Mobile Device Biomonitoring to Prevent and Treat Obesity in Underserved Minority Youth
PI: Donna Spruijt-Metz

a. Specific aims of the proposed NCMHD telehealth/telemedicine research project

Pediatric obesity has emerged as a major national and international health crisis. National data from 2003-2006 show 18% of adolescents aged 12 - 19 years are at or above the 95th percentile of gender- and age-specific Body Mass Index (BMI), and thus considered obese. In addition, 34% are at or above the 85th percentile and thus considered overweight. These numbers are substantially higher in African American youth (30% ≥ 95th percentile, 38% ≥ 85th percentile) and Hispanic youth (21% ≥ 95th percentile, 39% ≥ 95th percentile) [1], placing minority children at disproportionate risk for type 2 diabetes [2], metabolic syndrome, and a host of other diseases [3]. Although physical activity (PA) is tightly related to lower obesity rates in children [4, 5], PA declines precipitously during early adolescence [6], particularly in minority populations [7, 8]. This severe pediatric decline in PA is not well understood [9]. Interventions to increase physical activity have generally been ineffective, with only a handful tailored to meet the needs of African American youth and very few tailored for Hispanic youth[8, 10] Novel approaches to increase physical activity as well as prevent and treat pediatric obesity in minority populations are therefore sorely needed [8]. The ability to record and interpret PA in real time and in real space with minimal intervention from the subject is the first step in understanding the complex interplay of environmental, genetic and socioeconomic reasons for weight gain. It is in this context that we propose to use mobile devices to play a significant role in non-intrusive monitoring of metabolic health and exercise habits continuously. The penetration of mobile phones even in populations with lower socioeconomic status is substantially higher than any other compute or communication device. More than 80% of the world population is within the reach of a cell tower and in the next five years it is expected that more than 90% of the world population will be within a cell tower reach. On the device front, the total number of mobile phones in the market is expected to touch roughly 4 billion by end of 2008. Such large mobile phone penetration coupled with near universal coverage creates new opportunities to use mobile phone technology to improve prevention and treatment efforts in pediatric populations, in particular difficult to reach, at-risk and underserved minority youth.

This project proposes to use mobile devices to develop new tools for pediatric obesity prevention and treatment. We propose to interface the ability of existing wearable wireless sensor devices to precisely monitor behavior, aspects of metabolism and geographical location with mobile phones to collect, store and transmit data to a secure web interface where health data will be analyzed, translated and displayed for participating health practitioners. More specifically, we will use off the shelf wearable wireless sensors to measure physical activity, blood pressure, sleep, heart rate, galvanic skin response and blood glucose levels and communicate the measured information to a mobile phone using a wireless interface. We will combine the external sensor data with the mobile phone's in-built sensors, in particular Geographic Positioning Systems (GPS), accelerometer, audio and video tags. This will deliver a record of behavior and health data that is time-stamped, synchronized, and geographically localized using GPS to a secure server. Data will then be analyzed and displayed to participating health professionals to provide them with readily interpretable records of continuously monitored energy expenditure, recorded and synchronized with other essential biological, behavioral and geographical data. **Therefore, the specific aims of this proposal are:**

1) To develop a synchronized, continuous health data monitoring system that
   a) Uses external sensors to record physical activity, blood pressure, sleep, heart rate, galvanic skin response, blood pressure, blood glucose levels and geographical position
   b) Can be easily worn
   c) Is relatively tamper-proof
   d) Can record 7 days of data without recharging

2) To program mobile phones that can interface with these external sensors to receive the wireless data periodically and to combine the external sensor data with data from mobile phone's in-built sensors GPS, accelerometers, audio and video tags

3) To upload data from the mobile phone wirelessly to a secure website for analyses and formatting

4) To provide secure web-enabled access for health care professionals to visualize this data from anywhere and at anytime that:
   a) Provides the data that health professionals deem most important
   b) Provides this data in a format that health professionals can easily interpret

