier than others as they get older. We want to discover if we can predict the causes of good health with aging and if we can find better ways to prevent and treat disease. If we can find the causes of good health, then we might find cures for some of the diseases related to aging. This is a research study where we will follow you for twenty

PATIENT IDENTIFICATION

CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

Protocol #

OPS Consent Approval Date: xx/xx/yyyy
File in Section 4: Protocol Consent (1)

years to see how you age. This will help us learn about diseases like heart disease, Alzheimer's disease, high blood pressure, diabetes and stroke. We are trying to understand why some Americans have higher rates of certain diseases and more severe diseases than other Americans.

WHAT ELSE SHOULD I KNOW ABOUT THIS RESEARCH STUDY?

It is important that you read and understand several points that apply to all who take part in our studies:

- Taking part in the study is entirely voluntary and refusal to participate will not affect any rights or benefits you normally have;
- You may or may not benefit from taking part in the study, but knowledge may be gained from your participation that may help others;
- You may stop being in the study at any time without any penalty or losing any of the benefits you would have normally received; and
- Some people have personal, religious or ethical beliefs that may limit the kinds of medical or research treatments they would want to receive. If you have such beliefs, please discuss them with the HANDLS research team before you agree to the study.

The nature of the study, the benefits, risks, discomforts and other information about the study are discussed further below. The information is also explained in the informed consent booklet that goes with this consent form. If any new information is learned, at any time during the research, which might affect your participation in the study, we will tell you. We urge you to ask any questions you have about this study with the staff members who explain it to you and with your own advisors before agreeing to participate.

WHO CAN PARTICIPATE IN THIS STUDY?

To be eligible for this research study the following must apply:

- You must be able to give informed consent - you must understand what the research is about and what we are requesting of you;
- You must have agreed to participate in Wave 1 of the HANDLS study;
- You must have one form of government issued identification

ARE THERE ANY REASONS I SHOULD NOT PARTICIPATE?

You will not be able to participate in this research study if any of the following apply:

- You were not enrolled in Wave 1 of the HANDLS study;
- You are pregnant;
- You are currently (or within the last 6 months of) undergoing cancer treatment (chemotherapy or radiation)

WHAT IF I AM PRESENTLY PARTICIPATING IN ANOTHER RESEARCH STUDY?

Are you presently participating in any other research studies? Yes No

PATIENT IDENTIFICATION

CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

Protocol #

OPS Consent Approval Date: xx/xx/yyyy
File in Section 4: Protocol Consent (1)

If yes, please state which study (ies) _____

While participating in this study, you should not take part in any other research project that in the judgment of the principal investigator is incompatible with this research study. This is to protect you from possible injury arising from such things as extra blood drawing, extra x-rays, interaction of research drugs, or similar hazards.

WHAT HAPPENS IF I AGREE TO BE IN THE STUDY?

The HANDLS Wave 3 study data will be collected in two parts. The first part of the study is the examination visit to the mobile Medical Research Vehicles. The second part of the study is a telephone interview that will happen 7-10 days after your examination visit. You may also be invited to participate in a third part of HANDLS Wave 3. The third part of HANDLS Wave 3 consists of three optional studies. You will learn more about those studies during this examination visit, if you are eligible to participate. You will be asked to sign a separate consent form if you decide to join any of those studies.

This is the consent form for HANDLS Wave 3. You will be asked to give your consent for all of the procedures and interviews that make up Wave 3 of HANDLS. Specifically, we want to be sure you understand the nature of the research we are doing and what is being requested of you. It is also important that you understand any potential risks to you. Please be sure to read the **HANDLS Examination Visit Informed Consent Booklet** that provides more information about each test and any risks or discomforts you may experience.

You may participate in any of the tests, but you do not have to participate in all of the tests. Choosing not to participate in a test will not affect your right to participate in the rest of this study. You may stop any test after it starts. If you are unable to complete all of the tests in one visit you may be invited to return to the MRVs to complete your testing. All of the tests are performed for the purpose of research and are not designed to improve your health at this time. There are no experimental medications, tests or procedures in this study. We perform these tests free of charge. If there are tests in which you do not wish to participate, please list them on the back of this form.

For the first part you will be required to spend a day at our Mobile Medical Research Vehicles (MRVs) to have testing. You will be asked to provide an update about your medical history since your last examination and you will receive a physical examination. We will ask you to remember all of the food you ate the day before your visit. We will assess your muscle strength and bone density. You will have a test to check the blood flow in your heart and to see if your heart valves are leaking. We will also ask you to complete a questionnaire and to participate in memory testing. You will be asked about activities of daily living, use of health care services, and any income and/or employment changes since your last visit to the MRVs. We will also take blood, tissue and urine samples.

You will be asked to give a DNA sample by providing a blood sample and by using a method that collects cells from a saliva (spit) sample you provide. Before you agree to give the DNA sample please review the information that explains the possible risks of providing DNA samples described below and in the Informed Consent Booklet. Genes are composed of the genetic material called DNA. DNA (deoxyribonucleic acid) is the part of the cell that is responsible for providing hereditary

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characteristics (such as eye color) and is used to build proteins. More and more, we are discovering that our genes are important for understanding our health. We will study genes and parts of genes that may cause age related diseases or make these diseases more severe. By finding out the genes that cause specific conditions associated with aging, we may be able to find ways to prevent certain diseases, find them at an earlier and milder stage, or at least be able to treat these conditions better. This study is particularly interested in genes that may be involved with loss of memory, high blood pressure, heart disease, stroke, cancer, diabetes, and arthritis.

As part of this study, you will be offered a test for the human immunodeficiency virus (HIV). This is the virus that causes AIDS. If you are infected with HIV, you will still be able to participate in this study. We will tell you what the results mean, how to find care, how to avoid infecting others, how we report newly diagnosed HIV infection, and the importance of informing your partners of the possible risk because of your HIV infection. If you decide to have the test, you will be asked to sign a separate consent form. It will explain the HIV testing procedures for the HANDLS study.

Below is a table that shows the tests you will be expected to complete during your MRV visit. This chart also tells you how long we think it will take each test to be done and in which vehicle it will be given.

HANDLS Wave 3 Part 1 – Medical Research Vehicle Examination

Measure or Procedure	Estimated Timing	Location
Consent	20 minutes	MRV2/3
Specimen Collection (Urine, Blood, DNA)	20 minutes	MRV 3
Anthropometrics (height & weight)	5 minutes	MRV 1
Interim Medical History	20 minutes	MRV 2
Interim Physical Exam	20 minutes	MRV 1
Dietary Recall I	30 minutes	MRV 2
Cognition	40 minutes	MRV 2
Physical Performance	15 minutes	MRV 1
Echocardiogram	20 minutes	MRV 1
Questionnaire Section	50 minutes	MRV 2
Test of Health Literacy	30 minutes	MRV 1
Body Composition/Bone Densitometry	30 minutes	MRV 1

HANDLS Wave 3 Part 2 – Telephone Interview

The HANDLS Wave 3-telephone interview is designed to take place after your visit to our Mobile Medical Research Vehicles (MRVs). We will ask you to complete an interview over the phone.

The telephone interview is a dietary recall questionnaire that asks you to remember what you had to eat and drink in the last 24 hours. We will use pictures to help you give us information about how much food and drink you had in the last 24 hours. We will also ask you about nutritional supplements and over-the counter medications that you take. You may remember the dietary recall interview from your last visit to the MRVs. The difference for this interview is that we will conduct the interview over

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the phone. All materials (pictures, etc.) for the phone interview will be delivered to you by US mail or given to you at the end of your MRV visit.

ARE THERE RISKS AND SIDE EFFECTS OF THIS STUDY?

The potential risks for this study are minimal. You should know that there are some risks in donating a blood sample. The trained HANDLS staff member will insert a needle in a vein in your arm. There is a risk of an infection from the needle puncture. There is also a risk of a black and blue mark, and you may feel faint. These risks are very small. Our staff is well trained and has drawn blood many times. It is common to have a small black and blue mark, but it disappears after a day or so. Some people have begun perspiring, or they felt nauseated and their pulse slowed. None of them had any after effects.

The risk of genetic testing (by providing the DNA sample) includes the possible misuse of personal, genetic information. Although rare, misuse of such information has caused problems for persons related to employment, life, or health insurance benefits and right. There is a risk that being in a genetics study can cause psychological distress or tension with other family members. Although there can be no absolute guarantees, every reasonable effort will be made to keep your personally identifiable information secret so that there will be no misuse. Even when the information is kept secret, if you are asked if you have ever been tested for a genetic disorder, answering "yes" could cause benefits to be denied or could cause other problems including discrimination.

This research study requires a small amount of radiation from the DEXA Scan. It must be noted that this radiation exposure is not needed for your medical care. It is for research purposes only. The total amount of radiation you will receive from this study is from one DEXA scan. The NIH Radiation Safety Committee has reviewed the use of radiation in this research study. It has approved this use as involving minimal risk and needed to obtain the research information desired.

Using the standard way of describing radiation exposure, from one DEXA Scan you will receive an effective dose of less than one thousandth of one rem. By comparison the average person in the United States receives this much radiation every day from natural sources, such as the sun. In this scan the only part of the body exposed is the skin, which is less sensitive to radiation than other parts of the body. There is a very small risk of cancer from the x-rays in DEXA scan, but it is too small to measure. If you are pregnant you may not participate in this study. Unborn babies are more sensitive to radiation than children or adults.

The risks for the dietary recall interview, the questionnaires and memory testing are very minimal. The only risk of this part of the study is that you may become tired and sometimes, people feel nervous when they do these tests. All examiners who are involved in giving these tests are experienced in using these procedures and they will minimize any discomfort that you might feel. If the tests are disturbing you, then you may stop testing any time you want.

For more information about risks and side effects, you should call the Principal Investigator, Michele K. Evans, M.D. at 410-558-8573.

WHAT WILL HAPPEN TO MY SAMPLES WHEN THE STUDY IS OVER?

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The NIA will retain custody of your samples for studies as outlined above. You will retain the right to have the sample material made unavailable for future genetic testing and other specific testing by completing the section below by initiating on the line next to your choice. The NIA will be the exclusive owner of any data, discoveries or derivative materials from the sample materials and is responsible for the restriction of sample use at your request. If a potential commercial product is developed from this research project, the NIA will develop patents and promote commercialization of the product as required by law. You will not profit financially from such a product.

Doctors often make new discoveries by testing blood and urine. We would like to freeze a portion of your blood and urine samples to save them in our frozen tissue bank. We are not sure what new discoveries will appear in the future. We want to set aside your samples until there are new tests that will help us understand health and aging.

Your samples will be stored in secured freezers at an NIA facility. Your name and identifying information will be removed and we will give the samples a code. The key to the code will be kept in a separate, secure area. Your samples will be used only for the study described in this consent form unless you give us permission to use them for other studies.

If a future research project arises where your samples could be useful, we ask you to designate as to whether or not your sample can be used. Any future research use will require approval by the Institutional Review Board (IRB).

Please initial by the line indicating your wishes:

YES, I give permission to use my (blood or other fluids, tissues) samples in future research studies under the following conditions:

These samples may be used for other research projects without contacting me only if the identification code is removed so that the sample can no longer be identified as mine.

These samples may be used for other research projects without contacting me even if the code is left on the samples. I understand that if the samples are coded, they may be able to be traced back to my personally identifiable information and my medical records.

MAYBE, I wish to be re-contacted if further studies with my samples are considered. After the study has been explained, I will then decide if I want my samples to be included.

NO under no circumstances shall my samples be used for any future studies. My samples should be discarded once the present study is complete.

If you allow future research on your sample and the research provides information important for your health, we will try to contact you. If you wish to be contacted please keep the principal investigator for this study or the NIA updated about changes in your address or phone number.

WHAT ARE THE POSSIBLE OR EXPECTED BENEFITS?

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This study is not designed to give direct benefits to any participants. If you agree to take part in this study, there may or may not be direct medical benefits to you. We hope the information learned from this study will benefit others in the future. There is no charge for any of the testing described. You may benefit by learning more about your health, or possibly from learning that you have a condition or problem.

DO I HAVE AN ALTERNATIVE TO PARTICIPATING?

There are no other options associated with your participation in this study. You may choose either to participate or not to participate in this research. Taking part in this study is entirely voluntary. You may choose to withdraw from the study at any time.

WILL I BE GIVEN MY STUDY RESULTS?

You will receive a Participant Report Packet in the mail, with results of your visit to the MRVs. If the study doctor discovers any condition or problem, the information will be provided to you and your doctor, if you authorize it. To authorize the reporting of results to your physician you will need to sign a form called "Release of Medical Information". You will be asked to sign this form only if you want us to communicate with your physician. The study doctors do not provide medical treatment.

CONFIDENTIALITY CERTIFICATE

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this certificate the researchers cannot be forced to disclose information that may identify you, even by court subpoena, in any federal, state, or local civil, criminal, administrative, legislative or other proceedings. The researchers will use the certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the U.S. Department of Health and Human Services that is used for auditing or program evaluation or for information that must be disclosed in order to meet federal regulations.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researcher may not use the Certificate to withhold that information.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following conditions: It does not apply to state requirements to report certain communicable diseases. In addition, the study doctor may be required to report certain cases of abuse, neglect, or suicidal or homicidal intent to the appropriate authorities.

WILL IT COST ME ANYTHING TO PARTICIPATE?

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You do not have to pay anything to be in this study. However, if taking part in this study leads to procedures or care not included in the study, it may lead to added costs for you or your insurance company. You will not be charged for tests that are part of this research study.

WILL I BE PAID FOR PARTICIPATING?

You will receive \$160 for the first phase (MRV visit) of the study. Your payment will be made in the form of an ATM debit card at the end of the MRV visit. If you are unable to complete all of the tests you may receive a portion of the payment. If you have to return to the MRVs to complete testing on another day, you could be compensated for the additional visit. The ATM card will be activated before you leave the vehicle. You will be able to take the card to an ATM machine in your neighborhood to withdraw your payment.

If you decide to participate in the second phase of this study, the follow-up telephone interview, scheduled to occur with-in 7-10 days after your MRV visit, you will be paid an additional \$40.00. Your payment will be added to the ATM debit card given to you during your MRV visit.

We will provide round-trip transportation from your home to our mobile testing center if you want it. We will serve a box breakfast and box lunch if you are participating in tests during mid-day. We will do our best to meet your dietary needs if you have any.

OTHER PERTINENT INFORMATION

- 1. Confidentiality.** When results of an NIH research study are reported in medical journals or at scientific meetings, the people who take part are not named and identified. In most cases, the NIH will not release any information about your research involvement without your written permission. However, if you sign a release of information form, for example, for an insurance company, the NIH will give the insurance company information from your medical record. This information might affect (either favorably or unfavorably) the willingness of the insurance company to sell you insurance.

The Federal Privacy Act protects the confidentiality of your NIH medical records. However, you should know that the Act allows release of some information from your medical record without your permission, for example, if it is required by the Food and Drug Administration (FDA), members of Congress, law enforcement officials, or authorized hospital accreditation organizations.

- 2. Conflict of Interest.** No NIH investigator involved in this study receives payments or other benefits from any company whose drug, product or device is being tested.
- 3. Policy Regarding Research-Related Injuries.** The National Institute on Aging will provide short-term medical care for any injury resulting from your participation in this research study. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the National Institute on Aging, National Institutes of Health, or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.
- 4. Payments.** The amount of payment to research volunteers is guided by the National Institute of Health policies. In general, patients are not paid for taking part in research studies at the National Institutes of Health. Reimbursement of travel and subsistence will be offered consistent with NIH guidelines. Compensation of \$600 or more in one year will be reported to the IRS per federal regulations.

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5. Problems or Questions. If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigator, Michele K. Evans, MD at 410-558-8573. You may also call the NIA Clinical Research Protocol Office at 410-350-3947.

6. Consent Document. Please keep a copy of this document in case you want to read it again.

COMPLETE APPROPRIATE ITEM(S) BELOW:			
A. Adult Patient's Consent I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby consent to take part in this study.		B. Parent's Permission for Minor Patient. I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby give permission for my child to take part in this study. (Attach NIH 2514-2, Minor's Assent, if applicable.)	
Signature of Adult Patient/Legal Representative	Date	Signature of Parent(s)/Guardian	Date
Print Name		Print Name	
C. Child's Verbal Assent (If Applicable) The information in the above consent was described to my child and my child agrees to participate in the study.			
Signature of Parent(s)/Guardian	Date	Print Name	
THIS CONSENT DOCUMENT HAS BEEN APPROVED FOR USE FROM <i>Continuing Review Approval Date</i> THROUGH <i>Expiration Date</i>.			
Signature of Investigator	Date	Signature of Witness	Date
Print Name		Print Name	

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Appendix 3.2: Informed consent documents – Exam booklet



Healthy Aging in Neighborhoods of Diversity across the Life Span

Examination Visit
Informed Consent Booklet

Introduction

We must have your written informed consent before we perform research tests or examinations.

We follow federal regulations for research with human subjects. These regulations require us to make sure that you understand what examinations we will perform and the risks that are involved, if there are any.

This booklet reviews the tests that we will perform in this research. We perform these tests free of charge. You should understand the purpose of this study before you agree to participate in this research. We welcome any questions that you might have about what to expect in this study. You may participate in any of the tests, but you need not participate in all of the tests. You may stop any time after a test starts. You may ask questions any time during a test.

We want to make sure that you understand the tests in this study. We must witness your signature on the consent form. Please do not sign the consent form until you arrive at the Mobile Medical Research Vehicles.

Purpose of the Study

The purpose of this study is to learn about changes in health over time in an urban, working and non-working group of African American and white, men and women residing in Baltimore city. We want to study as many people in different communities as we can by using our Mobile Medical Research Vehicles (MRVs).

Our goal is to study the rate of health change, as people grow older. We plan to do this by studying the

same people over many years. This gives us the information we want about how people's bodies change over time. We will continue to invite you to participate in our study every three to four years when we visit your neighborhood with our Mobile Research Vehicles (MRVs).

We also want to study why some people are healthier as they get older than others. We want to discover if we can predict the causes of good health with aging. If we can find the causes of good health, then we might find the cures for some of the diseases related to aging.

We call our study *Healthy Aging in Neighborhoods of Diversity across the Life Span*.

We are currently conducting the second visit to your neighborhood. The study data will be collected in two parts. The first part of the study consists of a visit to the MRVs. The MRV-1 will be used for the medical history and physical examination, body composition, test of the heart's function, strength testing, a health literacy assessment and bone density. MRV-2 will be used for consenting, the dietary recall interview, questionnaires, and to administer the cognitive and memory testing. MRV-3 will be used for consenting, initial medical screening and the collection of laboratory samples. You will begin your visit on MRV-2 for consenting and you will then have your screening and blood work on MRV-3. You will then proceed to either MRV-2 or MRV-1 depending on the schedule for the day. You will visit all three vehicles before the day is complete.

The second part of the study will be conducted as a telephone interview. You will be asked to complete another dietary recall interview just like the one you

did on MRV-2 and includes the use of over-the-counter medications and dietary supplements.

We plan to continue to administer similar tests every three to four years for the next 20 years.

List of Tests and Statements of Risk

We want you to understand the risks in taking some of these tests. We welcome your questions about the tests and any risks even after the test starts.

Risks, if any, are stated and discussed with the description of the test, or in the section on *Assessment of Risks* in this booklet.

Body Composition

We will weigh you and measure your height. There are no risks from this test.

Bone Density (DEXA)

We will measure the size and quality of the bones in your back and hip. We will also perform the instant vertebral assessment (IVA), which allows for screening of vertebral fractures. These measures will tell us if you are likely to have osteoporosis (thinning of the bones) – a risk factor for bone fractures. We will also measure how much lean tissue and fat tissue you have in your body.

We will ask you to lie down on a device called a DEXA scanner. The scanner uses small amounts of X-ray radiation to make measurements as a detector examines your body.

The risk to you, if any, is estimated to be slight. The risks are discussed in the section on *Assessment of Risks* in this booklet.

Muscle Strength Testing

The information we collect will help us to understand how strength changes as people get older.

Grip Strength Test

Handgrip strength in both hands will be measured using an adjustable, hand-held, hydraulic grip strength dynamometer. The hydraulic grip strength dynamometer is a device you hold in your hand and squeeze. It measures the strength of your handgrip.

You will be asked to sit with the arm to be tested resting on the table. The dynamometer is held in the hand to be tested and is resting on a mouse pad. We will ask you to grip the two bars of the dynamometer in your hand, and to slowly squeeze the bars as hard as you can. The test is repeated on the other hand.

Exclusions. If you have had arm or hand surgery like fusion, arthroplasty, tendon repair, synovectomy, or other related surgery in the past 3 months you will not be tested on the affected hand.

Chair Stand

Using a standard armless chair placed securely against a wall, you be asked to rise from the chair without using your arms and to return to a seated position. If this is done successfully, you will be asked to repeat that movement 10 times.

Exclusions. There are no formal exclusions from attempting the single chair stand; inability to rise from

a chair without using arms excludes participants from doing repeated chair stands.

Balance Test

We will ask you to stand with your feet together and with your feet in a heel-to-toe position for 30 seconds each. We will also ask you to try to stand on one leg for 30 seconds. You may stand on whichever leg is more comfortable. The examiner will demonstrate exactly what is expected. We will ask you to try to hold your foot up for thirty seconds. We will ask you to repeat this test 2 times.

We want you to know that there are very minimal risks associated with these tests. The only risks are that there is a slight risk of falling and you may feel tired after these tests.

Medical History and Physical Examination

Medical History

We will ask you questions about changes and updates to your medical history since your first MRV visit. The examiner will add information to the form when you have your physical examination.

Smoking, Drug and Alcohol History

We will ask you about your smoking habits and use of drugs and alcohol.

Physical Examination

Our physician or nurse practitioner will give you a physical exam in our private exam room. They will check your blood pressure and pulse in both arms. They will listen to your heart and lungs, examine your

eyes, joints, and check your reflexes and other parts of your nervous system. The physician or nurse practitioner will also examine your abdomen.

Our physician or nurse practitioner will not do a complete physical exam. You should still see your personal physician for regular check-ups.

Tests of your Heart Functions

We will do a test to see how well your heart functions. We will discuss the results with you after we finish the tests. If we find a heart problem, we will discuss the problem with you and we will send the results to your personal doctor if you want us to.

Resting Electrocardiogram (ECG)

We will place wires called electrodes on your skin to record your heartbeats. We will look at your heart rate and rhythm, electrical pulses of your heart, and check if you have an enlarged heart. We will check if you have had a heart attack or have any other heart condition.

There are no risks from this procedure.

Echocardiogram

An Echocardiogram is an ultrasound test that is used to examine the structure and function of the heart. We will measure the size of the chambers of the heart, the thickness of the walls, and the function of the chambers as the heart pumps. We will also examine how well the heart valves work as they open and close.

An ultrasound sensor is placed on the chest, over the heart. The echo sound waves produce images on the

monitor. These images show the action of the chambers and valves of heart.

The only possible risk from this procedure is irritation from the electrodes placed on the skin.

Nutritional Dietary Recall

During this interview we will ask you to remember all the foods and beverages you have consumed during the last 24 hours. We will have some cups and measures to help you remember the amounts.

A trained interviewer will record your answers and ask questions designed to help you remember using a method developed by the United States Department of Agriculture (USDA).

The risks for the dietary recall interview are very minimal. The only risk of this part of the study is that you may become tired. All examiners who are involved in asking these questions are experienced in using these procedures and they will minimize any discomfort that you might feel.

Problem Solving and Memory Testing

We will ask you to do some tasks that exercise your thinking and memory. These tasks ask you to remember words, numbers, and pictures. These tasks also ask you to find similar words or to think of words beginning with certain letters or belonging to certain categories. They will also ask you to imagine how objects look in different positions.

The tests for remembering are called the *Benton Visual Retention Test*, the *California Verbal Learning Test*, and the *Digit Span Test*. The tests for words are called

the *Wide Range Achievement Test* and the *Category Fluency Test*. The test for comparing objects is called the *Identical Pictures Test*. The test for switching letters and numbers is called the *Trailmaking Test*. The test for imagining objects in different positions is called the *Card Rotations Test*. Other tests, called *Mental Status Tests*, measure several types of memory abilities.

These tests are given in a private, quiet room with a tester who will help you understand how to do the best you can.

We want you to know that some people find these tests tiring. Sometimes, people feel nervous when they do these tests. All examiners who are involved in giving these tests are experienced in using these procedures and they will minimize any discomfort that you might feel. If the tests are disturbing you, then you may stop testing any time you want.

Questionnaires

We will ask you to complete several questionnaires about your use of health care services, present health status, your level of physical activity, your use of nutrition supplements and over-the-counter medicines, your neighborhood, income and other financial interests, mental health, household composition, if you provide care to others, education and employment.

These questionnaires will be filled out on the Mobile Research Vehicles by using a computer and headphones and/or by telephone interview. While on the MRV, we will help you do the questionnaires if you want us to. If you have trouble seeing or reading the questions you may ask one of our testers to help you. These tests are given in a private, quiet room.

Blood, Tissue, and Urine Sampling

If you agree, we will ask you to give us a blood sample and a urine sample. To prepare you for the blood tests we will ask you not to eat or drink anything after midnight the night before your visit to the MRVs. The blood draw will be performed right before you are served breakfast. We will use these samples to measure your health and so that we can measure changes in your health if we test you again. We will measure your white and red blood cells, your cholesterol, salt, and sugar, and how well your blood carries oxygen through your body and how fast you heal from minor cuts. We will also measure blood chemistry that may tell us how well your body organs work, such as the heart, liver, and kidneys. Women between the ages of 30 and 55 years will get a pregnancy test. We will be testing for communicable diseases including Hepatitis B, Hepatitis C, and Syphilis.

You will be offered a test for HIV. If you decide to have the test, you will be asked to sign a separate consent form that explains the HIV testing procedures for the HANDLS study.

We will ask you to donate about 87.5 milliliters of blood (~6 tablespoons). For comparison, the Red Cross usually asks for a donation of about 500 milliliters of blood (about two cups).

The risk to you, if any, is estimated to be slight. The risks are discussed below in the section on *Assessment of Risks* in this booklet.

Buccal Cell Collection

As part of the medical evaluation buccal mucosa cells will be collected from you, if you agree, using the DNA

Genotek Oragene RNA and DNA self collection system. This system collects buccal cells from inside your mouth by asking you to give a saliva sample by spitting into a small cup. The extracted DNA will be used for epigenetic analysis. Epigenetic analysis lets us study chemical changes to the DNA that may also lead to changes in the way genes and cells in your body work.

There are no known risks associated with the DNA Genotek Oragene RNA and DNA self collection system (the saliva collection system using a cup).

If you are unable to provide a saliva sample we will use another method to collect the sample called the Whatman FTA collection system. You may remember we used the Whatman system during your last MRV visit. This system collects buccal cells using a foam tipped applicator. We will ask you to place the applicator into your mouth and rub on the inside of both cheeks for 30 seconds. You will then hand the applicator to staff and they will transfer the sample to a card and send it to the lab for analysis.

Buccal Mucosa smear (Watman FTA collection system) risks include irritation of the inside of the cheek and/or gum line by the foam tipped swab used to collect cells and saliva when using the Watman system.

Genetics/DNA Testing

Genes are composed of the genetic material called DNA. DNA (deoxyribonucleic acid) is the part of the cell that is responsible for providing hereditary characteristics (such as eye color) and is used to build proteins. More and more, we are discovering that our genes are important for understanding our health. Your genes are the parts of each cell inherited from your mother and father. Your genes are what make you a unique individual. Genes

are made from DNA. We want to use some of your donated blood to freeze your DNA. We are not sure what studies will use your DNA. New studies may look at how your genes affect age-related diseases. The risks associated with participating in genetics testing are discussed below in the section on *Assessment of Risks* in this booklet.

Future Use of Samples

Doctors often make new discoveries by testing blood and urine. We would like to freeze a portion of your blood and urine samples to save them in our frozen tissue bank. We are not sure what new discoveries will appear in the future. We want to set aside your samples until there are new tests that will help us understand health and aging.

The samples saved in our bank will be stored at very low temperatures. Unlike household freezers, these freezers can preserve samples for many years, perhaps many decades. We will label your samples with code numbers. Only the principal investigators in this study will know your code number. Only researchers in this study will know the results of tests using your genes. We will not reveal your results to anyone who is not associated with this research.

Results

We will ask you if you want the results of the tests that we perform on your blood and urine. We will also ask you if you want us to send your results to your personal physician.

We do not plan to report the results of the studies we do on your genes because at this time, these tests do not diagnose or predict the development of specific

diseases. In the future, we may offer you some of the results if the Food and Drug Administration approve some of the tests.

Assessment of Risks

Blood Sampling

We want you to know that there are some risks in donating a blood sample. The trained HANDLS staff member will insert a needle in a vein in your arm. There is a risk of an infection from the needle puncture. There is also a risk of a black and blue mark, and you may feel faint. These risks are very small. Our staff is well trained and has drawn blood many times. It is common to have a small black and blue mark, but it disappears after a day or so. Some people have begun perspiring, or they felt nauseated and their pulse slowed. None of them had any after effects.

Genetics Testing

You will be asked to be part of the study involving genetic testing. Risks of genetic testing include the misuse of personal, genetic information. Although rare, misuse of such information has caused problems for persons related to employment, life, or health insurance benefits and right. There is a risk that being in a genetics study can cause psychological distress or tension with other family members. Although there can be no absolute guarantees, every reasonable effort will be made to keep your personally identifiable information secret so that there will be no misuse. Even when the information is kept secret, if you are asked if you have ever been tested for a genetic disorder, answering "yes" could cause benefits to be denied or could cause other problems including discrimination.

Radiation - Bone Density test (DEXA)

Each day everyone receives a certain amount of natural radiation from various sources in the environment. The exact amount of radiation is measured in units called millirems. The National Council on Radiation Protection and Measurements measures average radiation exposure. They estimate that people in our country receive 300 millirems of annual exposure.

The radiation you will receive from participating in this study is equivalent to an exposure of less than 1 millirem to your whole body. This whole body dose is called the effective dose. The average annual background radiation in the United States is an effective dose of 300 millirems per year. The amount of radiation in this study is equal to the background radiation in about one day. Using the standard way of describing radiation dose, you will receive 9.4 millirems to the skin over your lower spine and hip area, and total body. Thus, your body will receive a small dose of radiation.

Please be aware that this radiation exposure is for research purposes only, and is not essential for your medical care. The NIH Radiation Safety Committee, a group of experts on radiation matters, has reviewed the use of radiation in this research study and has approved this use as being necessary to obtain the research information desired.

The radiation dose you will receive is within the NIH Radiation Safety Guidelines for research subjects, that

is, the effective dose is less than 5000 millirem in one year. The potential long-term risk from the radiation doses in this study is uncertain, but these doses have never been associated with any definite adverse effects. Thus the risk to you, if any, is estimated to be slight.

Please advise your doctor if you have participated in research studies at the NIH or other institutions that involved the use of radiation so that it may be determined that the total radiation dose from all studies is not excessive. Examples of such studies include x-ray studies conducted in radiology departments, cardiac catheterization, and fluoroscopy as well as nuclear medicine studies, for example technetium and PET scans.

If you are female, you may participate in this study only if you are certain you are not pregnant. If you become pregnant (or suspect pregnancy) before the study is completed, you must inform the investigator.

You are participating in a research study and our physicians and technicians are not your primary health-care providers. We will provide medical feedback to you and, with your permission, to your personal physician about your health based on the tests in which you participate. If you need a referral to a physician, we will provide a list of local physicians and assist you in locating a health care provider in your area if you like.

If you have any questions about the study or the specific procedures or risks, please ask the HANDLS study staff members. They will be happy to answer any questions you may have at any time during the study.

Appendix 3.3: Informed consent documents – Home visit consent

HEALTH DISPARITIES RESEARCH SECTION
LABORATORY OF EPIDEMIOLOGY AND POPULATION SCIENCES
NATIONAL INSTITUTE ON AGING, INTRAMURAL RESEARCH PROGRAM
NATIONAL INSTITUTES OF HEALTH
DEPARTMENT OF HEALTH AND HUMAN SERVICES

INFORMED CONSENT FOR RESEARCH WITH HUMAN SUBJECTS

Study: Healthy Aging in Neighborhoods of Diversity across the Life Span (HANDLS) – Wave 3
HOME VISIT

Principal Investigators: Michele K. Evans, M.D.

Lead Associate Investigator: Alan B. Zonderman, Ph.D.

Associate Investigators: Deidra C. Crews, MD; Ngozi Ejiogu, MD; Marie T. Fanelli Kuczmarski, PhD, RD, LDN; Michael Nalls, PhD

Medical Advisory Investigator: Michele K. Evans, M.D.

Study Number: 09-AG-N248

This consent will either be done in person and obtained signatures or as an oral consent. When conducted as an oral consent, it will be read to the informant. All elements required by 45 CFR 46.116 are included, as well as required documentation of the oral consenting process.

INTRODUCTION

We invite you to take part in the next phase of a National Institute on Aging (NIA) research study called Healthy Aging in Neighborhoods of Diversity across the Life Span (HANDLS). You were selected as a participant in this study because when we were looking for residents from 30 and 64 years old in your neighborhood, you decided you wanted to take part in the study. It is time for us to return to your neighborhood for the first follow-up examination. You now have an opportunity to decide whether you would like to participate in the next phase of HANDLS. You will notice that some of the tests are the same as the last time we saw you. We have added some different tests and questionnaires that you might not be familiar with. Please take your time to read this form. Be sure to ask any questions you may have before making your decision. We encourage you to discuss your decision with your family, friends and your doctor(s).

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to learn about changes in health over time in an urban group of African-American and white men and women residing in Baltimore city. Our goal is to study health change, as people grow older. We plan to do this by studying many people in different neighborhoods and the

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same people over many years. This gives us the information we want about how peoples' bodies change over time.

We also want to study why some people are healthier than others as they get older. We want to discover if we can predict the causes of good health with aging and if we can find better ways to prevent and treat disease. If we can find the causes of good health, then we might find cures for some of the diseases related to aging. This is a research study where we will follow you for twenty years to see how you age. This will help us learn about diseases like heart disease, Alzheimer's disease, high blood pressure, diabetes and stroke. We are trying to understand why some Americans have higher rates of certain diseases and more severe diseases than other Americans.

WHAT ELSE SHOULD I KNOW ABOUT THIS RESEARCH STUDY?

It is important that you read and understand several points that apply to all who take part in our studies:

- Taking part in the study is entirely voluntary and refusal to participate will not affect any rights or benefits you normally have;
- You may or may not benefit from taking part in the study, but knowledge may be gained from your participation that may help others;
- You may stop being in the study at any time without any penalty or losing any of the benefits you would have normally received; and
- Some people have personal, religious or ethical beliefs that may limit the kinds of medical or research treatments they would want to receive. If you have such beliefs, please discuss them with the HANDLS research team before you agree to the study.

The nature of the study, the benefits, risks, discomforts and other information about the study are discussed further below. The information is also explained in the informed consent booklet that goes with this consent form. If any new information is learned, at any time during the research, which might affect your participation in the study, we will tell you. We urge you to ask any questions you have about this study with the staff members who explain it to you and with your own advisors before agreeing to participate.

WHO CAN PARTICIPATE IN THIS STUDY?

To be eligible for this research study the following must apply:

- You must be able to give informed consent - you must understand what the research is about and what we are requesting of you;
- You must have agreed to participate in Wave 1 of the HANDLS study;
- You must have one form of government issued identification

ARE THERE ANY REASONS I SHOULD NOT PARTICIPATE?

You will not be able to participate in this research study if any of the following apply:

- You were not enrolled in Wave 1 of the HANDLS study;

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- You are pregnant;
- You are currently (or within the last 6 months of) undergoing cancer treatment (chemotherapy or radiation)

WHAT IF I AM PRESENTLY PARTICIPATING IN ANOTHER RESEARCH STUDY?

Are you presently participating in any other research studies? Yes No

If yes, please state which study (ies) _____

While participating in this study, you should not take part in any other research project that in the judgment of the principal investigator is incompatible with this research study. This is to protect you from possible injury arising from such things as extra blood drawing, extra x-rays, interaction of research drugs, or similar hazards.

WHAT HAPPENS IF I AGREE TO BE IN THE STUDY?

The HANDLS Wave 3 study data will be collected in two parts. The first part of the study is a medical examination visit that requires you have the HANDLS medical staff come to your home to provide testing. The second part of the study is made up of two telephone interviews that will be scheduled 7-10 days after your examination visit. You may also be invited to participate in a third part of HANDLS Wave 3. The third part of HANDLS Wave 3 consists of three optional studies. You will learn more about those studies during this examination visit, if you are eligible to participate. You will be asked to sign a separate consent form if you decide to join any of those studies.

This is the consent form for HANDLS Wave 3 Home Visit. You will be asked to give your consent for all of the procedures and interviews that make up Wave 3 of HANDLS. Specifically, we want to be sure you understand the nature of the research we are doing and what is being requested of you. It is also important that you understand any potential risks to you. Please be sure to read the **HANDLS Home Visit Informed Consent Booklet** that provides more information about each test and any risks or discomforts you may experience.

You may participate in any of the tests, but you do not have to participate in all of the tests. Choosing not to participate in a test will not affect your right to participate in the rest of this study. You may stop any test after it starts. If you are unable to complete all of the tests in one visit, our staff may return to your home to complete your testing. All of the tests are performed for the purpose of research and are not designed to improve your health at this time. There are no experimental medications, tests or procedures in this study. We perform these tests free of charge. If there are tests in which you do not wish to participate, please list them on the back of this form.

During the home visit you will be asked to provide an update about your medical history since your last examination and you will receive a physical examination. We will assess your muscle strength and test your memory. We will also take blood, tissue and urine samples. You will be asked about activities of daily living, use of health care services, and any income and/or employment changes since your last visit.

You will be asked to give a DNA sample by providing a blood sample and by using a method that collects cells from a saliva (spit) sample you provide. Before you agree to give the DNA sample

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please review the information that explains the possible risks of providing DNA samples described below and in the Informed Consent Booklet. Genes are composed of the genetic material called DNA. DNA (deoxyribonucleic acid) is the part of the cell that is responsible for providing hereditary characteristics (such as eye color) and is used to build proteins. More and more, we are discovering that our genes are important for understanding our health. We will study genes and parts of genes that may cause age related diseases or make these diseases more severe. By finding out the genes that cause specific conditions associated with aging, we may be able to find ways to prevent certain diseases, find them at an earlier and milder stage, or at least be able to treat these conditions better. This study is particularly interested in genes that may be involved with loss of memory, high blood pressure, heart disease, stroke, cancer, diabetes, and arthritis.

As part of this study, you will be offered a test for the human immunodeficiency virus (HIV). This is the virus that causes AIDS. If you are infected with HIV, you will still be able to participate in this study. We will tell you what the results mean, how to find care, how to avoid infecting others, how we report newly diagnosed HIV infection, and the importance of informing your partners of the possible risk because of your HIV infection. If you decide to have the test, you will be asked to sign a separate consent form. It will explain the HIV testing procedures for the HANDLS study.

Below is a table that shows the tests you will be expected to complete. This chart also tells you how long we think it will take each test to be done.

HANDLS Wave 3 Part 1A – Home Visit Examination

Measure or Procedure	Estimated Timing	Location
Consent (completed by phone or in-person)	20 minutes	Home
Specimen Collection, Vitals and EKG	45 minutes	Home
Cognition	60 minutes	Home
Interim Medical History	30 minutes	Home
Interim Physical Exam	45 minutes	Home
Hand Grip	10 minutes	Home
Questionnaires	15 minutes	Home

HANDLS Wave 3 Part 2 – Telephone Interview

The HANDLS Wave 3 telephone interviews are designed to take place within 7-10 days of your home visit and will be given one week apart. We ask that you agree to take part in both of the telephone interviews.

The telephone interview is a dietary recall questionnaire that asks you to remember what you had to eat and drink in the last 24 hours. We will use pictures to help you give us information about how much food and drink you had in the last 24 hours. We will also ask you about nutritional supplements

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and over-the counter medications that you take. You may remember the dietary recall interview from your last study visit. The difference for this interview is that we will conduct both interviews over the phone. All materials (pictures, etc.) for the phone interview will be delivered to you by US mail or given to you at the end of your home visit.

ARE THERE RISKS AND SIDE EFFECTS OF THIS STUDY?

The potential risks for this study are minimal. You should know that there are some risks in donating a blood sample. The trained HANDLS staff member will insert a needle in a vein in your arm. There is a risk of an infection from the needle puncture. There is also a risk of a black and blue mark, and you may feel faint. These risks are very small. Our staff is well trained and has drawn blood many times. It is common to have a small black and blue mark, but it disappears after a day or so. Some people have begun perspiring, or they felt nauseated and their pulse slowed. None of them had any after effects.

The risk of genetic testing (by providing the DNA sample) includes the possible misuse of personal genetic information. Although rare, misuse of such information has caused problems for persons related to employment, life, or health insurance benefits and right. There is a risk that being in a genetics study can cause psychological distress or tension with other family members. Although there can be no absolute guarantees, every reasonable effort will be made to keep your personally identifiable information secret so that there will be no misuse. Even when the information is kept secret, if you are asked if you have ever been tested for a genetic disorder, answering "yes" could cause benefits to be denied or could cause other problems including discrimination.

The risks for the dietary recall interview, the questionnaires and memory testing are very minimal. The only risk of this part of the study is that you may become tired and sometimes, people feel nervous when they do these tests. All examiners who are involved in giving these tests are experienced in using these procedures and they will minimize any discomfort that you might feel. If the tests are disturbing you, then you may stop testing any time you want.

For more information about risks and side effects, you should call the Principal Investigator, Michele K. Evans, M.D. at 410-558-8573.

WHAT WILL HAPPEN TO MY SAMPLES WHEN THE STUDY IS OVER?

The NIA will retain custody of your samples for studies as outlined above. You will retain the right to have the sample material made unavailable for future genetic testing and other specific testing by completing the section below by initiating on the line next to your choice. The NIA will be the exclusive owner of any data, discoveries or derivative materials from the sample materials and is responsible for the restriction of sample use at your request. If a potential commercial product is developed from this research project, the NIA will develop patents and promote commercialization of the product as required by law. You will not profit financially from such a product.

Doctors often make new discoveries by testing blood and urine. We would like to freeze a portion of your blood and urine samples to save them in our frozen tissue bank. We are not sure what new discoveries will appear in the future. We want to set aside your samples until there are new tests that will help us understand health and aging.

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Your samples will be stored in secured freezers at an NIA facility. Your name and identifying information will be removed and we will give the samples a code. The key to the code will be kept in a separate, secure area. Your samples will be used only for the study described in this consent form unless you give us permission to use them for other studies.

If a future research project arises where your samples could be useful, we ask you to designate as to whether or not your sample can be used. Any future research use will require approval by the Institutional Review Board (IRB).

Please initial by the line indicating your wishes:

YES, I give permission to use my (blood or other fluids, tissues) samples in future research studies under the following conditions:

These samples may be used for other research projects without contacting me only if the identification code is removed so that the sample can no longer be identified as mine.

These samples may be used for other research projects without contacting me even if the code is left on the samples. I understand that if the samples are coded, they may be able to be traced back to my personally identifiable information and my medical records.

MAYBE, I wish to be re-contacted if further studies with my samples are considered. After the study has been explained, I will then decide if I want my samples to be included.

NO under no circumstances shall my samples be used for any future studies. My samples should be discarded once the present study is complete.

If you allow future research on your sample and the research provides information important for your health, we will try to contact you. If you wish to be contacted please keep the principal investigator for this study or the NIA updated about changes in your address or phone number.

WHAT ARE THE POSSIBLE OR EXPECTED BENEFITS?

This study is not designed to give direct benefits to any participants. If you agree to take part in this study, there may or may not be direct medical benefits to you. We hope the information learned from this study will benefit others in the future. There is no charge for any of the testing described. You may benefit by learning more about your health, or possibly from learning that you have a condition or problem.

