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ICPSR 29282

Midlife in the United States (MIDUS 2): Biomarker Project, 2004-2009

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IRB Approval/Certificate of Confidentiality Documentation

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THE UNIVERSITY of WISCONSIN MADISON

Health Sciences IRB

NOTICE OF ACTION

Approval

Date of Correspondence: 1/4/2010

Principal Investigator:	Carol Ryff, Ph.D. Rm. 2245 Medical Sciences Ctr. (MSC) 1300 University Ave., Madison, WI 53706
Point of Contact:	Gayle D Love Rm. 2245 Med. Sciences Ctr (MSC) 1300 University Ave., Madison, WI 53706
Protocol:	**H-2008-0060** "Connecting Psychosocial Factors in Biological Mechanisms"
Review Period:	12 months
Approval Expires:	January 03, 2011
IRB Staff Contact:	Carol A Pech, (608) 263-2705, cap@medicine.wisc.edu

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Your Continuing Review Protocol Progress Report was reviewed and approved by an IRB member on January 04, 2010 pursuant to 45 CFR 46.110(b)(1) and 21 CFR 56.110(b)(1), if applicable. This protocol qualified for expedited review because the remaining research activities are limited to data analysis. This action will be reported to the Health Sciences Institutional Review Board. You may continue your research. The review period and expiration date of your approval are listed above.

Please be sure to do the following:

- Use your Health Sciences IRB protocol number (listed above) on any documents or correspondence with us concerning your protocol.
- Keep a copy of this approval letter with your files.
- Comply with all requirements described in the **Investigator Responsibilities Related to the Protection of Human Subjects** attachment.

Sincerely,

Carol A Pech, PhD
Assistant Director, Health Sciences IRB Office

Enclosure(s):
Investigator Responsibilities Related to the Protection of Human Subjects

CONFIDENTIALITY CERTIFICATE

NIA-22-2003

issued to

University of Wisconsin Madison

Conducting Research known as

MIDUS II Psychosocial Contributors to Health and Illness

In accordance with the provisions of section 301(d) of the Public Health Service Act 42 U.S.C. 241(d), this Certificate is issued in response to the request of the Principal Investigator, Carol D. Ryff, Ph.D., to protect the privacy of research subjects by withholding their identities from all persons not connected with this research. Dr. Ryff is primarily responsible for the conduct of this research which is funded by the National Institute on Aging.

Under the authority vested in the Secretary of Health and Human Services by section 301(d), all persons who:

1. are enrolled in, employed by, or associated with the University of Wisconsin - Madison, and its contractors or cooperating agencies, and

2. have in the course of their employment or association access to information that would identify individuals who are the subjects of the research pertaining to the project known as "MIDUS II Psychosocial Contributors to Health and Illness,"

are hereby authorized to protect the privacy of the individuals who are the subjects of that research by withholding their names and other identifying characteristics from all persons not connected with the conduct of that research.

The primary aims of this study are to collect a second wave of data, approximately 9-10 years later, or the Midlife Study of the US (MIDUS I) core sample (N = 3,485), metropolitan over-samples (N = 757), twins (N = 998 pairs), and siblings (N = 951) of core respondents. Respondents will be 35 to 86 years of age, thereby allowing for investigation of age changes and differences in a wide array of behavioral, psychosocial, and experiential factors hypothesized to influence unfolding trajectories of health and illness. Data collection will include a phone interview, self administered questionnaire plus cognitive functioning, optimism and coping, stressful life events and caregiving information. The study also will recruit a Milwaukee, WI sample of African Americans (N = 400) to participate in a field interview and questionnaire paralleling the above instruments. The overarching hypothesis to be investigated is that behavioral and psychosocial factors are consequential for health.

To protect identities of subjects, all interview and questionnaire materials will be identified by number only in all electronic data files. All hard copies of original questionnaires will be kept in locked files to which only the main investigators have access. All data (e.g., interviews and questionnaires) are coded only by subject number. The master list pairing numbers with names is stored in a separate, locked location and in a password-protected computer file. Investigators and student workers do not have access to subject names.

A Certificate of Confidentiality is necessary because sensitive information is being collected on the mental health of subjects and on drug and alcohol use.

This research will begin on August 1, 2002 and terminate on July 31, 2008.

As provided in section 301 (d) of the Public Health Service Act 42 U.S.C. 241(d):

> "Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals."

This Certificate does not provide protection from compelled disclosures that: (1) have been consented to in writing by the research subject or the subject's legally authorized representative; (2) are required by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or regulations issued under that Act; or (3) have been requested from a research project funded by NIH or DHHS by authorized representatives of those agencies for the purpose of audit or program review.

This Certificate does not represent an endorsement of the research project by the Department of Health and Human Services. This Certificate is now in effect and will expire on July 31, 2008. The protection afforded by this Confidentiality Certificate is permanent with respect to subjects who participate in the research during the time the Certificate is in effect.

Date: 11/25/03

Judith A Salerno, M.D.
Deputy Director, NIA

CONFIDENTIALITY CERTIFICATE

AMENDENT TO CERTIFICATE

Number: NIA – 22-2003

Issued to

University of Wisconsin -Madison

conducting research known as

MIDUS II Psychosocial Contributors to Health and Illness

The Certificate issued to the MIDUS II Psychosocial Contributors to Health and Illness, is amended to cover data collection at 3 sites: UW-Madison, UCLA, Georgetown University for Project 4 of 1 P01 AG020166.

Date: 5-5-04

Judith A Salerno, M.D.
Deputy Director, NIA