5) To assist adolescent users of the devises in using and managing usage of the devices

b. Abstract

This project proposes to use mobile devices to develop new tools for pediatric obesity prevention and treatment targeting underserved minority adolescent populations at high risk for obesity and related diseasaes. We will use off the shelf, validated and wearable wireless sensors to measure physical activity, blood pressure, sleep, heart rate, galvanic skin response and blood glucose levels and communicate the measured information to a mobile phone using a wireless interface. This will deliver a record of behavior and health data that is time-stamped, synchronized, and geographically localized using GPS to a secure server. Data will then be analyzed and displayed to participating health professionals to provide them with readily interpretable records of continuously monitored energy expenditure, recorded and synchronized with other essential biological, behavioral and geographical data. To accomplish this project, 50 African American and Hispanic youth (50% female, ages 12-17) will be recruited into the research in advisory capacities, to test the sensors during development, and to wear the sensors for three non-contiguous weeks. To test the sensors prior to use with minority youth, 30 college students age 18 and above will be recruited to try out the sensors in and outside of the laboratory in order to make sure that all sensors are in perfect working order before testing them in minority youth populations. An advisory group of medical professionals will be assembled to guide us through the process of developing a web interface that will ensure that the right information will be displayed in an easily interpretable fashion. The advisory group will participate in regular meetings to develop and test the web interface. Using the data acquired, health professionals will be able to visualize average amounts of physical activity, sleep, sedentary behaviors (daily or weekly) as well as daily patterns. Average blood glucose, heart rate, and stress levels (daily or weekly) as well as daily patterns will also be available. Practitioners will be able to see when and where activity and metabolic events are occurring, enabling preemptive and preventive strategies as well as targeted interventions to prevent and treat pediatric obesity in underserved and at-risk minority youth.

c. Research Plan

1. Priority populations served

African American and Hispanic Youth: Populations at Risk: Our Comprehensive NCMHD Research Center of Excellence focuses on African American and Latino youth in order to understand the etiology of obesity, insulin resistance, and PA behavior change in these populations. African American and Hispanic youth have been identified as populations most in need of interventions to promote PA [11]. Adequate levels of PA decrease BMI, protect against cardiovascular disease and some cancers, and promote insulin sensitivity. We have shown that Hispanic and African-American children are more insulin resistant than white adolescents independent of adiposity [12] leading to impaired glucose tolerance and elevated risk for type 2 diabetes. We focus our Center program on Hispanic and African-American children because they are not only at high risk but also "under-served and under-studied", with respect to obesity and its metabolic complications. The population of Hispanics in particular in the U.S. is increasing at an accelerated rate. African American and Hispanics constitute the two largest minority groups in the U.S. Furthermore, Hispanics and African Americans are disproportionately affected by higher levels of body fatness, increased incidence of type 2 diabetes and cardiovascular diseases, and lower levels of daily PA. Therefore, potential for spread of the obesity epidemic among increasing numbers of children in these populations are a particular public health problem. Studies in the ecology of health care show that greater proportions of children aged 13 to 17 years than 6 to 12 years received care in emergency departments, outpatient clinics, and hospitals, but not physicians' offices, despite recommendations for adolescents to have more frequent preventive health visits than 6 to 12 year olds [13]. Adolescents are also less likely to receive preventive health care if they are not white, Hispanic, or live in low socio-economic conditions. Mobile device biomonitoring will provide an easily accessible, culturally and developmentally tailored, user friendly and sustainable gateway for health care professionals to catch risky health-related behaviors and metabolic health indicators before obesity, impaired glucose tolerance, diabetes, or other detrimental health conditions occur. Mobile device biomonitoring as proposed here will also provide time-sensitive information that will be extremely useful for treatment of overweight youth.