DO I HAVE AN ALTERNATIVE TO PARTICIPATING?

There are no other options associated with your participation in this study. You may choose either to participate or not to participate in this research. Taking part in this study is entirely voluntary. You may choose to withdraw from the study at any time.

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WILL I BE GIVEN MY STUDY RESULTS?

You will receive a Participant Report Packet in the mail, with results of your examination visit. If the study doctor discovers any condition or problem, the information will be provided to you and your doctor, if you authorize it. To authorize the reporting of results to your physician you will need to sign a form called "Release of Medical Information". You will be asked to sign this form only if you want us to communicate with your physician. The study doctors do not provide medical treatment.

CONFIDENTIALITY CERTIFICATE

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this certificate the researchers cannot be forced to disclose information that may identify you, even by court subpoena, in any federal, state, or local civil, criminal, administrative, legislative or other proceedings. The researchers will use the certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the U.S. Department of Health and Human Services that is used for auditing or program evaluation or for information that must be disclosed in order to meet federal regulations.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researcher may not use the Certificate to withhold that information.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following conditions: It does not apply to state requirements to report certain communicable diseases. In addition, the study doctor may be required to report certain cases of abuse, neglect, or suicidal or homicidal intent to the appropriate authorities.

WILL IT COST ME ANYTHING TO PARTICIPATE?

You do not have to pay anything to be in this study. However, if taking part in this study leads to procedures or care not included in the study, it may lead to added costs for you or your insurance company. You will not be charged for tests that are part of this research study.

WILL I BE PAID FOR PARTICIPATING?

You will receive \$100 for the examination visit that takes place in your home. Your payment will be made in the form of an ATM debit card at the end of the visit. If you are unable to complete all of the tests you may receive a portion of the payment. If we have to return to your home to complete testing on another day, you could be compensated for the additional visit. The ATM card will be activated within 24 hours of your visit. You will be able to take the card to an ATM machine in your neighborhood to withdraw your payment.

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If you decide to participate in the second phase of this study, the follow-up telephone interviews, scheduled to occur with-in 7-10 days after your home visit, you will be paid an additional \$40.00 for each interview. Your payment will be added to the ATM debit card given to you during your home visit.

OTHER PERTINENT INFORMATION

- 1. Confidentiality.** When results of an NIH research study are reported in medical journals or at scientific meetings, the people who take part are not named and identified. In most cases, the NIH will not release any information about your research involvement without your written permission. However, if you sign a release of information form, for example, for an insurance company, the NIH will give the insurance company information from your medical record. This information might affect (either favorably or unfavorably) the willingness of the insurance company to sell you insurance.

The Federal Privacy Act protects the confidentiality of your NIH medical records. However, you should know that the Act allows release of some information from your medical record without your permission, for example, if it is required by the Food and Drug Administration (FDA), members of Congress, law enforcement officials, or authorized hospital accreditation organizations.

- 2. Conflict of Interest.** No NIH investigator involved in this study receives payments or other benefits from any company whose drug, product or device is being tested.
- 3. Policy Regarding Research-Related Injuries.** The National Institute on Aging will provide short-term medical care for any injury resulting from your participation in this research study. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the National Institute on Aging, National Institutes of Health, or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.
- 4. Payments.** The amount of payment to research volunteers is guided by the National Institute of Health policies. In general, patients are not paid for taking part in research studies at the National Institutes of Health. Reimbursement of travel and subsistence will be offered consistent with NIH guidelines. Compensation of \$600 or more in one year will be reported to the IRS per federal regulations.
- 5. Problems or Questions.** If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigator, Michele K. Evans, MD at 410-558-8573. You may also call the NIA Clinical Research Protocol Office at 410-350-3947.
- 6. Consent Document.** Please keep a copy of this document in case you want to read it again.

ORAL DOCUMENTATION (to be used only if consent is obtained by telephone):

Is there anything you would like me to repeat? (Responded) Yes No

Have you understood everything I have told you? (Responded) Yes No

Do you have any questions? (Responded) Yes No

Do you agree to participate? (Responded) Yes No

I have read the above informed consent over the phone to (print name of person being consented) _____ and s/he has agreed to answer the questions and participate in this research study.

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Print name of person reading this consent _____

Print name of witness who observed: _____

Date _____ Time: _____

COMPLETE APPROPRIATE ITEM(S) BELOW:			
A. Adult Patient's Consent I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby consent to take part in this study.		B. Parent's Permission for Minor Patient. I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby give permission for my child to take part in this study. (Attach NIH 2514-2, Minor's Assent, if applicable.)	
Signature of Adult Patient/Legal Representative	Date	Signature of Parent(s)/Guardian	Date
Print Name		Print Name	
C. Child's Verbal Assent (If Applicable) The information in the above consent was described to my child and my child agrees to participate in the study.			
Signature of Parent(s)/Guardian	Date	Print Name	
THIS CONSENT DOCUMENT HAS BEEN APPROVED FOR USE FROM <i>Continuing Review Approval Date</i> THROUGH <i>Expiration Date</i>.			
Signature of Investigator	Date	Signature of Witness	Date
Print Name		Print Name	

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HEALTH DISPARITIES RESEARCH SECTION
LABORATORY OF EPIDEMIOLOGY AND POPULATION SCIENCES
NATIONAL INSTITUTE ON AGING, INTRAMURAL RESEARCH PROGRAM
NATIONAL INSTITUTES OF HEALTH
DEPARTMENT OF HEALTH AND HUMAN SERVICES

INFORMED CONSENT FOR RESEARCH WITH HUMAN SUBJECTS

Study: Healthy Aging in Neighborhoods of Diversity across the Life Span (HANDLS) – Wave 3
HOME VISIT

Principal Investigators: Michele K. Evans, M.D.

Lead Associate Investigator: Alan B. Zonderman, Ph.D.

Associate Investigators: Deidra C. Crews, MD; Ngozi Ejiogu, MD; Marie T. Fanelli Kuczmarski, PhD, RD, LDN; Michael Nalls, PhD

Medical Advisory Investigator: Michele K. Evans, M.D.

Study Number: 09-AG-N248

This consent will either be done in person and obtained signatures or as an oral consent. When conducted as an oral consent, it will be read to the informant. All elements required by 45 CFR 46.116 are included, as well as required documentation of the oral consenting process.

INTRODUCTION

We invite you to take part in the next phase of a National Institute on Aging (NIA) research study called Healthy Aging in Neighborhoods of Diversity across the Life Span (HANDLS). You were selected as a participant in this study because when we were looking for residents from 30 and 64 years old in your neighborhood, you decided you wanted to take part in the study. It is time for us to return to your neighborhood for the first follow-up examination. You now have an opportunity to decide whether you would like to participate in the next phase of HANDLS. You will notice that some of the tests are the same as the last time we saw you. We have added some different tests and questionnaires that you might not be familiar with. Please take your time to read this form. Be sure to ask any questions you may have before making your decision. We encourage you to discuss your decision with your family, friends and your doctor(s).

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to learn about changes in health over time in an urban group of African-American and white men and women residing in Baltimore city. Our goal is to study health change, as people grow older. We plan to do this by studying many people in different neighborhoods and the

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Appendix 3.4: Informed consent documents – Home visit consent booklet



Healthy Aging in Neighborhoods of Diversity across the Life Span

Home Visit

Informed Consent Booklet

Introduction

We must have your written informed consent before we perform research tests or examinations.

We follow federal regulations for research with human subjects. These regulations require us to make sure that you understand what examinations we will perform and the risks that are involved, if there are any.

This booklet reviews the tests that we will perform in this research. We perform these tests free of charge. You should understand the purpose of this study before you agree to participate in this research. We welcome any questions that you might have about what to expect in this study. You may participate in any of the tests, but you need not participate in all of the tests. You may stop any time after a test starts. You may ask questions any time during a test.

We want to make sure that you understand the tests in this study. We must have a witness of your signature on the consent form. Please do not sign the consent form until the HANDLS staff reviews the consent form with you, either in your home or over the phone. If we review the consent form over the phone you must have someone available to sign as the witness.

Purpose of the Study

The purpose of this study is to learn about changes in health over time in an urban, working and non-working group of African American and white, men and women residing in Baltimore city. We want to study as many people in different communities as we can by using our Mobile Medical Research Vehicles (MRVs).

Our goal is to study the rate of health change, as people grow older. We plan to do this by studying the same people over many years. This gives us the information we want about how people's bodies change over time. We will continue to invite you to participate in our study every three to four years when we visit your neighborhood with our Mobile Research Vehicles (MRVs). If you are unable to come to the MRVs to have your examination visit due to physical limitations, we will visit you in your home.

We also want to study why some people are healthier as they get older than others. We want to discover if we can predict the causes of good health with aging. If we can find the causes of good health, then we might find the cures for some of the diseases related to aging.

We call our study *Healthy Aging in Neighborhoods of Diversity across the Life Span.*

We are currently conducting the second visit to your neighborhood. The study data will be collected in two parts. The first part of the study will be conducted in your home if you agree. The HANDLS medical staff will provide testing. During this visit you will be asked to provide an update about your medical history since your last HANDLS examination and you will receive a physical examination. We will assess your muscle strength, test your memory and ask you to complete a brief questionnaire. We will also take blood, tissue and urine samples.

The second phase of the study will be conducted as two telephone interviews, about a week apart. For each interview you will be asked to complete a dietary recall interview just like the one you did on the MRV during your first visit. The telephone interview also includes a questionnaire about the use of dietary supplements and over-the-counter medications.

We plan to continue to administer similar tests every three to four years for the next 20 years.

List of Tests and Statements of Risk

You may participate in some or all of our tests. You may stop any test anytime you want even after you agree to do it. We want you to understand the risks in taking some of these tests. We welcome your questions about the tests and any risks even after the test starts. Risks, if any, are stated and discussed with the description of the test in this booklet.

Body Composition

We will weigh you and measure your height. There are no risks from this test.

Blood, Tissue, and Urine Sampling

If you agree, we will ask you to give us a blood sample and a urine sample. To prepare you for the blood tests we will ask you not to eat or drink anything after midnight the night before your visit. The blood draw will be performed at the beginning of your examination. We will use these samples to measure your health and so that we can measure changes in your health if we test you again. We will measure your white and red blood cells, your cholesterol, salt, and sugar, and how well your blood carries oxygen through your body and how fast you heal from minor cuts. We will also measure blood chemistry that may tell us how well your body organs work, such as the heart, liver, and kidneys. Women between the ages of 30 and 55 years will get a pregnancy test. We will be testing for communicable diseases including Hepatitis B, Hepatitis C, and Syphilis.

You will be offered a test for HIV. If you decide to have the test, you will be asked to sign a separate consent form that explains the HIV testing procedures for the HANDLS study.

We will ask you to donate about 87.5 milliliters of blood (~6 tablespoons). For comparison, the Red Cross usually asks for a donation of about 500 milliliters of blood (about two cups).

We want you to know that there are some risks in donating a blood sample. The trained HANDLS staff member will insert a needle in a vein in your arm. There is a risk of an infection from the needle puncture. There is also a risk of a black and blue mark, and you may feel faint. These risks are very small. Our staff is well trained and has drawn blood many times. It is common to have a small black and blue mark, but it disappears after a day or so. Some people have begun perspiring, or they felt nauseated and their pulse slowed. None of them had any after effects.

Buccal Cell Collection

As part of the medical evaluation buccal mucosa cells will be collected from you, if you agree, using the DNA Genotek Oragene RNA and DNA self collection system. This system collects buccal cells from inside your mouth by asking you to give a saliva sample by spitting into a small cup. The extracted DNA will be used for epigenetic analysis. Epigenetic analysis lets us study chemical changes to the DNA that may also lead to changes in the way genes and cells in your body work.

There are no known risks associated with the DNA Genotek Oragene RNA and DNA self collection system (the saliva collection system using a cup).

If you are unable to provide a saliva sample we will use another method to collect the sample called the Whatman FTA collection system. You may remember we used the Whatman system during your last MRV visit. This system collects buccal cells using a foam tipped applicator. We will ask you to place the applicator into your mouth and rub on the inside of both cheeks for 30 seconds. You will then hand the applicator to staff and they will transfer the sample to a card and send it to the lab for analysis.

Buccal Mucosa smear (the Watman collection system using an applicator) risks include irritation of the inside of the cheek and/or gum line by the foam tipped swab used to collect cells and saliva when using the Watman system.

Genetics/DNA Testing

Genes are composed of the genetic material called DNA. DNA (deoxyribonucleic acid) is the part of the cell that is responsible for providing hereditary

characteristics (such as eye color) and is used to build proteins. More and more, we are discovering that our genes are important for understanding our health. Your genes are the parts of each cell inherited from your mother and father. Your genes are what make you a unique individual. Genes are made from DNA. We want to use some of your donated blood to freeze your DNA. We are not sure what studies will use your DNA. New studies may look at how your genes affect age-related diseases.

Risks of genetic testing include the misuse of personal, genetic information. Although rare, misuse of such information has caused problems for persons related to employment, life, or health insurance benefits and right. There is a risk that being in a genetics study can cause psychological distress or tension with other family members. Although there can be no absolute guarantees, every reasonable effort will be made to keep your personally identifiable information secret so that there will be no misuse. Even when the information is kept secret, if you are asked if you have ever been tested for a genetic disorder, answering "yes" could cause benefits to be denied or could cause other problems including discrimination.

Future Use of Samples

Doctors often make new discoveries by testing blood and urine. We would like to freeze a portion of your blood and urine samples to save them in our frozen tissue bank. We are not sure what new discoveries will appear in the future. We want to set aside your samples until there are new tests that will help us understand health and aging.

The samples saved in our bank will be stored at very low temperatures. Unlike household freezers, these freezers can preserve samples for many years, perhaps many decades. We will label your samples with code numbers. Only the principal investigators in this study will know your code number. Only researchers in this study will know the results of tests using your genes. We will not reveal your results to anyone who is not associated with this research.

Results

We will ask you if you want the results of the tests that we perform on your blood and urine. We will also ask you if you want us to send your results to your personal physician. We do not plan to report the results of the studies we do on your genes because at this time, these tests do not diagnose or predict the development of specific diseases. In the future, we may offer you some of the results if the Food and Drug Administration approve some of the tests.

Resting Electrocardiogram (ECG)

We will place wires called electrodes on your skin to record your heartbeats. We will look at your heart rate and rhythm, electrical pulses of your heart, and check if you have an enlarged heart. We will check if you have had a heart attack or have any other heart condition.

There are no risks from this procedure.

Medical History and Physical Examination

Medical History

We will ask you questions about changes and updates to your medical history since your first MRV visit. The examiner will add information to the form when you have your physical examination.

Smoking, Drug and Alcohol History

We will ask you about your smoking habits and use of drugs and alcohol.

Physical Examination

Our physician or nurse practitioner will give you a physical exam. They will check your blood pressure and pulse in both arms. They will listen to your heart and lungs, examine your eyes, joints, and check your reflexes and other parts of your nervous system. The physician or nurse practitioner will also examine your abdomen.

Our physician or nurse practitioner will not do a complete physical exam. You should still see your personal physician for regular check-ups.

There is minimal risk associated with the medical history and physical examination. Some of the questions may make you feel uncomfortable. You have the right to skip any question you do not wish to answer.

Problem Solving and Memory Testing

We will ask you to do some tasks that exercise your thinking and memory. These tasks ask you to remember words, numbers, and pictures. These tasks also ask you to find similar words or to think of words beginning with certain letters or belonging to certain categories. They will also ask you to imagine how objects look in different positions.

The tests for remembering are called the *Benton Visual Retention Test*, the *California Verbal Learning Test*, and the *Digit Span Test*. The tests for words are called the *Wide Range Achievement Test* and the *Category Fluency Test*. The

test for comparing objects is called the *Identical Pictures Test*. The test for switching letters and numbers is called the *Trailmaking Test*. The test for imagining objects in different positions is called the *Card Rotations Test*. Other tests, called *Mental Status Tests*, measure several types of memory abilities. These tests are given in the privacy of your home with a tester who will help you understand how to do the best you can.

We want you to know that some people find these tests tiring. Sometimes, people feel nervous when they do these tests. All examiners who are involved in giving these tests are experienced in using these procedures and they will minimize any discomfort that you might feel. If the tests are disturbing you, then you may stop testing any time you want.

Grip Strength Test

Handgrip strength in both hands will be measured using an adjustable, hand-held, hydraulic grip strength dynamometer. The hydraulic grip strength dynamometer is a device you hold in your hand and squeeze. It measures the strength of your handgrip. You will be asked to sit with the arm to be tested resting on the table. The dynamometer is held in the hand to be tested and is resting on a mouse pad. We will ask you to grip the two bars of the dynamometer in your hand, and to slowly squeeze the bars as hard as you can. The test is repeated on the other hand.

Exclusions. If you have had arm or hand surgery like fusion, arthroplasty, tendon repair, synovectomy, or other related surgery in the past 3 months you will not be tested on the affected hand.

Nutritional Dietary Recall

During this interview we will ask you to remember all the foods and beverages you have consumed during the last 24 hours. We will use pictures to help you give us information about how food or drink you had in the last 24 hours. We also ask you about nutritional supplements and over-the-counter medications that you take.

A trained interviewer will record your answers and ask questions designed to help you remember using a method developed by the United States Department of Agriculture (USDA).

The risks for the dietary recall interview are very minimal. The only risk of this part of the study is that you may become tired. All examiners who are involved in asking these questions are experienced in using these procedures and they will minimize any discomfort that you might feel.

Questionnaires

We will ask you to complete a questionnaire about your use of health care services, present health status, your level of physical activity, your use of nutrition supplements and over-the-counter medicines, your neighborhood, income and other financial interests, mental health, household composition, if you provide care to others, education and employment.

There is minimal risk associated with the questionnaires. Some of the questions may make you feel uncomfortable. You have the right to skip any question you do not wish to answer. All examiners who are involved in giving these questionnaires are experienced in using these procedures and they will minimize any discomfort that you might feel. If the questions are disturbing you, then you may stop testing any time you want.

You are participating in a research study and our physicians and technicians are not your primary health-care providers. We will provide medical feedback to you and, with your permission, to your personal physician about your health based on the tests in which you participate. If you need a referral to a physician, we will provide a list of local physicians and assist you in locating a health care provider in your area if you like.

If you have any questions about the study or the specific procedures, please ask the HANDLS study staff members. They will be happy to answer any questions you may have at any time during the study.

Appendix 3.5: Informed consent documents – HIV testing

Informed Consent and Agreement to HIV Testing

I understand the following information, which I have read or has been read to me:

- Blood, or another body fluid or tissue sample, will be tested for human immunodeficiency virus (HIV) infection;
 - Consent to be tested for HIV, the virus that causes AIDS, should be given FREELY;
 - Results of this test, like all medical records, are confidential, but confidentiality cannot be guaranteed; and
 - If positive test results become known, an individual may experience discrimination from family or friends and at school or work.

What a NEGATIVE Result Means:

- A negative test means that HIV infection has not been found at the time of the test.

What a POSITIVE Result Means:

- A positive HIV test means that a person is infected with HIV and can transmit the virus by having sex, sharing needles, childbearing (from mother to child), breastfeeding, or donating organs, blood, plasma, tissue, or breast milk.
 - A positive HIV test DOES NOT mean a diagnosis of AIDS -- other tests are needed.

What Will Happen if the Test Is Positive:

- A copy of the Department of Health and Mental Hygiene's publication "Information for HIV Infected Persons" will be provided;
 - The health department or my doctor will offer advice about services that are available;
 - Women who are pregnant or may become pregnant will be told of treatment options which may reduce the risk of transmitting HIV to the unborn child;
 - Information will be provided on how to keep from transmitting HIV infection;
 - My name will be reported to the health department for tests that indicate HIV infection. This includes, but is not limited to: HIV Antibody (Western blot), HIV Viral Load (RNA or DNA quantification), HIV viral sequencing or HIV p24 antigen tests;
 - My name will be reported to the health department if my doctor finds that I have AIDS;
 - I will be offered assistance in notifying and referring my partners for services. If I refuse to notify my partners, a doctor may notify them or have a representative of the local health department do so. If a representative of the local health department notifies my partners, my name will not be used. Maryland law requires that when a local health department knows of my partners, it must refer them for care, support, and treatment.

I have been given a chance to have my questions about this test answered.

I hereby agree to be tested for HIV infection.

Print name of individual to be tested in the boxes below:

Page 10 of 10

First Name

Middle Init.

Last Name

**Signature of Individual to be Tested
(or Authorized Substitute)**

Date

Signature of Counselor or Health Care Provider

Date

State of Maryland – DHMH AIDS Administration

Form 4667 (revised 5/2007)

Consent for Post Test Counseling by Phone

We may be able to give you your test result over the phone. You can choose to call us or we may call you at the time specified below. You can also choose to come back for your test result. The test result for HIV will **NOT** be mailed to you.

You will have to provide the following information when you call for your results or when we call you.

- Name
- Date of Birth
- Any other information that we may find relevant to maintain your confidentiality
- Password or code

If you are unable to provide all the above information and /or we cannot identify you, we will be unable to give you the results over the phone and will ask you to come in person for your result.

Also we ask every tenth (10th) person tested for HIV to come back to the medical research vehicle for their test result.

Name: _____

Date of Birth: _____

Password/Code: _____

Question to help remember password: _____

Phone Number(s): _____

Signature of participant: _____ Date: _____

Signature of Counselor: _____ Date: _____

UI NUMBER

last 4 digits ss#

date of birth

race/ethnicity

sex

m m d d y y y y

CODES:

RACE/ETHNICITY: 1-White, Not Hispanic; 2-Af. Am., Not Hispanic; 3- Hispanic; 4-Asian/Pacific Is.; 5-Am. Indian/Ak. Native; 6-Other; 9-Undetermined. SEX: 1-Male; 2-Female

Appendix 3.6: Informed consent documents – Circadian rhythm consent

HEALTH DISPARITIES RESEARCH SECTION
LABORATORY OF EPIDEMIOLOGY AND POPULATION SCIENCES
NATIONAL INSTITUTE ON AGING, INTRAMURAL RESEARCH PROGRAM
NATIONAL INSTITUTES OF HEALTH
DEPARTMENT OF HEALTH AND HUMAN SERVICES

INFORMED CONSENT FOR RESEARCH WITH HUMAN SUBJECTS

Study: Healthy Aging in Neighborhoods of Diversity across the Life Span (HANDLS) – Wave 3

Principal Investigators: Michele K. Evans, M.D.

Lead Associate Investigator: Alan B. Zonderman, Ph.D.

Medical Advisory Investigator: Michele K. Evans, M.D.

Study Number: 09-AG-N248

INTRODUCTION

We invite you to take part in a research study as part of the Health Aging in Neighborhoods of Diversity across the Life Span (HANDLS) study at the National Institute on Aging (NIA). This research study looks at light/dark cycles and activity/rest cycles to see if there is a link between a disruption in these cycles and certain diseases, like diabetes. The light/dark and activity/rest cycles are known as circadian rhythms. Every rhythm in your body that repeats every 24 hours is known as circadian rhythm. We are interested in knowing how disruptions to these cycles may affect health and aging.

Please take your time to read this form. Be sure to ask any questions you may have before making your decision. We encourage you to discuss your decision with your family, friends and your doctor(s). If you need time to discuss your decision with others please let us know and we will schedule your initial visit after you have had time to do so.

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to learn about changes in circadian rhythms and the effect they may have on health status. Specifically, we will explore whether there is a link between circadian disruption and the development of certain diseases, like diabetes.

WHAT ELSE SHOULD I KNOW ABOUT THIS RESEARCH STUDY?

It is important that you read and understand several points that apply to all who take part in our studies:

PATIENT IDENTIFICATION

CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

Protocol #

OPS Consent Approval Date: xx/xx/yyyy
File in Section 4: Protocol Consent (1)

- Taking part in the study is entirely voluntary and refusal to participate will not affect any rights or benefits you normally have;
- You may or may not benefit from taking part in the study, but knowledge may be gained from your participation that may help others;
- You may stop being in the study at any time without any penalty or losing any of the benefits you would have normally received; and
- Some people have personal, religious or ethical beliefs that may limit the kinds of medical or research treatments they would want to receive. If you have such beliefs, please discuss them with the HANDLS research team before you agree to the study.

The nature of the study, the benefits, risks, discomforts and other information about the study are discussed further below. If any new information is learned, at any time during the research, which might affect your participation in the study, we will tell you. We urge you to ask any questions you have about this study with the staff members who explain it to you and with your own advisors before agreeing to participate.

WHO CAN PARTICIPATE IN THIS STUDY?

To be eligible for this research study the following must apply:

- You must be able to give informed consent - you must understand what the research is about and what we are requesting of you;
- You must have agreed to participate in Wave 3 of the HANDLS study;
- You must have one form of government issued identification

ARE THERE ANY REASONS I SHOULD NOT PARTICIPATE?

You cannot be in this study if any of the following apply to you:

- Did not give your consent to be in the HANDLS Wave 3 study
- Do not have a picture ID
- Are unable to give informed consent
- Are pregnant
- Are currently undergoing cancer treatment (chemotherapy or radiation)
- Have undergone cancer treatment (chemotherapy or radiation) within the last 6 months

WHAT HAPPENS IF I AGREE TO BE IN THE STUDY?

This is a one-week study and includes two 30-minute visits to the MRV. We will call you every day to make sure you remember to wear the device and to answer any questions you may have

Pre-Visit Eligibility: During your Wave 3 visit to the MRVs you will be screened for inclusion in this study.

Visit 1: Informed Consent will be obtained. We will then measure your height and weight to calculate your Body Mass Index (BMI). You will complete a brief questionnaire about your sleep habits and exposure to the sun.

PATIENT IDENTIFICATION

CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

Protocol #

OPS Consent Approval Date: xx/xx/yyyy

File in Section 4: Protocol Consent (1)

We will provide you with a device called a Daysimeter. The Daysimeter is a research tool designed to measure a person's exposure to light and their activity during their normal daily routine. The information will be collected as you wear the Daysimeter throughout the testing week. When it is returned to us a week later we will be able to download and evaluate the information the Daysimeter collected.

We will provide you with detailed instructions for use and placement of the Daysimeter. You will not need to wear the Daysimeter while you are sleeping, but you will be asked to leave it by your bedside (beside table or anywhere close to your bed) while you are sleeping.

We will schedule your daily telephone calls and you final visit during the first study visit.

Daily Telephone Contact: We will want to talk with you about your experience of wearing the Daysimeter every day. We will schedule these calls during your first study visit. We will be available throughout the week if you have any questions or concerns. We will provide you with the name and contact information of the study nurse.

Visit 2: You will return to the MRVs for your second visit 8 days following your initial visit. You will be required to bring the Daysimeter with you. We will ask you to provide information about your overall impression of wearing the Daysimeter and you will collect your compensation.

WHAT ARE THE RISKS AND SIDE EFFECTS OF THIS STUDY?

There are no known risks related to wearing the Daysimeter. The inconvenience you may experience with this study will be the wearing of the device. The Daysimeter should not interfere with your daily activities. You may experience slight discomfort from the placement of the Daysimeter on your clothing. If this occurs, you may reposition the device or request it be removed. It uses a battery similar to a watch battery. There is no greater risk than wearing a digital watch.

For more information about risks and side effects, you should call the Principal Investigator, Michele K. Evans, M.D. at 410-558-8573.

WHAT ARE THE POSSIBLE OR EXPECTED BENEFITS?

This study is not designed to provide direct benefits to any participants. If you agree to take part in this study, there may or may not be direct medical benefits to you. We hope the information learned from this study will benefit others in the future. There is no charge for participating in this study.

DO I HAVE AN ALTERNATE TO PARTICIPATING?

There are no other options associated with your participation in this study. You may choose either to participate or not to participate in this research. Taking part in this study is entirely voluntary. You may choose to withdraw from the study at any time.

PATIENT IDENTIFICATION

CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

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File in Section 4: Protocol Consent (1)

WHAT IF I WANT TO STOP PARTICIPATING IN THIS STUDY?

You may choose to withdraw from the study at any time. However, if you decide to stop participating in this study, we ask that you talk to the researchers first. Any information (data) collected until that point in time will remain part of the study.

WILL I BE GIVEN MY STUDY RESULTS?

The information we obtain from this study will not provide information on your health. You will not receive any individual results.

WILL IT COST ME ANYTHING TO PARTICIPATE?

There are no costs to you other than your time and travel for participating.

WILL I BE PAID FOR PARTICIPATING?

The amount of payment to research volunteers is guided by the National Institutes of Health policies. In general, patients are not paid for taking part in research studies at the National Institutes of Health. Reimbursement of travel and subsistence will be offered consistent with NIH guidelines.

You will receive \$40.00 for participating in the study. If you return the device on the day of your 2nd visit, as scheduled, you will be paid an additional \$20.00. The total amount you will be reimbursed for this study is \$60.00. Your payment will be made in the form of an ATM debit card at the end of the second visit. If you are unable to complete the study you may receive a portion of the payment. The ATM card will be activated before you leave the vehicle. You will be able to take the card to an ATM machine in your neighborhood to withdraw your payment.

We will ask you to provide round-trip transportation from your home to our mobile testing center.

OTHER PERTINENT INFORMATION

- Confidentiality.** When results of an NIH research study are reported in medical journals or at scientific meetings, the people who take part are not named and identified. In most cases, the NIH will not release any information about your research involvement without your written permission. However, if you sign a release of information form, for example, for an insurance company, the NIH will give the insurance company information from your medical record. This information might affect (either favorably or unfavorably) the willingness of the insurance company to sell you insurance.

The Federal Privacy Act protects the confidentiality of your NIH medical records. However, you should know that the Act allows release of some information from your medical record without your permission, for example, if it is required by the Food and Drug Administration (FDA), members of Congress, law enforcement officials, or authorized hospital accreditation organizations.

- Policy Regarding Research-Related Injuries.** The National Institute on Aging will provide short-term medical care for any injury resulting from your participation in this research study. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the National Institute on Aging, National Institutes of

PATIENT IDENTIFICATION

CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

Protocol #

OPS Consent Approval Date: xx/xx/yyyy

File in Section 4: Protocol Consent (1)

Health, or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

- 3. Conflict of Interest.** No NIH investigator involved in this study receives payments or other benefits from any company whose drug, product or device is being tested.
- 4. Payments.** The amount of payment to research volunteers is guided by the National Institute of Health policies. In general, patients are not paid for taking part in research studies at the National Institutes of Health. Reimbursement of travel and subsistence will be offered consistent with NIH guidelines. Compensation of \$600 or more in one year will be reported to the IRS per federal regulations.
- 5. Problems or Questions.** If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigator, Michele K. Evans, MD at 410-558-8573. You may also call the NIA Clinical Research Protocol Office at 410-350-3947.
- 6. Consent Document.** Please keep a copy of this document in case you want to read it again.

COMPLETE APPROPRIATE ITEM(S) BELOW:			
A. Adult Patient's Consent I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby consent to take part in this study.		B. Parent's Permission for Minor Patient. I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby give permission for my child to take part in this study. (Attach NIH 2514-2, Minor's Assent, if applicable.)	
Signature of Adult Patient/Legal Representative	Date	Signature of Parent(s)/Guardian	Date
Print Name		Print Name	
C. Child's Verbal Assent (If Applicable) The information in the above consent was described to my child and my child agrees to participate in the study.			
Signature of Parent(s)/Guardian	Date	Print Name	
THIS CONSENT DOCUMENT HAS BEEN APPROVED FOR USE FROM <i>Continuing Review Approval Date</i> THROUGH <i>Expiration Date</i>.			
Signature of Investigator	Date	Signature of Witness	Date
Print Name		Print Name	

PATIENT IDENTIFICATION

CONSENT TO PARTICIPATE IN A CLINICAL RESEARCH STUDY

Protocol #

OPS Consent Approval Date: xx/xx/yyyy
File in Section 4: Protocol Consent (1)

Appendix 3.7: Informed consent documents – HIPAA

Note: These Instructions Should Not Be Presented to Research Participants or to the IRB

INVESTIGATORS INSTRUCTIONS FOR PREPARING THE RESEARCH AUTHORIZATION FORM

When Is This Form Required? In addition to an approved Informed Consent, this form is required to be signed by study participants in all research involving the use of Protected Health Information (PHI), unless the IRB specifically approves a Full Waiver of this Authorization or unless another exception applies.^{*} **Please Note:** This authorization may NOT be used for the access, use or release of Mental Health information in the District of Columbia. If such information is needed a separate form is required.

Which Study Participants Need To Sign This Authorization? Study participants enrolled prior to April 14, 2003 who have already signed an Informed Consent **DO NOT** need to sign this Authorization also, unless changes in the protocol would require the participant to sign an amended Informed Consent. All study participants enrolled after April 14, 2003 must sign this Authorization in conjunction with the approved Informed Consent.

What Happens If Authorization (or Waiver of Authorization) Is Not Obtained? MedStar Researchers may not be able to use PHI in their study and a Covered Entity's Privacy Officer (or their designee) may deny the use and disclosure of PHI unless this form is properly completed by the Principal Investigator.

What do I do if a research participant revokes this Authorization? Research participants have the right to revoke this Authorization at any time. However, an individual may not revoke an Authorization to the extent the researcher has acted in reliance on the Authorization. For example, this would permit the continued use and disclosure of PHI to account for a subject's withdrawal, from the research study, as necessary to incorporate the information as part of a marketing application submitted to the Food and Drug Administration, to conduct investigations of scientific misconduct, or to report adverse events. After the subject has revoked the Authorization, no additional PHI may be collected or used for the study protocol. In the event a subject revokes this Authorization the investigator must notify **the custodian of records which maintains the records received pursuant** to this Authorization.

Can I or a research sponsor make any revisions to this form? Yes, all dark blue fields require user revision. All other proposed revisions require MedStar Privacy Office review and IRB approval of the Alteration of Authorization.

Where to Direct Questions About this Form? Any questions about the Research Authorization form should be directed to the Privacy Officer or to the Privacy Officer's designee. They will assess, the Principal Investigator's request for permission to use or disclose PHI for research.

Specific Form Completion Instructions

Who may have and use my health information? – This section identifies who is permitted to receive and use PHI for research activities. Please identify the Principal Investigator, class of other persons (i.e. Co-Investigators), and when applicable, sponsors or other organizations (including government agencies, companies, etc.) which are involved in the research and may be permitted to obtain and use PHI for research purposes. *Please note, however, that the persons and organizations listed beside the boxes are not intended to be all-inclusive.* If a person, class of persons or an organization is not included on the research authorization form, that person or organization may not be able to receive, use or create PHI for research purposes.

Who may give (release or disclose) my health information? – This section identifies who is permitted to disclose/release PHI to the researchers for research purposes. The section is broadly written to include any health care providers or others who generate or use health information. When known, please identify the specific hospital/trial site which will be releasing PHI for the research activity.

What health information may be used for this research study? (check all that apply) – This section identifies what health information may be used or disclosed in connection with the research. Researchers are required to obtain and use only the PHI minimally necessary to conduct the research. For instance, if the PHI required for the research is a subset of all medical records, please indicate the records requested in the space provided. Acceptable descriptions might be "laboratory results from July 2002 to present," "all laboratory results," or "results of MRI performed in July 2002." Check all appropriate box(es) describing the PHI in a way that allows both the prospective research participant, and any person or organization that must use or disclose information pursuant to this Authorization, to understand what information may be used or disclosed.

What could happen if I agree to this use or disclosure of my health information? – This section contains required language which describes potential consequences for agreeing to the authorization. Any alterations require IRB approval of a Waiver or Alteration of Authorization.

What rights do I have? – This section describes certain rights of research participants and limitations on those rights. For blinded studies, if the IRB approves the restriction of access to a patient's medical record during the course of the study, you may include a statement informing the individual that he or she will not be permitted to inspect or copy the PHI described in the Research Authorization while the research study is in progress. To monitor this requirement, you may need to obtain an agreement with the health care facility that maintains the patient's PHI. *This optional statement should be removed if the individual will be permitted to access his or her information during the study.*

^{*} Note: Reviews preparatory to research and research on decedents which require the use of PHI may be performed without this Authorization form provided the Principal Investigator provides the Covered Entity with appropriate certifications of use. A Limited Data Set/Data Use Agreement may also be used in lieu of this Authorization upon approval from the MedStar Privacy Office. A Full or Partial Waiver of Authorization may also be granted by the IRB if the required conditions are met.



MedStar Research
Institute



National Institute on Aging, NIH

2.8.07.v.7

NIA Protocol # 2009-149

NIA Protocol Title: Healthy Aging in Neighborhoods of Diversity across the Life Span – Wave 3

RESEARCH AUTHORIZATION TO USE AND DISCLOSE HEALTH INFORMATION

Who may have and use my health information?

I agree to allow **National Institute on Aging, NIH** and their staff (together called “Researchers”), as well as (when applicable) the other people or companies listed below, to receive, use, have and disclose my personal health information (as permitted below) for the reason(s) described in the Informed Consent Form used for this study (identified above) and as needed to conduct the research.

- The study Sponsor -National Institute on Aging (NIA), NIH, including others working as approved collaborators with the NIA, NIH
- Laboratories and other individuals and organizations that look at my health information in connection with this study;
- Members and staff of the Institutional Review Board(s), Ethics Committee(s), Data Safety Monitoring Boards (DSMB) and all other review boards or persons who watch over how the research is performed and/or monitor the safety and success of the research, including the Institution that approves this study;
- The Patient Advocate or Research Ombudsman (people who watch out for my best interest);
- The United States Food and Drug Administration (FDA), any other Federal or State Agencies that watch over the safety of the study and how the study is managed or run, and/or governmental agencies in other countries which fill similar oversight roles;
- Others: [Other researchers with contractual obligations with the National Institute on Aging, NIH.](#)

Who may give (release or disclose) my health information?

I wish to allow the National Institute on Aging, NIH, all my doctors and my other health care providers, and others who generate or use my health information, to give my health information in my medical or other records to the Researchers, Sponsor(s) and others listed above, for the research purposes described in the Informed Consent Form used in this study and as otherwise described below.

What health information may be used for this research study? (Check all that apply)

- All my personal information in my medical records or other health care related records requested by the Researchers to be able to do the research described in the Informed Consent Form for this study;
- All my personal information made or collected during the research described in the Informed Consent Form for this study; *and/or*
- Only the following information:

***Note: if any of the above records contain any information about HIV/AIDS status, cancer diagnosis, drug/alcohol abuse, sexually transmitted disease, or includes records or information from another healthcare provider, I agree that I am hereby authorizing the release and use of this information.**

What could happen if I agree to this use or disclosure of my health information?

- There is the possibility that Federal privacy laws (laws that protect the privacy to my personal health information) may no longer protect it from being given to another person, class of persons, and/or company.
- Once information that could be used to identify me has been removed and my information is no longer identifiable (connected to my identity), the information that remains is no longer protected by this Authorization (agreement) and may be used and given by the Researchers and Sponsor to others, including for other research reasons.
- The National Institute on Aging, NIH have agreed that no publication or presentation of the research will reveal my identity without my separate specific written permission and authorization (agreement) (even if I revoke (take back) this Authorization (agreement)).

What rights do I have?

- While my health care and benefits relating to healthcare outside the study will not be affected if I do not sign this form, I understand I have the right to refuse to sign this Authorization (agreement), but that I will not be able to participate in the research referred to in this form.
- I may change my mind and cancel this agreement at any time. To cancel this agreement, I must write to: NIA Clinical Director, NIA Clinical Research Unit, 5th Floor, Harbor Hospital, 3001 S Hanover Street, Baltimore, MD 21225. However, if I cancel this agreement, I may no longer be allowed to participate in the research and may no longer receive research-related treatment. Also, even if I cancel this agreement, the information already obtained may remain a part of the research as necessary to preserve the integrity of the research study.
- I will be given a copy of this agreement after I have signed it.

When does this Authorization expire?

This Authorization has no expiration date, but shall expire at the end of the research study identified above.
By signing below I represent and warrant that I have authority to sign this document and authorize the use or disclosure of PHI and that there are no restrictions that would prevent me from authorizing the use or disclosure of this PHI.

Signature of Participant (or Participant's Personal Representative)

Date

Printed Name of Participant (and if applicable print name of Participant's Personal Representative)

Representative's authority to sign for Participant, (parent, guardian, power of attorney for healthcare, etc.)



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Appendix 4.1: Procedures – Clinical laboratory panel

Wave 3 HANDLS Lab Panel

PSA, Total	Amylase
HIV w/ WB reflex	Folate
CBC w/ DIFF/PLT	Vitamin B12
ESR	Hep B surf Ag w/ Confirm
HGBA1C	Hep C virus Ab
UA, microscopic	Ferritin
Na	Insulin
K	RPR w/ Reflex Titer & Confirm reflex
Chloride	Cardio CRP
CO2	LDH
Urea Nitrogen	Fibrinogen
Creatinine	D-dimer
Glucose	
Calcium	
Phosphate	
Uric Acid	
Protein	
Albumin	
Globulin, calculated	
Bilirubin, Total	
AST	
ALT	
Alkaline Phosphatase	
GGT	
Cholesterol	
Triglycerides	
HDL	
LDL, calculated	
VLDL, calculated	
T4, Total	
T3 Uptake	
T4, Free, calculated	
TSH	
T4, Free	
Microalbumin, Random Urine:	
Creatinine, Random Urine	
Vitamin D25-Hydroxy	
1,25-Dihydroxy	
Magnesium	
Iron	
TIBC (Iron Binding Capacity)	
% Saturation	
Lipase	

Appendix 4.2: Procedures – Questionnaire script

HNDID1:

Please SCAN HANDLS ID _____

HNDID2:

Please RE-SCAN HANDLS ID _____

Welcome to HANDLS, you will be asked a series of questions in this interview.

Press the "START" button when you are ready to begin.

Now we would like to ask you some questions about who lives in your household.

SF12Q01:

In general, would you say your health is:

- Excellent (5)
- Very good (4)
- Good (3)
- Fair (2)
- Poor (1)

The next two questions ask about activities that you might do during a typical day.

SF12Q02:

Does your health now limit you in moderate activities, such as moving a table, pushing a vacuum cleaner or playing golf?

- Yes, limited a lot (3)
- Yes, limited a little (2)
- No, not limited at all (1)

SF12Q03:

Does your health now limit you in climbing several flights of stairs?

- Yes, limited a lot (3)
- Yes, limited a little (2)
- No, not limited at all (1)

The next two questions ask about problems doing work or other regular daily activities as a result of your physical health.

SF12Q04:

During the past 4 weeks, how much of the time have you accomplished less than you would like as a result of your physical health?

- All of the time (5)
- Most of the time (4)
- Some of the time (3)
- A little of the time (2)
- None of the time (1)

SF12Q05:

During the past 4 weeks, how much of the time were you limited in the kind of work you did or in other activities as a result of your physical health?

- All of the time (5)
- Most of the time (4)
- Some of the time (3)
- A little of the time (2)
- None of the time (1)

The next two questions ask about how much time you had any problems with your work or other regular activities as a result of emotional problems (such as feeling depressed or anxious).

SF12Q06:

During the past 4 weeks, how much of the time have you accomplished less than you would like as a result of emotional problems?

- All of the time (5)
- Most of the time (4)
- Some of the time (3)
- A little of the time (2)
- None of the time (1)

SF12Q07:

During the past 4 weeks, how much of the time did you do work or other activities less carefully than usual?

- All of the time (5)
- Most of the time (4)
- Some of the time (3)
- A little of the time (2)
- None of the time (1)

SF12Q08:

During the past 4 weeks, how much did pain interfere with your normal work (include both work outside the home and housework)?

- Not at all (5)
- A little bit (4)
- Moderately (3)
- Quite a bit (2)
- Extremely (1)

The next three questions ask about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling.

SF12Q09:

How much of the time during the past 4 weeks have you felt calm and peaceful?

- All of the time (5)
- Most of the time (4)
- Some of the time (3)
- A little of the time (2)
- None of the time (1)

SF12Q10:

How much of the time during the past 4 weeks did you have a lot of energy?