Place matters: Poverty, Access, Fear and Stress: According to the 2000 U.S. Census, African American and Hispanic adults are nearly twice as likely to be unemployed as non-Hispanic white adults [14], and are at increased risk for poverty. In children, PA levels are inversely related to low socio-economic status [15, 16], and this might be due in part by inequalities in community tax base and fiscal health, amenities levels in neighborhood environments, and access to these key facilities. A recent review of built-environmental impacts on children's PA showed that levels in youth are positively associated with publicly provided recreational infrastructure (access to recreational facilities and schools) and transport infrastructure (presence of sidewalks and controlled intersections, access to destinations and public transportation) [17]. Studies have documented that today, more than ever, parents tend to impose more restrictions on their children's use of public spaces because of fear for their safety [18]. Inner city African American and Hispanic adolescents are frequently exposed to specific environmental factors which have been linked to chronic stress, including crime, disturbed family and social connections (82), noise levels [19] and neighborhood disorganization [20]. Physical activity has been shown to decrease stress in Hispanic youth [21] and buffer the effect of stress on central adiposity in African American youth [22]. However, the increasing amount of environmental stress upon today's adolescents may promote both general obesity (through lifestyle behaviors such as decreased physical activity) and visceral obesity (through hypothalamic-pituitary-adrenal [HPA] axis activation and increased cortisol secretion)[23]. The Biomonitoring system proposed here will track stress levels, physical activity levels, blood glucose levels and other vital signs simultaneously, as well as anchor these levels to time of day and geographical location. This system will provide the first context rich data feed that will allow practitioners and researchers alike to track environmental influences on health in real time, as well as provide the data that will allow the study of mutual simultaneous and time-lagged influences of behavior, stress, metabolism and environment. This data will help to generate data-driven solutions to the obesity epidemic that can be tailored to individuals or groups of individuals. **The biomonitoring system proposed here will provide health care professionals with preemptive tools to catch metabolic and behavioral risks before children become obese, as well as tools to develop interventions to prevent and treat obesity that are meaningful, culturally appropriate and child-centered.**

Experience working with minority populations: The PI of this proposed project has significant independent funding in research, prevention and treatment of childhood obesity and has extensive experience in research, recruitment and retention in minority youth in this area. Currently, she is PI on a project to understand the decline in physical activity in Hispanic and Latina girls (Project 2 U54CA116848) and PI of Project 2 of the NCMHD Center at USC as described above. She is Co-Investigator on two projects that involve intensive laboratory-based interventions to improve diet and physical activity in Hispanic (R01-HD/HL 33064, Goran PI) and African American youth (Project 1 U54CA116848, Goran PI). There is a clear need for better and more attractive tools for comprehensive monitoring of behavior and health in minority youth. These tools must be acceptable and attractive to the target populations and they provide more in-depth information than is currently available. We are aware of current innovations such as the Lifeshirt ™ and other available technologies that measure a host of vital signs. However, our focus group interviews with African American and Hispanic teens have repeatedly shown that these youth are not willing to wear such intrusive devices. We are therefore poised to make significant and lasting contributions the field of minority health through a focus on biomonitoring using mobile phones and miniature devices for prevention and treatment of childhood obesity and its associated complications in minority youth.

2. Diseases or clinical conditions to be addressed

This proposal addresses pediatric obesity, chronic and acute stress, impaired glucose tolerance and type 2 diabetes, cardiovascular disease risk and the metabolic syndrome in at-risk minority youth.

3. Research study design and methods

Overview:

This research will have three phases:

1) In the initial exploration phase we plan to source off the shelf wearable medical sensors that monitor vital signs and are capable of transmitting that data wirelessly. We propose to program mobile phones that can interface with these sensors to receive the wireless data periodically. Data obtained from the sensors is then combined with mobile phone's in-built sensor data such as GPS, audio and video tags. The combined data is stored locally on mobile device and transmitted to a backend server. To achieve this goal, we will build a mobile software suite that runs on mobile phones and interfaces with vital sign monitors to receive data wirelessly and transmit the data to a server. Apart from interfacing with external sensors with mobile phones we will also develop software that uses integrated GPS and accelerometers to continuously monitor location and motion estimation information of a person.
2) The sensor data received at the server is likely to be noisy due to the interactions between the sensor devices, surrounding environment and subjects' body movements. Hence, it is essential to reduce the noise in sensor data to be able to effectively utilize the data. Apart from improving data quality in the second phase we will develop programs for on-line data analyses to enable real time monitoring of behavior and vital signs by health practitioners. Data analyses will be specific to pediatric populations including appropriate accelerometer cut-points to determine levels of physical activity and energy expenditure[24] and, where appropriate, age-specific parameters for all data collected including heart rate monitors and all other sensors
3) In the third phase we will develop secure web-enabled and user-friendly access to this data so that health practitioners can visualize this data from anywhere and at anytime. We will work with pediatricians, promotoras (outreach workers in a Hispanic community who is responsible for raising awareness of health and educational issues) and local health care clinics to determine the data visualization needs. We recognize the importance of sensitivity of the data collected from sensors and as such we will develop techniques to protect the sensitive data from unwanted use with a combination of authentication, trust and data retention mechanisms.

The major components of this research are described below:

Part 1: Developing a Mobile Software Suite for Biomonitoring

The software suite proposed in this research will be implemented using a three-tier architecture as shown in Figure 1. The front tier of this architecture is the data collection sensors coupled with mobile phones that acts as data transmission device. The middle tier is a web server that receives and processes information and sends it to a back-end database server that stores the information.

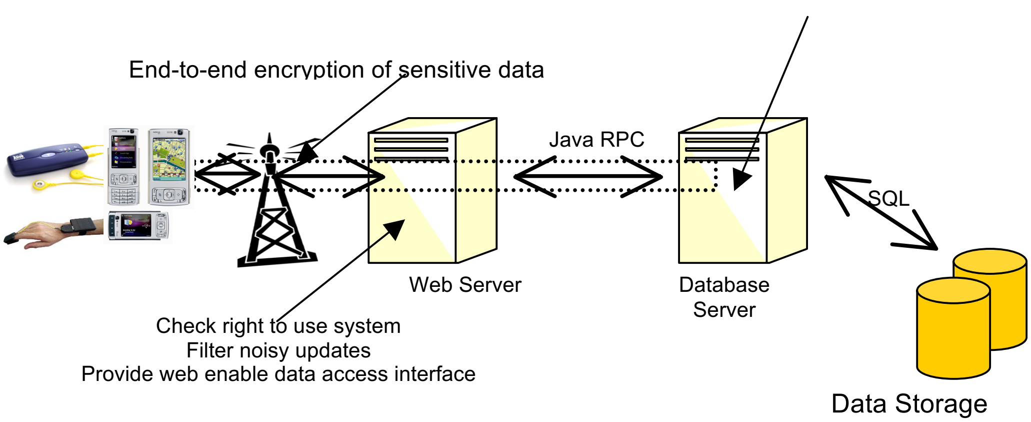

Figure 1 : Simplified Three-Tier Architecture Overview

The sensor layer is a collection of off-the-shelf devices that measure the metabolic activity. In particular, we propose to use heart rate, blood pressure, and blood glucose monitors currently available from Alive Technologies[25]. We also propose to use BodyMedia WMS™ sensors to measure the Galvanic Skin Response (GSR) and motion estimation using accelerometers. In addition to measuring the metabolic activity all these sensors are also capable of wirelessly transmitting this data over Bluetooth interface. We propose to use feature rich Nokia N95 as the mobile phone platform. N95 supports Bluetooth 2.0 +EDR for quick pairing with external Bluetooth sensors, and has 3G and WiFi radios for high bandwidth data transfer. All the external sensors listed above stream data to the Bluetooth enabled N95 mobile phone. In addition to the high bandwidth radio capabilities, the N95 mobile phone platform has a highly accurate built-in assisted GPS unit that uses a combination of GPS satellites, cellular tower and WiFi scanning to obtain a GPS position lock in less than 10 seconds. The stated location accuracy of GPS unit is 30 meters, while in practice the observed accuracy is around 3 meters.