- All of the time (5)
- Most of the time (4)
- Some of the time (3)
- A little of the time (2)
- None of the time (1)

SF12Q11:

How much of the time during the past 4 weeks have you felt downhearted and blue?

- All of the time (5)
- Most of the time (4)
- Some of the time (3)
- A little of the time (2)
- None of the time (1)

SF12Q12:

During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc)?

- All of the time (5)
- Most of the time (4)
- Some of the time (3)
- A little of the time (2)
- None of the time (1)

Now we would like to ask you about any headaches that you may have experienced in the past year.

HEAD00:

Have you experienced any headaches in the past year?

- Yes (1)
- No (0)

If HEAD00 = "No" then go to FINSTRAIN01

HEAD01:

Over the past year, how often have you seen things like visual spots, stars, lines, flashing lights, zigzag lines, or "heat waves" around the time of your headaches?

- Never
- Rarely
- Less than half the time
- Half the time or more
- I don't know

HEAD02:

Over the past year, how often have you had a feeling of numbness or tingling in any part of your body or face around the time of your headache?

- Never
- Rarely
- Less than half the time
- Half the time or more
- I don't know

Now we would like to ask you some questions about how well you can afford to live.

FINSTRAIN01:

Are you able to afford a home suitable for you or your family?

- Yes (1)
- No (0)

FINSTRAIN02:

Are you able to afford furniture or household equipment that needs to be replaced?

- Yes (1)
- No (0)

FINSTRAIN03:

Are you able to afford the kind of car you need?

- Yes (1)
- No (0)

FINSTRAIN04:

Do you have enough money for the kind of food you or your family should have?

- Yes (1)
- No (0)

FINSTRAIN05:

Do you have enough money for the kind of medical care you or your family should have?

- Yes (1)
- No (0)

FINSTRAIN06:

Do you have enough money for the kind of clothing you or your family should have?

- Yes (1)
- No (0)

FINSTRAIN07:

Do you have a great deal, some, little, or no difficulty paying your bills?

- Great deal (1)
- Some (2)
- Little (3)
- None (4)

FINSTRAIN08:

At the end of the month do you end up with some money left over, just enough to make ends meet, or not enough money to make ends meet?

- Some left over (1)
- Just enough (2)
- Not enough (3)

FINSTRAIN09:

Would you say that your total family income is higher, lower, or about the same as most of your friends?

- Higher (3)
- Lower (1)
- Same (2)

FINSTRAIN10:

Would you say that your total family income is higher, lower, or about the same as people with the same education as you?

- Higher (3)
- Lower (1)
- Same (2)

FINSTRAIN11:

Would you say that your total family income is higher, lower, or about the same as most of your relatives?

- Higher (3)
- Lower (1)
- Same (2)

FINSTRAIN12:

Would you say that your total family income is higher, lower, or about the same as most of your neighbors?

- Higher (3)
- Lower (1)
- Same (2)

FINSTRAIN13:

How do you think that your standard of living a year or two from now will compare with the one that you now have?

- Higher (3)
- Lower (1)
- Same (2)

FINSTRAIN14:

Compared to four years ago, are you able to afford better, the same, or lower standard of living?

- Higher (3)
- Lower (1)
- Same (2)

FINSTRAIN15:

Thinking of you and your family, how much do you agree or disagree that financial success does not interest me or us?

- Disagree strongly (1)
- Disagree somewhat (2)
- Neither agree nor disagree (3)
- Agree somewhat (4)
- Agree strongly (5)

FINSTRAIN16:

Thinking of you and your family, how much do you agree or disagree that our money never seems to be enough for our wants?

- Disagree strongly (1)
- Disagree somewhat (2)
- Neither agree nor disagree (3)
- Agree somewhat (4)
- Agree strongly (5)

FINSTRAIN17:

Thinking of you and your family, how much do you agree or disagree that one of the most important things about a person or a family is the amount of money they have?

- Disagree strongly (1)
- Disagree somewhat (2)
- Neither agree nor disagree (3)
- Agree somewhat (4)
- Agree strongly (5)

FOODSECURITY:

In the past 12 months, did you ever eat less than you felt you should because there was not enough money to buy food?

- Yes, very often (1)
- Yes, occasionally or very few times (2)
- No (3)
- Don't know (4)

FINLIT01:

Suppose you had \$100 in a savings account and the interest rate was 2% per year. After 5 years, how much do you think you would have in the account if you left the money to grow?

- more than \$102 (1)
- exactly \$102 (2)
- less than \$102 (3)
- do not know (8)
- refuse to answer (9)

FINLIT02:

Imagine that the interest rate on your savings account was 1% per year and inflation was 2% per year. After 1 year, would you be able to buy?

- more than today with the money in this account (1)
- exactly the same as (2)
- less than today (3)
- do not know (8)
- refuse to answer (9)

FINLIT03:

Do you think the following statement is true or false? Buying a single company stock usually provides a safer return than a stock mutual fund.

- True (1)
- False (0)
- do not know (8)
- refuse to answer (9)

FINLIT04:

If 5 people all have the winning number in the lottery and the prize is 2 million dollars, how much will each of them get? _____

FINLIT05:

Say you have \$200 in a savings account. The account earns 10 percent interest per year. How much would you have in the account at the end of 10 years? _____

Now we want to ask you about your usual activities.**HOUSTON01:**

In the previous month, I avoided walking or exerting myself by using elevators instead of stairs and driving instead of walking.

- Yes (1)
- No (0)

HOUSTON02:

In the previous month, I walked for pleasure, routinely used stairs, and occasionally exercised enough to cause heavy breathing or perspiration

- Yes (1)
- No (0)

HOUSTON03:

In the previous month, for 10 to 60 minutes per week I participated in recreation or work requiring modest physical activity, such as golf, horseback riding, calisthenics, gymnastics, table tennis, bowling, weight lifting, or yard work.

- Yes (1)
- No (0)

HOUSTON04:

In the previous month, for more than an hour per week I participated in recreation or work requiring modest physical activity, such as golf, horseback riding, calisthenics, gymnastics, table tennis, bowling, weight lifting, or yard work.

- Yes (1)
- No (0)

HOUSTON05:

In the previous month, I ran less than a mile each week or I spent less than 30 minutes doing comparable physical activity.

- Yes (1)
- No (0)

HOUSTON06:

In the previous month, I ran 5 to 10 miles each week or I spent 1-3 hours doing comparable physical activity.

- Yes (1)
- No (0)

HOUSTON07:

In the previous month, I ran 10 miles per week or I spent 1-3 hours doing comparable physical activity.

- Yes (1)
- No (0)

Now we want to ask you about your mortgage if you have one.

MORTGAGE:

Please select the answer that BEST applies to your CURRENT mortgage.

- I do not have a mortgage (1)
- I am NOT in default or foreclosure on my mortgage (2)
- I am in default on my mortgage (I am more than 30 days behind in payments, or I received a default notice). (3)
- I received a foreclosure notice (a letter from my lender with the foreclosure date). (4)

Now we want to ask you about drinking.

ETOH:

How many times in the past year have you had 5 or more drinks in a day?

- Never (0)
- Once (1)
- Twice (2)
- More than twice (3)

Now we would like to ask you some questions about the health of your teeth.

DDSSany:

Do you still have some or all of your natural teeth?

- Yes (1)
- No (0)

If DDSSany = "Did not have any natural teeth remaining" then go to HLTHSERV01

DDS01:

How would you rate the condition of your natural teeth?

- Excellent (5)
- Very good (4)
- Good (3)
- Fair (2)
- Poor (1)

DDS02:

Have you been to the dentist since your last HANDLS examination?

- Yes (1)
- No (0)

DDS03:

Do you have dental insurance now?

- Yes (1)
- No (0)

Now we would like to ask you some questions about using health care services.

HLTHSERV01:

Since your last HANDLS examination, have you put off or postponed seeking health care that you felt you needed?

- Yes (1)
- No, needed health care but did not put off or postpone (2)
- Did not need health care since last examination (3)

If HlthServ01 = "Did not need health care in since last examination" then go to HlthServIns01

HLTHSERV02:

Since your last HANDLS examination, have you been refused health care?

- Yes (1)
- No (0)

HLTHSERVINS01:

Do you have any health insurance now (including Medicare or Medicaid)?

- Yes (1)
- No (0)

If HlthServIns01 = YES then go to HlthServIns03

HLTHSERVINS02:

- What is the main reason you do not have health insurance now?
- Not employed (1)
- No coverage by employer (2)
- No family insurance (3)
- Rejected by insurance company (4)
- Insurance is too expensive (5)
- Do not need insurance (6)
- Lost eligibility (7)

HLTHSERVINS03:

Since your last HANDLS examination, was there any time when you did not have any health or medical insurance?

- Yes (1)
- No (0)

Now we would like to ask you some questions about mistreatment you may have experienced.

VIOLENCE01:

Since your last HANDLS examination, have you been hit, slapped, kicked or otherwise physically hurt by someone?

- Yes (1)
- No (0)

If Violence01 = No then go to Violence03

VIOLENCE02:

Who hit, slapped, kicked or otherwise physically hurt you? (Check all that apply.)

- Partner (1)
- Someone you know (2)
- Stranger (3)

VIOLENCE03:

Since your last HANDLS examination, has anyone forced you to have an unwanted sexual act?

- Yes (1)
- No (0)

If Violence03 = No then go to PTSD01

VIOLENCE04:

Who forced you to have unwanted sexual act(s)? (Check all that apply.)

- Partner (1)
- Someone you know (2)
- Stranger (3)

PTSD01:

In your life, have you ever had any experience that was so frightening, horrible, or upsetting that in the past month you have had nightmares about it or thought about it when you did not want to?

- Yes (1)
- No (0)

PTSD02:

In your life, have you ever had any experience that was so frightening, horrible, or upsetting that in the past month you tried hard not to think about it or went out of your way to avoid situations that reminded you of it?

- Yes (1)
- No (0)

PTSD03:

In your life, have you ever had any experience that was so frightening, horrible, or upsetting that in the past month you were constantly on guard, watchful, or easily startled?

- Yes (1)
- No (0)

PTSD04:

In your life, have you ever had any experience that was so frightening, horrible, or upsetting that in the past month you felt numb or detached from others, activities, or your surroundings?

- Yes (1)
- No (0)

ABUSE01:

When I was growing up people in my family hit me so hard that it left me with bruises or marks.

- Never (1)
- Rarely (2)
- Sometimes (3)
- Often (4)
- Very often (5)

ABUSE02:

When I was growing up someone tried to touch me in a sexual way or tried to make me touch them.

- Never (1)
- Rarely (2)
- Sometimes (3)
- Often (4)
- Very often (5)

Now we would like to ask you some questions about your education.

EDUCHS:

Do you have a high school diploma or did you pass a high school equivalency or GED test?

- Diploma (1)
- High school equivalency or GED (2)
- Neither (3)

If EducHS not equal to Neither then go to EducCollege1

EDUC8GRADE:

Did you attend school past the 8th grade?

- Yes (1)
- No (0)

GOTO Empsay

EDUCCOLLEGE1:

Did you attend college?

- Yes (1)
- No (0)

If EducCollege1 = No then go to Empsay

EDUCCOLLEGE2:

Did you get a bachelor's level college degree?

- Yes (1)
- No (0)

Now we would like to ask you some questions about your spirituality, religion, and similar beliefs.

SPIRITO1:

How often do you read the Bible/Torah/Koran/Geeta?

- Never
- About once a month
- Several times a week
- About once or twice a year
- 2 or 3 times a month
- Several times a year
- Nearly every week

SPIRITO2:

How often do you read religious literature other than the Bible/Torah/Koran/Geeta?

- Never
- About once a month
- Several times a week
- About once or twice a year
- 2 or 3 times a month
- Several times a year
- Nearly every week

SPIRITO3:

How often do you pray?

- Never
- About once a month
- Several times a week
- About once or twice a year
- 2 or 3 times a month
- Several times a year
- Nearly every week

SPIRITO4:

How frequently do you attend religious services?

- Never
- Rarely
- Occasionally
- Often
- Quite Often

SPIRITO5:

I feel that God is punishing me.

- Strongly disagree
- Disagree
- Neutral
- Agree
- Strongly Agree

SPIRITO6:

I feel abandoned by God.

- Strongly disagree
- Disagree
- Neutral
- Agree
- Strongly Agree

SPIRITO7:

I feel isolated from others in my faith group.

- Strongly disagree
- Disagree
- Neutral
- Agree
- Strongly Agree

SPIRITO8:

I find myself unable, or unwilling, to involve God in the decisions I make about my life.

- Strongly disagree
- Disagree
- Neutral
- Agree
- Strongly Agree

Now we would like to ask you about your employment.

EMPLOY00:

Are you currently employed?

- Yes (1)
- No (0)

If Employee = No then go to Employ00b

EMPLOY00A:

For how many years have you been employed? _____

GOTO Employ09

EMPLOY00B:

For how many years have you been unemployed? _____

EMPLOY01:

During the past month did you spend any time at a job or business?

- Yes (1)
- No (0)

If Employ01 = No then go to Employ07

EMPLOY02:

Have you ever had a job that paid you money?

- Yes (1)
- No (0)

If Employ02 = No then go to Employ07

EMPLOY03:

For how long did you work at your last job?

- Less than 1 month (1)
- More than a month, less than a year (2)
- 1 year (3)
- More than a year, less than 3 years (4)
- 3 years or more (5)

EMPLOY04:

How many hours per week did you usually work at your last job?

- More than 40 hours (1)
- 40 hours (2)
- 35-39 hours (3)
- 30-34 hours (4)
- 21-29 hours (5)
- 20 hours (6)
- 11-19 hours (7)
- 10 or fewer hours (8)

EMPLOY05:

How long ago did you leave your last job?

- Less than 1 month (1)
- More than a month, less than a year (2)
- 1 year (3)
- More than a year, less than 3 years (4)
- 3 years or more (5)

EMPLOY06:

Why did you leave your last job?

- Retired (1)
- Laid off permanently (2)
- Laid off temporarily (3)
- Quit (4)
- Fired (5)
- Finished temporary job (6)

If Employ06 = Retired then go to PSQII/INTRO

EMPLOY07:

What is the main reason you are not working now?

- Cannot find a job (1)
- Taking care of household (2)
- Disabled (3)
- Do not want to work (4)
- Do not need to work (5)
- Too discouraged to look for work (6)

EMPLOY08:

Are you looking for a job now?

- Yes (1)
- No (0)

GOTO PSQI/INTRO

EMPLOY09:

Including full-time, part-time, evenings, and weekends, how many jobs or businesses do you have now?

- 1 (1)
- 2 (2)
- 3 (3)
- 4 or more (4)

EMPLOY10:

For how long have you worked at your primary job?

- Less than 1 month (1)
- More than a month, less than a year (2)
- 1 year (3)
- More than a year, less than 3 years (4)
- 3 years or more (5)

EMPLOY11:

How many hours per week did you usually work at all of your jobs?

- More than 50 hours (1)
- More than 40 but less than 50 hours (2)
- 40 hours (3)
- 36-39 hours (4)
- 35 hours (5)
- 21-34 hours (6)
- 20 hours (7)
- less than 20 hours (8)

EMPLOY12:

Are all of your jobs permanent or are the jobs temporary until the project is done?

- All permanent (1)
- Some permanent, some temporary (2)
- All temporary (3)

**Now the following questions are about your usual sleep habits during the past month only.
Your answers should indicate the best reply for most of the days in the past month.**

PSQI01

During the past month, when have you usually gone to bed?

- Evening (5 to 8pm) (1)
- Night (8 to 11pm) (2)
- Late night (11 to 2am) (3)
- Early morning (2 to 5am) (4)
- Morning (5 to 7am) (5)
- Mid morning (7 to 9am) (6)
- Late morning (9am to 12 noon) (7)
- Afternoon (12 noon to 5pm) (8)

PSQI02

During the past month, how long (in minutes) has it taken you to fall asleep each night?

- Less than 15 minutes (0)
- 16 to 30 minutes (1)
- 31 to 60 minutes (2)
- 60 minutes or more (3)

PSQI03

During the past month, when have you usually gotten up from bed to start your day?

- Early morning (2 to 5am) (1)
- Morning (5 to 7am) (2)
- Mid morning (7 to 9am) (3)
- Late morning (9am to 12 noon) (4)
- Afternoon (12 noon to 5pm) (5)
- Evening (5 to 8pm) (6)
- Night (8 to 11pm) (7)
- Late night (11 to 2am) (8)

PSQI04

During the past month, how many hours of actual sleep did you get each night?
(Note that this may be different than the number of hours you spent in bed.)

- More than 7 hours (0)
- 6 to 7 hours (1)
- 5 to 6 hours (2)
- Less than 5 hours (3)

PSQI05a

During the past month, how often had you had trouble sleeping because you ...

Cannot get to sleep within 30 minutes?

- Not during the past month (0)
- Less than once a week (1)
- Once or twice a week (2)
- Three or more times a week (3)

PSQI05b

During the past month, how often had you had trouble sleeping because you ...

Wake up in the middle of the night, early morning, or other time when you should be sleeping?

- Not during the past month (0)
- Less than once a week (1)
- Once or twice a week (2)
- Three or more times a week (3)

PSQI05c

During the past month, how often had you had trouble sleeping because you ...

Have to get up to use the bathroom?

- Not during the past month (0)
- Less than once a week (1)
- Once or twice a week (2)
- Three or more times a week (3)

PSQI05d

During the past month, how often had you had trouble sleeping because you ...

Cannot breathe comfortably?

- Not during the past month (0)
- Less than once a week (1)
- Once or twice a week (2)
- Three or more times a week (3)

PSQI05e

During the past month, how often had you had trouble sleeping because you ...

Cough or snore loudly?

- Not during the past month (0)
- Less than once a week (1)
- Once or twice a week (2)
- Three or more times a week (3)

PSQI05f

During the past month, how often had you had trouble sleeping because you ...

Feel too cold?

- Not during the past month (0)
- Less than once a week (1)
- Once or twice a week (2)
- Three or more times a week (3)

PSQI05g

During the past month, how often had you had trouble sleeping because you ...

Feel too hot?

- Not during the past month (0)
- Less than once a week (1)
- Once or twice a week (2)
- Three or more times a week (3)

PSQI05h

During the past month, how often had you had trouble sleeping because you ...

Have bad dreams?

- Not during the past month (0)
- Less than once a week (1)
- Once or twice a week (2)
- Three or more times a week (3)

PSQI05i

During the past month, how often had you had trouble sleeping because you ...

Have pain?

- Not during the past month (0)
- Less than once a week (1)
- Once or twice a week (2)
- Three or more times a week (3)

PSQI05jother

During the past month, have you had any other reasons for having trouble sleeping?

- No (0)
- Yes (1)

If PSQI05jdescript=0 then GOTO PSQI06

PSQI05jdescript

Please describe or list the other reasons for having trouble sleeping: _____

PSQI05j

During the past month, how often had you had trouble sleeping because of your other reasons:

[REASONS DESCRIBED]?

- Not during the past month (0)
- Less than once a week (1)
- Once or twice a week (2)
- Three or more times a week (3)

PSQI06

During the past month, how often have you taken medicine (prescribed or “over-the-counter”) to help you sleep?

- Not during the past month (0)
- Less than once a week (1)
- Once or twice a week (2)
- Three or more times a week (3)

PSQI07

During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?

- Not during the past month (0)
- Less than once a week (1)
- Once or twice a week (2)
- Three or more times a week (3)

PSQI08

During the past month, how much of a problem has it been for you to keep up enthusiasm to get things done?

- Not during the past month (0)
- Less than once a week (1)
- Once or twice a week (2)
- Three or more times a week (3)

PSQI09

During the past month, how would you rate your sleep quality overall?

- Very good (0)
- Fairly good (1)
- Fairly bad (2)
- Very bad (3)

LIVEALONE:

Do you live alone?

- Yes (1)
- No (0)

CHILDREN:

How many children do you have? _____

If LiveAlone = Yes then go to CareGive00

HSEHLD02A:

Does your spouse or significant other live with you?

- No (1)
- All the time (2)
- Sometimes (3)

If Children = 0 then go to HseHld02c

HSEHLD02B:

Do your children live with you?

- No (1)
- All the time (2)
- Sometimes (3)

HSEHLD02C:

Do children from other parents live with you?

- No (1)
- All the time (2)
- Sometimes (3)

HSEHLD02D:

Do your parents or in-laws live with you?

- No (1)
- All the time (2)
- Sometimes (3)

HSEHLD02E:

Do your grandparent(s) or your spouse's grandparent(s) live with you?

- No (1)
- All the time (2)
- Sometimes (3)

HSEHLD02F:

Do any other relatives live with you?

- No (1)
- All the time (2)
- Sometimes (3)

HSEHLD02G:

Do any of your friends live with you?

- No (1)
- All the time (2)
- Sometimes (3)

If Children = 0 AND LiveAlone = 1 then go to HseHld05

If Children = 0 then go to HseHld03a

CAREGIVE01:

Do you have any grandchildren?

- Yes (1)
- No (0)

If CareGive01 = No then go to HseHld03a

CAREGIVE02:

Do any of your grandchildren live with you?

- Yes (1)
- No (0)

CAREGIVE03:

How often do you spend time caring for your grandchildren?

- Almost every day (1)
- Once or twice a week (2)
- Once or twice a month (3)
- Once or twice a year (4)
- Never (5)

If CareGive03 not "almost every day" or "once or twice a week" then go to CareGive05

CAREGIVE04:

For how many grandchildren do you provide care? _____

CAREGIVE05:

Excluding your biological children and grandchildren, how many other persons are you caring for without pay? _____

If CareGive05 = 0 then go to HseHld03a

CAREGIVE06:

How often do you care for people other than your children and grandchildren without pay?

- Almost every day (1)
- Once or twice a week (2)
- Once or twice a month (3)
- Once or twice a year (4)
- Never (5)

If LiveAlone = Yes then go to HseHld05

HSEHLD03A:

Including yourself, how many people live in your house now? _____

If HseHld03a = 1 then go to HseHld04

HSEHLD03B:

How many people living with you are male? _____

HSEHLD03C:

How many people living with you are children 18 years old or younger? _____

HSEHLD04:

Including yourself, how many adults contribute income to the household? _____

HSEHLD05:

Which of these best describes your current relationship status?

- Single (1)
- Married (2)
- Partnered (3)
- Divorced (4)
- Separated (5)
- Widowed (6)
- Never married (7)

HSEHLD06:

- Do you...?
- Own your home (1)
- Rent your home (2)
- Live in a home owned or rented by someone else (3)

HSEHLD07:

For how long have you lived in your current home?

- Less than a month (1)
- 1-11 months (2)
- 1 year (3)
- More than 1 year (4)

The next questions ask about difficulties you might have doing every day activities. A health problem is any illness or physical, mental, or emotional difficulty not including pregnancy.

ADL:

Do you have any health problems that require you to use special equipment such as a cane, wheelchair, or a special bed or telephone?

- Yes (1)
- No (0)

PF01:

Because of health or physical problems, do you have any difficulty walking a quarter of mile (about 2 or 3 blocks) without stopping?

- Yes (1)
- No (0)

If PF01 = No then go to PF01b

PF01A:

How much difficulty do you have walking a quarter of a mile?

- A little (1)
- Some (2)
- A lot (3)
- Unable to do (4)

If PF01a=Unable to do then GOTO PF02, otherwise GOTO PF01c

PF01B:

- How easy is it for you to walk a quarter of a mile?
- Very easy (1)
- Somewhat easy (2)
- Not so easy (3)

PF01C:

Because of a health or physical problem, do you have any difficulty walking one mile?

- Yes (1)
- No (0)

If PF01c = Yes then go to PF02

PF01D:

How easy is it for you to walk one mile?

- Very easy (1)
- Somewhat easy (2)
- Not so easy (3)

PF02:

Because of health or physical problems, do you have any difficulty walking up 10 steps without resting (about 1 flight of stairs)?

- Yes (1)
- No (0)

If PF02 = No then go to PF02b

PF02A:

How much difficulty do you have walking up 10 steps?

- A little (1)
- Some (2)
- A lot (3)
- Unable to do (4)

GOTO PF03

PF02B:

How easy is it for you to walk up 10 steps?

- Very easy (1)
- Somewhat easy (2)
- Not so easy (3)

PF02C:

Because of a health or physical problem, do you have any difficulty walking up 20 steps without resting (about 2 flights of stairs)?

- Yes (1)
- No (0)

If PF02c = Yes then go to PF03

PF02D:

How easy is it for you to walk up 20 steps?

- Very easy (1)
- Somewhat easy (2)
- Not so easy (3)

PF03:

Because of a health or physical problem, do you have difficulty lifting or carrying something weighing 10 pounds such as a small bag of groceries or an infant?

- Yes (1)
- No (0)

If PF03 = No then go to PF03b

PF03A:

How much difficulty do you have lifting or carrying 10 pounds?

- A little (1)
- Some (2)
- A lot (3)
- Unable to do (4)

GOTO PhysActIntro

PF03B:

How easy is it for you to lift or carry something weighing 10 pounds?

- Very easy (1)
- Somewhat easy (2)
- Not so easy (3)

PF03C:

Because of a health or physical problem, do you have any difficulty lifting or carrying something weighing 20 pounds such as a large, full bag of groceries?

- Yes (1)
- No (0)

If PF03c = Yes then go to PhysActIntro

PF03D:

How easy is it for you to lift or carry something weighing 20 pounds?

- Very easy (1)
- Somewhat easy (2)
- Not so easy (3)

The next questions ask about the types of activities you did in a typical week in the past month.

For each activity that you typically did, tell us how many days you did and for how long you did it each day.

PHYSACT01:

In a typical week in the past month, did you do light household chores such as cooking, washing dishes, ironing, straightening up, laundry, and shopping?

- Yes (1)
- No (0)

If PhysAct01 = No then go to PhysAct02

PHYSACT01A:

In a typical week in the past month, on how many days did you do light household chores such as cooking, washing dishes, ironing, straightening up, laundry, and shopping?

- 1 day (1)
- 2 days (2)
- 3 days (3)
- 4 days (4)
- 5 days (5)
- 6 days (6)
- 7 days (7)

PHYSACT01B:

In a typical week in the past month, for how many hours did you do light household chores such as cooking, washing dishes, ironing, straightening up, laundry, and shopping?

- 0 hours (0)
- 1 hour (1)
- 2 hours (2)
- 3 hours (3)
- 4 hours (4)
- 5 hours (5)
- 5+ hours (6)

IF PhysAct01b=5+ hours GOTO PhysAct02

PHYSACT01C:

In a typical week in the past month, for how many minutes did you do light household chores such as cooking, washing dishes, ironing, straightening up, laundry, and shopping?

- 0 minutes (0)
- 5 minutes (1)
- 10 minutes (2)
- 15 minutes (3)
- 30 minutes (4)
- 45 minutes (5)

IF PhysAct01b=0 AND PhysAct01c=0 GOTO PhysAct01b (Cannot have Hours=0 and Minutes=0 when Days>0)

PHYSACT02:

In a typical week in the past month, did you do moderate household chores such as heavy cleaning, scrubbing, mopping, home repairs, washing car, and vacuuming?

- Yes (1)
- No (0)

If PhysAct02 = No then go to PhysAct03

PHYSACT02A:

In a typical week in the past month, on how many days did you do moderate household chores such as heavy cleaning, scrubbing, mopping, home repairs, washing car, and vacuuming?

- 1 day (1)
- 2 days (2)
- 3 days (3)
- 4 days (4)
- 5 days (5)
- 6 days (6)
- 7 days (7)

PHYSACT02B:

In a typical week in the past month, for how many hours did you do moderate household chores such as heavy cleaning, scrubbing, mopping, home repairs, washing car, and vacuuming?

- 0 hours (0)
- 1 hour (1)
- 2 hours (2)
- 3 hours (3)
- 4 hours (4)
- 5 hours (5)
- 5+ hours (6)

IF PhysAct02b=5+ hours GOTO PhysAct03

PHYSACT02C:

In a typical week in the past month, for how many minutes did you do moderate household chores such as heavy cleaning, scrubbing, mopping, home repairs, washing car, and vacuuming?

- 0 minutes (0)
- 5 minutes (1)
- 10 minutes (2)
- 15 minutes (3)
- 30 minutes (4)
- 45 minutes (5)

IF PhysAct02b=0 AND PhysAct02c=0 GOTO PhysAct02b (Cannot have Hours=0 and Minutes=0 when Days>0)

PHYSACT03:

In a typical week in the past month, did you do moderate yard or garden work such as weeding, mowing grass, raking, cleaning garage, or sweeping?

- Yes (1)
- No (0)

If PhysAct03 = No then go to PhysAct04

PHYSACT03A:

In a typical week in the past month, on how many days did you do moderate yard or garden work such as weeding, mowing grass, raking, cleaning garage, or sweeping?

- 1 day (1)
- 2 days (2)
- 3 days (3)
- 4 days (4)
- 5 days (5)
- 6 days (6)
- 7 days (7)

PHYSACT03B:

In a typical week in the past month, for how many hours did you do moderate yard or garden work such as weeding, mowing grass, raking, cleaning garage, or sweeping?

- 0 hours (0)
- 1 hour (1)
- 2 hours (2)
- 3 hours (3)
- 4 hours (4)
- 5 hours (5)
- 5+ hours (6)

IF PhysAct03b=5+ hours GOTO PhysAct04

PHYSACT03C:

In a typical week in the past month, for how many minutes did you do moderate yard or garden work such as weeding, mowing grass, raking, cleaning garage, or sweeping?

- 0 minutes (0)
- 5 minutes (1)
- 10 minutes (2)
- 15 minutes (3)
- 30 minutes (4)
- 45 minutes (5)

IF PhysAct03b=0 AND PhysAct03c=0 GOTO PhysAct03b (Cannot have Hours=0 and Minutes=0 when Days>0)

PHYSACT04:

In a typical week in the past month, did you do heavy yard or garden work such as digging dirt, shoveling snow, mending fences, or chopping wood?

- Yes (1)
- No (0)

If PhysAct04 = No then go to PhysAct05

PHYSACT04A:

In a typical week in the past month, on how many days did you do heavy yard or garden work such as digging dirt, shoveling snow, mending fences, or chopping wood?

- 1 day (1)
- 2 days (2)
- 3 days (3)
- 4 days (4)
- 5 days (5)
- 6 days (6)
- 7 days (7)

PHYSACT04B:

In a typical week in the past month, for how many hours did you do heavy yard or garden work such as digging dirt, shoveling snow, mending fences, or chopping wood?

- 0 hours (0)
- 1 hour (1)
- 2 hours (2)
- 3 hours (3)
- 4 hours (4)
- 5 hours (5)
- 5+ hours (6)

IF PhysAct04b=5+ hours GOTO PhysAct05

PHYSACT04C:

In a typical week in the past month, for how many minutes did you do heavy yard or garden work such as digging dirt, shoveling snow, mending fences, or chopping wood?

- 0 minutes (0)
- 5 minutes (1)
- 10 minutes (2)
- 15 minutes (3)
- 30 minutes (4)
- 45 minutes (5)

IF PhysAct04b=0 AND PhysAct04c=0 GOTO PhysAct04b (Cannot have Hours=0 and Minutes=0 when Days>0)

PHYSACT05:

In a typical week in the past month, did you take care of children or adults such as bathing them, feeding them, changing diapers, and playing?

- Yes (1)
- No (0)

If PhysAct05 = No then go to PhysAct06

PHYSACT05A:

In a typical week in the past month, on how many days did you take care of children or adults such as bathing them, feeding them, changing diapers, and playing?

- 1 day (1)
- 2 days (2)
- 3 days (3)
- 4 days (4)
- 5 days (5)
- 6 days (6)
- 7 days (7)

PHYSACT05B:

In a typical week in the past month, for how many hours did you take care of children or adults such as bathing them, feeding them, changing diapers, and playing?

- 0 hours (0)
- 1 hour (1)
- 2 hours (2)
- 3 hours (3)
- 4 hours (4)
- 5 hours (5)
- 5+ hours (6)

IF PhysAct05b=5+ hours GOTO PhysAct06

PHYSACT05C:

In a typical week in the past month, for how many minutes did you take care of children or adults such as bathing them, feeding them, changing diapers, and playing?

- 0 minutes (0)
- 5 minutes (1)
- 10 minutes (2)
- 15 minutes (3)
- 30 minutes (4)
- 45 minutes (5)

IF PhysAct05b=0 AND PhysAct05c=0 GOTO PhysAct05b (Cannot have Hours=0 and Minutes=0 when Days>0)

PHYSACT06:

In a typical week in the past month, did you take care of children or adults such as lifting and carrying them or pushing a stroller or a wheelchair?

- Yes (1)
- No (0)

If PhysAct06 = No then go to PhysAct07

PHYSACT06A:

In a typical week in the past month, on how many days did you take care of children or adults such as lifting and carrying them or pushing a stroller or a wheelchair?

- 1 day (1)
- 2 days (2)
- 3 days (3)
- 4 days (4)
- 5 days (5)
- 6 days (6)
- 7 days (7)

PHYSACT06B:

In a typical week in the past month, for how many hours did you take care of children or adults such as lifting and carrying them or pushing a stroller or a wheelchair?

- 0 hours (0)
- 1 hour (1)
- 2 hours (2)
- 3 hours (3)
- 4 hours (4)
- 5 hours (5)
- 5+ hours (6)

IF PhysAct06b=5+ hours GOTO PhysAct07

PHYSACT06C:

In a typical week in the past month, for how many minutes did you take care of children or adults such as lifting and carrying them or pushing a stroller or a wheelchair?

- 0 minutes (0)
- 5 minutes (1)
- 10 minutes (2)
- 15 minutes (3)
- 30 minutes (4)
- 45 minutes (5)

IF PhysAct06b=0 AND PhysAct06c=0 GOTO PhysAct06b (Cannot have Hours=0 and Minutes=0 when Days>0)

PHYSACT07:

In a typical week in the past month, did you drive or ride in a car, ride the bus or subway anytime including going to or returning from work?

- Yes (1)
- No (0)

If PhysAct07 = No then go to PhysAct08

PHYSACT07A:

In a typical week in the past month, on how many days did you drive or ride in a car, ride the bus or subway anytime including going to or returning from work?

- 1 day (1)
- 2 days (2)
- 3 days (3)
- 4 days (4)
- 5 days (5)
- 6 days (6)
- 7 days (7)

PHYSACT07B:

In a typical week in the past month, for how many hours did you drive or ride in a car, ride the bus or subway anytime including going to or returning from work?

- 0 hours (0)
- 1 hour (1)
- 2 hours (2)
- 3 hours (3)
- 4 hours (4)
- 5 hours (5)
- 5+ hours (6)

IF PhysAct07b=5+ hours GOTO PhysAct08

PHYSACT07C:

In a typical week in the past month, for how many minutes did you drive or ride in a car, ride the bus or subway anytime including going to or returning from work?

- 0 minutes (0)
- 5 minutes (1)
- 10 minutes (2)
- 15 minutes (3)
- 30 minutes (4)
- 45 minutes (5)

IF PhysAct07b=0 AND PhysAct07c=0 GOTO PhysAct07b (Cannot have Hours=0 and Minutes=0 when Days>0)

PHYSACT08:

In a typical week in the past month, did you walk to get to places such as a bus, car, work, or into a store?

- Yes (1)
- No (0)

If PhysAct08 = No then go to PhysAct09

PHYSACT08A:

In a typical week in the past month, on how many days did you walk to get to places such as a bus, car, work, or into a store?

- 1 day (1)
- 2 days (2)
- 3 days (3)
- 4 days (4)
- 5 days (5)
- 6 days (6)
- 7 days (7)

PHYSACT08B:

In a typical week in the past month, for how many hours did you walk to get to places such as a bus, car, work, or into a store?

- 0 hours (0)
- 1 hour (1)
- 2 hours (2)
- 3 hours (3)
- 4 hours (4)
- 5 hours (5)
- 5+ hours (6)

IF PhysAct08b=5+ hours GOTO PhysAct09

PHYSACT08C:

In a typical week in the past month, for how many minutes did you walk to get to places such as a bus, car, work, or into a store?

- 0 minutes (0)
- 5 minutes (1)
- 10 minutes (2)
- 15 minutes (3)
- 30 minutes (4)
- 45 minutes (5)

IF PhysAct08b=0 AND PhysAct08c=0 GOTO PhysAct08b (Cannot have Hours=0 and Minutes=0 when Days>0)

PHYSACT09:

In a typical week in the past month, did you walk for exercise, pleasure, social reasons, during work breaks, or walk with your dog?

- Yes (1)
- No (0)

If PhysAct09 = No then go to PhysAct10

PHYSACT09A:

In a typical week in the past month, on how many days did you walk for exercise, pleasure, social reasons, during work breaks, or walk with your dog?

- 1 day (1)
- 2 days (2)
- 3 days (3)
- 4 days (4)
- 5 days (5)
- 6 days (6)
- 7 days (7)

PHYSACT09B:

In a typical week in the past month, for how many hours did you walk for exercise, pleasure, social reasons, during work breaks, or walk with your dog?

- 0 hours (0)
- 1 hour (1)
- 2 hours (2)
- 3 hours (3)
- 4 hours (4)
- 5 hours (5)
- 5+ hours (6)

IF PhysAct09b=5+ hours GOTO PhysAct10

PHYSACT09C:

In a typical week in the past month, for how many minutes did you walk for exercise, pleasure, social reasons, during work breaks, or walk with your dog?

- 0 minutes (0)
- 5 minutes (1)
- 10 minutes (2)
- 15 minutes (3)
- 30 minutes (4)
- 45 minutes (5)

IF PhysAct09b=0 AND PhysAct09c=0 GOTO PhysAct09b (Cannot have Hours=0 and Minutes=0 when Days>0)

PHYSACT10:

In a typical week in the past month, did you dance in church ceremonies or for pleasure?

- Yes (1)
- No (0)

If PhysAct10 = No then go to PhysAct11

PHYSACT10A:

In a typical week in the past month, on how many days did you dance in church ceremonies or for pleasure?

- 1 day (1)
- 2 days (2)
- 3 days (3)
- 4 days (4)
- 5 days (5)
- 6 days (6)
- 7 days (7)

PHYSACT10B:

In a typical week in the past month, for how many hours did you dance in church ceremonies or for pleasure?

- 0 hours (0)
- 1 hour (1)
- 2 hours (2)
- 3 hours (3)
- 4 hours (4)
- 5 hours (5)
- 5+ hours (6)

IF PhysAct10b=5+ hours GOTO PhysAct11

PHYSACT10C:

In a typical week in the past month, for how many minutes did you dance in church ceremonies or for pleasure?

- 0 minutes (0)
- 5 minutes (1)
- 10 minutes (2)
- 15 minutes (3)
- 30 minutes (4)
- 45 minutes (5)

IF PhysAct10b=0 AND PhysAct10c=0 GOTO PhysAct10b (Cannot have Hours=0 and Minutes=0 when Days>0)

PHYSACT11:

In a typical week in the past month, did you play in team sports such as softball, volleyball, basketball, or soccer?

- Yes (1)
- No (0)

If PhysAct11 = No then go to PhysAct12

PHYSACT11A:

In a typical week in the past month, on how many days did you play in team sports such as softball, volleyball, basketball, or soccer?

- 1 day (1)
- 2 days (2)
- 3 days (3)
- 4 days (4)
- 5 days (5)
- 6 days (6)
- 7 days (7)

PHYSACT11B:

In a typical week in the past month, for how many hours did you play in team sports such as softball, volleyball, basketball, or soccer?

- 0 hours (0)
- 1 hour (1)
- 2 hours (2)
- 3 hours (3)
- 4 hours (4)
- 5 hours (5)
- 5+ hours (6)

IF PhysAct11b=5+ hours GOTO PhysAct12

PHYSACT11C:

In a typical week in the past month, for how many minutes did you play in team sports such as softball, volleyball, basketball, or soccer?

- 0 minutes (0)
- 5 minutes (1)
- 10 minutes (2)
- 15 minutes (3)
- 30 minutes (4)
- 45 minutes (5)

IF PhysAct11b=0 AND PhysAct11c=0 GOTO PhysAct11b (Cannot have Hours=0 and Minutes=0 when Days>0)

PHYSACT12:

In a typical week in the past month, did you play against someone such as tennis, racquetball, or paddleball?

- Yes (1)
- No (0)

If PhysAct12 = No then go to PhysAct13

PHYSACT12A:

In a typical week in the past month, on how many days did you play against someone such as tennis, racquetball, or paddleball?

- 1 day (1)
- 2 days (2)
- 3 days (3)
- 4 days (4)
- 5 days (5)
- 6 days (6)
- 7 days (7)

PHYSACT12B:

In a typical week in the past month, for how many hours did you play against someone such as tennis, racquetball, or paddleball?

- 0 hours (0)
- 1 hour (1)
- 2 hours (2)
- 3 hours (3)
- 4 hours (4)
- 5 hours (5)
- 5+ hours (6)

IF PhysAct12b=5+ hours GOTO PhysAct13

PHYSACT12C:

In a typical week in the past month, for how many minutes did you play against someone such as tennis, racquetball, or paddleball?

- 0 minutes (0)
- 5 minutes (1)
- 10 minutes (2)
- 15 minutes (3)
- 30 minutes (4)
- 45 minutes (5)

IF PhysAct12b=0 AND PhysAct12c=0 GOTO PhysAct12b (Cannot have Hours=0 and Minutes=0 when Days>0)

PHYSACT13:

In a typical week in the past month, did you do an individual activity such as golf, bowling, yoga, or Tai Chi?

- Yes (1)
- No (0)

If PhysAct13 = No then go to PhysAct14

PHYSACT13A:

In a typical week in the past month, on how many days did you do an individual activity such as golf, bowling, yoga, or Tai Chi?

- 1 day (1)
- 2 days (2)
- 3 days (3)
- 4 days (4)
- 5 days (5)
- 6 days (6)
- 7 days (7)

PHYSACT13B:

In a typical week in the past month, for how many hours did you do an individual activity such as golf, bowling, yoga, or Tai Chi?

- 0 hours (0)
- 1 hour (1)
- 2 hours (2)
- 3 hours (3)
- 4 hours (4)
- 5 hours (5)
- 5+ hours (6)

IF PhysAct13b=5+ hours GOTO PhysAct14

PHYSACT13C:

In a typical week in the past month, for how many minutes did you do an individual activity such as golf, bowling, yoga, or Tai Chi?

- 0 minutes (0)
- 5 minutes (1)
- 10 minutes (2)
- 15 minutes (3)
- 30 minutes (4)
- 45 minutes (5)

IF PhysAct13b=0 AND PhysAct13c=0 GOTO PhysAct13b (Cannot have Hours=0 and Minutes=0 when Days>0)

PHYSACT14:

In a typical week in the past month, did you do low impact aerobics, slow bicycling, rowing, leisure swimming, or moderate weight lifting?

- Yes (1)
- No (0)

If PhysAct14 = No then go to PhysAct15

PHYSACT14A:

In a typical week in the past month, on how many days did you do low impact aerobics, slow bicycling, rowing, leisure swimming, or moderate weight lifting?

- 1 day (1)
- 2 days (2)
- 3 days (3)
- 4 days (4)
- 5 days (5)
- 6 days (6)
- 7 days (7)

PHYSACT14B:

In a typical week in the past month, for how many hours did you do low impact aerobics, slow bicycling, rowing, leisure swimming, or moderate weight lifting?

- 0 hours (0)
- 1 hour (1)
- 2 hours (2)
- 3 hours (3)
- 4 hours (4)
- 5 hours (5)
- 5+ hours (6)

IF PhysAct14b=5+ hours GOTO PhysAct15

PHYSACT14C:

In a typical week in the past month, for how many minutes did you do low impact aerobics, slow bicycling, rowing, leisure swimming, or moderate weight lifting?

- 0 minutes (0)
- 5 minutes (1)
- 10 minutes (2)
- 15 minutes (3)
- 30 minutes (4)
- 45 minutes (5)

IF PhysAct14b=0 AND PhysAct14c=0 GOTO PhysAct14b (Cannot have Hours=0 and Minutes=0 when Days>0)

PHYSACT15:

In a typical week in the past month, did you do high impact aerobics, fast bicycling, running, jogging, fast swimming, vigorous weight lifting, judo, kickboxing, or karate?