The Principal Investigator of this project has extensive experience using accelerometers in minority youth, and is Co-Director of the Human Measurement Core of the USC Center for Transdisciplinary Research on Energetics and Cancer (TREC) funded by NCI, which is responsible for physical activity measures across all TREC center projects. Accelerometer data for assessment of physical activity is one of the most prevalent measures (coupled with dietary data) used to evaluate energy expenditure[6, 26, 27]. However, most research involves the wear of a single accelerometer which does not yield truly accurate data [24]. Therefore, in this project we propose to synchronize multiple accelerometery data sources to estimate energy expenditure more accurately[28].

Part 1a: Testing and Initial Deployment of sensors in target populations: We will use unit testing to extensively test our mobile software suite. We will recreate several usage scenarios and environmental conditions that our deployment test bed is likely to encounter. A total of 50 Hispanic and African American youth will be recruited to assist in technology development: 1) an advisory group of 10 youth, 2) 20 youth to participate in laboratory testing of the biomonitors and 3) 20 youth to wear the biomonitors and provide data and feedback. The advisory group of 5 African American and 5 Hispanic youth will be retained throughout the developmental phase to periodically visit our laboratory and test-run the sensors (50% female, 12-17 years of age). We will recruit a separate group of 10 African American and 10 Hispanic youth (50% female, 12-17 years of age) to participate in idea building sessions to ensure that sensors will be attractive and wearable, and to test the ease of usability of our mobile software suite. The initial deployment phase includes training the children on how to wear and remove the sensors. In order to minimize errors in configuring the software, we envision that our mobile software will have several in-built checks to advise the user if any of the sensor readings do not match expected sensor behavior, and suggest simple solutions to properly configure the sensors. In addition to providing the wearable sensors we will also provide each child with a mobile phone platform which interfaces with these sensors. Since the mobile device has to transmit the data to the backend servers, we will opportunistically use an open WiFi network that a phone can connect to transfer data both efficiently and economically. In the absence of WiFi networks the mobile software will automatically use the cellular data network to transmit the data. For using cellular data network we plan to explore several available options that allow users to send unlimited data for less than 10$ a month in the Los Angeles area from their mobile phones. For laboratory testing of sensors, 10 Hispanic and 10 African American youth will spend 3-6 hours wearing the sensors and following protocols for walking, sitting, standing and doing various daily activities either at Dr. Spruijt-Metz's Physical Activity Observation Laboratory at USC HSA, or to the Motion Capture Laboratory at the Viterbi School of Engineering on USC Main Campus. Once the software and hardware is determined to be robust enough for deployment we will conduct our initial monitoring study with 10 African American and 10 Hispanic youth (50% female, 12-17 years of age). Children will wear the devices for three periods of one week (7 days), after which they will participate in brief individual interviews and surveys to ascertain ease of wear and to find ways to motivate and incentivize teens for wearing the sensors. Data collected from these weeks of wear will be used for the remaining data analysis and web presentation phases of the study.

Table 1 Sensor Data Rates	
Vital and healthcare data	**Data Rate**
Heart rate	100 bps
Blood pressure	100 bps
Body temperature	100 bps
Blood glucose levels	100 bps
Assisted GPS	250 bps
Accelerometer	100 bps
Galvanic Skin Response	200 bps

Part 2: Data Capture and Transmission to a Backend Server: We propose to write a comprehensive mobile software suite that will allow the mobile phone to use Bluetooth to pair with wireless monitoring devices to collect vital health and behavioral data along with reading the built-in GPS data. The BodyMedia and MemSensse units will provide accelerometry data on physical activity and sleep. These measures will be validated in our physical activity lab against the Actigraph accelerometer (which has been extensively validated in youth) and Continuous Observation using the SOFIT system, a gold standard for physical activity measurement in youth [32, 33]. By using time stamps the sensor data from Accelerometer can be correlated to the vital signs data collected from wearable sensors. We will use the data collected from all these sensors to automatically classify the user's activity. In particular, the software creates user specific movement signatures to account for differences in user's gait, walking/running/bicycling speed, usual route taken between work and home etc. The software will be able to use a combination of GPS and accelerometers to recognize the differences between driving on road and walking. This sensor information will be recorded continuously on the local storage on the mobile phone. For reference, our mobile device platform has an 8GB in-built flash memory that can be used for storing sensor information. Table 1 shows the approximate data rate of sensors. Using these data rates, we estimate that our 8GB local storage can store approximately 1000 days worth of data.

While data may be stored locally on the mobile phone the real value of our approach is the fact that these mobile devices can transmit the sensor information to any remote server using cellular data network or even WiFi. The information collected from the sensors in the mobile phone is sent to the web server for processing. The web server acts as data integrity manager that prevents illegal data read/writes by using simple authentication mechanisms, such as personal authentication. The web server utilizes HTTP/SMTP protocol to receive information from the mobile phones. The web server also provides web enabled access to the data for physician's around the globe.

Part 3: Simultaneous Data Analysis and Interpretation: The web server sends the data to the back-end database server for storing and further analysis of the data. Sensor data is likely to be noisy. Therefore, the experts in engineering and pediatric obesity in minority populations gathered on this team will work together to create adaptive algorithms to distill important health and behavioral information from noisy sensors. All data will be analyzed and displayed in two modalities: 1) Average values over a week and 2) High and low points according to geographical position. To accomplish the first modality, accelerometery data will be reduced to display average time spent in sedentary, light, moderate and vigorous activity and average daily energy expenditure. Average heart rate, blood pressure, blood glucose and body temperature will be displayed along with the accelerometer data. We will use current literature and existing software examples to develop systems that will allow us to use Heart Rate and Galvanic Skin Response to measure and display stress and autonomic nervous system (ANS) function appropriately for these pediatric populations. We will fine-tune models for activity levels and correlate activity levels via accelerometry with our other sensing modalities (heart rate, blood pressure, blood glucose, etc.). An objective is to develop new signal processing tools based on multi-modal signal processing strategies to evaluate activity levels with the potential of developing a continuum of activity measures (sedentary, light, moderate and vigorous activity). The development of such algorithms will allow for accurate measurements even when one sensor is not working properly. In addition, we shall investigate the possibility of monitoring whether a child is properly wearing all sensors.

To accomplish modality 2), displaying high and low data points according to geographical position, all data will be time-stamped and synchronized to the Geographic Positioning System (GPS). This will yield high insight into the impact of the environment on physical activity in this population. We will develop methodologies for data and device synchronization. These methodologies may enable the turning on and off of key sensing devices after a particular event has occurred (e.g. GPS data is interpreted and it is observed that a child has moved into a playground or a convenience store – certain sensing devices are turned on or off, or sample at a higher rate). This data will reveal where children are more active, where they are sedentary and where they are experiencing stress. Finally, the web interface will be equipped to signal health practitioners when average values fall above or below prescribed health guidelines.

3a) Web interface capabilities: What, when and where:

Using the data acquired, health professionals will be able to visualize:

- Average amount of moderate to vigorous physical activity a child is getting (daily or weekly), plus daily patterns of exercise
- Average number of steps a child is taking (daily or weekly), plus daily patterns of steps
- Average amount of sedentary behavior a child is experiencing per day or per week, plus daily patterns of sedentary behaviors
- Average amounts of sleep a child is getting per day or per week, plus daily patterns of sleep
- Average blood glucose levels (daily or weekly), plus daily patterns of glucose levels
- Average levels of stress or arousal (daily or weekly), plus daily patterns of stress
- All patterns of behavioral and metabolic data will be time stamped. Therefore, practitioners will be able to see **when** a child is active, sedentary, stressed, or experiencing high blood glucose levels.
- All patterns of behavioral and metabolic data will be geo-coded. Therefore, practitioners will be able to see **where** a child is active, sedentary, stressed, or experiencing high blood glucose levels.