- Yes (1)
- No (0)

If PhysAct15 = No then go to PhysAct16

PHYSACT15A:

In a typical week in the past month, on how many days did you do high impact aerobics, fast bicycling, running, jogging, fast swimming, vigorous weight lifting, judo, kickboxing, or karate?

- 1 day (1)
- 2 days (2)
- 3 days (3)
- 4 days (4)
- 5 days (5)
- 6 days (6)
- 7 days (7)

PHYSACT15B:

In a typical week in the past month, for how many hours did you do high impact aerobics, fast bicycling, running, jogging, fast swimming, vigorous weight lifting, judo, kickboxing, or karate?

- 0 hours (0)
- 1 hour (1)
- 2 hours (2)
- 3 hours (3)
- 4 hours (4)
- 5 hours (5)
- 5+ hours (6)

IF PhysAct15b=5+ hours GOTO PhysAct16

PHYSACT15C:

In a typical week in the past month, for how many minutes did you do high impact aerobics, fast bicycling, running, jogging, fast swimming, vigorous weight lifting, judo, kickboxing, or karate?

- 0 minutes (0)
- 5 minutes (1)
- 10 minutes (2)
- 15 minutes (3)
- 30 minutes (4)
- 45 minutes (5)

IF PhysAct15b=0 AND PhysAct15c=0 GOTO PhysAct15b (Cannot have Hours=0 and Minutes=0 when Days>0)

PHYSACT16:

In a typical week in the past month, did you watch TV while sitting or reclining?

- Yes (1)
- No (0)

If PhysAct16 = No then go to PhysAct17

PHYSACT16A:

In a typical week in the past month, on how many days did you watch TV while sitting or reclining?

- 1 day (1)
- 2 days (2)
- 3 days (3)
- 4 days (4)
- 5 days (5)
- 6 days (6)
- 7 days (7)

PHYSACT16B:

In a typical week in the past month, for how many hours did you watch TV while sitting or reclining?

- 0 hours (0)
- 1 hour (1)
- 2 hours (2)
- 3 hours (3)
- 4 hours (4)
- 5 hours (5)
- 5+ hours (6)

IF PhysAct16b=5+ hours GOTO PhysAct17

PHYSACT16C:

In a typical week in the past month, for how many minutes did you watch TV while sitting or reclining?

- 0 minutes (0)
- 5 minutes (1)
- 10 minutes (2)
- 15 minutes (3)
- 30 minutes (4)
- 45 minutes (5)

IF PhysAct16b=0 AND PhysAct16c=0 GOTO PhysAct16b (Cannot have Hours=0 and Minutes=0 when Days>0)

PHYSACT17:

In a typical week in the past month, did you read, knit, sew, visit, do nothing?

- Yes (1)
- No (0)

If PhysAct17 = No then go to PhysAct18

PHYSACT17A:

In a typical week in the past month, on how many days did you read, knit, sew, visit, do nothing?

- 1 day (1)
- 2 days (2)
- 3 days (3)
- 4 days (4)
- 5 days (5)
- 6 days (6)
- 7 days (7)

PHYSACT17B:

In a typical week in the past month, for how many hours did you read, knit, sew, visit, do nothing?

- 0 hours (0)
- 1 hour (1)
- 2 hours (2)
- 3 hours (3)
- 4 hours (4)
- 5 hours (5)
- 5+ hours (6)

IF PhysAct17b=5+ hours GOTO PhysAct18

PHYSACT17C:

In a typical week in the past month, for how many minutes did you read, knit, sew, visit, do nothing?

- 0 minutes (0)
- 5 minutes (1)
- 10 minutes (2)
- 15 minutes (3)
- 30 minutes (4)
- 45 minutes (5)

IF PhysAct17b=0 AND PhysAct17c=0 GOTO PhysAct17b (Cannot have Hours=0 and Minutes=0 when Days>0)

PHYSACT18:

Do you work to earn money?

- Yes (1)
- No (0)

If PhysAct18 = No then go to PhysAct24

PHYSACT19A:

How many days per week do you work in all of your jobs?

- 1 day (1)
- 2 days (2)
- 3 days (3)
- 4 days (4)
- 5 days (5)
- 6 days (6)
- 7 days (7)

PHYSACT19B:

How many hours per day do you work in all of your jobs?

Enter 0 to 24 hours, using 0 if answer is "less than 1 hour". _____

PHYSACT20A:

At work, did you do light work while sitting such as office work, laboratory work, or child care?

- Yes (1)
- No (0)

If PhysAct20a = No then go to PhysAct21a

PHYSACT20B:

How many hours per day did you do light work while sitting such as office work, laboratory work, or child care? Enter 0 to 24 hours, using 0 if answer is "less than 1 hour". _____

PHYSACT21A:

At work, did you do light work while standing such as filing paperwork, copying papers, assembling products, nursing, or farming?

- Yes (1)
- No (0)

If *PhysAct21a* = No then go to *PhysAct22a*

PHYSACT21B:

How many hours per day did you do light work while standing such as filing paperwork, copying papers, assembling products, nursing, or farming?

Enter 0 to 24 hours, using 0 if answer is "less than 1 hour". _____

PHYSACT22A:

At work, did you do moderate work while standing or walking such as nursing, custodial work, or housekeeping work, lifting or pushing thing, or sustained walking such as making deliveries?

- Yes (1)
- No (0)

If *PhysAct22a* = No then go to *PhysAct23a*

PHYSACT22B:

How many hours per day did you do moderate work while standing or walking such as nursing, custodial work, or housekeeping work, lifting or pushing thing, or sustained walking such as making deliveries?

Enter 0 to 24 hours, using 0 if answer is "less than 1 hour". _____

PHYSACT23A:

At work, did you do heavy work such as manual labor, ranch or farm work, or loading and unloading trucks?

- Yes (1)
- No (0)

If *PhysAct23a* = No then go to *PhysAct24*

PHYSACT23B:

How many hours per day did you do heavy work such as manual labor, ranch or farm work, or loading and unloading trucks?

Enter 0 to 24 hours, using 0 if answer is "less than 1 hour". _____

PHYSACT24:

Did you work as a volunteer or at church in activities you have not yet mentioned?

- Yes (1)
- No (0)

If *PhysAct24* = No then go to *PhysAct28*

PHYSACT25:

Did your volunteer work include light work while you were sitting or standing?

- Yes (1)
- No (0)

If PhysAct25 = No then go to PhysAct26

PHYSACT25A:

How many days per week did you do light volunteer work while you were sitting or standing?

- 1 day (1)
- 2 days (2)
- 3 days (3)
- 4 days (4)
- 5 days (5)
- 6 days (6)
- 7 days (7)

PHYSACT25B:

For how many hours per week did you do light volunteer work while you were sitting or standing?

- 1 hour (1)
- 2 hours (2)
- 3 hours (3)
- 4 hours (4)
- 5 hours (5)
- 5+ hours (6)

PHYSACT26:

Did your volunteer work include moderate work while you were standing or walking?

- Yes (1)
- No (0)

If PhysAct26 = No then go to PhysAct27

PHYSACT26A:

How many days per week did you do moderate volunteer work while you were standing or walking?

- 1 day (1)
- 2 days (2)
- 3 days (3)
- 4 days (4)
- 5 days (5)
- 6 days (6)
- 7 days (7)

PHYSACT26B:

For how many hours per week did you do moderate volunteer work while you were standing or walking?

- 1 hour (1)
- 2 hours (2)
- 3 hours (3)
- 4 hours (4)
- 5 hours (5)
- 5+ hours (6)

PHYSACT27:

Did your volunteer work include heavy work such as pushing, lifting, carrying, or climbing?

- Yes (1)
- No (0)

If PhysAct27 = No then go to PhysAct28

PHYSACT27A:

How many days per week did you do heavy volunteer work such as pushing, lifting, carrying, or climbing?

- 1 day (1)
- 2 days (2)
- 3 days (3)
- 4 days (4)
- 5 days (5)
- 6 days (6)
- 7 days (7)

PHYSACT27B:

For how many hours per week did you do moderate volunteer work such as pushing, lifting, carrying, or climbing?

- 1 hour (1)
- 2 hours (2)
- 3 hours (3)
- 4 hours (4)
- 5 hours (5)
- 5+ hours (6)

PHYSACT28:

What is your usual pace when you walk outside of your home?

- I do not walk (0)
- Casual strolling (up to 2 MPH) (1)
- Average or normal (2-3 MPH) (2)
- Fairly briskly (4-5 MPH) (3)
- Brisk or striding (>5 MPH) (4)

Now we would like to ask you some questions about your education.

EDUC06A:

What was the name of the elementary school you attended when you were 6 years old?

EDUC06B:

What was the street address of the elementary school you attended when you were 6 years old?

EDUC06C:

What was the city, state, and zip code of the elementary school you attended when you were 6 years old?

EDUC16:

Did you attend high school when you were 16 years old?

- Yes (1)
 No (0)

If Educ16 = No then go to Educ16d

EDUC16A:

What was the name of the high school you attended when you were 16 years old?

EDUC16B:

What was the street address of the high school you attended when you were 16 years old?

EDUC16C:

What was the city, state, and zip code of the high school you attended when you were 16 years old?

Go to Neigh

EDUC16D:

How old were you when you last attended school? _____

EDUC16E:

What grade were you in when you last attended school? _____

EDUC16F:

What was the name of the last school you attended? _____

EDUC16G:

What was the street address of the last school you attended? _____

EDUC16H:

What was the city, state, and zip code of the last school you attended? _____

NEIGH: Even though you may be satisfied with your neighborhood as a place to live, there may be some unwanted activities that concern you. The next questions are about problems that some neighborhoods experience

NEIGH01:

How often do you see graffiti on buildings and walls in your neighborhood?

- Never (1)
- Rarely (2)
- Sometimes (3)
- Often (4)
- Very often (5)

NEIGH02:

How often do you see litter on the sidewalks and streets in your neighborhood?

- Never (1)
- Rarely (2)
- Sometimes (3)
- Often (4)
- Very often (5)

NEIGH03:

How often do you see drug dealers, drug users or drunks hanging around in your neighborhood?

- Never (1)
- Rarely (2)
- Sometimes (3)
- Often (4)
- Very often (5)

NEIGH04:

How often do you see unemployed adults loitering in your neighborhood?

- Never (1)
- Rarely (2)
- Sometimes (3)
- Often (4)
- Very often (5)

NEIGH05:

How often do you see gang activity in your neighborhood?

- Never (1)
- Rarely (2)
- Sometimes (3)
- Often (4)
- Very often (5)

NEIGH06:

How often do you see disorderly or misbehaving groups of teens or children in your neighborhood?

- Never (1)
- Rarely (2)
- Sometimes (3)
- Often (4)
- Very often (5)

NEIGH07:

How often do you see prostitution in your neighborhood?

- Never (1)
- Rarely (2)
- Sometimes (3)
- Often (4)
- Very often (5)

NEIGH08:

How often do you see vacant, abandoned, or boarded up buildings in your neighborhood?

- Never (1)
- Rarely (2)
- Sometimes (3)
- Often (4)
- Very often (5)

NEIGH09:

How often do you see broken windows in your neighborhood?

- Never (1)
- Rarely (2)
- Sometimes (3)
- Often (4)
- Very often (5)

NEIGH10:

How rare is serious crime such as assault, mugging, or robbery in your neighborhood?

- Never (1)
- Rarely (2)
- Sometimes (3)
- Often (4)
- Very often (5)

NEIGH11:

How often do you see houses or yards not kept up in your neighborhood?

- Never (1)
- Rarely (2)
- Sometimes (3)
- Often (4)
- Very often (5)

SOCCHOH01:

- People in my neighborhood are willing to help their neighbors?
- Disagree strongly (1)
- Disagree somewhat (2)
- Neither agree nor disagree (3)
- Agree somewhat (4)
- Agree strongly (5)

SOCCHOH02:

I live in a close-knit neighborhood.

- People in my neighborhood are willing to help their neighbors?
- Disagree strongly (1)
- Disagree somewhat (2)
- Neither agree nor disagree (3)
- Agree somewhat (4)
- Agree strongly (5)

SOCCHOH03:

People in my neighborhood can be trusted.

- People in my neighborhood are willing to help their neighbors?
- Disagree strongly (1)
- Disagree somewhat (2)
- Neither agree nor disagree (3)
- Agree somewhat (4)
- Agree strongly (5)

SOCCHOH04:

People in my neighborhood generally do not get along with each other.

- People in my neighborhood are willing to help their neighbors?
- Disagree strongly (1)
- Disagree somewhat (2)
- Neither agree nor disagree (3)
- Agree somewhat (4)
- Agree strongly (5)

SOCCHO05:

People in my neighborhood do not share the same values.

- People in my neighborhood are willing to help their neighbors?
- Disagree strongly (1)
- Disagree somewhat (2)
- Neither agree nor disagree (3)
- Agree somewhat (4)
- Agree strongly (5)

SOCCON01:

If children were spray-painting graffiti on a local building, how likely would you say that your neighbors would take action?

- Very likely (1)
- Likely (2)
- Neither likely nor unlikely (3)
- Unlikely (4)
- Very unlikely (5)

SOCCON02:

If children were showing disrespect to an adult, how likely would you say that your neighbors would take action?

- Very likely (1)
- Likely (2)
- Neither likely nor unlikely (3)
- Unlikely (4)
- Very unlikely (5)

SOCCON03:

If a fight broke out in front of your house, how likely would you say that your neighbors would take action?

- Very likely (1)
- Likely (2)
- Neither likely nor unlikely (3)
- Unlikely (4)
- Very unlikely (5)

NEIGHTRAV01:

How much difficulty do you have getting to places in your neighborhood?

- No difficulty (1)
- Little difficulty (2)
- Lots of difficulty (3)
- Unable to go where I want to go (4)

NEIGHTRAV02:

What is your main way of getting around outside your neighborhood?

- Walking (1)
- Driving car (2)
- Riding in car (3)
- Public transportation (4)
- Taxi or shuttle (5)

Thank you for completing this questionnaire.

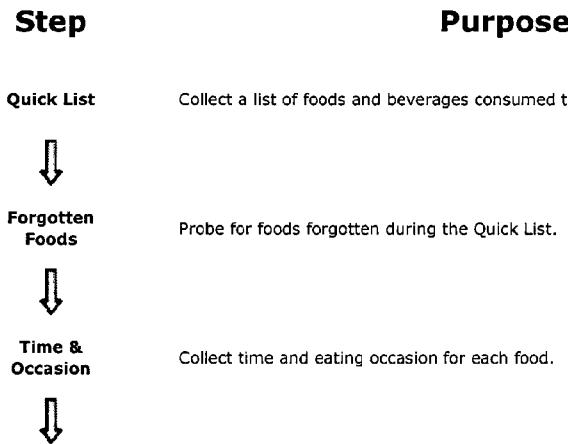
Appendix 4.3: Procedures – Dietary recall interview



Features of AMPM

- Employs research-based strategies to enhance dietary recall:
 - Respondent-driven approach allowing initial recall to be self-defined
 - Association with the day's events
 - Probes for frequently forgotten foods
 - Repetition with minimal burden
 - Reviews 24-hour day
 - Placement of foods with eating occasions
- Interviewer-administered, in person or by telephone
- Extensive automated capabilities, including:
 - Unique questions and response options specific for each food
 - Routing of questions based on previous responses
 - Food lookup tables reflecting today's food market
 - Ability to add, change, or delete foods anytime during the interview
 - Automated edit checks performed during data entry
 - Notepad features for interviewer comments
- Companion Food Model Booklet, an aid for estimating portion sizes
- Companion, supportive computer systems for auto-coding, manual coding, and quality control
- Utilizes the Food and Nutrient Database for Dietary Studies

5-Step Multiple-Pass Approach



Detail Cycle For each food, collect detailed description, amount, and additions. Review 24-hour day.



Final Probe Final probe for anything else consumed.

Read more about USDA's Automated Multiple-Pass Method:

Bliss, R.M. (2004). Researchers produce innovation in dietary recall. *Agric Res* 52(6):10-12.

Raper N, Perloff B, Ingwersen L, Steinfeldt L, and Anand J. (2004). An overview of USDA's Dietary Intake Data System. *J Food Compos Anal* 17(3-4):545-55.

McBride J. (2001). Was it a slab, a slice, or a sliver? High tech innovations take survey to new level. *Agric Res* 49(3):4-7.

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Information Collected by AMPM](#)

Last Modified: 09/29/2010

Appendix 4.4: Procedures – Nutritional supplements questionnaire

Appendix 1: Questionnaire

HANDLS OVER-THE-COUNTER AND PRESCRIPTION DIETARY SUPPLEMENTS QUESTIONNAIRE

SP NAME:

HH ID:

INTERVIEW:

DATE:

Interviewer: First, if you have any bottles or containers of any over the counter and prescription supplements or antacids, I would like to ask you to get them if you do not have them in front of you for this part of the interview. Do you have any questions before we begin?

Q.1 Do you take any **over the counter** vitamin and/or mineral supplements?

Circle: YES or NO If yes, list the names

Names of OTC Supplements (at least 10 fields)

Q.2 Do you take any **nonprescription** antacids? (such as rolaids, tums, or pepcid AC?)

Circle: YES or NO If yes, list the names

Name of Antacids (at least 5 fields)

Q.3 Do you take any **prescription** vitamins and/or minerals, antacids, or receive any prescription supplement injections?

Circle: YES or NO If yes, list the prescription supplements and antacids

Name of Prescription Supplements and Antacids (at least 10 fields)

Q.4 Do you have the containers for **all** the OTC vitamins and minerals that you've reported available in front of you?

(If NO ask SP to go get the containers)

YES	1
NO	2
REFUSED	7
DON'T KNOW	9

Interviewer Instructions: First I am going to ask you some questions about (INSERT NAME OF OTC SUPPLEMENT).

Q. 5 What appears on the front label of the supplement you took, please include the brand name?

Interviewer Instruction: Refer SP to handcard 1. Can you please read me all the words on the

front label? Was it a special type? (silver, women's, men's, prenatal, liquid)?

Q5.1a. **text boxes w/ unlimited space** _____
ENTER SUPPLEMENT NAME

Q5.1b _____
ENTER SUPPLEMENT NAME

Q5.1c _____
ENTER SUPPLEMENT NAME

Q5.1d _____
ENTER SUPPLEMENT NAME

Q5.1e _____
ENTER SUPPLEMENT NAME

Q5.1f _____
ENTER SUPPLEMENT NAME

REFUSED	7
DON'T KNOW	9

Probe if brand name unknown

SINGLE ELEMENTS

VITAMIN A.....	10
VITAMIN B6.....	12
VITAMIN B12.....	13
VITAMIN C (WITH OR WITHOUT ROSE HIPS).....	14
VITAMIN D	15
VITAMIN E.....	16
CALCIUM	18
CHROMIUM (CHROMIUM PICOLINATE)	19
FOLATE (FOLIC ACID).....	20
IRON (FERROUS XXXATE)	21
MAGNESIUM	27
POTASSIUM	28
SELENIUM	29
ZINC (ZINC GLUCONATE).....	40

MULTI ELEMENTS

VITAMINS A & D	50
CALCIUM & VITAMIN D.....	51
CALCIUM & MAGNESIUM.....	52

Q.6 ENTER MANUFACTURER/DISTRIBUTOR/STORE BRAND NAME.

ENTER AS MUCH INFORMATION AS POSSIBLE.

Q6.1a _____

Q6.1b _____

Q6.1c _____

Q6.1d _____

Q6.1e _____

Q6.1f _____

REFUSED 7

DON'T KNOW 9

Q.7 ENTER CITY NAME.

ENTER AS MUCH INFORMATION AS POSSIBLE.

Q7.1a _____

Q7.1b _____

Q7.1c _____

Q7.1d _____

Q7.1e _____

Q7.1f _____

REFUSED 7

DON'T KNOW 9

Q.8

ENTER **STATE NAME.**

ENTER 2-LETTER
STATE ABBREVIATION.

Q8.1a _____

Q8.1b _____

Q8.1c _____

Q8.1d _____

Q8.1e _____

Q8.1f _____

REFUSED 7

DON'T KNOW 9

Q.9 What is the form of the supplement taken as stated on the container? (Ex: pill, tablet, liquid etc.)**Interviewer Instructions : Write in code corresponding to product name**

Q9.1a _____

Q9.1b _____

Q9.1c _____

Q9.1d _____

Q9.1e _____

Q9.1f _____

Label	Code
Caplet	1
Capsule	2
Dropper	3
Drop	4
Fluid Ounce	5
Gel Cap	6
Injection/Shot	8
Lozenge	9
Milliliter	10
Package/Packet	12
Pill	13
Tablespoon/Powder	14
Softgel	16
Tablespoon/Liquid	17
Tablet	18
Teaspoon/Liquid	19

Wafer	20
Ounce/Powder	21
Spray/Squirt	22
Scoop/Powder	24
Cup/Powder	25
Chew	27
Other	28
Vegicap	29
Can/Liquid	30
Capful	31
Gumball	32
Gram/Powder	33
Teaspoon/Powder	34
Can/Powder	35
Scoop/Liquid	36
Cup/Liquid	37
Gram/Liquid	38
Drop/Lozenge	39
Unknown Dosage Form	99

REFUSED	77
DON'T KNOW	99

Q.10 What was the strength per tablet/pill/etc? Interviewer Instruction: Please if it is a double/triple element ask for the strength of each element. (Check the front label or the nutrition; if there is no information on the front label, check the nutrition facts)

Q10.1a _____

Q10.1b _____

Q10.1c _____

Q10.1d _____

Q10.1e _____

Q10.1f _____

REFUSED	7
DON'T KNOW	9

Q.11 Between midnight and midnight, how much of a dose did you take? What is your usual dosage? (Ex: 2 gelcaps)

*Number taken, then type. (Example: 4, 6 = means they took 4 lozenges)

Q11.1a _____

Q11.1b _____

Q11.1c _____

Q11.1d _____

Q11.1e _____

Q11.1f _____

REFUSED	7
DON'T KNOW	9

TABLETS/CAPSULES/PILLS/CAPLETS/ SOFTGELS/GEL CAPS/VEGICAPS/	
CHEWABLE TABLETS	1
DROPPERS	2
DROPS.....	3
INJECTIONS/SHOTS.....	5
LOZENGES/COUGH DROPS.....	6
MILLILITERS.....	7
POWDER/GRANULES	10
TABLESPOONS.....	11
TEASPOONS.....	12
WAFERS.....	13
CANS	15
GRAMS	16
DOTS	17
CUPS	18
SPRAYS/SQUIRTS.....	19
CHEWS/GUMMIES.....	20
SCOOPS	21
CC	22
CAPFULS.....	23
MG.....	24
UNITS.....	25
GULP.....	26
OUNCES	27
PACKAGES/PACKETS.....	28
VIALS	29
GUMBALLS.....	30
OTHER FORM (SPECIFY)	91
REFUSED	77
DON'T KNOW	99

Q.12 For how long have you been taking the supplement?
ENTER NUMBER AND UNIT (DAYS, WEEKS, MONTHS OR YEARS)

Q12.1a _____

Q12.1b _____

Q12.1c _____

Q12.1d _____

Q12.1e _____

Q12.1f _____

_____ Days _____ Months _____ Years

Q.12(a) If taken seasonally, which months out of the year do you take the supplement?
ENTER THE MONTHS SEPARATED BY COMMAS (EX: August, September)

Q12.a. 1a _____

Q.12(b) When you do take the supplement how many days per week do you take it?
ENTER NUMBER

Q12.b. 1 a _____

Q.13 Do you take it **daily**?
YES or NO

Q.13(a) If not daily, how often? _____ Days/ Week or _____ Days/ Month

Q.14 Did you take it **yesterday**?
YES or NO

Q.15 Did you decide to take {INSERT PRODUCT NAME} for reasons of your own or did a doctor or other health provider tell you to take it?

Q15.1a _____

Q15.1b _____

Q15.1c _____

Q15.1d _____

Q15.1e _____

Q15.1f _____

DECIDED TO TAKE IT FOR REASONS
OF MY OWN 1

A DOCTOR OR OTHER HEALTH PROVIDER TOLD ME TO.....	2
REFUSED	7
DON'T KNOW	9

Q.16 For what reason or reasons do you take or the doctor or other health professional tell you to take {INSERT PRODUCT NAME}? Interviewer Instructions: Refer SP to Handcard 2

- Q16.1a _____
- Q16.1b _____
- Q16.1c _____
- Q16.1d _____
- Q16.1e _____
- Q16.1f _____

CODE ALL THAT APPLY.

FOR GOOD BOWEL/COLON HEALTH.....	10
FOR PROSTATE HEALTH	11
FOR MENTAL HEALTH.....	12
TO PREVENT HEALTH PROBLEMS	13
TO IMPROVE MY OVERALL HEALTH.....	14
FOR TEETH, PREVENT CAVITIES.....	15
TO SUPPLEMENT MY DIET (BECAUSE I DON'T GET ENOUGH FROM FOOD).....	16
TO MAINTAIN HEALTH (TO STAY HEALTHY).....	17
TO PREVENT COLDS, BOOST IMMUNE SYSTEM.....	18
FOR HEART HEALTH, CHOLESTEROL.....	19
FOR EYE HEALTH	20
FOR HEALTHY JOINTS, ARTHRITIS	21
FOR SKIN HEALTH, DRY SKIN	22
FOR WEIGHT LOSS.....	23
FOR BONE HEALTH, BUILD STRONG BONES, OSTEOPOROSIS.....	24
TO GET MORE ENERGY	25
FOR PREGNANCY	26
FOR ANEMIA, SUCH AS LOW IRON.....	27
LACTOSE INTOLERANCE.....	28
OTHER SPECIFY	91
REFUSED	77
DON'T KNOW	99

Q.17 Any other over the counter supplements such as herbals (Echinacea, Ginseng, Ginkgo),

fiber supplements (Metamucil, Fibercon, Benefiber), or protein or amino acids (Lysine, Methionine, Tryptophan)? Circle: YES or NO (If yes, repeat questions Q5 – Q15)

NON-PRESCRIPTION ANTACIDS

Interviewer Instructions: Now I am going to be asking you a few questions about your use of nonprescription antacids.

- Q.18 Do you have the containers for all nonprescription antacids that you've reported in front of you?
(If NO ask SP to go get the containers)

YES	1
NO	2
REFUSED	7
DON'T KNOW	9

Interviewer Instructions: First I am going to ask you some questions about INSERT NAME OF ANATACID).

- Q. 19 What appears on the front label of the non-prescription antacids you took? Please include the brand name. Was it extra strength, regular strength, ultra, maximum?

Interviewer Instruction: Refer SP to Handcard 1 of antacid. Can you please read me all of the words on the front label?

Q19.1a. _____

ENTER SUPPLEMENT NAME

Q19.1b _____

ENTER SUPPLEMENT NAME

Q19.1c _____

ENTER SUPPLEMENT NAME

Q19.1d _____

ENTER SUPPLEMENT NAME

Q19.1e _____

ENTER SUPPLEMENT NAME

Q19.1f _____

ENTER SUPPLEMENT NAME

REFUSED	7
DON'T KNOW	9

Q.20 ENTER **MANUFACTURER/DISTRIBUTOR/STORE** BRAND NAME.

ENTER AS MUCH INFORMATION AS POSSIBLE.

Q20.1a _____

Q20.1b _____

Q20.1c _____

Q20.1d _____

Q20.1e _____

Q20.1f _____

REFUSED 7

DON'T KNOW 9

Q.21 ENTER **CITY NAME**.

ENTER AS MUCH INFORMATION AS POSSIBLE.

Q22.1a _____

Q22.1b _____

Q22.1c _____

Q22.1d _____

Q22.1e _____

Q22.1f _____

REFUSED 7

DON'T KNOW 9

Q.22 ENTER **STATE NAME**.

ENTER 2-LETTER
STATE ABBREVIATION.

Q22.1a _____

Q22.1b _____

Q22.1c _____

Q22.1d _____

Q22.1e _____

Q22.1f _____

REFUSED 7
DON'T KNOW 9

Q.23 What was the form of the **nonprescription** antacid taken? (Ex: pill, tablet, liquid etc)

Q23.1a _____

Q23.1b _____

Q23.1c _____

Q23.1d _____

Q23.1e _____

Q23.1f _____

Label	Code
Caplet	1
Capsule	2
Dropper	3
Drop	4
Fluid Ounce	5
Gel Cap	6
Injection/Shot	8
Lozenge	9
Milliliter	10
Package/Packet	12
Pill	13
Tablespoon/Powder	14
Softgel	16
Tablespoon/Liquid	17
Tablet	18
Teaspoon/Liquid	19

Wafer	20
Ounce/Powder	21
Spray/Squirt	22
Scoop/Powder	24
Cup/Powder	25
Chew	27
Other	28
Vegicap	29
Can/Liquid	30
Capful	31
Gumball	32
Gram/Powder	33
Teaspoon/Powder	34
Can/Powder	35
Scoop/Liquid	36
Cup/Liquid	37
Gram/Liquid	38
Drop/Lozenge	39
Unknown Dosage Form	99
REFUSED	77
DON'T KNOW	99

Q.24 What was the strength per antacid tablet/pill/etc?

Interviewer instruction: Please, if it is a double/ triple element ask for the strength of each element (check the front label or the nutrition facts label if it is not listed on front).

- Q24.1a _____
- Q24.1b _____
- Q24.1c _____
- Q24.1d _____
- Q24.1e _____
- Q24.1f _____

REFUSED 7
DON'T KNOW 9

Q.25 Between midnight and midnight, how much of a dose did you take? What is your usual dosage? (Ex: 2 gelcaps)

*Number taken, then type. (Example: 4, 6 = means they took 4 lozenges)

Q25.1a _____

Q25.1b _____

Q25.1c _____

Q25.1d _____

Q25.1e _____

Q25.1f _____

REFUSED	7
DON'T KNOW	9

TABLETS/CAPSULES/PILLS/CAPLETS/ SOFTGELS/GEL CAPS/VEGICAPS/ CHEWABLE TABLETS	1
DROPPERS	2
DROPS.....	3
INJECTIONS/SHOTS.....	5
LOZENGES/COUGH DROPS.....	6
MILLILITERS.....	7
POWDER/GRANULES	10
TABLESPOONS.....	11
TEASPOONS.....	12
WAFERS.....	13
CANS	15
GRAMS	16
DOTS	17
CUPS	18
SPRAYS/SQUIRTS.....	19
CHEWS/GUMMIES.....	20
SCOOPS	21
CC	22
CAPFULS.....	23
MG.....	24
UNITS.....	25
GULP.....	26
OUNCES	27
PACKAGES/PACKETS.....	28
VIALS	29
GUMBALLS.....	30
OTHER FORM (SPECIFY)	91
REFUSED	77
DON'T KNOW	99

Q.26 For how long have you been taking the supplement?
ENTER NUMBER AND UNIT (OF DAYS, WEEKS, MONTHS OR YEARS)

Q26.1a _____

Q26.1b _____

Q26.1c _____

Q26.1d _____

Q26.1e _____

Q26.1f _____

_____ Days _____ Months _____ Years

Q.26(a) If taken seasonally, which months out of the year do you take the supplement?
ENTER THE MONTHS SEPARATED BY COMMAS (EX: August, September)

Q26.a. 1a _____

Q.26(b) When you do take the supplement how many days per week do you take it?
ENTER NUMBER

Q26.b. 1 a _____

Q.27 Do you take it **daily**?
YES or NO

Q.28 If not daily, how often? _____ Days/ Week or _____ Days/ Month

Q.29 Did you take it **yesterday**?
YES or NO

Q.30 Did you decide to take {INSERT PRODUCT NAME} for reasons of your own or did a doctor or other health provider tell you to take it?

Q30.1a _____

Q30.1b _____

Q30.1c _____

Q30.1d _____

Q30.1e _____

Q30.1f _____

DECIDED TO TAKE IT FOR REASONS	
OF MY OWN	1
A DOCTOR OR OTHER HEALTH PROVIDER TOLD ME TO.....	2
REFUSED	7
DON'T KNOW	9

Q.31 For what reason or reasons do you take or the doctor or other health professional tell you to take {PRODUCT}? Interviewer Instructions: Refer SP to Handcard 2

Q31.1a _____

Q31.1b _____

Q31.1c _____

Q31.1d _____

Q31.1e _____

Q31.1f _____

CODE ALL THAT APPLY.

FOR GOOD BOWEL/COLON HEALTH.....	10
FOR PROSTATE HEALTH.....	11
FOR MENTAL HEALTH.....	12
TO PREVENT HEALTH PROBLEMS	13
TO IMPROVE MY OVERALL HEALTH.....	14
FOR TEETH, PREVENT CAVITIES.....	15
TO SUPPLEMENT MY DIET (BECAUSE I DON'T GET ENOUGH FROM FOOD).....	16
TO MAINTAIN HEALTH (TO STAY HEALTHY).....	17
TO PREVENT COLDS, BOOST IMMUNE SYSTEM.....	18
FOR HEART HEALTH, CHOLESTEROL.....	19
FOR EYE HEALTH	20
FOR HEALTHY JOINTS, ARTHRITIS	21
FOR SKIN HEALTH, DRY SKIN	22
FOR WEIGHT LOSS	23
FOR BONE HEALTH, BUILD STRONG BONES, OSTEOPOROSIS.....	24
TO GET MORE ENERGY	25
FOR PREGNANCY	26
FOR ANEMIA, SUCH AS LOW IRON.....	27
LACTOSE INTOLERANCE.....	28
OTHER SPECIFY	91
REFUSED	77
DON'T KNOW	99

Q.32 Any other antacids (such as rolaids, tums, or pepsid AC)? Circle YES or No (If yes repeat Q17 – Q29)
If no, proceed to Q34.

PREScription VITAMINS, MINERALS AND ANTACIDS

Interviewer Instruction: Now I am going to be asking you a few questions about your use of **prescription** vitamins, and/or minerals, antacids, and supplement injections.

- Q.33 Do you have the containers for **all** the prescription supplements that you've reported available in front of you?

(If NO ask SP to go get the containers)

YES	1
NO	2
REFUSED	7
DON'T KNOW	9

Interviewer Instructions: First I am going to ask you some questions about **INSERT NAME OF PRESCRIPTION**).

- Q. 34 What appears on the front label of the prescription supplement or antacid you took?
Can you please read me all the words on the front label, if available?

Q34.1a. _____
ENTER SUPPLEMENT NAME

Q34.1b _____
ENTER SUPPLEMENT NAME

Q34.1c _____
ENTER SUPPLEMENT NAME

Q34.1d _____
ENTER SUPPLEMENT NAME

Q34.1e _____
ENTER SUPPLEMENT NAME

Q34.1f _____
ENTER SUPPLEMENT NAME

REFUSED	7
DON'T KNOW	9

Q.35

ENTER **MANUFACTURER/DISTRIBUTOR/STORE** BRAND NAME.

ENTER AS MUCH INFORMATION AS POSSIBLE.

Q35.1a _____

Q35.1b _____

Q35.1c _____

Q35.1d _____

Q35.1e _____

Q35.1f _____

REFUSED	7
DON'T KNOW	9

Q.36 What was the form of the supplement taken? (Ex: pill, tablet, liquid etc.)

.....
Q36.1a _____

Q36.1b _____

Q36.1c _____

Q36.1d _____

Q36.1e _____

Q36.1f _____

Label	Code
Caplet	1
Capsule	2
Dropper	3
Drop	4
Fluid Ounce	5
Gel Cap	6
Injection/Shot	8
Lozenge	9
Milliliter	10
Package/Packet	12
Pill	13
Tablespoon/Powder	14
Softgel	16
Tablespoon/Liquid	17
Tablet	18
Teaspoon/Liquid	19
Wafer	20
Ounce/Powder	21
Spray/Squirt	22
Scoop/Powder	24

Cup/Powder	25
Chew	27
Other	28
Vegicap	29
Can/Liquid	30
Capful	31
Gumball	32
Gram/Powder	33
Teaspoon/Powder	34
Can/Powder	35
Scoop/Liquid	36
Cup/Liquid	37
Gram/Liquid	38
Drop/Lozenge	39
Unknown Dosage Form	99

REFUSED	77
DON'T KNOW	99

Q.37 What was the strength per **prescription** tablet/pill/etc? Please if it is a double/triple element ask for the strength of each element.

Q37.1a _____

Q37.1b _____

Q37.1c _____

Q37.1d _____

Q37.1e _____

Q37.1f _____

REFUSED	7
DON'T KNOW	9

Q.38 Between midnight and midnight, how much of a dose did you take? What is your usual dosage? (Ex: 2 gelcaps)

*Number taken, then type. (Example: 4, 6 = means they took 4 lozenges)

Q38.1a _____

Q38.1b _____

Q38.1c _____

Q38.1d _____

Q38.1e _____

Q38.1f _____

REFUSED 7
DON'T KNOW 9

TABLETS/CAPSULES/PILLS/CAPLETS/	
SOFTGELS/GEL CAPS/VEGICAPS/	
CHEWABLE TABLETS	1
DROPPERS	2
DROPS.....	3
INJECTIONS/SHOTS.....	5
LOZENGES/COUGH DROPS.....	6
MILLILITERS.....	7
POWDER/GRANULES	10
TABLESPOONS.....	11
TEASPOONS.....	12
WAFERS.....	13
CANS	15
GRAMS	16
DOTS	17
CUPS	18
SPRAYS/SQUIRTS.....	19
CHEWS/GUMMIES.....	20
SCOOPS	21
CC	22
CAPFULS.....	23
MG.....	24
UNITS.....	25
GULP.....	26
OUNCES	27
PACKAGES/PACKETS.....	28
VIALS	29
GUMBALLS.....	30
OTHER FORM (SPECIFY)	91
REFUSED	77
DON'T KNOW	99

Q.38(a) If taken seasonally, which months out of the year do you take the supplement?
ENTER THE MONTHS SEPARATED BY COMMAS (EX: August, September)

Q38.a. 1a _____

Q.38(b) When you do take the supplement how many days per week do you take it?
ENTER NUMBER

Q38.b. 1 a _____

Q.39 How long have you been taking the prescription supplement/antacid?
ENTER NUMBER AND UNIT (DAYS, WEEKS, MONTHS OR YEARS)

Q39.1a _____

Q39.1b _____

Q39.1c _____

Q39.1d _____

Q39.1e _____

Q39.1f _____

_____ Days _____ Months _____ Years

Q. 40 Do you take it **daily**?
YES or NO

Q. 41 If not daily, how often? _____ Days/ Week or _____ Days/ Month

Q. 42 Did you take it **yesterday**?
YES or NO

Q.43 Did you decide to take {INSERT PRODUCT NAME} for reasons of your own or did a doctor or other health provider tell you to take it?

Q43.1a _____

Q43.1b _____

Q43.1c _____

Q43.1d _____

Q43.1e _____

Q43.1f _____

DECIDED TO TAKE IT FOR REASONS	
OF MY OWN	1
A DOCTOR OR OTHER HEALTH	
PROVIDER TOLD ME TO.....	2
REFUSED	7
DON'T KNOW	9

Q.44 For what reason or reasons do you take or the doctor or other health professional tell you to take {PRODUCT}? Interviewer Instruction: Refer SP to Hand card 2.

Q44.1a _____

Q44.1b _____

Q44.1c _____

Q44.1d _____

Q44.1e _____

Q44.1f _____

CODE ALL THAT APPLY.

FOR GOOD BOWEL/COLON HEALTH.....	10
FOR PROSTATE HEALTH	11
FOR MENTAL HEALTH	12
TO PREVENT HEALTH PROBLEMS	13
TO IMPROVE MY OVERALL HEALTH.....	14
FOR TEETH, PREVENT CAVITIES.....	15
TO SUPPLEMENT MY DIET (BECAUSE I DON'T GET ENOUGH FROM FOOD).....	16
TO MAINTAIN HEALTH (TO STAY HEALTHY).....	17
TO PREVENT COLDS, BOOST IMMUNE SYSTEM.....	18
FOR HEART HEALTH, CHOLESTEROL.....	19
FOR EYE HEALTH	20
FOR HEALTHY JOINTS, ARTHRITIS	21
FOR SKIN HEALTH, DRY SKIN	22
FOR WEIGHT LOSS	23
FOR BONE HEALTH, BUILD STRONG BONES, OSTEOPOROSIS.....	24
TO GET MORE ENERGY	25
FOR PREGNANCY	26
FOR ANEMIA, SUCH AS LOW IRON.....	27
LACTOSE INTOLERANCE.....	28
OTHER SPECIFY	91
REFUSED	77
DON'T KNOW	99

Q.45 Any other **prescription** supplements or antacids? Circle Yes or No (If yes repeat Q31-41)

When list is complete review total number of dietary supplements and antacids and their names with respondent, then proceed to Q46

Q46. Do you chew gum?

If no proceed to question Q52
If yes proceed to question Q47

Q47. What is the usual brand of the gum you chew?

Code all that apply
If other, please specify _____

Q48. How often do you chew sugarless gum or sugarless bubblegum?

Number of times _____
Frequency _____
If other, specify _____

Q49. How often do you chew sugar gum or sugar bubblegum?

Number of times _____
Frequency _____
If other, specify _____

Q50. When you chew gum how much do you chew?

_____ number of sticks _____ number of chiclets

Q51. Did you chew gum **yesterday**?

YES or NO

Q. 52 Who was the main respondent for this interview?

Sample person	1
Mother of sample person	2
Father of sample person	3
Wife of sample person	4
Husband of sample person	5
Daughter of SP	6
Son of SP	7
Friend, partner, non relative	8
Care provider or caretaker	9
Other relative	10
Other, specify	11

Q.53 Who else helped in responding for this interview?

Yes	1
No	2

If yes,

Sample person	1
Mother of sample person	2

Father of sample person	3
Wife of sample person	4
Husband of sample person	5
Daughter of SP	6
Son of SP	7
Grandchild of SP	8
Friend, partner, non relative	9
Care provider or caretaker	10
Other relative	11
Other, specify	12

Q. 54 Did you or the respondent have difficulty or any comments about this supplement interview?

Yes	1
No	2

If no....questionnaire ends

If yes....What were the reasons for this difficulty or comments about this interview?

Did not understand questions	1
Not familiar with handcards	2
Did not have handcards	3
Poor memory of supplements taken	4
Sick	5
Hearing impairment	6
Telephone connection problems	7
Interruptions	8
Uncooperative/impatient	9
Distracted/uninterested	10
Supplement list may be incomplete (explain in remark box)	11
Unreliable (explain in remark box)	12
Not ascertained	13
Other specify (explain in remark box)	14

Appendix 4.5: Procedures – Health literacy inventory

PASSAGE A

Your doctor has sent you to have a _____ X-ray.

- a. stomach
- b. diabetes
- c. stitches
- d. germs

You must have an _____ stomach when you come for _____.

- | | |
|-----------|--------|
| a. asthma | a. is. |
| b. empty | b. am. |
| c. incest | c. if. |
| d. anemia | d. it. |

The X-ray will _____ from 1 to 3 _____ to do.

- | | |
|---------|-----------|
| a. take | a. beds |
| b. view | b. brains |
| c. talk | c. hours |
| d. look | d. diets |

THE DAY BEFORE THE X-RAY.

For supper have only a _____ snack of fruit, _____ and jelly,

- | | |
|-----------|-----------|
| a. little | a. toes |
| b. broth | b. throat |
| c. attack | c. toast |
| d. nausea | d. thigh |

with coffee or tea.

After _____, you must not _____ or drink

- | | |
|--------------|----------|
| a. minute, | a. easy |
| b. midnight, | b. ate |
| c. during, | c. drank |
| d. before, | d. eat |

anything at _____ until after you have _____ the X-ray.

- | | |
|---------|--------|
| a. ill | a. are |
| b. all | b. has |
| c. each | c. had |
| d. any | d. was |

THE DAY OF THE X-RAY.

Do not eat _____.

- a. appointment.
- b. walk-in.
- c. breakfast.
- d. clinic.

Do not _____, even _____.

- | | |
|-----------|------------|
| a. drive, | a. heart. |
| b. drink, | b. breath. |
| c. dress, | c. water. |
| d. dose, | d. cancer. |

If you have any _____, call the X-ray _____ at 616-4500.

- | | |
|---------------|---------------|
| a. answers, | a. Department |
| b. exercises, | b. Sprain |
| c. tracts, | c. Pharmacy |
| d. questions, | d. Toothache |

PASSAGE B

I agree to give correct information to _____ if I can receive Medicaid.

- a. hair
- b. salt
- c. see
- d. ache

I _____ to provide the county information to _____ any

- a. agree
- b. probe
- c. send
- d. gain
- a. hide
- b. risk
- c. discharge
- d. prove

statements given in this _____ and hereby give permission to

- a. emphysema
- b. application
- c. gallbladder
- d. relationship

the _____ to get such proof. I _____ that for

- a. inflammation
- b. religion
- c. iron
- d. county
- a. investigate
- b. entertain
- c. understand
- d. establish

Medicaid I must report any _____ in my circumstances

- a. changes
- b. hormones
- c. antacids
- d. charges

within _____ (10) days of becoming _____ of the change.

- | | |
|----------|----------|
| a. three | a. award |
| b. one | b. aware |
| c. five | c. away |
| d. ten | d. await |

I understand _____ if I DO NOT like the _____ made on my

- | | |
|---------|---------------|
| a. thus | a. marital |
| b. this | b. occupation |
| c. that | c. adult |
| d. than | d. decision |

case, I have the _____ to a fair hearing. I can _____ a

- | | |
|-----------|------------|
| a. bright | a. request |
| b. left | b. refuse |
| c. wrong | c. fail |
| d. right | d. mend |

hearing by writing or _____ the county where I applied.

- | |
|-------------|
| a. counting |
| b. reading |
| c. calling |
| d. smelling |

If you _____ TANF for any family _____, you will have to

- | | |
|----------|--------------|
| a. wash | a. member, |
| b. want | b. history, |
| c. cover | c. weight, |
| d. tape | d. seatbelt, |

_____ a different application form. _____, we will use

- a. relax
- b. break
- c. inhale
- d. sign

- a. Since,
- b. Whether,
- c. However,
- d. Because,

the _____ on this form to determine your _____

a. lung	a. hypoglycemia.
b. date	b. eligibility.
c. meal	c. osteoporosis.
d. pelvic	d. schizophrenia.

PASSAGE C

It has been explained to _____ that during the course of the

- a. my
- b. me
- c. he
- d. she

_____ or procedure, unforeseen conditions may be _____

- | | |
|--------------|--------------|
| a. syphilis | a. revealed |
| b. hepatitis | b. depressed |
| c. colitis | c. directed |
| d. operation | d. notified |

that necessitate an extension of the _____ procedure(s) or

- a. appendix
- b. another
- c. original
- d. addict

different procedure(s) than those _____ forth in paragraph 2.

- a. get
- b. set
- c. see
- d. go

I, therefore, _____ and request that the above named

- a. exercise
- b. authorize
- c. energize
- d. pressurize

_____ his assistants or attending physicians _____ such

- a. infection,
 - b. pregnant,
 - c. insurance,
 - d. physician,
- a. perform
 - b. smear
 - c. onset
 - d. stress

procedures as are necessary and _____ in the exercise of professional judgment.

- a. undesirable
- b. emergency
- c. desirable
- d. diagnosis

The authority _____ under this Paragraph 3 shall _____

- a. granted
 - b. treated
 - c. tested
 - d. X-rayed
- a. pretend
 - b. extend
 - c. recede
 - d. proceed

to treating all conditions that _____ treatment and are not known

- a. reason
- b. refer
- c. require
- d. relate

_____ the time the operation or _____ is commenced.

- a. us
 - b. be
 - c. or
 - d. at
- a. cholesterol
 - b. menopause
 - c. gonorrhea
 - d. procedure

Appendix 4.6: Procedures – Rapid estimate of adult literacy in medicine

RAPID ESTIMATE OF ADULT LITERACY IN MEDICINE (REALM)®

Terry Davis, PhD • Michael Crouch, MD • Sandy Long, PhD

Patient Name/
Subject # _____ Date of Birth _____

Reading
Level _____
Grade
Completed _____

Date _____ Clinic _____ Examiner _____

List 1	List 2	List 3
fat	fatigue	allergic
flu	pelvic	menstrual
pill	jaundice	testicle
dose	infection	colitis
eye	exercise	emergency
stress	behavior	medication
smear	prescription	occupation
nerves	notify	sexually
gems	gallbladder	alcoholism
meals	calories	irritation
disease	depression	constipation
cancer	miscarriage	gonorrhea
caffeine	pregnancy	inflammatory
attack	arthritis	diabetes
kidney	nutrition	hepatitis
hormones	menopause	antibiotics
herpes	appendix	diagnosis
seizure	abnormal	potassium
bowel	syphilis	anemia
asthma	hemorrhoids	obesity
rectal	nausea	osteoporosis
incest	directed	impetigo

SCORE	
List 1	_____
List 2	_____
List 3	_____
Raw Score	_____

Appendix 5.1: Medical follow-up – Clinical laboratory letter for normal results



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute on Aging
Intramural Research Program
Biomedical Research Building
251 Bayview Blvd
Baltimore, Maryland 21224-2816

Date

XXXXXXX
XXXXX
XXXXXXXXXX
Baltimore, Maryland XXXXX

Dear ,

Thank you for being a participant in the National Institute on Aging's study Healthy Aging in Neighborhoods of Diversity across the Life Span (HANDLS). As you know, we will send you a complete report of the clinical tests done during your visit when all results have been evaluated.

Enclosed is a copy of your final lab results. Please note that your lab report shows that your lab values are **normal**.

If you do not have a health care provider, please contact us so that we can forward a listing of healthcare providers and facilities in your area.

Please note that the HANDLS study is a research study and we do not provide medical work-ups or treatment of health problems. All tests were done for research purposes only and will be used to describe the health status of men and women who are taking part in the study. These tests are not done to replace any tests that might be ordered to check for health problems. We hope this information is useful to you and your doctor.

If you should have any questions, please feel free to contact me at 410-558-8627. Thank you for your support.

Sincerely,

Ngozi Ejiogu, M.D.
Staff Clinician
HANDLS/NIA/NIH

cc: Michele K. Evans
Medical Record
Enclosure

Voice: 410-558-8627 Toll free: 1-866-207-8363 Fax: 410-558-8067



Appendix 5.2: Medical follow-up – Clinical laboratory letter for abnormal results



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute on Aging
Intramural Research Program
Biomedical Research Building
251 Bayview Blvd
Baltimore, Maryland 21224-2816

Date

XXXXXXX
XXXXXX
XXXXXXXXXXXX
Baltimore, Maryland XXXXX

Dear ,

Thank you for being a participant in the National Institute on Aging's study Healthy Aging in Neighborhoods of Diversity across the Life Span (HANDLS). As you know, we will send you a complete report of the clinical tests done during your visit when all results have been evaluated. However, your lab tests have come back with abnormal results and you need to arrange a visit with your physician as soon as possible.

Enclosed is a copy of your final lab results. Please note that **NE** on your lab report means **needs evaluation**. Also **NCS** on your lab report means **not clinically significant** and does not need immediate attention. Please discuss these results with your doctor as soon as possible so that he/she may provide a complete work-up and treatment.

If you do not have a health care provider, please contact us so that we can forward a listing of healthcare providers and facilities in your area.

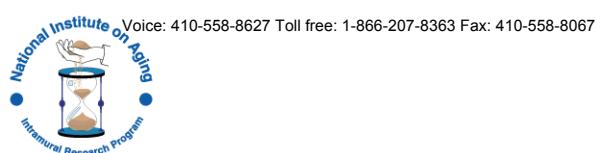
Please note that the HANDLS study is a research study and we do not provide medical work-ups or treatment of health problems. All tests were done for research purposes only and will be used to describe the health status of men and women who are taking part in the study. These tests are not done to replace any tests that might be ordered to check for health problems. We hope this information is useful to you and your doctor.

If you should have any questions, please feel free to contact me at 410-558-8627. Thank you for your support.

Sincerely,

Ngozi Ejiogu, M.D.
Staff Clinician
HANDLS/NIA/NIH

cc: Michele K. Evans
Medical Record
Enclosure



Voice: 410-558-8627 Toll free: 1-866-207-8363 Fax: 410-558-8067



Appendix 5.3: Medical follow-up – Clinical laboratory letter to participant’s physician



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Date

National Institutes of Health
National Institute on Aging
Intramural Research Program
Biomedical Research Building
251 Bayview Blvd
Baltimore, Maryland 21224-2816

XXXXXXX, M.D.
XXXXXXXXXXXXXXXXXX
Baltimore, Maryland 21228

Re: XXXXX
DOB: XXXXX

Dear Dr. XXXX,

Your patient, **XXXXXX DOB: XXXXX**, is a participant in Healthy Aging in Neighborhoods of Diversity across the Life Span (HANDLS) study. During her participation she had a blood specimen taken for laboratory analysis. Accompanying this letter is a copy of the laboratory report. A copy of the laboratory report has also been sent to Ms. XXXX. Please discuss these abnormal results with Ms. XXXX as soon as possible for further evaluation and management.

Participants are made aware that the HANDLS study is a research study and we do not provide medical work-ups or treatment of health problems. All tests were done for research purposes only and will be used to describe the health status of men and women who are taking part in the study. These tests are not done to replace any tests that might be ordered to further evaluate this patient. We hope this information is useful to you and your patient. If you should have any questions, please feel free to contact me during work hours, phone 410-558-8627. Thank you.

Sincerely,

Ngozi Ejiogu, M.D.
Staff Clinician
HANDLS/NIA/NIH
cc: HANDLS Medical Records
Enclosure

Voice 410-558-8627
Toll free 1-877-677-9538
Fax 410-558-8067



Appendix 5.4: Medical follow-up – Sample participant report



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute on Aging
Intramural Research Program
Biomedical Research Building
251 Bayview Blvd
Baltimore, Maryland 21224-2816

March 7, 2013

[REDACTED]

Dear [REDACTED],

We hope that your recent HANDLS examination was rewarding. During your recent examination, you provided your medical history, our physician performed a medical examination, and you had several tests. This package contains the copies of the consent forms that you signed and results for your:

- **Blood Tests**
- **Urine Tests**
- **ECG (heart test)**
- **Echocardiogram**
- **Bone Scan**

HANDLS is a research study. We do not provide diagnoses or treatment. You must contact a doctor for a check-up about any findings in this report. Your doctor can help you understand any abnormal findings. You should discuss the ways to manage these conditions with your doctors. Even if none of your tests were abnormal, it is a good idea to share these results with your health-care provider. This will help you keep track of your health and it may help you to prevent illnesses by finding problems early. If you do not have a doctor or a regular medical clinic where you get care then you may use the enclosed referral list to find one.

HANDLS cannot provide documentation of disability to state agencies, the Social Security Administration, Disability Determination Services, or personal legal representation.

HANDLS is a longitudinal study – we are examining changes in health over time. We will contact you again in three or four years to repeat your medical examinations and tests. Please let us know if you move to a new address or if you change your telephone number.



Voice 410-558-8627
Toll free 1-877-677-9538
Fax 410-558-8067



Please call us toll-free at 1-866-207-8363 if you have any questions about these results, any questions about HANDLS, or if you want to provide new contact information.

We are grateful for your participation in the HANDLS study and we look forward to maintaining our partnership with you for better health over the life span.

Sincerely,



Ngozi Ejiogu, M.D.
Staff Clinician
HANDLS/NIA/NIH

cc: HANDLS Medical Records
Enclosure

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Healthy Aging in Neighborhoods of Diversity across the Life Span



ID: [REDACTED]

Name: [REDACTED]

DOB: [REDACTED]

Sex: M / Race: African American

Age: 56

Test Date: 01/09/2013

Height and Weight

Height: 165 cm (5 feet 4 inches)

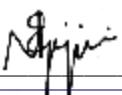
Weight: 67 kilos (148 pounds)

Body Mass Index (BMI): 24.6

Blood Pressure (while sitting)

Right Arm: 146/92

Left Arm: 154/96

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Healthy Aging in Neighborhoods of Diversity across the Life Span



ID: 821-34611-01

Name: [REDACTED]

DOB: [REDACTED]

Blood and Urine Tests

The next pages have the results of your blood and urine tests.

How to read your results:

Test Name of the test.

Flag If your result was not normal, a code will appear here.

H means your result was higher than normal.

L means your result was lower than normal.

AB means your result was not normal.

Next to the abnormal results, I have written either "NCS" or "NE."

NCS means the result is "**Not Clinically Significant.**" In other words, the result is not normal, but it does not need your immediate attention.

NE stands for "**Needs Evaluation.**" It means just what it says. You need to see your doctor as soon as possible to discuss these results. Your doctor will evaluate you and decide if you need treatment. The next section of this packet explains the "NE" results you had.

Result Your test result appears here.

Units The units of measure used in this test (for example, grams).

Reference Range The normal range for this test.

Healthy Aging in Neighborhoods of Diversity across the Life Span



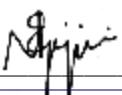
ID: [REDACTED] Name: [REDACTED]
 Sex: M / Race: African American Age: 56 DOB: [REDACTED]
 Test Date: 01/09/2013

Ngozi Ejiogu, MD
 HANDLS
 251 Bayview Blvd
 Baltimore, MD 21224-2816
 410-558-8627

Quest Nichols Institute
 P.O. Box 10841
 Chantilly, VA 20153-0841

CBC with Differential and Platelets

Test	Flag	Result	Units	Ref. Range	Eval.
Red Blood Cell Count		4.85	Mill/uL	4.20-5.80	
Hemoglobin		14.8	g/dL	13.2-17.1	
Hematocrit		44.5	%	38.5-50.0	
MCV		91.8	fL	80.0-100.0	
MCH		30.5	pg	27.0-33.0	
MCHC		33.3	g/dL	32.0-36.0	
RDW		13.9	%	11.0-15.0	
Platelet Count		255	Thous/uL	140-400	
White Blood Cell Count		9.10	Thous/uL	3.8-10.8	
Neutrophil %		53.6	%	45.0-75.0	
Lymphocyte %		37.5	%	15.0-42.0	
Monocyte %		6.1	%	4.0-12.0	
Eosinophil %		2.5	%	1.0-8.0	
Basophil %		0.3	%	0.0-1.0	
Neutrophil		4878	Cells/mcL	1500-7800	
Lymphocytes		3413	Cells/mcL	850-3900	
Monocytes		555	Cells/mcL	200-950	
Eosinophils		228	Cells/mcL	15-550	
Basophils		27	Cells/mcL	0-200	
RBC Morphology		NORMAL			

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ID: [REDACTED] Name: [REDACTED]
 Sex: M / Race: African American Age: 56 DOB: [REDACTED]
 Test Date: 01/09/2013

Sedimentation Rate

Test	Flag	Result	Units	Ref. Range	Eval.
SED RATE, WESTERGREN	H	29	mm/h	0-20	NCS

Lipids

Test	Flag	Result	Units	Ref. Range	Eval.
Cholesterol - Total	H	286	mg/dL	125-200	NE
LDL (calc)	H	194	mg/dL	<130	NE
VLDL (calc)		18	mg/dL	8-32	
HDL Cholesterol		74	mg/dL	>=40	
Cholesterol/HDL ratio		3.9		<=5.0	
Triglycerides, Serum		89	mg/dL	<150	

Hemoglobin A1c

Test	Flag	Result	Units	Ref. Range	Eval.
Hemoglobin A1c	H	5.7	%	<5.7	NCS

Chemistry

Test	Flag	Result	Units	Ref. Range	Eval.
Glucose		87	mg/dL	65-99	
Calcium		9.4	mg/dL	8.6-10.3	
Calcium - Ionized (calc)		3.7	mg/dL	3.6-4.6	
Phosphate (as Phosphorus)		4.4	mg/dL	2.5-4.5	
Magnesium		2.2	mg/dL	1.5-2.5	
Sodium		141	mmol/L	135-146	

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ID: [REDACTED] Name: [REDACTED]
 Sex: M / Race: African American Age: 56 DOB: [REDACTED]
 Test Date: 01/09/2013

Potassium		4.2	mmol/L	3.5-5.3	
Chloride		104	mmol/L	98-110	
Carbon Dioxide		23	mmol/L	21-33	
BUN		13	mg/dL	7-25	
Creatinine		1.20	mg/dL	0.70-1.33	
Creatinine/BUN ratio		0.09		0.03-0.12	
Protein, Total	H	8.4	g/dL	6.2-8.3	NCS
Albumin		5.0	g/dL	3.6-5.1	
Globulin [calc]		3.4	g/dL	2.1-3.7	
Albumin/Globulin ratio		1.5		1.0-2.1	
ALP		76	U/L	40-115	
ALT		36	U/L	9-60	
AST		25	U/L	10-35	
Bilirubin - Total		1.1	mg/dL	0.2-1.2	
GGT		47	U/L	3-85	
LD		180	U/L	120-250	
Uric Acid		6.9	mg/dL	4.0-8.0	
EGFR Non-African American		67		>=60	
EGFR African American		78		>=60	

Amylase and Lipase

Test	Flag	Result	Units	Ref. Range	Eval.
Lipase		16	U/L	7-60	
Amylase		48	U/L	21-101	

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ID: [REDACTED] Name: [REDACTED]
 Sex: M / Race: African American Age: 56 DOB: [REDACTED]
 Test Date: 01/09/2013

Iron and Iron Binding

Test	Flag	Result	Units	Ref. Range	Eval.
Iron, Total		89	mcg/dL	45-170	
Iron Binding Capacity		344	mcg/dL	250-425	
% Iron Saturation		26	%	20-50	

Ferritin

Test	Flag	Result	Units	Ref. Range	Eval.
Ferritin		165	ng/mL	19-370	

Insulin

Test	Flag	Result	Units	Ref. Range	Eval.
Insulin		<2	uIU/mL	<17	

Thyroid

Test	Flag	Result	Units	Ref. Range	Eval.
THYROID GROUP #28		Thyroid Group #28			
TSH, 3rd Generation		0.86	mIU/L	0.40-4.50	
T3 - Total		115	ng/dL	76-181	
T3 - Uptake		23	%	22-35	
T4 - Total		8.7	mcg/dL	4.5-12.0	
T4, Free		1.2	ng/dL	0.8-1.8	
FREE T4 RIA INCL. TOTAL T4		Free T4 RIA Incl.			

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ID: [REDACTED] Name: [REDACTED]
 Sex: M / Race: African American Age: 56 DOB: [REDACTED]
 Test Date: 01/09/2013

Vitamin B12 and Folate

Test	Flag	Result	Units	Ref. Range	Eval.
Vitamin B12, Serum		447	pg/mL	400-1100	
Folate		>24.0	ng/mL	>5.4	

Vitamin D

Test	Flag	Result	Units	Ref. Range	Eval.
VITAMIN D, 25-OH, TOTAL	L	19	ng/mL	30-100	NE
VITAMIN D, 25-OH, D3		19	ng/mL		
VITAMIN D, 25-OH, D2		<4	ng/mL		
VITAMIN D, 1, 25 TOTAL		70	pg/mL	18-72	
VITAMIN D3, 1, 25		70	pg/mL		
VITAMIN D2, 1, 25		<8	pg/mL		

Cardiac

Test	Flag	Result	Units	Ref. Range	Eval.
CRP		0.6	mg/dL	<0.8	
Fibrinogen	H	435	mg/dL	175-425	NCS
D-Dimer, Quantitative		0.26	mcg/mL FEU	<0.50	

PSA

Test	Flag	Result	Units	Ref. Range	Eval.
PSA		0.8	ng/mL	0.0-4.0	

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Healthy Aging in Neighborhoods of Diversity across the Life Span



ID: [REDACTED] Name: [REDACTED]
 Sex: M / Race: African American Age: 56 DOB: [REDACTED]
 Test Date: 01/09/2013

Hepatitis B

Test	Flag	Result	Units	Ref. Range	Eval.
Hepatitis B Surface Antigen		Nonreactive		Nonreactive	
Hepatitis B Surface Antigen -		Not required			

Hepatitis C

Test	Flag	Result	Units	Ref. Range	Eval.
Hepatitis C Antibody	A	Reactive		Nonreactive	NE
HEPATITIS C ANTIBODY CutOff	H	22.80	ratio	<1.00	NE

RPR

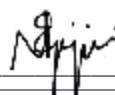
Test	Flag	Result	Units	Ref. Range	Eval.
RPR additional testing		Not indicated.			
FTA-ABS		Not indicated			
RPR Screen		Nonreactive		Nonreactive	

Urine - Random Creatinine

Test	Flag	Result	Units	Ref. Range	Eval.
Urine - Random Creatinine		227.2	mg/dL	20-370	

Urine - Random Microalbumin

Test	Flag	Result	Units	Ref. Range	Eval.
Urine - Random Microalbumin	A	0.8	mg/dL		NCS

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Healthy Aging in Neighborhoods of Diversity across the Life Span



ID: [REDACTED] Name: [REDACTED]
 Sex: M / Race: African American Age: 56 DOB: [REDACTED]
 Test Date: 01/09/2013

Microalbumin/Creatinine Ratio

Test	Flag	Result	Units	Ref. Range	Eval.
MICROALBUMIN/CREATININE		4	mcg/mg Cr	<30.0	

Urinalysis, Macroscopic

Test	Flag	Result	Units	Ref. Range	Eval.
Urine - Color		YELLOW		YELLOW	
Urine - Clarity		HAZY		CLEAR	
Urine - Specific Gravity		1.019		1.001-1.035	
Urine - pH		5.5		5.0-8.0	
Urine - Blood		NEG		Negative	
Urine - Protein		NEG		Negative	
Urine - Glucose		NEG		Negative	
Urine - Ketones		NEG		Negative	
Urine - Bilirubin		NEG		Negative	
Urine - Leukocyte Esterase		NEG		Negative	
Urine - Nitrite		NEG		Negative	

Urinalysis, Microscopic

Test	Flag	Result	Units	Ref. Range	Eval.
Urine - White Blood Cells		1-2	/HPF	0-4	
Urine - Red Blood Cells		0-1	RBC/HPF	0-3	
Urine - Bacteria		NONE			
Urine - Squam Epi		NONE			
COMMENTS		Amorphous			

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Healthy Aging in Neighborhoods of Diversity across the Life Span



ID: [REDACTED]

Name: [REDACTED]

DOB: [REDACTED]

Blood and Urine Tests Summary

This section explains the labs that I marked with "NE" (for Needs Evaluation). You need to see your doctor as soon as possible to discuss these results. Your doctor will evaluate you and decide if you need treatment.

Lipids

Your body needs some cholesterol to work properly. But too much cholesterol can plug up your blood vessels. This increases your risk for a heart attack or stroke. Diet and exercise can help you lower your cholesterol. Medication can help as well. Please share this result with your doctor for a complete evaluation.

Lipids

LDL and VLDL are the 'bad' cholesterol. If you have too much, it can build up in your blood vessels. This is called 'hardening of the arteries' or atherosclerosis. It is a major risk factor for heart and blood vessel disease. When the arteries feeding the heart become plugged, a heart attack may occur. If the arteries that go to the brain get plugged, you could have a stroke. Diet, exercise, and medications can help you lower your LDL. Please share this result with your doctor for a complete evaluation.

Vitamin D

Vitamin D, also called the sunshine vitamin is essential for healthy bones, muscles, blood vessels and nerves. Increased use of sunscreens and decreased time in the sun have resulted in many people having low vitamin D levels. The darker your skin the harder it is for you to absorb vitamin D. If your levels are low discuss with your doctor whether or not you should use supplements.

Hepatitis C

Your blood test shows that you might have hepatitis C. You need to see your doctor for a complete evaluation. The long-term effects of hepatitis C are serious. Please see your doctor as soon as possible.

Healthy Aging in Neighborhoods of Diversity across the Life Span



ID: [REDACTED]

Name: [REDACTED]

DOB: [REDACTED]

Sex: M / Race: African American

Age: 56

Test Date: 01/09/2013

Electrocardiogram (ECG) report

The ECG test you had done on 01/09/2013 provides measurements and interpretations that are used to evaluate your heart. The electrical impulses made by your heart during the test were recorded and printed. The printed copy of your test is included in this packet.

The HANDLS cardiologist (heart doctor) has found your ECG to be borderline. Please share these findings with your physician. He/she will evaluate you and decide if you need treatment.

Harry A. Silber, M.D., Ph.D.
HANDLS Cardiologist
National Institute on Aging, NIH

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Healthy Aging in Neighborhoods of Diversity across the Life Span



ID: [REDACTED]

Name: [REDACTED]

DOB: [REDACTED]

Sex: M / Race: African American

Age: 56

Test Date: 01/09/2013

ECG Results

The next section has the results of your ECG (heart test). It contains your ECG print out and the cardiologist's (heart doctor's) description of the results.

ECG Findings:

Rate: 79
PR-Interval: 148
QRS: 104
Axis: 61

INTERPRETATION:

1. Voltage criteria for left ventricular hypertrophy
2. Normal sinus rhythm
3. Borderline ECG

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ID: [REDACTED]

Sex: M / Race: African American

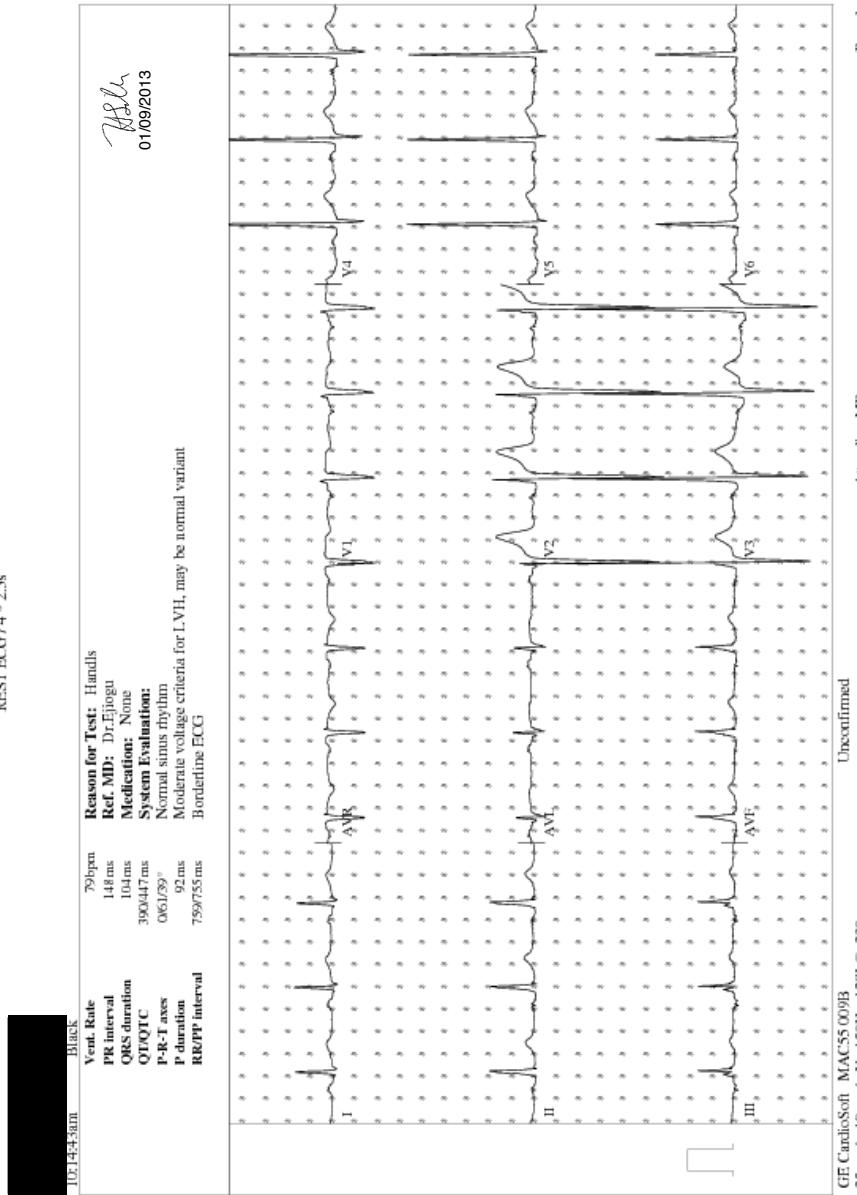
Name: [REDACTED]

Age: 56

DOB: [REDACTED]

Test Date: 01/09/2013

REST ECG / 4 * 2.5s



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Healthy Aging in Neighborhoods of Diversity across the Life Span



ID: [REDACTED]

Name: [REDACTED]

DOB: [REDACTED]

Sex: M / Race: African American

Age: 56

Test Date: 01/09/2013

Echocardiogram report

The echocardiogram test you had done on 01/09/2013 is a type of ultrasound that uses sound waves to examine the heart. The measurements and interpretations that contribute to the overall finding of your echocardiogram are included in this packet.

The HANDLS cardiologist (heart doctor) has found your echocardiogram to have no significant findings.

Harry A. Silber, M.D., Ph.D.
HANDLS Cardiologist
National Institute on Aging, NIH

Healthy Aging in Neighborhoods of Diversity across the Life Span



ID: [REDACTED]

Name: [REDACTED]

DOB: [REDACTED]

Sex: M / Race: African American

Age: 56

Test Date: 01/09/2013

Echocardiogram Results

Overall there were no significant findings in your Echocardiogram.

Test	Result	Reference
Left Atrial Dimension	3.2 cm	< 4.0
Left Atrial Volume	54.3 cm	
Left Atrial Volume Index		
Left Ventricular Diastolic Diameter	4.2 cm	< 5.5
Left Ventricular Septal Wall Thickness	1.1 cm	< 1.2
Left Ventricular Posterior Wall Thickness	1.0 cm	< 1.2
Aortic Root Dimension	3.0 cm	< 3.8
Left Ventricular Ejection Fraction	60 %	> 50
E Wave Size	77.2 cm/sec	
A Wave Size	79.8 cm/sec	
E' Size	10.1 cm/sec	
E/A (calculated)	0.97	
E/E' (calculated)	7.64	
Right Ventricular Systolic Pressure	32 mmhg	< 40
Mitral Annular Calcification	no	no
Mitral Regurgitation	none	none or trace
Aortic Valve Thickening/Calcification	no	no
Aortic Regurgitation	none	none or trace
Tricuspid Regurgitation	mild	none or trace
Possible Aortic Stenosis Present	no	no
Aortic Stenosis Present	no	no
Possible Mitral Stenosis Present	no	no
Mitral Stenosis Present	no	no
Note: Mild tricuspid regurgitation		

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PARTICIPANT COPY

Healthy Aging in Neighborhoods of Diversity across the Life Span



ID: [REDACTED]

Name: [REDACTED]

DOB: 01/02/1957

Sex: M / Race: African American

Age: 56

Test Date: 01/09/2013

Bone density and body composition (DXA) scan report

The DXA scan you had done on 01/09/2013 provides two pieces of health information; the first is your bone density and the second how much body fat you have.

Bone Density

The results from the DXA scan of your hip and spine showed that your lowest bone density reading is 1.010 g/cm², and your T-score is -1.7. This is low bone density when compared to clinical standards.

The results of your DXA scan indicate that you have low bone density. This is a decrease in the density of the bone. If low bone density is not treated it can progress to osteoporosis. In osteoporosis the density and quality of the bones are reduced, while the risk of fracture (broken bone) is greatly increased. Osteoporosis increases your risk for fractured bones, particularly in the hip, spine, and wrist. Usually there are no symptoms until the first fracture occurs. While low bone density is not considered a disease, being diagnosed with low bone density requires further monitoring. It is important that you discuss this abnormal finding with your doctor.

Percentage of Body Fat

The body composition analysis done showed that your total body fat is 26.10%. The percentage body fat, that is the amount of fat you have relative to your entire body, varies considerably among normal people. According to the American College of Sports Medicine, the desired total body fat % for adults is between 11-25% if you are a man, and 19-30% if you are a woman.

Mary L. Lassiter
Research Assistant, CRB/HRDS
National Institute on Aging, NIH
410-558-8425

Ngozi Ejogu, MD CCD
Staff Clinician
National Institute on Aging, NIH
410-558-8627

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Healthy Aging in Neighborhoods of Diversity across the Life Span



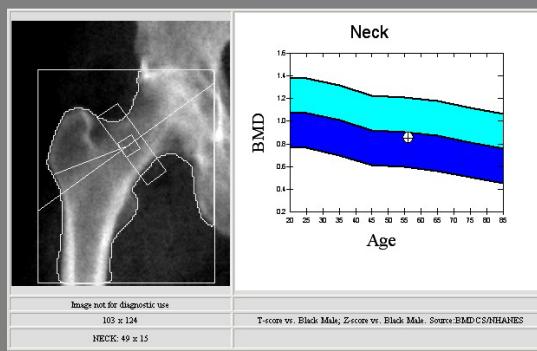
ID: [REDACTED]
Sex: M / Race: African American

Name: [REDACTED]
Age: 56

DOB: [REDACTED]
Test Date: 01/09/2013

Patient Information:

Name:	[REDACTED]
Social Security No:	[REDACTED]
Patient ID:	[REDACTED]
Postal Code:	
Sex:	Male
Ethnicity:	Black
Height:	
Weight:	
DOB:	
Age:	56
Menopause Age:	
Referring Physician:	



Scan Information:

Scan Date:	January 09, 2013 - A01091309
Scan Type:	x Right Hip
Analysis Date:	01/09/2013 11:36
Report Date:	01/09/2013 11:38
Institution:	Geronontology Research Study
Operator:	MLL
Model:	Discovery A (S/N83211)
Comment:	
Software version:	12.7.3.2

Results Summary:

Region	Area[cm ²]	BMC[g]	BMD[g/cm ²]	T-score	PR (Peak Reference)	Z-score	AM (Age Matched)
Neck	5.02	4.29	0.854	-1.4	80	-0.3	95
Troch	11.05	7.07	0.640	-1.7	73	-1.1	81
Inter	26.32	33.65	1.278	-0.4	94	0.2	104
Total	42.40	45.01	1.061	-0.7	90	0.1	101
Ward's	1.04	0.77	0.747	-1.0	81	0.5	114

Total BMD CV 1.0%, ACF = 1.028, BCF = 0.992

Fracture Risk Increased, WHO Classification: Osteopenia

Physician's Comment:

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Healthy Aging in Neighborhoods of Diversity across the Life Span



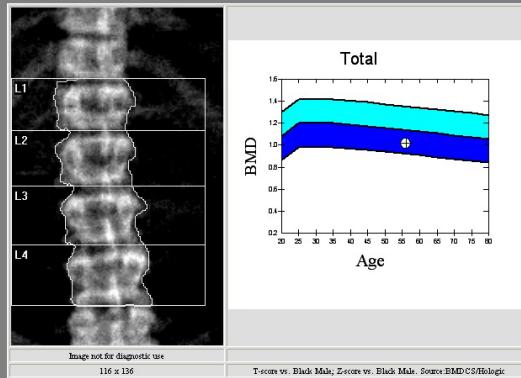
ID: [REDACTED]
Sex: M / Race: African American

Name: [REDACTED]
Age: 56

DOB: [REDACTED]
Test Date: 01/09/2013

Patient Information:

Name:	[REDACTED]
Social Security No:	[REDACTED]
Patient ID:	[REDACTED]
Postal Code:	[REDACTED]
Sex:	Male
Ethnicity:	Black
Height:	[REDACTED]
Weight:	[REDACTED]
DOB:	[REDACTED]
Age:	56
Menopause Age:	[REDACTED]
Referring Physician:	[REDACTED]



Scan Information:

Scan Date:	January 09, 2013 - A01091308
Scan Type:	x Lumbar Spine
Analysis Date:	01/09/2013 11:36
Report Date:	01/09/2013 11:39
Institution:	Gerontology Research Study
Operator:	MLL
Model:	Discovery A (S/N83211)
Comment:	[REDACTED]
Software version:	12.7.3.2

sBMD Results Summary (L2 - L4)

Region	sBMD[mg/cm²]	T-score	Z-score
Total	1105	-1.8	-1.2

Total BMD CV 1.0%

Fracture Risk: Increased, WHO Classification: Osteopenia

Extended Results Summary

Region	Area[cm²]	BMC[g]	BMD[g/cm²]	T-score	PR (Peak Reference)	Z-score	AM (Age Matched)
L1	13.46	13.05	0.969	-1.8	83	-1.3	87
L2	13.97	14.11	1.010	-1.7	84	-1.2	89
L3	15.43	15.69	1.017	-1.8	84	-1.2	89
L4	16.94	17.82	1.051	-1.4	87	-0.8	92
L1-L2	27.43	27.15	0.990	-1.5	86	-1.0	90
L1,L3	28.89	28.73	0.995	-1.5	86	-1.0	90
L1,L4	30.40	30.86	1.015	-1.6	85	-1.0	90
L2-L3	29.40	29.79	1.013	-1.8	84	-1.2	89
L2,L4	30.92	31.92	1.033	-1.8	84	-1.2	89
L3-L4	32.37	33.50	1.035	-1.8	84	-1.2	88
L1-L3	42.86	42.84	1.000	-1.6	85	-1.0	90
L1-L2,L4	44.37	44.97	1.013	-1.6	85	-1.1	90
L1,L3-L4	45.83	46.55	1.016	-1.6	85	-1.1	89
L2-L4	46.34	47.61	1.027	-1.8	84	-1.2	88
L1-L4	59.80	60.66	1.014	-1.7	85	-1.1	89

Total BMD CV 1.0%, ACF = 1.028, BCF = 0.992

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Healthy Aging in Neighborhoods of Diversity across the Life Span



ID: [REDACTED]

Name: [REDACTED]

DOB: [REDACTED]

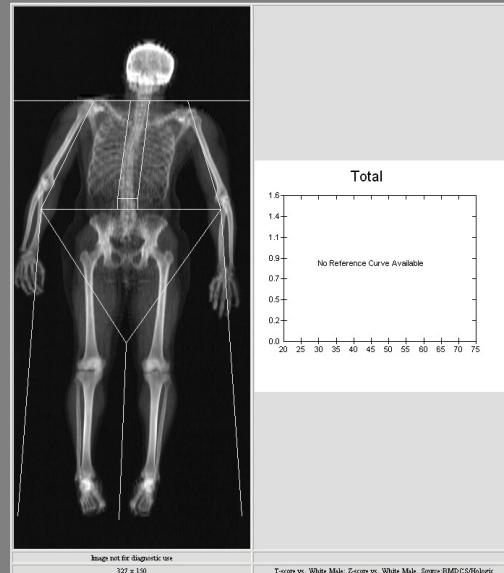
Sex: M / Race: African American

Age: 56

Test Date: 01/09/2013

Patient Information:

Name:	[REDACTED]
Social Security No.:	[REDACTED]
Patient ID:	[REDACTED]
Postal Code:	[REDACTED]
Sex:	Male
Ethnicity:	Black
Height:	[REDACTED]
Weight:	[REDACTED]
DOB:	[REDACTED]
Age:	56
Menopause Age:	[REDACTED]
Referring Physician:	[REDACTED]



Scan Information:

Scan Date:	January 09, 2013 - A01091307
Scan Type:	a Whole Body
Analysis Date:	01/09/2013 11:38
Report Date:	01/09/2013 11:39
Institution:	Gerontology Research Study
Operator:	MLL
Model:	Discovery A (S/N3211)
Comment:	
Software version:	12.7.3.2

Results Summary:

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Region	Area [cm ²]	BMC [g]	BMD [g/cm ²]	Fat(g)	Lean [g]	Lean+BMC [g]	Total [g]	% Fat [%]	T-score	PR (Peak Reference)	Z- score	AM (Age Matched)
L Arm	134.44	145.94	1.086	506.9	1736.3	1882.2	2389.1	21.2				
R Arm	214.47	199.20	0.929	764.5	2305.7	2504.9	3269.5	23.4				
L Ribs	172.45	117.91	0.684									
R Ribs	152.85	105.31	0.689									
T Spine	140.04	131.15	0.936									
L Spine	15.60	17.61	1.129									
Pelvis	294.49	383.46	1.302									
Trunk				11023.1	28548.1	29303.6	40296.6	27.3				
L Leg	274.89	337.77	1.229	2251.3	5794.3	6132.1	8383.4	26.9				
R Leg	293.69	368.10	1.253	2275.2	6177.8	6545.9	8821.1	25.8				
Subtotal	1692.94	1806.43	1.067	16821.0	44562.3	46368.7	63189.7	26.6				
Head	228.47	509.22	2.229	1015.5	3545.0	4054.2	5069.7	20.0				
Total	1921.41	2315.65	1.205	17836.5	48107.2	50422.9	68259.3	26.1	-0.3	97		

Total BMD CV 1.0%, ACF = 1.028, ECF = 0.992
TBAR1904

Physician's Comment:

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Appendix 6.1: Neuroimaging substudy – IRB approval letter



University of Maryland, Baltimore
Institutional Review Board (IRB)
Phone: (410) 706-5037
Fax: (410) 706-4189
Email: hrpo@som.umaryland.edu

APPROVAL OF RESEARCH NOTIFICATION

Date: March 5, 2013

To: Leslie Katzel
RE: HM-HP-00041271-7
Protocol Version and ID #: modification 7 version march 4 2013
Type of Submission: Modification
Type of IRB Review: Expedited
Modification request dated: 3/4/2013

Modification Approval Date: 3/5/2013
Approval for this project is valid until
1/24/2014

This is to certify that the University of Maryland, Baltimore (UMB) Institutional Review Board (IRB) approved the above referenced modification request for the protocol entitled, "*Healthy Aging In Neighborhoods of Diversity Across the Life Span (HANDLS) Scan*".

The IRB approved this modification via expedited review pursuant to Federal regulations 45 CFR 46.110(b)(2)/21 CFR 56.110(b)(2).

The IRB made the following determinations regarding this submission:
- No specific determinations made.

Below is a list of the documents attached to your application that have been approved:
Eligibility Checklist for HP-00041271_4 v11-2-2011-1320261259437
handls nih grant scientific section
HANDLS Scan study schedule version 03242009.doc
handls parent study certificate of confidentiality may 2010
neuropsych questionnaire
response to administrative modifications may 13 2010
nih grant
handls scan information booklet reupload04292010
hipaa consent
data safety monitoring plan
MRI screening form
response to ad min mods June 18 2009
Data analysis SEM figures
study schedule

In conducting this research you are required to follow the requirements listed in the INVESTIGATOR MANUAL. Investigators are reminded that the IRB must be notified of any changes in the study. In addition, the PI is responsible for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not

be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject (45 CFR 46.103(4)(iii)). The PI must also inform the IRB of any new and significant information that may impact a research participants' safety or willingness to continue in the study and any unanticipated problems involving risks to participants or others.

Research activity in which the VA Maryland Healthcare System (VAMHCS) is a recruitment site or in which VA resources (i.e., space, equipment, personnel, funding, data) are otherwise involved, must also be approved by the VAMHCS Research and Development Committee prior to initiation at the VAMHCS. Contact the VA Research Office at 410-605-7000 ext. 6568 for assistance.

The UMB IRB is organized and operated according to guidelines of the International Council on Harmonization, the United States Office for Human Research Protections and the United States Code of Federal Regulations and operates under Federal Wide Assurance No. FWA00007145.

If you have any questions about this review or questions, concerns, and/or suggestions regarding the Human Research Protection Program (HRPP), please do not hesitate to contact the Human Research Protections Office (HRPO) at (410) 706-5037 or HRPO@som.umaryland.edu.

Appendix 6.2: Neuroimaging substudy – protocol

HANDLS Neuroimaging Sub-study Protocol HANDLS SCAN

For this *sub-study*, an equal sample of 250 African Americans and 250 whites, aged 30-64 years matched for age, sex, and SES will be recruited from an expected 3,000 HANDLS Wave 3 participants. Based on the HANDLS Wave 2 follow-up agreement rates, it is estimated that approximately 1,000-1,500 of the 3,000 returning participants will need to be approached to enroll 500 eligible subjects into this ancillary study. The ancillary study will proceed concurrently with HANDLS Wave 3 and we expect this will provide ample time for recruitment. The exclusion criteria for this sub-study are more stringent than the criteria used for the parent study. These additional criteria enhance the scientific integrity of this neuroimaging sub-study and include additional safeguards that reduce risk to subjects by excluding subjects with contraindications to the MRI scans. Accordingly, additional exclusion criteria for HANDLS scan are: history of dementia, stroke or transient ischemic attack (TIA); history of carotid endarterectomy; contraindications to MRI scan (e.g., claustrophobia, indwelling ferromagnetic material); diagnosis of a terminal illness (e.g., metastatic cancer, end-stage liver or pulmonary diseases); within 6 months of active treatment of cancer (e.g., chemotherapy, biologic, radiation); or other neurological disorder (e.g., multiple sclerosis, Parkinson's disease).

If deemed potentially eligible to participate based on prior HANDLS data (which will be obtained from the NIA prior to scheduled visits), HANDLS investigators or a HANDLS SCAN investigator or coordinator will recruit participants during their MRV visit. The study will be described to participants, and they will be assured that they can decline participation in this ancillary study without affecting their status in the main protocol. For those agreeing to participate in this ancillary study, research subjects will sign an additional NIA HANDLS SCAN sub-study informed consent form. After a brief screening interview for further determination of eligibility, participants will be scheduled for a visit to the University of Maryland School of Medicine. Transportation will be reimbursed. Written informed consent and HIPAA consent will be obtained at University of Maryland using documents approved by the NIA Institutional Review Board and the University of Maryland Human Research Protection Office. IRB approval for the studies will be obtained at the 5 participating institutions (National Institute on Aging, University of Maryland Baltimore County, University of Maryland School of Medicine, University of Pennsylvania, and George Mason University).

Methods

After obtaining written informed consent and HIPAA consent, participants will first be seen by Dr. Katzel or Dr. Seliger at the University of Maryland School of Medicine for a brief medical evaluation. The focus of this medical evaluation is to determine if there were any acute medical problems since their last HANDLS visit, and to review current medications, administer the MRI eligibility checklist, and assess whether there are any contraindications to the performing the supplemental testing. Participants will also undergo brief testing to supplement the HANDLS neurocognitive (executive function) and physical function batteries. To limit the additional testing burden, these proposed measures have been kept to a minimum. Lastly, they will undergo MR imaging. Participants will receive \$50 for HANDLS Scan.

Measures

Measure or Procedure	Estimated Timing	Location
MRI	1 hour	UMB
Cognitive tests	20 minutes	UMB
Corridor walk	10 minutes	UMB

Magnetic Resonance Imaging. Cranial MRI will be performed utilizing a Siemens Tim-Trio 3.0 Tesla unit in the Department of Diagnostic Radiology at the University of Maryland Medical Center. A sagittal scan of the brain will be obtained with T1 weighting (TR/TE/TI = 2660/12/1150), 5 mm slice thickness, 0.2 distance factor, 240 mm read FOV, 100% phase FOV, 1 signal average resulting in 24 slices. An axial scan will be obtained with FLAIR weighting (TR/TE/TI = 8000/67/2500), 5 mm slice thickness, 0.2 distance factor, 220 mm read FOV, 81.3% phase FOV, and 1 average for 26 slices. An axial scan of the brain will also be obtained with T1 weighting (TR/TE/TI = 2660/12/1150), 5 mm slice thickness, 0.2 distance factor, 220 mm read FOV, 100% phase FOV, and 1 average for 26 slices. An axial scan will be obtained with T2 weighting (TR/TE= 6000/103), 5 mm slice thickness, 0.2 distance factor, 220 mm read FOV, 100% phase FOV, and 2 averages for 26 slices. Volumetric T1-weighted magnetization prepared - rapid acquisition gradient echo (MP-RAGE) scans (TR/TE/TI/flip angle = 1900/2.4/900/9°) will be obtained with 256 mm read FOV, 100% phase FOV, and 1 average for 192 slices.

Diffusion tensor imaging (DTI) sequences will sample the diffusion tensor with a single-shot echo-planar spin echo imaging sequence in 128 non-collinear directions using diffusion-weighting gradients at a ‘b’ value of 1000 s/mm², and a non-diffusion weighted (B0) scan. Base sequence parameters of (TR/TE = 9300/84) will be applied in each of these directions with 2 mm slice thickness, 230 mm read FOV, 100% phase FOV, and 1 average for 68 slices. The DTI FOV will be encompass the entire brain including the cerebellum, and provide isotropic resolution (2x2x2 mm³). The total scan time for the conventional, DTI, and T1-weighted volumetric sequences will be approximately 40 minutes.

Grooved Pegboard. The Grooved Pegboard Test requires manual dexterity, eye-hand coordination, and motor speed.⁸¹ Participants are asked to insert 25 pegs (with a key on each end), as quickly as possible, into rows of slotted holes angled in different directions on a 4 × 4 inch pegboard. The pegs are rotated and inserted into the holes as quickly as possible, first with the dominant hand and then the non-dominant hand. Time to completion is scored for the performance of each hand. This test has proven particularly sensitive to cardiovascular risk factors and disease and chronic kidney disease in our investigations.

Contingency Naming Test. The Contingency Naming Test⁸² was modeled after the Stroop Color-Word Test. It measures the ability to inhibit and switch mental set, functions thought to be mediated by a frontal-striatal network. It uses color and shape stimuli and, unlike the Stroop and other similar tests, does not make any demands on literacy or word knowledge. Part 1 requires the naming of colors; Part 2 requires the naming of shapes; and Part 3 requires the naming of color if outside and inside shapes match or the naming of the primary shape if the outside and inside shapes don’t match.

Timed Walk. Self-selected walking speed will be measured during the course of a 10-meter walk. A reduced self-selected walking velocity, a commonly measured index of function performance

has been shown to predict subsequent morbidity and mortality, and correlates with severity of white matter disease.⁸³

Post-acquisition data processing

MRI Image Analyses. Atlas warping and labeling using HAMMER: Manually labeling a large number of regions of interest (ROIs), in order to obtain a complete picture of brain atrophy is prohibitively costly in terms of time and effort, and less likely to be feasible in the typical clinical setting. As a first step toward obtaining a more comprehensive set of volumetric measurements from the entire brain, Dr. Davatzikos and colleagues previously developed and used in a variety of studies an atlas-based labeling and parcelation method.^{84,85} Atlas-based methods start with a digital atlas, which has been partitioned to a number of ROIs. In our case we use an atlas previously labeled at the Montreal Neurological Institute into a set of 92 ROIs that includes all major cortical gyri and subcortical structures, as well as lobar white matter subdivisions. In order to define these ROIs on individual scans, we use a 3-D elastic warping computer algorithm, which finds the spatial transformation (warping) of the template that best matches the morphology of a new scan. The labels of the atlas are then transferred to the individual scan via this spatial transformation. Volumes of these ROIs are readily determined by summing up all voxels within an ROI. Lesion load within each ROI is also determined after initial segmentation of the lesions, as described later in the proposal. This way, we obtain a set of 92 volumes for each brain scan in our studies, which is subsequently treated in multivariate statistical analysis frameworks seeking group differences and associations between these regional brain volumes and clinical, neuropsychological, or demographic variables.^{86,87}

Diffusion Tensor Imaging Analyses. As a first step, we will spatially normalize the DTI data to a template (as explained in preliminary results). The statistical analysis will consist of (1) voxel-wise group based analysis of FA and ADC computed from the tensors; (2) regression of these scalar maps with respect to age and clinical scores; (3) ROI-based correlation with age and other relevant variables with ROIs chosen on an atlas; and, (4) tract-based analysis across groups and their correlation with age and clinical variables.

Sample size

We plan to perform a number of different analyses, the most restrictive of which examines a structural equation model. Sample size determination for structural equation modeling is considerably more complex than for bivariate relations or regression models. At one extreme, Raykov and Marcoulides⁸⁸ suggest that “a cautious and simplified attempt at a rule of thumb might suggest that sample size would desirably be more than 10 times the number of free model parameters.” Sartorra and Sarris⁸⁹ describe an elegant method of sample size computation that requires specification of all parameters in null and alternative models. This is impossible at the beginning of the study for the complex models we are hypothesizing. Even the standard textbook by Bollen (p. 346)⁹⁰ states that such an approach of specifying the parameters “is somewhat arbitrary”. The parameters may be estimable to some degree after some preliminary data on the correlations among observed variables becomes available. A series of 3 SAS program written by Co-Investigator Rosenberger can be used to determine appropriate power and sample size considerations given reasonable estimations of all the parameters. As we obtain more data during the course of the study, we will use Sartorra and Sarris’s method to determine if the sample size goals are adequate.

We need another approach to determine the sample size for testing our primary hypotheses, which is provided by MacCallum and colleagues.⁹¹ The Table below shows the sample size required to determine an appropriate level of goodness of fit for our most complex model. We have assumed correlated error structures where appropriate. Here we give the power of the test for an exact fitting model, and the effect size represents the model discrepancy in the population, as measured by Steiger's deviation of the root mean square error of approximation (RMSEA).⁹² Brown and Cudeck⁹³ use empirical evidence to suggest that the RMSEA effect size should be less than 0.05 for a good-fitting model. Based on this preliminary analysis, it would appear that the proposed 500 subjects would be adequate for testing goodness of fit at an effect size of between 0.015 and 0.020, which is well below Brown and Cudeck's recommended threshold.

Table. Minimum sample size for 90% power for testing goodness of fit of structural equations model. Effect size represents deviation from an exact fit.⁹¹

Effect size	Minimum Sample Size
0.010	1238
0.015	550
0.020	310
0.025	200

Risks and Benefits

Risks. There are potential risks associated with some of the procedures included in this study. However, the procedures have been planned by the investigators to minimize the danger of any major complication. All medical procedures will be supervised by qualified medical personnel who will carefully monitor the participant.

Neuropsychological Testing. Although there are no significant risks to subjects during psychological and neuropsychological testing, every effort will be made to make participants feel comfortable. The only risk of this study is "psychologic discomfort." HANDLS participants are accustomed to these procedures because we administered neuropsychological tests as part of their baseline examination.

Physical Function Tests. These tests involve a timed walk. No tests will be performed before a physician examines participants. A crash cart and emergency medications are available in the area where these tests are performed.

Magnetic Resonance Imaging (MR). Medical personnel associated with this sub-study will carefully screen participants for MRI contraindications (e.g., pacemaker, aneurysm clip, metallic prostheses). MRI will not be performed if we find a contraindication. If there is a history of occupational exposure to metallic fragments or questionable history of other exposures to metal, pilot x-rays are performed of the skull and orbits to evaluate the presence of metal. Tests will not be performed if there are contraindications.

Medical personnel associated with this sub-study will interview participants about claustrophobia before the procedure. We will stop the MRI if the participant experiences any discomfort or

anxiety. All MRI scans will be reviewed for unexpected abnormalities (e.g., mass lesion, blood) by a licensed neuroradiologist at the University of Maryland School of Medicine. We will refer participants with abnormalities requiring further follow-up to their physician for further assessment. If they do not have a physician then we will refer them to facilities available in Baltimore City as part of the HANDLS referral network. Study co-investigators Drs. Katznel and Seliger are available on site to deal with any medical issues, adverse events, unanticipated problems to participants or others that arise during the study. We will include twenty-four hour contact information on the consent forms.

Benefits. Participants may benefit from the neuroimaging procedures by acquiring a “baseline” scan that can be used for comparison purposes at a later date. This may a pertinent benefit as patients with cardiovascular risk factors are at increased risk for cerebral infarction. In addition, the brain scans may find clinically significant results that warrant follow-up outside of this study.

We believe that the benefits associated with this study will exceed the risks, thereby resulting in a low risk: benefit ratio for participants.

Appendix 6.3: Neuroimaging substudy – informed consent



RESEARCH CONSENT FORM

**Protocol Title: HEALTHY AGING IN NEIGHBORHOODS OF DIVERSITY ACROSS
THE LIFE SPAN (HANDLS) SCAN**

Study No.: HP-00041271

Principal Investigator: Leslie I. Katznel, MD, PhD 410-605-7248

Sponsor: National Institutes of Health (NIH)

Your participation in this research study is voluntary. You may choose not to participate now or at any time without penalty or loss of benefits to which you are otherwise entitled.

Please read all of the following information carefully. Please ask the study physician or his/her representative to explain any words, terms, or sections that are unclear to you. You should also ask any questions that you have about this research study. Do not sign this consent form unless you understand the information in it and have had your questions answered to your satisfaction. If you decide to take part in this research study, you will be asked to sign this form. You will be given a copy of the signed form, which you should keep for your own records. It has information, including important names and telephone numbers, to which you may wish to refer to in the future. New things might be learned during this study that you should know about. The investigators will tell you about new information that may affect your willingness to stay in this study.

As part of this study, members of the research team will ask you questions about your medical history. The purpose of these questions is to ensure that no unnecessary risk will be posed to you by participating in this study. For your own well-being, you must give a true and complete medical history when asked. Giving false, incomplete, or misleading information about your medical history, including your past and present use of medicines, may prevent the study doctor from making the best decision about your participation. You must also say whether or not you are taking part in any other research studies or using any other experimental therapies.

Please take your time to read this form, and be sure to ask any questions you may have before making your decision. We encourage you to discuss your decision with your family and friends.

PURPOSE OF STUDY

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HP-00041271 UM IRB Approval Date 1/25/2013
Do Not Sign this Form after this Date 1/24/2014



High blood pressure (hypertension) is a major risk factor for stroke and decline in the ability to think and reason. However, milder problems with thinking and reasoning may occur in people who have high blood pressure, or have other risk factors for stroke such as high cholesterol, diabetes, smoking, etc. High blood pressure and these other risk factors may lead to changes in the brain that can lead to small silent strokes.

We are asking you to participate in a research study looking for how these risk factors influence your ability to pay attention, concentrate, learn and remember new information and perform speeded tasks. It is also a study of how these same risk factors affect your brain. You will be asked to participate in a brain scan procedure called magnetic resonance imaging (MRI). During this procedure, you will lie on a table in a box-like enclosure while the MRI scanner takes pictures of your brain.

This study is being conducted in collaboration of investigators at the University of Maryland Baltimore (Drs Katzel and Seliger), University of Maryland Baltimore County (Dr. Waldstein), and National Institute on Aging with (Michele K. Evans, M.D. and Alan B. Zonderman, Ph.D) as the primary investigators.

500 HANDLS participants will be participate in this study.

PROCEDURES

This research study will be completed in one visit to the University of Maryland Medical Center that will take approximately 2 hours to complete. However, it is part of a long-term study, called HANDLS. As you know, the HANDLS Mobile Medical Research Vehicles will be back in your neighborhood every three years and we will ask you again at that time to participate in the long-term study.

After obtaining written informed consent and HIPAA consent, you will be seen by the study doctor at the University of Maryland, School of Medicine General Clinical Research Center (GCRC) for a brief medical evaluation. The focus of this medical evaluation is to determine if you have had any medical problems since your last HANDLS visit, and to review your current medications. The doctor will also review the MRI eligibility checklist with you to see if there are any reasons why you should not participate in this research study. If you are premenopausal woman, a urine pregnancy test will be performed.

Next, you will be asked to complete two behavioral tests that measure attention, concentration, learning and memory, hand-eye coordination and motor speed. You will also be asked to take a brief walk down and back a hallway, at a pace that is comfortable for you. Completion of these tasks takes approximately 30 minutes.

Page 2 of 8



HP-00041271 UM IRB Approval Date 1/25/2013
Do Not Sign this Form after this Date 1/24/2014



The last part of this study will be the brain scan. You will be asked to participate in a brain scan procedure called magnetic resonance imaging (MRI). During this procedure, you will lie on a table in a box-like enclosure while the MRI scanner takes pictures of your brain. This examination takes approximately 1 hour to complete. This MRI test will be performed either at University of Maryland Medical Center or at the Paca-Pratt building.

You may participate in any of the tests, but you do not have to participate in all of the tests. This will not affect your right to participate in the other parts of the HANDLS study. You may stop any test after it starts.

Measure or Procedure	Estimated Timing	Location
MRI	1 hour	UMB
Cognitive tests	20 minutes	UMB
Corridor walk	10 minutes	UMB

If any medical problems are detected during this visit, we will tell you and with your permission we will notify your doctor.

POTENTIAL RISKS/DISCOMFORTS:

There are potential risks involved in your participation in several of the study procedures; however, the procedures have been planned by the investigators to minimize the danger of any major complication. Before you participate in any aspect of this research, the procedure will be explained to you in detail. Risks associated with different portions of the protocol are described below:

Corridor walk: There is a small risk that you will fall, get chest pain, short of breath or become dizzy during these tests. You will stop the test if there are any untoward symptoms such as chest pain. There is a small risk of muscle strain or pulled muscles. We have performed more than walking tests without complication.

Questionnaires: The behavioral & memory tests are given in a private, quiet room with a tester who will help you understand how to do the best you can. We want you to know that some people find these tests tiring. Sometimes, people feel nervous when they do these tests. All examiners who are involved in giving these tests are experienced in using these procedures and they will minimize any discomfort that you might feel. If the tests are disturbing you, then you may stop testing any time you want.

MRI: You will not be allowed to participate in MRI scanning if you have a pacemaker, an aneurysm clip, a metallic prosthesis, or certain other metal objects in the body, or if you are

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pregnant. Some people experience anxiety while undergoing the MRI procedure due to the noises made by the machine and the box-like nature of the space in which the test is done. If you feel at all uncomfortable, the test will be stopped immediately.

Privacy and Confidentiality: Your personal health information (PHI) will be kept private to the extent allowed by law. You will not be identified by name in any publications resulting from this study. You will be asked to sign a separate form that will give permission to the investigator, the sponsor, and certain other people, agencies or entities to look at and review the records related to this study including your personal health information and the information discovered during this study. If you do not wish to sign this permission form you will not be allowed to participate in this study.

Research records will not be released to your private physician without your prior consent. The signed informed consent form and some of the results of the research tests will be kept in locked cabinets in locked offices. The MRI scans will be sent to colleagues at the University of Pennsylvania for further analyses of the MRI images. Your name and other identifying information will be deleted from these scans and a study subject number will be put in its place. Any study data sent to colleagues at the University of Maryland Baltimore County and George Mason University for analysis will similar be stripped of identifying information and a study subject number will be put in its place.

Loss of confidentiality will be minimized by storing data in a secure location such as a locked office and locked cabinet. Electronic data will be password-protected. You have the right to expect that all communications and records about your care and participation in this research study will be treated as confidential. Monitors from the University of Maryland IRB and the VA Research Quality Assurance Office and from the other participating institutions (the National Institute on Aging, Office of Human Research Protection, MedStar Research Institute, Institutional Review Board (IRB) etc) may need to see your research records to help ensure that the rights and welfare of the research participants are protected and that the study is carried out in an ethical manner. Therefore, absolute confidentiality cannot be guaranteed.

Loss of privacy is a risk of participation in this research. The investigators have taken steps to protect your privacy. All research testing activities will be conducted in a private examination/interview area, away from public traffic where only the member(s) of study research team may see or hear you. Only members of the study research team will interact with you or have access to you during study activities.

To help us protect your confidentiality, investigators from the National Institutes of Health have obtained a Certificate of Confidentiality from the National Institutes of Health. With this certificate the researchers cannot be forced to disclose information that may identify you, even by court subpoena, in any federal, state, or local civil, criminal, administrative, legislative or





other proceedings. The researchers will use the certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the U.S. Department of Health and Human Services that is used for auditing or program evaluation or for information that must be disclosed in order to meet federal regulations.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researcher may not use the Certificate to withhold that information.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following conditions: It does not apply to state requirements to report certain communicable diseases. In addition, the study doctor may be required to report certain cases of abuse, neglect, or suicidal or homicidal intent to the appropriate authorities.

In addition to the above risks, there may be risks in this study which are not yet known.

POTENTIAL BENEFITS

This study is not designed to provide direct benefits to any participants. If you agree to take part in this study, there may or may not be direct medical benefits to you. We hope the information learned from this study will benefit others in the future. There is no charge for any of the testing described. You may benefit by learning more about your health, or possibly from learning that you have a condition or problem. If the study doctor discovers any condition or problem, the information will be provided to you and your doctor, if you authorize it. To authorize the reporting of results to your physician you will need to sign a form called "Release of Medical Information". You will be asked to sign this form only if you want us to communicate with your physician. The study doctors do not provide medical treatment.

ALTERNATIVES TO PARTICIPATION

This is not a treatment study. Your alternative is to not take part. If you choose not to take part, your healthcare at University of Maryland, Baltimore will not be affected. Taking part in this study is entirely voluntary. You may choose to withdraw from the study at any time.

COSTS TO PARTICIPANTS

You do not have to pay anything to be in this study. However, if taking part in this study leads to procedures or care not included in the study, it may lead to added costs for you or your insurance company. You will not be charged for any tests or procedures that are part of this research study.

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PAYMENT TO PARTICIPANTS

You will be paid \$50 at the end of your visit for participating in this study.

CONFIDENTIALITY AND ACCESS TO RECORDS

Efforts will be made to limit your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

The data from the study may be published. However, you will not be identified by name. People designated from the institutions where the study is being conducted and people from the sponsor will be allowed to inspect sections of your medical and research records related to the study. Everyone using study information will work to keep your personal information confidential. Your personal information will not be given out unless required by law.

RIGHT TO WITHDRAW

Your participation in this study is voluntary. You do not have to take part in this research. You are free to withdraw your consent at anytime. Refusal to take part or to stop taking part in the study will involve no penalty or loss of benefits to which you are otherwise entitled. If you decide to stop taking part, if you have questions, concerns, or complaints, or if you need to report a medical injury related to the research, please contact the investigator: Leslie Katzel MD, PhD at 410-605-7248 during the day or at (410-328-2337 pager 2182) after hours. Dr. Stephen Seliger can be reached at 410-605-7000 extension 5231. Dr. Shari Waldstein at UMBC can be reached at 410-455-2374. The main number for the Division of Gerontology at the Baltimore VA Medical Center is 410-605-7185.

There are no adverse consequences (physical, social, economic, legal, or psychological) of a participant's decision to withdraw from the research. You will be told of any significant new findings which develop during the study which may affect your willingness to participate in the study.

CAN I BE REMOVED FROM THE RESEARCH?

The investigator LESLIE KATZEL or sponsor can decide to withdraw you from the study at any time. You could be removed from the study for reasons related solely to you (for example, not following study-related directions from the Investigator, or you have a serious reaction during the study). Also, the entire study may be stopped by the sponsor, the Investigator, the Institutional Review Board, the facility where the study is being carried out, or the University. The sponsor may also decide to stop the Investigator's participation in the study. In that case, your participation will end unless another investigator is identified and approved by the sponsor and the Institutional Review Board.

UNIVERSITY STATEMENT CONCERNING RESEARCH RISKS

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The University is committed to providing participants in its research all rights due them under State and federal law. You give up none of your legal rights by signing this consent form or by participating in the research project. This research has been reviewed and approved by the Institutional Review Board (IRB). Please call the Institutional Review Board (IRB) if you have questions about your rights as a research participant.

The research described in this consent form has been classified as minimal risk by the IRB of the University of Maryland, Baltimore (UMB). The IRB is a group of scientists, physicians, experts, and other persons. The IRB's membership includes persons who are not affiliated with UMB and persons who do not conduct research projects. The IRB's decision that the research is minimal risk does not mean that the research is risk-free. You are assuming risks of injury as a result of research participation, as discussed in the consent form.

If you are harmed as a result of the negligence of a researcher, you can make a claim for compensation. If you have questions, concerns, complaints, or believe you have been harmed through participation in this research study as a result of researcher negligence, you can contact members of the IRB or the staff of the Human Research Protections Office (HRPO) to ask questions, discuss problems or concerns, obtain information, or offer input about your rights as a research participant. The contact information for the IRB and the HRPO is:

University of Maryland School of Medicine
Human Research Protections Office
BioPark I
800 W. Baltimore Street, Suite 100
Baltimore, MD 21201
410-706-5037

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Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

If you agree to participate in this study, please sign your name below.

Participant's Signature

Date: _____

Investigator or Designee Obtaining Consent
Signature

Date: _____

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Appendix 6.3: Neuroimaging substudy – HIPAA

**Health Insurance Portability and Accountability Act (HIPAA)
AUTHORIZATION TO OBTAIN, USE AND DISCLOSE
PROTECTED HEALTH INFORMATION FOR RESEARCH**

Name of Study Volunteer: _____

Date of Birth: _____ **Medical Record Number:** _____

NAME OF THIS RESEARCH STUDY: **HEALTHY AGING IN NEIGHBORHOODS OF DIVERSITY ACROSS THE LIFE SPAN (HANDLS) SCAN**

UMB IRB APPROVAL NUMBER: **H41271**

RESEARCHER'S NAME: **LESLIE I. KATZEL, M.D., PH.D.**

RESEARCHER'S CONTACT INFORMATION:

Department of Medicine, Division of Gerontology
University of Maryland School of Medicine (UMSOM)
Baltimore VA Medical Center
GRECC 4b-189
10 N. Greene Street
Baltimore, MD 21201
410-605-7248

This research study will use health information that identifies you. If you agree to participate, this researcher will use just the health information listed below.

THE SPECIFIC HEALTH INFORMATION TO BE USED OR SHARED:

- *Billing and payment information and the medical information required to justify it.*
- Health-related information you have been asked to provide for the study during interviews, and via questionnaires.
- Your medical records from your health care provider relating to eligibility for the study and participation in the study including: doctors' notes or summaries, records of medications and other treatments, laboratory results, reports of x-rays and other diagnostic tests
- Results of medical tests, laboratory tests, x-rays, research procedures carried out for the purposes of the study
- Medical records from another health care facility that may be needed to determine whether a side effect or other problem is related to the study.

Federal laws require this researcher to protect the privacy of this health information. He will share it only with the people and groups described here.

PEOPLE AND ORGANIZATIONS WHO WILL USE OR SHARE THIS INFORMATION:

- Dr. Leslie I. Katzel, MD, PhD and his research team.
- The sponsor of the study, or its agents, such as data repositories or contract research organizations
- Organization that will coordinate health care billing or compliance such as offices within UMSOM; the University of Maryland, Baltimore (UMB); University Physicians, Inc. (UPI) and the faculty practices of the UMB; University of Maryland Medical System (UMMS) and the Veterans Affairs Maryland Health Care System (VAMHCS).
- The Baltimore GRECC and University of Maryland Pepper Center safety monitoring boards
- The University of Maryland General Clinical Research Center (GCRC)
- Clinical staff not involved in the study who may become involved in your care, if medically indicated

**Health Insurance Portability and Accountability Act (HIPAA)
AUTHORIZATION TO OBTAIN, USE AND DISCLOSE
PROTECTED HEALTH INFORMATION FOR RESEARCH**

- To your health insurer or payer, if necessary, in order to secure their payment for any covered treatment not paid for through the research

THIS AUTHORIZATION WILL NOT EXPIRE. BUT YOU CAN REVOKE IT AT ANY TIME.

To revoke this Authorization, send a letter to this researcher stating your decision. He will stop collecting health information about you. This researcher might not allow you to continue in this study. He can use or share health information already gathered. The data will be destroyed at the time indicated below:

Three years after the submission of the final funding report to NIH, or 5 years after the final research paper is published on this research which ever period of time is greater. Research data obtained from tests performed in the Department of Radiology at the University of Maryland Medical Center will be maintained as per their clinical policies.

ADDITIONAL INFORMATION:

- You can refuse to sign this form. If you do not sign it, you cannot participate in this study. This will not affect the care you receive at:
 - University Physicians, Inc. (UPI)
 - University of Maryland Medical System (UMMS)
 - Veteran Affairs Maryland Health Care System (VAMHCS)

It will not cause any loss of benefits to which you/your child are otherwise entitled.

- Sometimes, government agencies such as the Food and Drug Administration or the Department of Social Services request copies of health information. The law may require this researcher, the UMSOM, UPI, UMMS or VAMHCS to give it to them.
- This researcher will take reasonable steps to protect your health information. However, federal protection laws may not apply to people or groups outside the UMSOM, UMB, UPI, UMMS or VAMHCS.
- Except for certain special cases, you have the right to a copy of your health information created during this research study. You may have to wait until the study ends. Ask this research how to get a copy of this information from him.

My signature indicates that I authorize the use and sharing of my protected health information for the purposes described above. I also permit my doctors and other health care providers to share my protected health information with this researcher for the purposes described above.

Signature: _____ Date: _____

Name (printed) _____

Privacy Questions? Call the UMSOM Privacy Official (410-706-0337) with questions about your/ rights and protections under privacy rules.

Other Questions? Call the researcher named on this form with any other questions.

Appendix 7.1: Circadian rhythm substudy – protocol

Circadian Rhythm Protocol

Ecological Measurement of Circadian Entrainment

Background

African Americans in Baltimore are statistically more likely to exhibit higher rates of mortality and morbidity than age-matched whites. Disruption of circadian rhythms has been linked to a wide range of maladies from diabetes to cancer. To our knowledge no formal study of circadian disruption in African American populations has been undertaken, particularly in a natural setting.^{31,32} The HANDLS cohort is an ideal population to compare circadian disruption among sub-populations in Baltimore. If shown that this population is in fact disrupted, non-pharmacological interventions can be then developed to increase circadian entrainment, and possibly, reduce risks in this population.

Circadian rhythms are a fundamental part of life. All species on Earth exhibit 24-patterns at behavioral, physiological, and cellular levels. Circadian disruption associated with a lot of maladies.^{33,34} Light is the primary zeitgeber (time-giver) for the circadian system. Disruption of a regular, 24-hour pattern of light and dark leads to circadian disruption. The Lighting Research Center at Rensselaer Polytechnic Institute (LRC) has developed personal light exposure devices (e.g., the Daysimeter) for deployment in natural settings^{31,32}. The LRC has also pioneered analytical methods for quantifying circadian disruption in humans and in other species, including nocturnal rodents, called phasor analysis.³⁵ Phasor analysis is based upon the functional relationship between two periodic cycles. The Daysimeter measures actual light-dark cycles together with activity- rest cycles, and based upon phasor analysis circadian disruption can be measured. From the Nurse's Health Study we were able to quantitatively compare circadian disruption in dayshift and in rotating-shift nurses, the latter population being at higher risk of breast cancer than the former. Disease and mortality are exhibited differentially in subpopulations within the city of Baltimore. A totally unexplored area is the quantification of circadian disruption through ecological measurements of patterns of light-dark and activity-rest in these subpopulations to determine whether there is an association between circadian disruption and disease and mortality. This is an entirely plausible line of research because (a) circadian rhythms are essential for life, (b) circadian disruption is associated with a wide spectrum of maladies, including increased risk for cancer, diabetes, obesity, cardiovascular disease, and seasonal depression and (c) the ecological approach proposed here has been successfully demonstrated in several populations including, nurses, submariners, teens, young adults, and those with dementia.

Aim 1: Collect rest/activity and dark/light data using the Daysimeter from participants in the HANDLS cohort using the Daysimeter. It is hypothesized that those sub-populations with greater incidence of mortality and morbidity will exhibit greater levels of circadian disruption as determined by phasor analysis, based on the measured rest/activity and dark/light profiles, compared to those with lower incidence.

Study Design

For this pilot study we will employ a basic 2×2 experimental design; two races by two levels of BMI. We plan to enroll all interested subjects until we reach 100 participants (25 per group). The criteria for participation will be race (African American and Caucasians) and BMI (below 25 and above 30). We will collect data from each subject for seven consecutive days and nights using the Daysimeter. The study is designed to look at the main effects and interaction between race and BMI; we hypothesize that race will not matter, but BMI will, for both the degree of circadian entrainment and total sleep. We will use chronotype as a covariate. Depending upon initial results we may use this as a second stratification variable. Assuming we can enroll 10 subjects per week, and considering a 20% attrition rate, we anticipate completing the study in 13 weeks.

Methods

Participants will have two study visits, the first for initial screening and enrollment and the second at completion of the seven-day protocol. Height and weight will be measured for calculation of BMI and responses to the Munich Chronotype questionnaire data will be obtained. Participants are provided the Daysimeter at the first visit with detailed instructions for placement and use (Figure 1). We will contact participants every day to remind them to wear the device, and to answer any questions.

Risks

There are no known risks related to wearing the Daysimeter. This device has been used by healthy older adults (age 65 and older), Alzheimer's disease patients, and young adults (ages between 12 and 17 years) and no adverse events were reported. It uses a battery similar to a watch battery. There is no greater risk than wearing a digital watch.

Compensation

Participants will be paid \$40.00 for participation (up to 7 consecutive days) with an additional \$20.00 incentive for returning the Daysimeter during the second and final study visit.



Figure 1. Model wearing Daysimeter on wrist.

Appendix 7.2: Circadian rhythm substudy – User’s guide

User's Guide HANDLS Circadian Rhythm Study

You have agreed to participate in a research study looking at light/dark cycles and activity/rest cycles to see if there is a link between a disruption in these cycles and certain diseases, like diabetes. The light/dark and activity/rest cycles are known as circadian rhythms. Every rhythm in your body that repeats every 24 hours is known as a circadian rhythm. We are interested in knowing how disruptions to these cycles may affect health and aging.

This is a one-week (7 day) study and includes two 30-minute visits to the MRV. We will make **telephone contact with you every day for the next 7 days** to make sure you remember to wear the Daysimeter and to answer any questions you may have. If we are unable to call you because you do not have a working telephone, we expect you to contact us at 410-292-5905 between 8:00a-9:30a every day for the next 7 days.

General use guidelines

Placement

- The Daysimeter12 is worn on the wrist much like a watch



- The Daysimeter12 should be worn on the non-dominant hand (the one you DO NOT write with)
- The wearer should be careful to keep clothing from covering the Daysimeter12
- When sitting at a table or desk, the wearer should keep the Daysimeter12 above the surface to prevent the blocking of light
- The Daysimeter12 is water-proof and can be worn in the shower (but does not have to be, but don't forget to put it back on when you get out of the shower/bath)
- The Daysimeter should be worn while the wearer is sleeping, keeping it above the covers as much as possible
- Any problems with or questions about the Daysimeter12 should be reported to HANDLS staff during your daily call

Appendix 7.3: Circadian rhythm substudy – sleep questionnaire



Ludwig-Maximilians-Universität München

Institut für Medizinische Psychologie
Goethestr. 31 D-80336 München



Instructions: The following questionnaire will ask you questions in regards to your sleep and wake behaviour. Please respond to the questions according to your perception of a standard week, based on your most current living conditions. All fields are required unless otherwise specified.

Personal Information

Date	2012.9.7 - 21:43
Name	[Redacted]
Email	[Redacted] (We cannot send you a personal assessment of your chronotype if you do not provide an email address.)
Age	[Redacted]
Gender	<input type="radio"/> Female <input checked="" type="radio"/> Male
Height	[Redacted] cm
Weight	[Redacted] kg
Country	[Redacted]
City	[Redacted]
Postal Code	[Redacted]

Referral Information

If you were referred to this site by a particular doctor or if you are part of a specific project, then please enter the keyword or key phrase that you were given below: [Redacted]

Work Schedule

I have a regular work schedule (this includes being a housewife or househusband):

Yes No

If 'YES', how many days per week? [Redacted]

Instructions: Please complete all of the following sections, regardless of whether you are working on a regular basis or not. Use the 24 hour scale, for example 23:00 instead of 11:00PM!!!!

Work Days

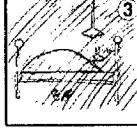
1 I go to bed at _____ o'clock.



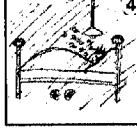
2 Note that some people stay awake for some time when in bed!



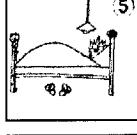
3 I actually get ready to fall asleep at _____ o'clock.



4 I need _____ minutes to fall asleep.



5 I wake up at _____ o'clock.
 with an alarm clock
 without an alarm clock



6 After _____ minutes, I get up.

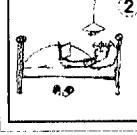


Free Days

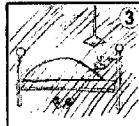
1 I go to bed at _____ o'clock.



2 Note that some people stay awake for some time when in bed!



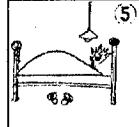
3 I actually get ready to fall asleep at _____ o'clock.



4 I need _____ minutes to fall asleep.



5 I wake up at _____ : _____ o'clock.
 with an alarm clock
 without an alarm clock



6 After _____ minutes, I get up.



Comment Field: Please leave a comment if you currently have NO possibility of freely choosing your sleep times (e.g. because of pet(s), child(ren) etc.). Use this field also to provide additional information, if the system asks for it:

Daylight Exposure

On average, I spend the following amount of time outdoors in daylight (without a roof above my head):

on workdays	_____ hours	_____ minutes
on free days	_____ hours	_____ minutes

(C)2006, Till Roenneberg, & Martha Merrow, LMU München

Appendix 8.1: Diabetes substudy – expedited IRB approval

UMBC

A N H O N O R S U N I V E R S I T Y I N M A R Y L A N D

Date: January 8, 2013

To: Kevin Eckert, Sarah Chard, Bob Rubinstein
Erin Roth, Brandy Harris-Wallace

Re: Expedited Review Approval
Protocol #: Y12KE21206

Office for Research Protections and

Compliance

University of Maryland, Baltimore County
1000 Hilltop Circle
Baltimore, MD 21250

PHONE: 410-455-2737

FAX: 410-455-3868

EMAIL: compliance@umbc.edu

Your protocol entitled **The Subjective Experience of Diabetes Among Urban Older Adults** has been approved by expedited review by the Institutional Review Board. This study fulfills the criteria for expedited review under 45 CFR 46.110, category # **6&7** as less than minimal risk or minimal risk and applies, if applicable, to the following sponsored project titles and numbers:

- NIH - IROIAG041709-01AI, The Subjective Experience of Diabetes Among Urban Older Adults, 00007920
-
-

Approval of this protocol will terminate on the below end date unless an Annual Continuation Report is submitted, in writing, to the IRB. The Office for Research Protections and Compliance will send you an email reminder prior to the end of the protocol; it is your responsibility, however, to assure that project activities are not conducted past the expiration date.

Reporting Calendar

Original approval date	Current end date	The next Annual Continuation Report is due by	Expect a reminder to renew by
01/04/2013	01/03/2014	12/06/2013	11/22/2013

Investigators are responsible for reporting **in writing** to the IRB any changes to the human subject research protocol, measures or in the informed consent documents. This includes changes to the research design or procedures that could introduce new or increased risks to human subjects and thereby change the nature of the research. In addition, you must report any adverse events or unanticipated problems to the IRB for review and approval. All correspondence and materials used in this protocol must reference the above IRB number.

Investigators are also reminded that all UMBC IRB approved consent forms will display an expiration date at the bottom of each page. Please check this date carefully each time an approved consent form is used, as using an expired form to consent participants is considered a substantial deviation from the Federal regulations governing research involving human subjects.

The investigator(s) identified above are required to retain an IRB protocol file, including a record of IRB-related activity, data summaries and consent forms. This file is to be made available for review for internal procedural (audit) monitoring.

Expedited review approved by:



Susan Sonnenschein, Ph.D.
IRB Chair

Expedited Review Approval 043012

Appendix 8.2: Diabetes substudy – IRB application

Hello and thank you for accessing this form from the University of Maryland, Baltimore County Institutional Review Board web site.

Prior to submitting, please ensure that spelling and grammar are correct; this will assist in the timely review of this form during the IRB evaluation process. Complete all sections of the protocol application (indicate N/A in the section not applicable to your protocol). "See attached proposal" or "See the previous section" are not an acceptable responses.

Further instruction on the use of this form and guidance about submission may be found on the [Expedited Review](#) or [Full Board Review](#) link.



AN HONORS UNIVERSITY IN MARYLAND

**APPLICATION FOR APPROVAL OF USE OF HUMAN PARTICIPANTS
INSTITUTIONAL REVIEW BOARD**

Electronically submit the protocol and any accompanying documents to irbsubmissions@umbc.edu. The Office for Research Protections and Compliance prefer applications submitted in MS Word format, but Adobe Acrobat versions will be accepted.
Please do not submit "hard-copy" or paper documents.

Protocol Title: The Subjective Experience of Diabetes Among Urban Older Adults

Will the procedures in this application be used for thesis, masters or dissertation research? Yes No
If yes, please list thesis or dissertation committee member names: _____
Planned graduation date? _____

If applicable, provide the Sponsored Project Title and Number:

Is this application associated with a Planning and Development activity? If yes, please provide the date the ORPC provide administrative approval, the IRB approval number and title: **Y12KE21206 June 22, 2012**

List all personnel associated with this project. Indicate with the Name who will be the Principal Investigator

Name	Role	Department	Phone Number	E-mail	Date UMBC or CITI Education Program was completed
Kevin Eckert	PI	Socy & Anth	5-5698	eckert@umbc.edu	
Sarah Chard	co-I	Socy & Anth	5-3380	schard@umbc.edu	
Bob Rubinstein	co-I	Socy & Anth	5-2059	rrubinst@umbc.edu	
Erin Roth	co-I	Center for Aging Studies	5-8732	eroth@umbc.edu	
Brandy Harris-Wallace	co-I	Socy & Anth	5-5815	bhwalla@umbc.edu	

Role: Faculty Advisor (FA) , Research Assistant (RA), Graduate Student (GS), Undergraduate Student(US)

Type of Review Requested: Full Board Expedited

Level of risk: Less than minimal risk Minimal Risk More than minimal risk *

* Complete the necessary information in question # 3 of the protocol application.

By signing, the investigator(s) will abide by all UMBC IRB policies and procedures and understand that no research activities will be conducted with human participants prior to obtaining the required approvals. The investigator(s) will inform the IRB at the earliest possible date of (1) any significant changes in the project with respect to human subject participation, (2) any adverse reactions or unexpected responses observed involving human participants, and (3) any need for continuation of the project activities beyond the approval date.

Investigator's Signature: _____ Date: _____

Investigator's Signature: _____ Date: _____

Faculty Advisor's Signature* _____ Date: _____

* I have read and reviewed this proposal and certify that it is ready for review by the IRB. I have worked with the student to prepare this research protocol. I agree to mentor the student during the research project.

This signature page may be scanned as a PDF document and submitted to irbsubmissions@umbc.edu. If that is not possible, fax this page (and this page only) to (410) 455-3868.

Approvals via expedited review will take approximately three (3) weeks;
Full board approvals will occur at the next regularly scheduled meeting.

IRB Action: Expedited _____ Full Board Review _____

Approved - IRB Chair _____ Date _____

(application for approval of use human participants form)-07/04/2012
compliance@umbc.edu

1) Anticipated start date of the research: January 2, 2012

Approximately how long will it take to complete

the research objectives (months/years): 3 years

2) Purpose of the Study: What are the specific scientific objectives (aims) of the research?

Please attach additional information to this application (i.e. specific aims, project description, etc.) if you wish to provide additional information about the protocol.

The proposed 36-month study investigates the subjective construction of diabetes among African-American and non-Hispanic white older adults, age \geq 50, with Type 2 Diabetes Mellitus (T2DM), living in Baltimore City (n=80). We will use a modification of the McGill Illness Narrative Interview (MINI), a semi-structured ethnographic interview guide, for this study. We seek to identify how local social, cultural, and material contexts inform participants' conceptions of their diabetes, perceptions of its risk factors and comorbidities, and their approach to managing their illness.

This study involves a unique partnership with the National Institute on Aging's Intramural Healthy Aging in Neighborhoods of Diversity across the Lifespan Study (HANDLS), a community-based, epidemiological study of cardiovascular and cerebrovascular disease risk in Baltimore (n=3722). Initiated in 2004, HANDLS is a 20-year, prospective, fixed-cohort study with interview waves occurring approximately every 3 years. While HANDLS' staff inform participants about their diabetes status and will refer participants in need of treatment to local diabetes clinics, HANDLS provides no direct treatment. Our study provides no intervention or treatment. We will distribute information regarding diabetes management and local resources for diabetes care at the conclusion of each interview.

3) Investigator experience: Briefly describe the research staff/investigators level of experience.

Attach an abridged vita highlighting expertise as it relates to this study.

The PI and each of the co-Investigators have many years of experience running federally-funded ethnographic research on issues of aging and health.

4) Background: Please provide an evaluative summary of relevant literature on the topic **if** your protocol falls within the "**More than Minimal Risk**" category.(defined as: "where the probability and magnitude of harm or discomfort anticipated in the proposed research are greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or test". [45 CFR 46.102(i)]")

a. If adverse effects occurred, indicate how your research is addressing or attempting to prevent such effects. Include full citations for included research. If possible, also include a copy of relevant articles.

b. For **More than Minimal Risk** studies that ALSO include invasive procedures, indicate which databases have been consulted (e.g., Medline). Summarize findings, including findings of adverse effects and steps taken by you to prevent this from occurring in your protocol. You may reference your response in 3a, as appropriate.

5) Participant selection: Who will be the participants? How and from where will they be obtained? What are the criteria for inclusion and exclusion? What is the estimated number of participants and age range? How will eligibility be determined, and by whom? Will the participants be selected for any specific characteristics, e.g., age, sex, race, ethnic origin, religion, or any social or economic qualifications?

The sample for this study will be drawn from HANDLS (n=3,722), an epidemiological study of African American and non-Hispanic white health disparities in twelve Baltimore City neighborhoods. We will draw our initial sample from a HANDLS subsample (n=500) that represents the age, race, gender and

A8.2 Y12KE21206 Eckert, Chard Diabetes among older adults.doc 30 April 2013

poverty strata of the overall HANDLS sample. If it is not possible to draw our entire sample from this subsample (e.g., to meet our inclusion critera regarding gender, ethnicity, and variation in diabetes duration - see paragraph that follows) we will draw additional participants from members of the larger sample who have indicated a willingness to participate in further studies.

Our sample (n=80) will consist of 20 African-American males, 20 African-American females, 20 European-American males, and 20 European-American females aged ≥50 who have been diagnosed with T2DM. Our participants may have entered HANDLS knowing of their diabetes or they may have been diagnosed over the course of the study. We therefore anticipate our sample will include variation in illness duration. However, we will adjust our sampling strategy once the study begins if needed in order to ensure the inclusion of variation in diabetes duration. Within each cell we also will purposively sample to ensure inclusion of persons whose diabetes appeared controlled and persons whose diabetes appeared less controlled at the time of the most recent HANDLS assessment (i.e., fasting blood glucose levels above and below 154 mg/dl or HbA1c values above and below 7%). As noted above, at the close of each interview we will distribute diabetes management information and local clinical resources. For those persons whose blood tests or discussions over the interview indicate they are doing little diabetes management we will be certain to stress at the closing of the interview the importance of diabetes management.

Because of HANDLS' stringent screening medical evaluations that include both a medical exam and mini-mental state examinations, we anticipate our sample will not include persons with cognitive impairment. However, if an interviewer does observe that a participant is unable to coherently complete the informed consent or an interview, the interviewer will confer with the PI and co-Investigators regarding withdrawing the participant. In all cases, decisions regarding withdrawing the participant will be made on the side of caution.

Our recruitment process will begin with HANDLS staff creating a list of eligible persons who match our study's demographic critera (noted above). HANDLS will initiate contact with eligible persons through a mailed letter (attached) indicating that we will be contacting them regarding our study. HANDLS staff also will attempt to make telephone contact with these persons. In addition, eligible persons who have a regularly scheduled HANDLS follow up visit also will be given information regarding our study at that time. At all times HANDLS staff will communicate that participation in our study is completely voluntary and will not impact the individual's participation in HANDLS. If a person indicates at any point that they are not interested in our study their name will be removed from the list of eligible persons.

Once HANDLS has attempted mail and/or a telephone or in-person contact with eligible persons, the name will be given to our study staff (with the

exception of persons who indicate to HANDLS that they do not wish to participate in our study). Our study staff will then attempt to contact each person to determine their interest in participating in our study. This contact may be via the telephone or in-person. If we are unable to reach the eligible person we will attempt to recontact a maximum of four times. After four attempts, the name will be removed from the list.

Once a person indicates they are willing to participate the interviewer or study coordinator will schedule a time and location for meeting with the participant to complete the informed consent process and to conduct the ethnographic interview. Participants may elect at any time to complete the interview in one or two sessions.

6) Procedures: Describe the study design and all procedures to which human participants will be subjected.

At the start of the interview meeting, the interviewer will engage in the informed consent process. This process is described below in Section 11, Process of Consent. After the participant consents to participate, the ethnographer will begin the ethnographic interview. The ethnographic interview (attached) explores the participant's diabetes health beliefs, experiences, treatment seeking, and the role of the friends and family. The interview will be audio-recorded with the permission of the participant. Based on our experience we anticipate the interview will take 1.5 hours to complete. In order to limit fatigue, the interview will be conducted in one or two sessions at the discretion of the participant. If the participant decides to break the interview into two sessions, we will attempt to complete the second interview session within one week of the first session. At the beginning of the second session, the interviewer will re-establish rapport with the participant through an informal discussion of the participant's week and the prior interview portion. Ethnographers also may telephone participants within a week of completing the interview for a brief (10-15 minute) follow up to clarify any responses that are unclear in the interview.

The in-person interview will occur at participants' homes or the location of their choosing (e.g., a senior center, library, coffee shop). Each participant will receive \$50 upon the completion of the interview. If the interview is split into two sessions the participant will be given \$20 at the end of the first interview ; the remaining \$30 will be given at the completion of the interview.

In addition to the audio recording, interviewers will keep systematic field notes of all contacts with participants, including interesting or unusual data and physical descriptions of context not recorded in the oral interview. Interviewers will refer to participants by ID or pseudonyms in their fieldnotes. Interviewers will not place participant identifying information in their fieldnotes.

Interviewers and the senior investigators will meet regularly to discuss the status of the project and to review findings. These meetings will be recorded and become part of the project data records. Participants will be identified by

id numbers or pseudonyms during the team meetings.
A professional transcriptionist will transcribe all recorded sound files (i.e., interview and team meeting recordings) into Microsoft Word. The audiorecordings will be identified only with an id number prior to being sent to the transcriptionist.

7) Data Collection, Storage and Confidentiality: How will data be collected and recorded?

Will it be associated with personal identifiers or coded to protect personal privacy? Who will have access to the data and/or to the codes? If data with participant identifiers, who will have or maintain access to this information? If a participant decides to withdraw from this study, what procedures will you use to protect the confidentiality of the data during your analysis? Provide a location where data records or information will be stored or available. Where will data and associated protocol files reside upon completion of the study? Confidentiality of collection of sensitive information may require investigators to follow [reporting guidelines](#). Describe these steps in this section.

Study data include the audio recordings of interviews and their transcriptions, interviewer fieldnotes, and team meeting notes and their transcriptions. All participants will receive an id number and pseudonym, which will be used in all study records. The key linking participants' contact information and their id number/pseudonym will be kept in a locked cabinet and a password protected file on a password protected computer in the locked Center for Aging Studies. Only study staff will have access to this key. The key will be destroyed at the completion of the study.

Study data also will include measures of participants' demographic and diabetes status that were obtained by HANDLS as part of their epidemiological survey. This may include participants' age, income, education, insurance status, HbA1c test results, fasting blood glucose levels, patient history as it relates to diabetes (e.g., diagnosis and treatment history, complications, or referral history for diabetes care) and participants' self-reported diabetes history and diabetes medications. Participants completed a HIPAA waiver when they initially consented to participate in HANDLS. It is our understanding from the HANDLS PIs that this HIPAA waiver was designed to cover the use of patient medical data by HANDLS collaborators such as ourselves. The HANDLS HIPAA waiver is attached

All written and audio records will be stored in the locked Center for Aging Studies. All file cabinets are locked and computers are password protected. Copies of electronic and paper files also may be transferred to senior investigators and research staffs' UMBC password protected computers (i.e., laptops) for purposes of data coding and analysis. The electronic and paper data files used by senior investigators and research staff for data coding and analysis will not contain participants' identifying information.

If a participant decides to withdraw from the study, the information collected to that point will be included in the study.

Upon the completion of the study paper and electronic data files will continue to be stored in the Center for Aging studies. In addition, copies of the electronic data files also will be held by HANDLS investigators on their password protected computers in their secure offices located on the NIA Bayview campus.

A note about sharing data: data sharing provides an efficient and feasible method to making comparisons across populations, the promotion of interdisciplinary analysis, the validation of original results, etc. This openness has been a norm of science and a well established practice across the disciplines. Openness and transparency about the sharing of data should be discussed in the consent process with participants and that participants have the option of

being excluded from research participation if they do not also agree to data sharing. All participants must be informed in the consent process and document if their data will be shared to parties outside of the research team.

8) Research that use data, records or human biological specimens with direct participant contact:

What procedures will you and the research team put into place to minimize or eliminate exposure to potentially infectious agents that may be present in the specimens (i.e. human blood, tissues or body fluids)? Describe your plan for exposure control and personnel protection.

(see [IRB guidance](#))

Will the activities of this research fall under the HIPAA Privacy Rule? Yes No

If "Yes," describe the procedures you will use to comply with the HIPAA Privacy Rule
(review HIPAA information at http://www.umbc.edu/irb/IRBResearchersGuide_09_13_11.pdf) We will have access to participants' medical data related to their diabetes. It is our understanding from the HANDLS PIs that participants have completed a HIPAA waiver which allows us to access these records.

9) Research that use data, records or human biological specimens without direct participant contact: Additional information about the use of data may be found at <http://www.umbc.edu/research/ORPC/IRBspecialtopics.html#archival>

If you are requesting permission to collect or study existing data or biological specimens (**Expedited category #5**), complete the below. **If not, skip to # 10.**

What are the types of data or specimens?

- Data already collected for another research study
- Medical records
- Patient specimens (tissues, blood, serum, surgical discards, etc.)
- Other (specify): _____

What is the source of the data or specimens and how were they collected? Describe the process of data collection including consent, if applicable.

Are the data or specimens publicly available? (That is, can the general public obtain the data or specimens? Data are not considered publicly available if access is limited to researchers.)

If the data or specimens are not publicly available, are you required to obtain permission to access these? Yes No If the answer is "yes," attach a copy of the correspondence granting you permission.

Will you be receiving data or specimens in an identifiable format or that will remain identifiable in the research records? Yes No What confidentiality measures will you put into place to protect identities?

Data holders whose archives are available on a restricted basis have certain conditions for use and possession. Investigators (the "data users") must be aware of these provisions as their research must conform with confidentiality and data protection provisions of the [Confidential Information Protection and Statistical Efficiency Act of 2002 \(CIPSEA\)](#), the [Health Insurance Portability and Accountability Act \(HIPAA\) Privacy Rule](#) and/or the [Family Educational Rights and Privacy Act \(FERPA\)](#). Each of these regulations obligates "data users" to protect the privacy and confidentiality of personal identifiable information that they possess and to obtain permission, when warranted, from individuals to disclose information. Users may also be audited by federal agencies to make sure they are following proper procedures. Penalties for non-compliance with these regulations include financial fines and/or imprisonment.

What procedures will you and the research team put into place to minimize or eliminate exposure to potentially infectious agents that may be present in the specimens (i.e. human blood, tissues or body fluids)? Describe your plan for exposure control and personnel protection.

10) Risks/Benefits: What potential benefits may participants receive as a result of their participation in the research? What are the potential risks/discomforts associated with each intervention or research procedure? What procedure(s) will be utilized to prevent/minimize any potential risks or discomfort?

There is no physical or health risk in the proposed research. There is the possibility that a participant might become anxious or upset when discussing matters pertaining to their health or life experiences, but based on our previous research with difficult topics we believe the chances of this to be very slight. Should an upset occur, however, the interviewer will offer to stop the interview, remind the participant that participation is voluntary, and offer to reschedule the rest of the interview. Our general experience in conducting both community and institutional based research is that participants enjoy the opportunity to talk about their lives and experiences.

There are no direct study-related benefits to participants. However, participants may receive some benefit from interaction with friendly visitors who will listen attentively to their views. In addition, for participants who indicate that they are not engaging in any activities to control their diabetes or its complications the interviewer will encourage the participant to seek out medical attention.

11) Process of Consent: How and where will the consent process take place? Who, among the research team members, will obtain consent? What information will be provided to participants if a research study deals with anonymous research, recording instruments or reportable activities (e.g. illegal drug use, child abuse, etc.) What steps will be taken to avoid coercion or undue influence? Describe the process here and make sure the process is consistent with description in the consent or assent forms.

The consent and the interview will be conducted at a time and location that meets the needs and wishes of the participant. At the start of the consent process, the interviewer will ask for the participant's permission to turn on an audiorecorder. This will allow the interviewer to record the verbal consent. The interviewer and the participant will discuss the purpose of the study and the participant's rights using the information sheet as a guide for the discussion. The participant will receive a copy of the information sheet to keep. The interviewer will read the information sheet aloud, unless the participant specifically indicates that he or she does not want the interviewer to read the sheet. The interviewer will discuss the key points of the information sheet and ask the participant if he or she has any questions. The participant will then be asked to restate what he/she is agreeing to do in the study. The participant will be asked to state if he/she agrees to participate. The participant also will be asked to state permission to audiorecord the interview. We are using a process of recorded oral consent as we anticipate our population may be reluctant to sign their name. While persons may be very willing to participate, signing a document could cause undue anxiety.

Note: If there is any uncertainty as to the participant's degree of understanding the interviewer will confer with the PI and senior investigators regarding the participant's inclusion in the study.

Which forms are attached to this application?:

Informed consent form child assent form waiver of written consent *****
 Oral Consent Telephone consent Information sheet Electronic signature “check-box” via an on-line

***** Note: protocols of less than minimal risk will not require the submission of a waiver of written consent form. You must, though describe above, how participants will be informed and check below which document will be used to provide study information.

Use the appropriate forms found at http://www.umbc.edu/research/ORPC/IRB_consentsassent.

12) Location: Where will the study be conducted? If not on campus, what is the nature of your cooperative arrangement with those in charge of the research site? Provide approval documents from the cooperating institution.

Interviews will occur at the location of participants' choosing, such as their home private spot at a local restaurant, coffee shop, public library, or senior center.

13) Independent reviewers: If your protocol is **More than Minimal Risk**, please list the names and contact information (telephone, e-mail, address) of 3 experts in your field who can independently evaluate your proposal and assist the IRB in the review process.

Protocol Application checklist

- A one-paragraph abstract describing the protocol
- Copy of IRB approval from collaborative institutions
- Investigator(s) vita
- Consent documents
- Questionnaires, survey instruments
- Adverse reaction references/citations
- Advertisements/recruitment letters

If not needed for the study, please explain:

Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure

Applicability

(A) Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

(B) The categories in this list apply regardless of the age of subjects, except as noted.

(C) The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

(D) The expedited review procedure may not be used for classified research involving human subjects.

(E) IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the IRB.

(F) Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

Please check the category that applies

1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

(b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3) Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

6) Collection of data from voice, video, digital, or image recordings made for research purposes.

7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

Appendix 8.3: Diabetes substudy – oral consent form

**Information Sheet for Participation in the
Subjective Experience of Diabetes Research Project**

Whom to Contact about this study:

Principal Investigator: J. Kevin Eckert
 Department: UMBC Dept. of Sociology & Anthropology
 Telephone number: 410-455-5698

I. INTRODUCTION/PURPOSE:

I am being asked to participate in a research study. The purpose of this study is to understand what it is like to have diabetes. I am being asked to volunteer because I have participated in the HANDLS study and I have been diagnosed with Type 2 Diabetes (also known as Diabetes Mellitus or adult-onset diabetes). My involvement in this study will begin when I agree to participate and will continue until the completion of the interview, approximately 1 and 1/2 hours. This interview may occur over one or two interview sessions, depending on my preference. I also may be contacted for a 10-15 minutes follow-up telephone call if the interviewer needs to clarify any of my responses from the interview. About 80 persons will be invited to participate over the next two years.

II. PROCEDURES:

As a participant in this study I will be asked to complete an in-person interview that explores my experiences with my diabetes, including what I think has caused it, my eating, exercise, and treatment behaviors, and the reactions of my friends and family to my diabetes. I will be asked to come to a location of my choice or if I prefer, the interviewer will come to my home. My participation in this study will last for an interview of approximately 1 and ½ hours. This interview may occur over one or two interview sessions, depending on my preference. The interview will be audio-recorded and the interviewer also will take notes during the interview. No personal identifying information will be written with responses to the questions. I also may receive a follow-up telephone call that will last 10-15 minutes if the interviewer needs to clarify any of my responses from the interview.

III. RISKS AND BENEFITS:

My participation in this study does not involve any significant risks. I have been informed that my participation in this research will not benefit me personally, but that the findings may help health care providers to develop more effective diabetes programs. If I become uncomfortable answering any questions I can skip those questions or decide to answer at another time. I also can choose to end the interview at any time.

IV. CONFIDENTIALITY:

Any information learned and collected from this study in which I might be identified will remain confidential and will be disclosed ONLY if I give permission. All information collected in this study will be stored in a locked file cabinet in a locked room. Only the investigator and members of the

<p>Y12KE21206 info sheet</p> <p>UMBC AN HONORS UNIVERSITY IN MARYLAND</p> <p>Approved by the Institutional Review Board</p> <p>P a g e 1</p>	<p>Permitted for use</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="padding: 2px;">From</td><td style="padding: 2px;">01/04/2013</td></tr> <tr> <td style="padding: 2px;">To</td><td style="padding: 2px;">01/03/2014</td></tr> </table> <p>UMBC ORPC: 4/30/2013 7:35 PM</p>	From	01/04/2013	To	01/03/2014
From	01/04/2013				
To	01/03/2014				

research team will have access to these records. If information learned from this study is published, I will not be identified by name. By agreeing to participate, however, I allow the research study investigator to make my records available to the University of Maryland Baltimore County (UMBC) Institutional Review Board (IRB) and regulatory agencies as required to do so by law.

Consenting to participate in this research also indicates my agreement that all information collected from me individually may be used by current and future researchers in such a fashion that my personal identity will be protected. Such use will include sharing anonymous information with other researchers for checking the accuracy of study findings and for future approved research that has the potential for improving human knowledge.

I am being asked for permission for this interview to be audiotaped. I may choose whether I give permission to record my voice. The interviewer will ask me to state out loud whether I give permission for this audiotaping.

Although my confidentiality in this study is protected, confidentiality may not be absolute or perfect. There are some circumstances where research staff might be required by law to share information I have provided. For example, if an interviewer has reason to believe an elderly person is being abused (or has been abused), the interviewer is required by Maryland state law to file a report with the appropriate agencies. Similarly, if I report that I was abused as a child, the interviewer may also have to file a report. In addition, if I am threatening serious harm to myself or another person, it may be necessary for the interviewer to warn an intended victim, notify the police or take the steps to seek hospital based treatment.

V. SPONSOR OF THE RESEARCH:

The National Institutes on Aging of the National Institutes of Health is funding this research.

VI. COMPENSATION/COSTS:

My participation in this study will involve no cost to me. I will receive \$50 for my participation at the time of the interview. If I complete the interview in two sittings, I will receive \$20 at the completion of the first sitting. I will receive the remaining \$30 at the completion of the interview.

VII. CONTACTS AND QUESTIONS:

The interviewer, [Name of interviewer will be inserted], has offered to and has answered any and all of my questions regarding my participation in this research study. If I have any further questions, I can contact Susan Goldman, the project coordinator at 410-455-5534 or by email at sgoldman@umbc.edu. I also can contact the project PI, Kevin Eckert, at 410-455-5698 or by email at eckert@umbc.edu. If I have any questions about my rights as a participant in this research study, I can contact the UMBC Office for Research Protections and Compliance at (410) 455-2737 or compliance@umbc.edu

Y12KE21206 info sheet  AN HONORS UNIVERSITY IN MARYLAND Approved by the Institutional Review Board Page 2	Permitted for use From <u>01/04/2013</u> To <u>01/03/2014</u> UMBC ORPC: 4/30/2013 7:35 PM
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VIII. VOLUNTARY PARTICIPATION

I have been informed that my participation in this research study is voluntary and that I am free to withdraw or discontinue participation at any time. I have been informed that data collected for this study will be retained by the investigator and analyzed even if I choose to withdraw from the research. If I do choose to withdraw, the investigator and I have discussed my withdrawal and the investigator may use my information up to the time I decide to withdraw. Participation in this study does not impact my relationship with the HANDLS study or UMBC.

After I finish reviewing this information sheet with the interviewer and the interviewer answers all my questions, I will be asked to state aloud if I agree to participate in this research study. I will be given a copy of this information sheet to keep.

Y12KE21206 info sheet  AN HONORS UNIVERSITY IN MARYLAND Approved by the Institutional Review Board Page 3	<i>Permitted for use</i> From <u>01/04/2013</u> To <u>01/03/2014</u> <i>UMBC ORPC: 4/30/2013 7:35 PM</i>
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Appendix 8.4: Diabetes substudy – approved waiver of signed consent



**Office for Research Protections and
Compliance**

University of Maryland, Baltimore County
1000 Hilltop Circle
Baltimore, MD 21250

PHONE: 410-455-2737
FAX: 410-455-3868
EMAIL: compliance@umbc.edu

Approval of a Waiver of Signed Informed Consent

Attachment to approval letter dated January 8, 2013

Protocol #: Y12KE21206

Investigator(s): Kevin Eckert, Sarah Chard, Bob Rubinstein

Protocol Title: The Subjective Experience of Diabetes Among Urban Older Adults

Approval Date: January 4, 2013

The UMBC Institutional Review Board has approved your use of the waiver of signed informed consent for the above protocol. The below type of waiver you have requested has been approved:

- 1) A waiver of written informed consent because the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research and the subject's wishes will govern.
- 2) Waiver of written informed consent because the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.
- 3) Waiver or modification of specific written informed consent elements because the protocol meets **all four** of the following criteria:
- (1) The research presents no more than minimal risk of harm to subjects.
 - (2) The waiver or alteration will not adversely affect the rights and welfare of the subjects.
 - (3) The research could not practicably be carried out without the waiver or alteration.
 - (4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Researchers are reminded again that they are required to inform participants in written or verbal form of the primary purpose of the research project and of any procedures which they will undergo. Additionally, participants are to be informed of their rights regarding the study (voluntary participation, protecting anonymity and privacy) and any risks or benefits associated with the project. Evidence of this information must be maintained in the investigator's protocol file.

11/05/05

Appendix 8.5: Diabetes substudy – protocol

Specific Aims

Rates of type 2 diabetes mellitus (T2DM) have grown significantly in the last decade, with high prevalence rates particularly common among older adults and minorities.^{1, 2} Self-management is often promoted as a key to mitigating the effects of diabetes, but adherence to self-management recommendations can be difficult for patients, and providers often are limited in their ability to facilitate patient self-management.² We argue that the *subjective construction and definition* of diabetes and its management must be examined to more effectively address the diabetes epidemic. [By identifying what people themselves think about their illness and its management we can help providers to better attend to the self-management concerns and constraints facing African-American and non-Hispanic white older adults within urban settings.]

The proposed 36-month study investigates the subjective construction of diabetes among African-American and non-Hispanic white older adults, age ≥ 50 , with T2DM, living in Baltimore City ($n=80$). We will use the McGill Illness Narrative Interview (MINI), a semi-structured ethnographic interview guide that we have modified for this study.³ We seek to identify how local social, cultural, and material contexts inform participants' conceptions of their diabetes, perceptions of its risk factors and comorbidities, and their approach to managing their illness.

This study involves a unique partnership with the NIA Intramural Healthy Aging in Neighborhoods of Diversity across the Lifespan Study (HANDLS), a community-based, epidemiological study of cardiovascular and cerebrovascular disease risk in Baltimore ($n=3722$). Initiated in 2004, HANDLS is a 20-year, prospective, fixed-cohort study with interview waves occurring at least every 3 years. At baseline, the prevalence of T2DM in HANDLS' sample was 17% (Zonderman, personal communication, 4/28/11). While the HANDLS staff informed participants about their diabetes diagnosis, HANDLS provides no diabetes intervention or treatment and is not investigating participants' diabetes knowledge or management. By drawing our sample from HANDLS, we will have a community-based sample of persons with clinically diagnosed diabetes. As a community-based rather than clinic sample, our sample is not limited to persons who are predisposed to or able to access a biomedical clinic or intervention. Our sample will include adults who were diagnosed with diabetes and responded with whatever action they deemed fit, including no action.

The proposed research has four specific aims:

1. Identify participants' subjective accounts of their diabetes, including perceptions of the etiology, risk factors, symptoms, secondary conditions, and short and long term outcomes of their diabetes
2. Elicit participants' diabetes management practices, including perceptions and use of biomedical and lay (popular or folk) health care resources and self-management activities
3. Explore participants' accounts of the social context within which their diabetes is embedded, including how participants manage their diabetes with respect to other responsibilities and constraints, such as family care taking, job constraints, transportation, finances, time commitments, or other illnesses
4. Determine the race and gender variations in participants' subjective understanding of their diabetes, their diabetes management strategies, if any, and the social contexts surrounding their diabetes

Together, addressing these specific aims will provide rich, detailed insight into the subjective definition and construction of diabetes and diabetes management among urban older adults, and the race and gender variation in these constructions. [We believe these aims will offer providers a better understanding of the subjective arenas in patients' lives that must be taken into account when working conjointly with patients to develop self-management plans.]

(a) Significance Diabetes is the seventh leading cause of death in the United States.⁴ T2DM accounts for 90-95% of diagnosed diabetes and is predicted to nearly double over the next 15 years.¹ Diabetes disproportionately affects older adults, people of color, and individuals within urban environments,^{1, 5} with both African-American and women's diabetes mortality rates in particular increasing over the past several decades.^{4, 6} African-Americans and women also experience more diabetes-related complications.⁷ These secondary conditions such as cardiovascular disease, stroke, dementia, diabetic neuropathy, amputations, renal failure and blindness compound what has grown into a public health crisis. Diabetes-related health care costs consume approximately 20% of US total health care expenditures and are expected to nearly triple by 2034.^{4, 8} Notably, 91% of these costs are associated with persons aged ≥45.⁵ Addressing diabetes prevention and treatment, then, is a leading US public health priority.⁹

As with the prevalence of diabetes, urban, race, and gender disparities are found in diabetes treatment and self-management. With respect to geographic differences, medication adherence and self-management can be particularly challenging in urban environments with variable health care, transportation, food, and exercise opportunities.¹⁰⁻¹⁴ Overall, African-Americans with diabetes are less likely to meet national exercise recommendations than non-Hispanic whites.¹⁵ Similarly, women are less likely to engage in diabetes self-management than men,¹⁶ with older adult diabetic women in particular being less likely to meet national exercise recommendations.¹⁵ Women also report high levels of self-blame regarding their illness,^{17, 18} numerous barriers to self-care,¹⁹ and high rates of stress in managing care-giving responsibilities in addition to their own diabetes self-care.²⁰

To address race and gender disparities, many diabetes control efforts call for "cultural sensitivity" and for the creation of programs that recognize the cultural context of high-risk populations.²¹⁻²⁵ With very few exceptions,²⁶⁻³⁰ however, previous studies have not explored how persons with diabetes define and conceptualize their illness and illness management. Extant ethnographic research generally is limited to understanding diabetes in terms of the health beliefs of specific ethnic groups such as Latino, Native American, and Bangladeshi,^{27, 31-39} and may presuppose a belief system based upon group affinity. Furthermore, while research grounded in theories regarding cumulative disadvantage,⁴⁰ social ecology,⁴¹ and stress,^{29, 33, 42} have sought to explain race and gender differences in chronic conditions like diabetes with respect to broader political and economic disparities, few studies have examined how subjective understandings of diabetes and treatment vary both across and within male and female African-American and non-Hispanic white groups.^{43, 44}

[Finally, there is growing acknowledgement that decades of education and behavior change interventions have had mixed success in creating sustained diabetes self-management,^{45, 46} and renewed attention to patient-centered approaches to diabetes management is needed.⁴⁷ It is our premise that real progress in controlling diabetes cannot be made until we take seriously the individual's personal ideas about diabetes, such as diabetes' nature, definition, progression, priority and treatment. Providers in particular need a deeper understanding of patients' subjective diabetes worlds. Through attention to the subjectivity of diabetes, providers can promote clinical encounters that not only diagnose and educate, but that help patients to negotiate the beliefs and contexts that play a role in self-management.]

The proposed study, using ethnographic interviewing, will examine individual, subjective conceptualizations of diabetes and self-management among male and female, African-American and non-Hispanic white older adults in an urban environment. We should note that we employ the term "race" in this proposal to refer to socially constructed ideas of group difference; we are not presupposing the existence of biological difference. The study will provide critical information on the ways in which subjective definitions, subjective experiences, shared and idiosyncratic illness models and varied social contexts underlie participants' construction of and self-management of their diabetes. We will address the gap in understanding of the subjective experience of diabetes and the operation of cultural processes among male and female African American and non-Hispanic whites with diabetes.

(b) Innovation This application seeks to augment current research in several ways. *First, the proposal builds on a unique, community-based, longitudinal study with a population that already has*

been characterized with regard to diabetes. Once participants enter the HANDLS sample, there is no active follow up with a goal of modifying treatment behaviors or clinical outcomes. This community-based sample makes the study population distinctive from a clinical population that might have greater predisposition to seeking ongoing biomedical care.

Second, the research takes a novel approach to the study of diabetes. Unlike most studies of diabetes, we take a social constructionist perspective that allows us to focus on subjective and cultural understandings that research participants have concerning their diabetes, its symptoms, and its potential treatments. We strongly believe that non-biological understanding (i.e., lay and popular beliefs/theories) should not simply be dismissed as wrong; thus, our interest is in the empirical question: What is it that people *do* believe? The extremely limited research in this area shows that many sources, personal, popular, and biomedical, shape lay beliefs about diabetes.^{26, 38, 48, 49} Thus, our desire is to focus on participants' subjective beliefs and their sources. In so doing, we will examine peoples' understandings of diabetes in terms of both the meaning the illness has for individuals and the social, cultural, and contextual processes in which such meanings are embedded.

Third, our proposed study is innovative in that, as part of a social constructionist perspective, we hope to better understand the role of race and gender in peoples' understandings of diabetes, its causes, and treatment in an urban context. While clearly many prior analyses have examined ethnic and racial differences in diabetes and diabetes knowledge, this will be one of the first studies to treat race and gender as critical ethnographic components. We will dig deeper to understand how subjective experiences and cultural processes operate with respect to both male and female African-Americans and non-Hispanic whites, and the variation in those experiences within and across the groups.

Fourth, in order to achieve our aims, our methodology utilizes a modification of the McGill Illness Narrative Interview (MINI), a semi-structured ethnographic guide.³ The MINI is unique among published qualitative interviews by using primarily open-ended questions to elicit the complex lay explanations of the nature, symptoms, causes, course, and appropriate treatment of an illness, the responses to an illness, and the social context surrounding those illness responses.⁵⁰ [As noted below, the MINI has been modified to elicit participants' social construction of and subjective experience with diabetes. As is common with qualitatively oriented, open-ended interview protocols, questions in the MINI will evolve reflexively based on early findings and feedback from interviewers.³]

(c) Approach The proposed 36-month research project involves an ethnographic interview with a stratified sample (N=80) of HANDLS participants who have a diagnosis of T2DM and who meet the other inclusion criteria (aged ≥50, English-speaking, cognitively intact; see below). The sample will be stratified on the basis of gender and race (20 African-American males; 20 African-American females; 20 non-Hispanic white males; 20 non-Hispanic white females).

This study's methodological approach and theoretical grounding builds on the previous qualitative, ethnographic work of our research team. Eckert's previous research has focused on examining the social and cultural factors influencing well-being across community settings. More recently, Eckert's (PI) and Rubinstein's (co-Investigator) NIA-funded research has used similar methods of in-depth interviewing to explore the meaning and context of well-being in community assisted living settings. Rubinstein's work has explored health and suffering in later life (NIA), death and dying in nursing homes (NIA, MERIT award recipient), lifestyles, generativity, and health issues of older women who do not have children (NIA), and control in later life (NIA), among many others. Chard's (co-Investigator) NSF and VA-funded research likewise has incorporated a similar interviewing approach and she has published on several of the treatment seeking theories used in the proposed study.⁵¹ Harris-Wallace's (co-Investigator) currently funded (NIA) research on direct care workers in long term care has provided her with experience in recruiting and interviewing minority women in health-related research. Roth (co-Investigator) has over fifteen years of ethnographic field experience working with minority, urban communities, and eight years of experience as a key team member of several Center for Aging Studies NIA-funded studies. Quinn's (co-Investigator) research documents differences among health services utilization by older diabetics⁵² and current funded research evaluates mobile health interventions to improve diabetes self-care.⁵³⁻⁵⁵

1. Ethnographic interview: McGill Illness Narrative Interview (MINI) For the ethnographic interview we will employ a modification of the MINI.³ Rooted in constructionist theory, the MINI is designed to systematically elicit participants' overarching illness narrative or the "story" of their illness and then four dimensions of participants' subjective illness experience: illness prototypes, explanatory models, treatment seeking, and the life impact of the illness. The MINI, which is designed to be modified and evolve as we propose,³ has been found to be effective in examining the construction of a range of illness experiences.^{56, 57} To our knowledge, however, we are the first to employ the instrument to obtain a comprehensive view of the diabetes illness experience. The detailed, modified interview guide is attached (see Appendix).

We will briefly describe the relationship between our specific aims and the MINI interview guide. First, to address specific Aim 1, *Identify participants' subjective accounts of their diabetes, including perceptions of the etiology, risk factors, symptoms, secondary conditions, and short and long term outcomes of their diabetes*, section 1 of the MINI asks participants tell their own "story" of their diabetes, establishing an interviewing dynamic wherein participants are the narrators of and experts on their diabetes. From Kleinman's⁵⁸ argument that "illness," that is, the interpretation of biological processes, is the appropriate focus of study, the MINI is designed for the participant to elaborate on personal conceptions of an illness, rather than biomedical symptoms alone.

In section 2 the MINI interview then operationalizes three major models for understanding the subjective illness experience: illness chain complexes, prototypes and explanatory models. "Chain complexes" represent the historical life experiences or events that persons metonymically relate to their illness. Prototypes are the previous illness experiences that individuals associate with their own illness. These prior events or illnesses may have been experienced by the individual, family, or friends and often are used to interpret and attach meaning to a current illness. Identifying chain complexes and prototypes can provide a type of insight into participants' perceived "knowledge" or understandings of the illness experience that often is not revealed in traditional clinical interviews.⁵⁹⁻⁶¹ Kleinman's⁵⁸ related, but distinct, concept of illness explanatory models refers to participants' perceptions of the biological, social, and material roots of their illness, the perceived treatment, and their short and long term illness expectations. This includes exploring participants' understanding of the body's experience of diabetes and diabetes' relationship to other health conditions.

To address specific aim 2, *Elicit participants' diabetes management perceptions and practices, including perceptions and use of biomedical and lay (popular or folk) health care resources*, section 3 of the MINI explores participants' treatment seeking and self-management. Questions are designed to elicit all aspects of formal and informal care, including biomedical, popular, and lay or folk health care activities.^{62, 63} In this section of the interview participants are encouraged to talk about their experiences with health services sought (whether biomedical or other), and their response or reaction to treatment recommendations. Preliminary studies indicate health care experiences, (e.g., perceived participation in medical decision-making), correlate with understanding of self-management.^{64, 65} In addition, poor health care provider communication has been noted as a barrier to self-management activities, particularly among urban African-Americans.^{38, 66} To explore these relationships in more detail, we will include probes regarding participants' perceptions of the accessibility and limitations of their health service providers, as well as why participants view their health service agencies or providers as helpful or unhelpful with their diabetes.

Because self-management is a large component of public health efforts to address diabetes, a major portion of this section of the interview will be devoted to exploring participants' diabetes self-management. After participants fully describe their beliefs and experiences with self-management the interviewer will use probes to inquire about specific self-management activities if they are not mentioned in the initial response, including participants' views on glucose-monitoring, diet, exercise, and taking insulin. This use of open-ended questions followed by probes will ensure that we obtain participants' own conceptualizations of their self-management as well as the activities and obstacles surrounding self-management strategies that are well-defined in the literature as critical for diabetes care.^{67, 68, 69} [We will emphasize throughout this section the goal is to hear participants' personal views of diabetes management, including their frustrations with self-management and their approaches to

their diabetes that may not be discussed with their health care providers. The interviewers will make explicit that we are not seeking a “correct” answer.]

To address specific aim 3, *explore participants’ accounts of the social context within which their diabetes is embedded, including how participants manage their diabetes with respect to other responsibilities and constraints, such as family care taking, job constraints, finances, time commitments, or other illnesses*, the MINI’s section 4 elicits participants’ perceptions of the role of their personal, social, and material life in their diabetes. This section of the interview provides detail on the connection between participants’ broader social contexts and their diabetes. Rather than viewing illness beliefs in isolation from social context, participants relate their illness experience to the significant features of their broader social world. Participants will describe how formal (or informal) treatment seeking and self-management is (or isn’t) incorporated to daily life and how their social context influences their diabetes management. Building on the literature noting that both social and physical contexts correlate with treatment and self-management,^{70, 71} we will probe to identify more precisely *how* contexts, including participants’ self-identities, family roles, economic resources, and employment, interrelate with their diabetes experience.

Critiques of explanatory model approaches suggest studies of explanatory models should not overemphasize the role of personal belief systems relative to the social and material contexts that surround and inform the illness experience.^{51, 72, 73} Critics further suggest that studies of diabetes have too often focused on individual attitudes and behaviors without sufficient consideration of the influence of the local environment.^{41, 48} We have selected the MINI in part because we believe it *will* provide further insight into the sociocultural contexts and interpersonal issues that may inform subjective diabetes understandings, treatment seeking, and self-management.

Specific aim 4 *Determine the race and gender variations in participants’ subjective understanding of their diabetes, their diabetes management strategies, if any, and the social contexts surrounding their diabetes*, will be obtained by analyzing the responses described above within and across race and gender groups. Further details are included in the analysis section below. This specific aim is grounded in the literature indicating that knowledge of self-management and adherence to self-management varies by race and gender.^{19, 65, 74, 75} We seek to identify *how* identities, roles, and other social processes operate with respect to subjective understandings of diabetes and diabetes management, identifying the similarities and variation in these processes within and across the subgroups.

Thus, through the MINI, we will obtain detailed data on participants’ subjective diabetes experiences, from their conceptualization of their illness, to their treatment seeking and self-management, to the relationships among their illness experience, social roles, and broader social context. We will contribute to further understanding of these processes between male and female older adult African-American and non-Hispanic whites living in an urban context.

2. Sample Selection The sample for this study will be drawn from HANDLS (n=3,720), an epidemiological study of African-American and non-Hispanic white health disparities in twelve Baltimore City neighborhoods that began in 2004 and is designed as a 20-year, prospective, fixed-cohort study of adults aged 30-64. At baseline, the mean age of the HANDLS sample was 47.7, 59% were African-American, 45% were male, and 41% lived below the 125% household poverty line.⁷⁶ As HANDLS started in 2004, the cohort is now aged 38-72. We will draw our sample specifically from a HANDLS subsample (n=500) that represents the age, race, gender and poverty strata of the overall HANDLS sample; these participants have indicated willingness to participate in further studies.

Our study sample (n=80 HANDLS participants aged ≥50) will be stratified by race and gender. The sample stratification will allow us to address specific aim 4, *determine the race and gender variations in participants’ subjective understanding of their diabetes, their diabetes management strategies, if any, and the social contexts surrounding their diabetes*. Although HANDLS’ age range will limit our sample to persons aged 50-72, drawing our sample from HANDLS provides unique access to a community population that has been screened for diabetes. We will be able to characterize the diabetes burden of our sample, including at least one measure of diabetes control

and diabetes duration and we may capture persons who might not normally be included when using a clinic-based population, i.e., persons not seeking treatment for their diabetes.

We have selected a cell size of 20 (total N=80) based upon the existing literature and our extensive prior experience with qualitative research, all of which suggest that pattern saturation in code-based analysis can be reached with a cell size of 20.⁷⁷⁻⁸⁰ HANDLS anticipates that filling these cells from the subsample population is feasible. If necessary, should the subsample not contain enough participants to meet our sample criteria, we can recruit the remainder of our sample from the larger HANDLS population (Zonderman, personal communication, 4/28/11). [Within each cell we also will attempt to purposively sample to ensure inclusion of persons whose diabetes appeared controlled and persons whose diabetes appeared less controlled at the time of the most recent HANDLS assessment (i.e., fasting blood glucose levels above and below 154 mg/dl or HbA1c values above and below 7%)]. In the initial 2004 interview HANDLS participants were diagnosed with diabetes based on self-report, taking prescription medications for diabetes, or fasting glucose levels exceeding 125 mg/dl. HANDLS includes these measures and HbA1c testing in each three-year follow-up evaluation. Finally, our participants may have entered HANDLS knowing of their diabetes or they may have been diagnosed over the course of the study. [We therefore anticipate our sample will include variation in illness duration. However, we will adjust our sampling strategy in the field if needed in order to ensure the inclusion of variation in diabetes duration.]

To summarize our relationship with HANDLS, the HANDLS project provides a backdrop for the proposed research in that it will help us access a community sample with diabetes and to know their diabetes duration and at least one clinical measure of control. The proposed study's innovative focus, however, is on participants' subjective understandings of their diabetes and diabetes management.

3. Exclusion Criteria and Participant Honoraria As a subsample of HANDLS, our study incorporates HANDLS' exclusion criteria. HANDLS excludes persons with a diagnosis of AIDS (but not HIV), persons receiving cancer treatment within the past 6 months, and persons using illicit drugs. Persons on methadone maintenance who are not currently using illicit drugs, however, are not excluded. In addition, persons for whom an MRI is contraindicated (e.g., metal implants or claustrophobia) are excluded. Participants who are unable to give informed consent due to cognitive impairment also are excluded. Because of HANDLS' stringent screening medical evaluations that include both a medical exam and mini-mental state examinations, we anticipate our sample will not include persons with cognitive impairment. As noted in the human subjects plan, however, if an interviewer does observe that a participant is unable to coherently complete the informed consent or an interview, the interviewer will confer with the team regarding withdrawing the participant. In all cases, decisions regarding withdrawing the participant will be made on the side of caution. Each participant will receive \$50 upon the completion of the interview. This monetary amount and distribution method is consistent with HANDLS in respecting participants' decision-making autonomy regarding the use of the incentive.

4. Project Timeline

As Table 1 indicates, the proposed study consists of three general phases: 1) organization and training; 2) fieldwork, data processing, and coding; and 3) analysis and write-up.

Table 1: Project Timeline

Project Activities	Months 1-3	Months 4-27	Months 28-36
Phase 1: Organization & Training			
a. Hire & Train Staff	X		
b. Finalize MINI adaptations	X		
c. Biweekly Meetings	X	X	
d. Recruit participants - HANDLS sample	X	X	X

Table 1 continued: Project Timeline

Project Activities	Months 1-3	Months 4-27	Months 28-36
Phase 2: Fieldwork, Data Processing, & Coding			
a. Interview Participants 1-80		X	
b. Transcribe 1-80		X	
c. Create Atlas.ti database with transcriptions, fieldnotes, meeting notes		X	
d. Coding Step 1: Conceptualization		X	
e. Coding Step 2: Emergent Themes		X	
f. Coding Step 3: Codebook Construction & Testing on Interviews 1-10		X	
g. Coding interviews 11-80		X	X
Phase 3: Analysis & Write-Up			X
a. Code-based Analysis			X
b. Case-based Analysis			X

4a. Phase 1. Organization and Training (months 1-3) During the initial 3-month start-up of the project our research team, consisting of the PI, co-investigators, senior interviewer, and the project manager will finalize the MINI modifications, purchase equipment, hire an additional interviewer, and ensure all team members are trained on study procedures and the MINI interview guide. The research team has extensive research experience and we are very aware of the critical influence of the interviewers on data collection.⁸¹ We also recognize that marginalized populations may have particular concerns regarding research participation. We will attempt to mitigate these issues through careful training on interviewing procedures and the MINI interview guide. We also anticipate hiring an African-American interviewer in order to match participants and interviewers based on race and gender, when possible. In addition, the research team will meet with HANDLS' interviewers to debrief on their experiences with the study population,⁸² as well as work closely with HANDLS staff to develop a sample from which to recruit.

4b. Phase 2. Fieldwork, Data Processing and Coding (months 4-27) As described above, we will be using the MINI,³ modified to explore participants' diabetes experiences, to conduct our ethnographic interview (see Appendix for the interview guide). Our approach to ethnographic interviewing encourages participants to discuss their diabetes narrative in their own terms, relating the experiences, knowledge, or feelings that are most salient. Throughout the interview participants' natural utterances are used as starting points for additional lines of discovery and inquiry. [In this way, the MINI is an open interview that is reflexively modified during the interview. The opening section of the MINI, in which participants describes the "story" of their diabetes sets the stage for this open-ended interview process. By asking the participant to tell his or her story, the participant is the active narrator of his or her illness experience.] The interviewer then has an opportunity to develop rapport as a friendly and empathetic listener. This rapport will help participants feel more comfortable sharing detailed information regarding their lives. [The interviewer is not blind and does not assume an artificial stance of naivety regarding the participant's diabetes, but rather emphasizes at the outset of the interview that a) the interviewer is not medically trained; b) the interviewer is not judging the participant or his/her diabetes management; and c) responses will not be reported to providers or to HANDLS. As a non-clinician who is outside of the participant's regular social world, the interviewer is a neutral actor, well positioned to hear the details of the participant's experiences.]

The interview will be audio-recorded with the permission of the participant. Based on our experience we anticipate the interview will take 1.5 hours to complete.^{3, 50} In order to limit fatigue, the interview will be conducted in one or two sessions at the discretion of the participant. If the participant decides to break the interview into two sessions, we will attempt to complete the second interview session within one week of the first session. At the beginning of the second session, the interviewer

will re-establish rapport with the participant through an informal discussion of the participant's week and the prior interview portion. Interviews will occur at participants' homes or the location of their choosing (senior center, library, coffee shop).

i. Field notes: Interviewers will keep systematic field notes of all contacts with participants, including interesting or unusual data and physical descriptions of context not recorded in the oral interview. Interviewers themselves are regarded as data points because of their interactions with participants.⁸³ Fieldnotes are entered into the Atlas.ti database (see below).

ii. Team Meetings: Throughout data collection and data analysis the research team (comprised of the PI, co-investigators, interviewers and project manager) will meet bi-weekly. The team debriefs and interviewers have an opportunity to share their experiences with the on-going data collection process. Issues regarding data collection are addressed. These team meetings also bring together multiple levels of insight and engender analytic observations of the interviews. The meetings are the forum in which the inventory and first level of coding occurs (see inventory and first level coding below). Team meetings are recorded thereby becoming part of the overall data base and analytic strategy.

iii. Data Management and Processing Procedures: A professional transcriptionist will transcribe recorded sound files (i.e., interview and team meeting recordings) into Microsoft Word. The interviewers will review each transcript for clarity and accuracy, and remove identifiers. The files will be transferred to Atlas.ti, a qualitative data software management program with which we have extensive experience employing to develop publications.^{77, 84, 85}

iv. Data Coding: We have developed a rigorous approach to coding that involves establishing a small set of codes *a priori*, while the remainder and majority of codes emerge from the interviews as themes, or recurring topics and meanings. As Mishler,⁸⁶ among others, has established, qualitative coding categories and themes are generated from the meanings that are inherent within the data. *A priori* codes will include demographic and household characteristics, and codes regarding diabetes' etiology, course, and self-management, particularly insulin testing, diet, exercise and medication adherence. We anticipate emergent codes may revolve around the social experience of diabetes, challenges to diabetes management, co-morbidities, and outcome expectations (see section 4c., subsection iii. below for further discussion of the code-based themes that we anticipate for each specific aim). Our specific coding method involves a four-step process:

Step 1. Inventory and First Level Coding (months 4-6) The first step, inventory and first level coding, begins as soon as the first transcripts are available and continues through the completion of the first 10 interviews. This step involves an inventory, or a raw sort on a gross level of categorization. The research team also finalizes the *a priori* codes.

Step 2. Emergent Categories and Themes (months 6-7) After completing first level coding, the research team works in pairs to review 10 transcripts for meaningful, relevant quotations. This set of transcripts will reflect the race and gender distribution of the sample. During team meetings we then review the quotations or expressed ideas to determine how they can be categorized or organized into groups. These emergent categorizations complement the *a priori* coding by examining textual data more broadly. Through the creation of emergent categories, the words and meanings that participants express form the basis of the analysis.

Step 3. Codebook Construction and Codebook Testing (months 8-10) At this stage, the research team groups quotations and categories into formal codes that form the base of the codebook, usually around 35-40 distinct coding categories. Each research team member will independently test the codes on a new set of ten transcripts. The research team will then compare their results and revise the codebook as needed.

Step 4. Final Coding Once the codebook is developed, team members work in rotating pairs to code the additional transcripts as they become available. This process of paired, collaborative coding is designed to enhance the validity and reliability of coding.⁷⁷ The pair first codes interviews independently and then meets to reconcile differences. Irresolvable discrepancies are brought to the next team meeting for a consensus resolution.

It may be necessary to update the codebook periodically as concepts are refined or identified during the later months of the project.⁸⁷ We will adjust the codebook by adding to the definitions and meanings of coding categories and recode earlier interviews accordingly.

4c. Phase 3: Analysis & Write-Up (Months 4-36) The proposed study will address each specific aim using two types of analysis methods—code-based analysis and case-based analysis. We view the role of extant theories as sensitizing concepts that provide a frame of reference and guidance for analysis. However, with our grounding in constructionist theory, we also look to the words and actions of those interviewed to guide the analysis. Thus, theories provide direction, e.g., theories regarding racial and gendered barriers to diabetes self-management,^{20, 88} but the primary analytic goal in this proposed research is to understand the patterns and variation that emerge from participants themselves.

i. Code-based Analysis: Our code-based analysis involves moving between the formal codes described above and careful review and discussion of the transcripts and fieldnotes. We have honed our skills at this process through our 30+ years of NIA-funded ethnographic research that draws on substantial, established qualitative research literature.^{87, 89-103} Atlas.ti creates a searchable index of data codes across transcripts while at the same time permitting the review of complete transcripts. Atlas.ti also offers a memoing option to note ideas and themes that emerge during this review process. We conduct searches by codes and key concepts and identify how these codes group or form families across and within the sample cells. This allows us to systematically identify codes sharing common characteristics and/or patterns or idiosyncrasies. By also engaging in extensive reading and discussion of complete transcripts and fieldnotes, we can further consider how key concepts are contextualized in participants' diabetes narratives. For example, we can consider how poor diet and poor diabetes control are contextualized in a broader discussion of control over household meals and the availability and affordability of food within the community. Section iii below describes in detail how the case-based analysis will relate to each of the specific aims.]

ii. Case-based analysis: In this approach we view each interview as the participant's narrative of their diabetes and diabetes management. Narrative is a significant human way of processing and understanding experience.⁸⁷ The focus of the analysis is on discerning the social processes operating in a participant's illness experience. Descriptions of processes are likely to unfold over the course of the interview.

For these analyses, the unit of analysis is the individual. This approach involves carefully reviewing each interview in its entirety. An important task in analyzing such data is what Agar⁸⁷ calls "paraphrase," in this case the accounts, response and utterances of each participant. Each interview will be read by at least two project team members, with team members identifying key passages and entering memos in Atlas.ti regarding their interpretation of the meaning of an identified passage. Team members will focus on identifying ambiguous, complex or rich narrative accounts. These accounts will then be discussed at team meetings in order to identify cases that are "typical" and unique. The team will carefully consider alternative interpretations or the presence of contrasting themes in other interviews.

This analytic strategy complements the code-based effort described above by examining textual data in a more holistic, or "big-picture" manner. The words and stories that unfold over the course of the interview stand as a representation of the subjective experience and are the focus of the analysis. [This case-based analysis is critical for helping to identify the "why" of events and is one of the important, innovative, contributions of this study. While longitudinal, epidemiological studies such as HANDLS are able to document the catastrophic results of diabetes (e.g., a participant who was diagnosed with diabetes at HANDLS baseline became a double amputee by the three year follow up – in part because he did not address a stubbed toe), they are very limited in their ability to understand why persons respond or don't respond to a diabetes diagnosis (Michelle Evans, HANDLS PI, personal communication, March 8, 2010). Through this analytic approach, we are responding to the gap in the literature—we will identify not only the range of what participants do in relation to their diabetes, but the explanations for "why" that are embedded within the broader subjective life experience.]

iii. Relating data analysis to the study questions and clinical relevance. We will use these two analytic strategies to address each of the four specific aims as follows:]

Specific aim 1, identify participants' subjective accounts of their diabetes, will be obtained through direct open-ended questions regarding participants' diabetes "story," the illness chain complexes and

prototypes used to understand and explain their diabetes, and their explanatory models, i.e., perceptions of the etiology, risk factors, symptoms, and anticipated outcomes. The code-based analysis will focus on developing codes reflecting participants' illness experiences, illness prototypes, familial illnesses, diabetes' etiology, risk factors, perceived outcomes etc., and then determining how these codes group into patterned relationships. We also will code for connections between secondary conditions and perceived diabetes outcomes. We will explore how these conceptualizations vary by diabetes duration and control.

Complementing the code-based analysis, the case-based analysis will be critical for identifying points of consistency in participants' descriptions of their diabetes as a whole, and just as interestingly, how contradictions and inconsistencies are incorporated and resolved or not resolved within participants' diabetes accounts. We will examine how diabetes and diabetes illness processes are described within cases that vary according to diabetes duration and control.

[Although we cannot predict the specific content of participants' illness narratives, we anticipate participants are likely to relate their diabetes to the outcomes of other illness experiences and the disease experiences of family members. We will explore how this sociohistorical, subjective construction of diabetes informs participants' diabetes management. At the same time, we anticipate that participants are not likely to have discussed their constructions with providers. We will ascertain the reasons for this. These constructions also are likely to vary depending on the participants' diabetes duration, which would suggest the need for providers to periodically revisit patients' subjective understandings over time. As demonstrated in clinically oriented work conducted by the PI,¹⁰⁴ diabetes education that reaches beyond the biomedical aspects of disease has the potential to assist patients in building a positive and realistic understanding of their disease course, treatment, and prognosis. In our analysis we will seek to identify how illness prototypes and sociohistorical illness chain-complexes could be captured by providers and utilized within clinical encounters to develop clinical rapport and to facilitate treatment adherence.]

[We also anticipate participants' views of the status and outcome(s) of their diabetes and the types of self-management behaviors needed for its control will contain inconsistencies. While folk models of diabetes are documented in the literature, particularly for ethnic minorities,^{35, 42, 105, 106} we will seek to identify how persons with diabetes do or don't reconcile inconsistencies among folk, local and clinical models of diabetes. We anticipate participants may express some clinical diabetes knowledge, but daily life will be strongly guided by other belief systems and elements, as well as social realities. We see this information as critical for providers. Health care providers who approach patients with an awareness of potential inconsistencies will likely be better able to take an active role in helping patients to reconcile multiple belief systems.]

[Further, we will specifically explore the realm of bodily and possibly mental symptoms that participants attribute to their diabetes and to other co-morbidities they may experience. Such information may be critical in understanding how participants define, categorize and recognize their subjective definition of diabetes.]

Specific aim 2, elicit participants' diabetes management perceptions and practices, will be obtained through open-ended questions followed by structured probes regarding specific self-management activities, including diet, exercise, glucose-testing, and medication adherence. Codes will be developed that address each category of treatment and self-management activity. *A priori* codes also will include local health care facilities and pharmacists, but other sources of care, e.g., spiritualists and lay herbalists, or management activities, e.g., dietary supplements, may emerge. In our code-based analysis we will examine the types of treatment activities and health care resources utilized, participants' descriptions of their resources (with attention to favorable and unfavorable accounts of services), and how treatment activities and descriptions form into code families that lend understanding as to how participants conceptualize treatment and why activities may or may not be conducted. In addition, we will examine how management activities group according to diabetes explanations (see specific aim 1 above). Finally, treatment and self-management patterns will be examined with respect to diabetes duration and control.

In our case-based analysis we will focus on the *process* of treatment seeking. This will include the interrelationships among treatments and self-management practices. For example, we will identify the

treatment activities that occur concurrently vs. consecutively and more importantly, participants' explanations for *why* treatment activities co-occur or the issues surrounding the movement from one treatment to another. We will pay attention to how diabetes control and duration are described within the treatment process and how treatment processes vary depending on the control or duration of the case.

[Again, we are not attempting to predict the specific disease management patterns that we will discover; however, we anticipate participants' diabetes accounts will not indicate a linear progression from diagnosis to treatment to control. Rather, participants are likely to express diabetes treatment seeking as a complicated process based on a variety of knowledge domains that may involve seeking help from multiple sources, both concurrently and consecutively, as well as decisions to delay or not seek care. Some clinical information may not be relevant to participants' subjective definitions and understandings of diabetes. Similarly, the care process may also be interrupted by the intrusion of real-world events, for example cost or transportation difficulties, that make following providers' direct suggestions problematic (see below). We will pay attention to these patterns to understand the factors influencing treatment paths and delays.]

[We also anticipate participants will identify treatment seeking activities that providers may not view as relevant to diabetes, but yet are perceived by participants as clinically meaningful and/or personally significant. This may include the use of specific foods, types of physical activity that are perceived as more or less valuable, and the use of prayer or other forms of religious traditions or rituals.¹⁰⁷ We believe such data could help shed light on the direct ways in which subjective understandings of diabetes inform diabetes decision-making.]

[Finally, treatment seeking and self-management also are likely to be social processes that involve negotiation among family members and friends to identify and access the locally defined "appropriate" provider or treatment. We anticipate participants and their families will employ an internal, strategic logic in deciding how to allocate resources for treatment seeking and self-management. This internal, strategic logic is likely to assess the benefits, risks, and potential costs of action and inaction. Risks or costs may be related to personal safety or emotional well-being, including the experience of stigma, embarrassment, or belittlement. We anticipate these data may help to answer why persons with diabetes do and do not engage in self-management or preventive treatment, a question that remains unanswered by many intervention studies.¹⁰⁸]

Specific aim 3, *Explore participants' accounts of the social context within which their diabetes is embedded*, will be obtained through open-ended questions. The code-based analysis will involve codes related to family and work responsibilities, financial constraints, insurance, treatment costs, and co-morbidities. We will identify the range of ways that participants conceptualize the social context surrounding their diabetes. We will seek to examine how codes regarding participants' social context can be grouped to provide insight into disease explanations and treatment pathways (i.e., specific aims 1 and 2). We also will explore the ways in which social contexts vary according to diabetes duration, control, and severity.

[In our case-based analysis we will carefully review narratives to understand participants' social contexts more broadly, identifying how elements of the social context operate with respect to participants' disease understanding and diabetes management. In addition to the social assessment of benefits, risks, and costs of action and inaction that are described with respect to specific aim 2, immediately above, we will seek to uncover participants' own explanations of the process or the ways in which surrounding contexts, including the participant's social roles, promote as well as prevent treatment or self-management. Careful attention also will be paid to discussions that provide insight into the meaning of these issues and how they might be addressed to improve outcomes.]

[Existing research clearly indicates that financial access to care, transportation, and care availability are important in diabetes management.¹⁰⁸⁻¹¹⁰ These issues likely will arise among our participants and we anticipate being able to explore how participants make decisions in the face of structural constraints. We also anticipate, however, that participants' discussions of their social context will reveal the presence of many competing priorities, beyond issues of access that directly impact diabetes management. These priorities are likely to be related to the participant's social roles, relationships, and responsibilities and the management of other illnesses that are perceived as more

pressing. Furthermore, we anticipate participants' subjective illness models (specific aim 1) will attempt to rationalize the resulting fragmentation of their self-management activities. These findings can help providers understand the range of social issues participants must address in relation to their diabetes management; providers would then be better equipped to use their clinical training and resource knowledge to work with participants on pathways for resolving competing priorities.]

Specific aim 4, Determine the race and gender variations in participants' subjective understanding of their diabetes, their diabetes management strategies, if any, and the social contexts surrounding their diabetes, will be obtained through code and case-based analyses that explore the commonalities and differences within and between the race and gender categories. The unit of analysis is the group. We therefore will be attentive to data by group, examining the distinct aspects of each cell. This includes being attentive to places in which these "natural" groups break down, i.e., the within-group variation. For our code-based analysis we will explore how the codes regarding understandings of diabetes, diabetes prototypes, disease management, and the social context of diabetes group into families based on shared characteristics and/or patterns both between and within cells. Atlas.ti will be invaluable in this process as it allows us to group data and search for the types of explanations and descriptions within and among race and gender categories.

For the case-based analysis we will explore race differences in both the content of interviews and the ways of expressing answers to questions. We will examine how participants' narratives, including the stories, plots, and expressions found within those narratives, are similar and divergent for individual cases within each race and gender strata.

[We anticipate our participants' narratives will provide critical insight into how subjective understandings of diabetes and treatment practices are experienced as part of broader racial and gendered social contexts. Racial and gendered disparities in diabetes management continue despite considerable public health attention. At the same time, some interventions have found minority participants demonstrated greater improvements in diabetes management than non-Hispanic white participants.¹⁰⁸ Such findings call for a more nuanced examination of the ways in which race and gender influence social contexts and diabetes management. Our study will help to illustrate more precisely *how* social contexts⁴¹ and "chains of risk"¹¹¹⁻¹¹⁴ are operating and informing the diabetes experience. Such findings can then offer providers a fuller understanding of the ways in which patients' race and gender attributes can play a role in diabetes management, along with heightening awareness of the variability within race and gender categories.]

[In sum, the approach we take here will enable us to better understand the subjective diabetes worlds of our participants as individuals and as group members. In this way, we will use the narrative materials that we elicit in response to the MINI to reveal a more complete and thorough view of patients' subjective understandings of a significant illness. In such a manner, and through the analyses that we have proposed here, narrative accounts will be turned into a matrix for understanding what transpires in reality, not from the provider's point of view, which has been the dominant one in biomedicine to date, but more significantly from the patient's point of view, which has been heretofore under-represented. In such a way, we will be able to turn narratively-elicited ethnographic materials into data and approaches that will be useful to providers in the treatment process.]

5. Ensuring validity Qualitative research is often multi-methodological in approach, seeking understanding of phenomena while recognizing that "objective" reality can never be completely captured. While noting the absence of an "objective" reality, we employ several techniques to confirm our data and interpretations are concordant. First, we seek to identify "pattern saturation" in our coding and analyses as a specific type of qualitative validation.¹¹⁵⁻¹¹⁷ Pattern saturation occurs when a research team member hears or observes material that has become achingly repetitive: the same story, the same account, the same structure. This adds confirmation to field-collected knowledge. Identifying pattern saturation has been noted as a qualitative isomorph to a validity check.¹¹⁸

Second, we engage in a process of data triangulation in our analysis, which is noted as an alternative to validation.^{101, 119} We collect and code multiple types of data (see above regarding interviews, field notes, meeting notes) that together form a stream of mutually supporting or

disconfirming data. In our analysis, we move between the code-based and case-based analysis and across data sources to look for congruence and incongruence. We seek to attribute conclusions to as many data sources as possible and note disagreement when it occurs. It is important to note that in our process of data triangulation we actively search for disconfirming evidence, which helps to avoid three forms of bias found within qualitative research: the holistic fallacy (that life is more patterned than it really is), elite bias (over-reliance on data from the especially articulate), and “going native” (losing one’s critical perspective).¹²⁰

6. Addressing generalizability Qualitative research such as ethnographic interviewing is not generalizable in the sense that is asserted for quantitative social research. [As noted by Yin (2009: 43) commenting on case-based research, “... samples and universes is incorrect when dealing with case studies. Survey research relies on statistical generalizations, whereas case studies rely on analytic generalizations.”¹²¹] Through analytic generalization findings from the proposed research will go a long way to improving understanding of how older adults conceptualize their diabetes and diabetes management. What might be lost in relation to generality is gained through the depth of knowledge and insight into subjective understanding and social process.

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Appendix 8.6: Diabetes substudy – MINI interview form

Central to this study is the idea that each individual has an explanatory model(s) for their illness(es) (Kleinman, 1980; Kleinman, Eisenberg & Good, 1978). Self-management is often promoted as a key to mitigating the effects of diabetes, but adherence to self-management recommendations can be difficult for patients, and providers often are limited in their ability to facilitate patient self-management.

We argue that the *subjective construction and definition* of diabetes and its management must be examined to more effectively address the diabetes epidemic. By identifying what people themselves think about their illness and its management we can help providers to better attend to the self-management concerns and constraints facing African-American and non-Hispanic white older adults within urban settings.

This interview guide is a modification of the McGill Illness Narrative Interview (MINI) an established semi-structured interview schedule (Groleau, Young, and Kirmayer, 2006). The MINI not only elicits *explanatory models*, explanations for why they got the illness (e.g. 'I got diabetes because I was too stressed'), but also *prototypes*, reasoning based upon significant events or episodes that lead to an elaboration through analogy (e.g. 'When my dad who also has diabetes lost his toes and foot, I got scared and decided to take better care of my diabetes') and *chain complexes*, a string of events that are linked in ways that are not explicitly understood by the interviewee (e.g. 'Around the time I lost my job, I started not seeing as well. Then I got a cough that wouldn't go away'). These three types of reasoning about or presentations of illness, according to Groleau, et al, can be reliably coded in the coding process.

Study Aims:

1. Identify participants' subjective accounts of their diabetes, including perceptions of the etiology, risk factors, symptoms, secondary conditions, and short and long term outcomes of their diabetes
2. Elicit participants' diabetes management practices, including perceptions and use of biomedical and lay (popular or folk) health care resources and self-management activities
3. Explore participants' accounts of the social context within which their diabetes is embedded, including how participants manage their diabetes with respect to other responsibilities and constraints, such as family care taking, job constraints, transportation, finances, time commitments, or other illnesses
4. Determine the race and gender variations in participants' subjective understanding of their diabetes, their diabetes management strategies, if any, and the social contexts surrounding their diabetes

**Ethnographic Interview:
McGill Illness Narrative Interview Modified for Diabetes**

[The following information will be covered when the interviewer begins the consent process.]

Your name was given to us by the HANDLs study in which you participate. You were selected to participate in this study because you have been diagnosed with Type II diabetes. This interview should last about 1 to 1.5 hours. However, if we go a bit long or you get tired, please let me know so we can schedule a follow-up interview. We may call you for a short follow-up phone call to seek clarification on any response. You will receive \$50 for your participation. (If we do this interview in two sittings, you'll receive the \$20 today and \$30 after the second visit.)

Will begin by seeing if the basic information we have for you is correct: age, education, marital status...

Introduction

Think of this interview as a conversation. It is not a test: There are no right or wrong answers. I'm not medically trained and won't share what you tell me with your doctors.

What's it like having diabetes?

Begin with a question about their present experiences with diabetes.

Section 1. Illness Narrative – Aim 1

This section elicits an open-ended narrative of the participant's diabetes history and experience, forming the foundation of the ethnographic interview.

Note the participant's term or expression for diabetes. As they speak, jot down reminders of points to return to later in the interview or at the end of their "story." Listen carefully for conveyance of meaning and follow up to clarify and learn more. The idea is to find out what they think is important not simply because we've asked it – and to hear it in their own words and not using our terminology when it may not be their terminology.

1. Please tell me the story of your diabetes.

The interviewer will encourage the narrative to unfold at length with simple prompting. a-d below can be regarded as prompts as needed. If not needed, all the better so as not to interrupt the flow of their narrative.

- a. How and when did you first learn you had diabetes?
- b. What were your first thoughts when you learned you have diabetes?
- c. Did you tell anyone about your diagnosis? Who? What did they say?
- d. Did you suspect you might have diabetes? If so, what signs did you see?

Section 2. Subjective Understanding of Diabetes – Aim 1

This section is designed to encourage the interviewee to reflect on meaning and personal experience with the disease, as well as ascertain how other health issues interrelate with their diabetes.

Probes for causes – etiology. a-c should be treated as probes only

- a. What do you think is happening in your body that could explain your diabetes?
- b. Is there something happening in your family, at work or in your social life that you believe might have led to your being diabetic? If yes, can you tell me more?
- c. Do you ever think that your diabetes is somehow linked to specific events in your life?

1. Why do you think your diabetes started when it did? What do you think caused your diabetes?
2. Do you believe your diabetes was preventable? Was it just waiting to happen? Why?

Q2. exploring sense of destiny or inevitability of their diagnosis.

3. Who do you know (friends, family, neighbors) who has diabetes?
 - a. How is their experience different? How is it the same?
 - b. What usually happens to people who have diabetes?
4. Do you have any other sicknesses or illnesses?

Q4. Probe for conditions and how each is related to diabetes. 4a and 4b should not be asked in a survey format but are here to remind us to keep these details in mind. Goal here is to see how co-morbidities affect the way people think about and treat (or not) their diabetes, and if they believe they are interrelated.

- a. How is your experience with that illness similar to diabetes? How is it different?
- b. How does your diabetes affect ____ problem? How does ____ problem affect your diabetes?

Lived Experience of Diabetes: Over time – Past and Future

5. Has your diabetes changed your life in any way? How?

Q5. exploring what social meaning diabetes has had for the interviewee over time

6. How do you think your diabetes will affect you in the future?

Q6. exploring how diabetes is experienced in the body

7. Have you ever delayed getting care for your diabetes when you thought you needed it or when others have told you to get help? Why?
8. Have you ever experienced a time when you became especially ill as a result of your diabetes? If yes, what happened?

Probe for how often and what they think might have been the triggers.

9. Can you feel when your diabetes is “acting up” – blood levels are off? Please describe.
10. Do you feel like you have a handle on your diabetes now? What leads you to answer this way?
11. How has your diabetes/health changed over time? How has getting older affected how you think about your diabetes?
12. Do you think your diabetes will ever go away or be completely better? How do you think that would happen?

13. What do you fear most in terms of your diabetes? *Probe. E.g. administering injections, finger pricks, passing out, amputations, affording medication, possible long-term health effects, etc.*

Section 3. Diabetes Management Practices –Aims 1, 2 and 3

Obstacles, Self-Efficacy, Agency: Q1-3 addresses how the knowledge is implemented or not

Seeking to understand self-efficacy (Bandura 1977) – how much power they feel they have & what level of confidence they have in the treatments.

Behaviors and Practices—Aim 2

1. What do you do for your diabetes? *Probe could include activities, diet, exercise, medication.*
 - a. What has been easy to do? Why is that?

Q2-3 are ascertaining lay and biomedical knowledge of diabetes treatment.

 - b. What has been difficult to do? Why is that?
 - c. How has what you do or not do for your diabetes changed over time?
2. In your opinion, what are some of the most important things you can do for your diabetes?
 - a. What's most important and why? *Probe further by assessing a general ranking*
 - b. What do you think doctors would think about your list? Would they agree or disagree?
Change the order, add to it, etc.? Why do you think this?
3. What do you think makes your diabetes worse?
 - a. What makes it better?
 - b. Are you able to do these things? Why or why not?

Identifying obstacles and providing following probes as needed.

- How does money/insurance affect how you take care of your diabetes? *Probe for how it affects treatment seeking and at home care, e.g., Can you get your medications, blood glucose testing supplies, diabetic socks and/or shoes? Why or why not?*
- Is it difficult to travel to get to your doctor for diabetes appointments? Why or why not?
- How does where you live affect your ability to take care of your diabetes? *Probe regarding: availability of foods; neighborhood safety; places to exercise; transportation availability*

Treatment Seeking—Aim 1 and 2

4. Who has been helping you with your diabetes?
 - a. What have you learned from _____ about diabetes?
 - b. How have they helped you (or not)? What do you talk about in terms of your health/diabetes? *Probe for any beliefs, concerns, or problems previously mentioned*
- Follow their lead by probing about both the positive and negative sides of the experience, including, e.g., accessibility, effectiveness, level of trust and understanding, etc.**
- c. Which of the recommendations, medicine, or recommendations have you been able to do (or not do)? *Probe.*

Probe for any incongruence or contradiction between their beliefs and the various treatments or recommendations

- d. How effective have these treatments or recommendations been?

Social Supports – Aim 3

The goal here is to better understand social environment effects, as well as lay networks (Dressler 1991).

5. Are there people in your life who are helpful (or not) in terms of your diabetes? Your family, friends, co-workers, neighbors? *Probe: egs. transportation to doctor's visit/other healers, cooking, exercise or staying active, help with glucose testing, buying sweets*
 - a. How has this changed over time?
- Q5.a. is getting at how, over the course of this chronic illness, has support lessened or increased – in what ways and why they think this is so.
6. How do your daily responsibilities affect what you do for your diabetes each day? *Probe*
7. Has your spirituality, faith or religious practice/community helped you (or not) with your diabetes? How?
8. Do you feel judged/stigmatized because you are diabetic? *Probe*.
9. Does diabetes affect your involvement in social activities, church, volunteer work, and engagement in other social gatherings and leisure activities? If so, how?
10. Is there anything else you think we should know about your experience with diabetes?

[Natural end to the interview here.]

The following questions will likely be addressed earlier in the interview. But if not, these questions are not meant to determine compliance with these conventional standards of care—we see the labels of “compliant/non-compliant” too limiting—more of a process that changes over time than a single event or moment in time. The ultimate goal is to explore how distant or close the interviewee’s personal concepts are from the standard biomedical concepts. Again, these suggested questions should not be “administered” like a survey, but rather probes to get at attitudes, perceptions, and experiences.

Aim 2:

1. *Monitoring Glucose/Medications:*
 - a. Do you monitor your blood sugar? If yes, *probe:* How and how often?
 - i. blood pressure? cholesterol levels?
 - ii. What are your target levels/readings?
 - b. Do you take insulin or other medication such as pills for your diabetes? Do you take it as often as you are supposed to? Why or why not?
 - c. Are there some medicines you don’t take because of the side effects? What are they?
 - d. Do you take over the counter medicines, vitamins or supplements (e.g. cinnamon) for your diabetes? Have these made a difference? *Probe for how they learned about these ideas.*
2. *Exercise:*
 - a. How much physical activity (of any type) do you get in a day? Describe the activities.
 - b. How has your physical activity changed since you learned that you had diabetes?
 - c. Are you satisfied with your level of physical activity? Why or why not?

3. *Food/Eating:*

- a. What kinds of things do you eat/drink most often for breakfast? Lunch? Dinner?
- b. Do you cook? If yes, what food do you like to cook? *Probe how often cooks these items*
- c. How do you get ideas for what to eat/make/prepare?
- d. Please describe what it means to eat healthy for your diabetes. Describe what it means to not eat healthy for diabetes.
- e. Are you satisfied with the "healthiness" of what you eat? Why or why not?

Where do you shop for food?
Question posed by HANDLS.

Background info for the interviewer's information: Common symptoms related to diabetes (e.g. incontinence, blurred vision, pain/tingling in hands/feet, dry mouth); diseases related to diabetes (e.g. obesity, hypertension, stroke, periodontal disease).

References cited:

- Bandura, Albert. 1977. Self-Efficacy: Toward a Unifying Theory of Behavioral Change. *Psychological Review* 84(2):191-215.
- Dressler W. 1991. Social support, lifestyle incongruity, and arterial blood pressure in a Southern black community. *Psychosom. Med.* 53:608-620.
- Groleau D, Young A, Kirkmayer L. 2006. The McGill Illness Narrative Interview (MINI): An interview schedule to elicit meanings and modes of reasoning related to illness experience. *Transcultural Psychiatry* 43(4):671-691.
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Appendix 9.1: Agreements – Active confidential disclosure agreements

NIA Protocol 09-AG-N248 for submission to NIEHS IRB
 HANDLS Active Confidential Disclosure Agreements (CDA)
 (previously referred as data/materials transfer agreements)
 March 2013

	Collaborator	Institution	Study Domain	
26103-08	Deidra Crews	Johns Hopkins Medical Institutions	Nephrology	
31092-10	Roland Thorpe	Johns Hopkins University, School of Public Health	Functional capacity	
31311-11	Ravi Thadhani	Massachusetts General Hospital	Vitamin D / renal function	
10621-13	Marie Kuczmarski	University of Delaware	Nutrition	
10150-12	Ron Wilson	US Department of Housing & Urban Development	Violent crime in neighborhoods as it relates to health outcomes	
09985-12	Shari Waldstein	University of MD Baltimore	Neuroimaging	
32361-11	Lee B. Peterlin	Johns Hopkins Medical Institutions	Headaches and Obesity	
10408-13	Mark Rea & Mariana Figueiro	LRC Rensselaer Polytechnic Institute	Circadian Rhythms	
	Kevin Eckert & Sarah Chard	University of Maryland Baltimore County	Diabetes mellitus	

updated 3-14-2013

Appendix 9.2: Agreements – University of Delaware IRB authorization

IRB Authorization Agreement

Name of Institution or Organization Providing IRB Review (Institution A): MedStar Research Institute

IRB Registration #: (IRB #1) 0000598; (IRB #2) 0000779 Federalwide Assurance (FWA) #, if any:
00000504

Name of Institution Relying on the Designated IRB (Institution B): University of Delaware

OHRP Federalwide Assurance (FWA) #: 00004379

The Officials signing below agree that (Institution B) University of Delaware may rely on the designated IRB for review and continuing oversight of its human subject research described below: (check one)

- This agreement applies to all human subject research covered by Institution B's FWA.
 This agreement is limited to the following specific protocol(s):

Name of Research Project: Healthy Aging in Neighborhoods of Diversity across the Life Span (HANDLS)

Name of Principal Investigator: Michele K. Evans, M.D. and Alan B. Zonderman, Ph.D.

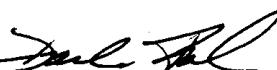
Sponsor or Funding Agency: National Institute on Aging/IRP Award Number, if any:

Other (describe): _____

The review and continuing oversight performed by the designated IRB will meet the human subjects protection requirements of Institution B's OHRP-approved FWA. The IRB at Institution A will follow written procedures for reporting its findings and actions to appropriate officials at Institution B. Relevant minutes of IRB meetings will be made available to Institution B upon request. Institution B remains responsible for ensuring compliance with the IRB's determinations and with the terms of its OHRP-approved Assurance. This document must be kept on file at both institutions and provided to OHRP upon request.

Signature of Signatory Official (Institution A):  Date: 3/31/15

Print Full Name: Barbara Howard, PhD Institutional Title: President, MedStar Research Institute

Signature of Signatory Official (Institution B):  Date: 4/25/05

Print Full Name: Daniel Rich Institutional Title: Provost

Appendix 9.3: Agreements – NIA-Johns Hopkins cooperative research

Cooperative Research with NIA
November 2004

Investigators Collaborating with the National Institute on Aging Intramural Research Program

- I. **Recitals.** The National Institute on Aging Intramural Research Program (NIA IRP) has a long-standing history of collaborative research with Johns Hopkins University investigators. Until recently, the NIA IRP was located exclusively on the JHBMC campus and JHM IRB 5 reviewed their human subjects research protocols. In April 2003, clinical investigators at the NIA IRP moved to Harbor Hospital and this necessitated a change in the IRB review process. NIA IRP was removed from the Johns Hopkins' Federal Wide Assurances and the MedStar Research Institute (MRI) IRB was designated as the IRB of record for NIA IRP projects. More recently, The Johns Hopkins University entered into an IRB review agreement with MRI. Under expanded terms of that agreement JHM and MRI agree to recognize IRB action of their respective IRB for limited purposes and under certain circumstances. The MRI agreement necessitated a revision in the guidelines for collaborative clinical research involving Johns Hopkins faculty and National Institute on Aging intramural investigators.
- II. **All NIA IRP clinical research conducted entirely or primarily at Harbor Hospital, or at other NIA IRP federal or leased facilities, will be reviewed by the MRI IRB.** The Johns Hopkins Institutional officials will be notified in writing of any protocol reviewed by the MRI IRB that includes a principal or associate investigator who is being paid by The Johns Hopkins University ("Hopkins Investigator") along with a copy of the approved protocol. The individuals to be notified are 1) The Director of the Office of Human Subjects Research and 2) The Assistant Dean for Human Subjects Research Compliance. The MRI IRB will have the approval authority and monitoring responsibility for these studies.
- III. **All NIA IRP clinical research conducted at other than Johns Hopkins facilities in which the involvement of Hopkins Investigators is limited to review of data, specimens, etc., will be reviewed by the Medstar IRB.** The MRI IRB will have approval authority and monitoring responsibility for these studies. The MRI IRB will provide to Johns Hopkins Institutional officials a copy of the MRI IRB-approved protocol for their information.
- IV. **All NIA IRP clinical research conducted in part at Johns Hopkins' facilities and involving an investigational drug or device on which an associate Hopkins Investigator holds the IND, will be reviewed by the JHM IRB for the part of the research involving the investigationaal drug or device.** JHM IRB review and approval and ongoing monitoring will be required for the part of the project involving the investigational drug or device. The JHM investigator

~~will be reviewed by the MRI IRB.~~ The review outcome, including consent documents, will be provided to the MRI IRB for their information.

VI. **Record Retention and Production.** Consent and HIPAA issues are addressed in the Memorandum of Understanding between Johns Hopkins and MRI

VII. **Term and Termination:** The initial term of this Agreement shall be from the 1st day of November 2004 and shall continue until the 30th day of November 2005 unless otherwise terminated by either party as provided herein. Unless earlier terminated, this Agreement shall continue for successive one year terms. Either party may terminate this Agreement upon 30 days written notice to the other party or may immediately terminate this Agreement upon filing written notice of any material breach of its terms by the other party.

VIII. **Miscellaneous**

Endorsement of JHUSOM:

Authorized Institutional Official

Michael J Klag
Signature:

Date: 10/11/04

Michael J. Klag, M.D., M.P.H.

Vice Dean for Clinical Investigation

733 N. Broadway, Vice Dean's Suite #115

Baltimore, MD 21205

Phone: 443-287-4234

Fax: 410-502-3667

E-Mail: mklag@jhmi.edu

Endorsement of NIA IRP:

Authorized Institutional Official

Dan L Longo
Signature:

Date: 10/20/04

Name: Dan Longo, M.D.

Appendix 10: Radiation safety approval

Evans, Christal (NIH/NIA/IRP) [C]

From: Kindrick, Sarah (NIH/OD/ORS) [E]
Sent: Thursday, January 27, 2011 1:23 PM
To: Evans, Michele (NIH/NIA/IRP) [E]
Cc: Kindrick, Sarah (NIH/OD/ORS) [E]; mckay.charles@medstar.net; Byrd, Linda Jo (NIH/NIA/IRP) [E]; Morris, Charlene (NIH/NIA/IRP) [C]; Coronado Lisa
Subject: RSC Approval Of Protocol Application

Dear Dr. Evans :

Re:
RSC Action Item # 2011-11
Rad Authorization No.: 1966-C
Clinical Project No. :
Title: Healthy Aging in Neighborhoods of Diversity Across the Life Span Authorized Investigators :
Principal Investigators :
Evans ,Michele ,M.D.

The NIH Radiation Safety Committee (RSC) approved the above-referenced triennial protocol application by expedited review committee. The committee appreciates your efforts in redesigning this study to reduce radiation exposure to the subjects. The originals of the Form 88-23(A) and the original, (Pink) approval have been sent to the IRB Coordinator who is responsible for forwarding the approved application to the Protocol Coordination Service Center for the permanent file associated with this application.

Your copies of the approval documents are forthcoming via interoffice mail.

Regards,

Sarah

Sarah Kindrick, M.D.
Clinical Protocol Administrator
NIH Radiation Safety Committee
301-496-2253

Appendix 11: Publications

HANDLS Publications

1. Chen Z, Tang H, Qayyum R, et al. Genome-wide association analysis of red blood cell traits in African Americans: the COGENT Network. *Hum Mol Genet.* March 2013
2. Hek K, Demirkan A, Lahti J, et al. A genome-wide association study of depressive symptoms. *Biol Psychiatry.* Jan 2 2013.
3. Trzeciak AR, Mohanty JG, Jacob KD, et al. Oxidative damage to DNA and single strand break repair capacity: relationship to other measures of oxidative stress in a population cohort. *Mutat Res.* Aug 1 2012;736(1-2):93-103.
4. Sutin AR, Evans MK, Zonderman AB. Personality traits and illicit substances: The moderating role of poverty. *Drug Alcohol Depend.* Dec 19 2012.
5. Smith JG, Avery CL, Evans DS, et al. The impact of ancestry and common genetic variants on QT interval in African Americans. *Circ Cardiovasc Genet.* Nov 19 2012.
6. Qayyum R, Snively BM, Ziv E, et al. A meta-analysis and genome-wide association study of platelet count and mean platelet volume in African Americans. *PLoS Genet.* Mar 2012;8(3):e1002491.
7. Olesnevich ME, Kuczmarski MF, Mason M, Fang C, Zonderman AB, Evans MK. Serum ferritin levels associated with increased risk for developing CHD in a low-income urban population. *Public Health Nutr.* Jan 10 2012:1-8.
8. Noren Hooten N, Ejiogu N, Zonderman AB, Evans MK. Association of oxidative DNA damage and C-reactive protein in women at risk for cardiovascular disease. *Arteriosclerosis, Thrombosis, and Vascular Biology.* Nov 2012;32(11):2776-2784.
9. Hernandez DG, Nalls MA, Moore M, et al. Integration of GWAS SNPs and tissue specific expression profiling reveal discrete eQTLs for human traits in blood and brain. *Neurobiol Dis.* Jul 2012;47(1):20-28.
10. Butler AM, Yin X, Evans DS, et al. Novel loci associated with PR interval in a genome-wide association study of ten African American cohorts. *Circulation. Cardiovascular Genetics.* Nov 8 2012.
11. Bhatnagar P, Lu X, Evans MK, et al. Genetic variants in Platelet Factor 4 modulate inflammatory and platelet activation biomarkers. *Circ Cardiovasc Genet.* Jul 4 2012.

03/11/2013

12. Tin A, Woodward OM, Kao WH, et al. Genome-wide association study for serum urate concentrations and gout among African Americans identifies genomic risk loci and a novel URAT1 loss-of-function allele. *Hum Mol Genet*. Oct 15 2011;20(20):4056-4068.
13. Szanton SL, Rifkind JM, Mohanty JG, et al. Racial discrimination is associated with a measure of red blood cell oxidative stress: A potential pathway for racial health disparities. *Int J Behav Med*. Sep 13 2011.
14. Smith JG, Magnani JW, Palmer C, et al. Genome-wide association studies of the PR interval in African Americans. *PLoS Genet*. 2011;7(2):e1001304.
15. Reiner AP, Lettre G, Nalls MA, et al. Genome-wide association study of white blood cell count in 16,388 African Americans: the continental origins and genetic epidemiology network (COGENT). *PLoS Genet*. Jun 2011;7(6):e1002108.
16. Parto JA, Evans MK, Zonderman AB. Symptoms of posttraumatic stress disorder among urban residents. *J Nerv Ment Dis*. Jul 2011;199(7):436-439.
17. N'Diaye A, Chen GK, Palmer CD, et al. Identification, replication, and fine-mapping of Loci associated with adult height in individuals of african ancestry. *PLoS Genet*. Oct 2011;7(10):e1002298.
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