Providing notifications: The final product will be influenced by the advisory group of medical professionals that we will assemble. We therefore provide a brief list of *examples* below *(thus not an exhaustive list)* of notifications that we envision the web interface supply to participating health professionals:

- Recommendations for physical activity range from 30-90 minutes of moderate to vigorous physical activity per day and are somewhat age-specific[34]. Automated system notifications could be generated when average daily physical activity moderate to vigorous falls below 60 minutes, and again below 30 minutes.
- Recommendations for steps per day are currently 11,000 to 12,000 steps per day for girls and 13.000 to 15,000 steps per day for boys. Automated system notifications will be generated when children fall below these recommendations. New recommendations for both physical activity and steps are expected to be made public soon[35]. Advances in the field will be scrupulously monitored and incorporated.
- Blood pressure values are specific to height and weight of children. This data will be fed into the database for analyses and blood pressure notifications will be posted when a child is at or above normal blood pressure according the Fourth Report on the Diagnosis, Evaluation, and Treatment of High Blood Pressure in Children and Adolescents[36].
- According to the American Diabetes Association, casual plasma glucose concentration ≥200 mg/dl (11.1 mmol/l) is indicative of type 2 diabetes in children. Casual is defined as any time of day without regard to time since last meal. Furthermore, concentrations of ≥140 mg/dl are considered to indicate pre-diabetes or Impaired Glucose Tolerance (IGT)[37]. Therefore, we envision that the web interface will provide system notifications at both of these values.
- There are currently no gold standards or threshold measures for stress or arousal in youth or in adults. However, Firstbeat technologies (http://www.firstbeattechnologies.com/) has been working to develop stress and recovery analysis in collaboration with several research projects in the area of stress measurement and autonomic nervous system (ANS) function, applying also research in the fields of exercise physiology, behavioral sciences, and applied mathematics. We will work with Firstbeat to explore development of guidelines for measurement and definition of cut-points for stress in youth. We will begin the design of multi-modal signal processing algorithms for determining personalized cut-points for individual youths.

Bio-monitoring for developing interventions and intervention strategies: Because practitioners will be able to attach time of day and geographic location to metabolic and behavioral indices and patterns, health practitioners will be able to pinpoint causes and effects as well as develop targeted intervention strategies. Furthermore, for researchers, the wealth of time and location stamped data will allow for much broader understanding of the effects of the environment and time of day of metabolic and behavioral events. Here follow some examples:

- Example 1: Adolescent gets less than 30 minutes of physical activity of any kind per day. The participating health practitioner finds that adolescent is particularly sedentary in the hours after school. A targeted approach would be to assist in finding accessible and attractive after school programs.
- Example 2: Adolescent stress levels rise steeply and physical activity levels plummet each Sunday at approximately noon. The participating health practitioner asks the adolescent what is occurring on Sunday afternoons, and finds that the adolescent is being teased at the park where the family typically spends Sunday afternoons. A targeted approach would be to suggest more adult supervision or another venue for physical activity to the family, or explore avenues for dealing with this kind of stress with the child.
- Example 3: Adolescent blood glucose levels have been high for a month. The participating health practitioner notices that this last week, blood glucose levels are normalized. A text message could be sent to the adolescent letting her know that she is making progress. Alternatively, a call or email asking how she changed her behavior in order to pinpoint and reinforce health behavior might be appropriate and timely.

Part 4: Developing a User-Friendly, Web Enabled and Secure Interface for Health Professionals: This part of the research will be ongoing and begin at the onset of the project. An advisory team including pediatricians, family doctors, pediatric endocrinologists, specialists in pediatric diabetes, African American health outreach professionals and promotoras (outreach workers in the Hispanic community) will be assembled to guide us through the process of developing a web interface that will ensure that the right information will be displayed in an easily interpretable fashion. The advisory group will participate in regular meetings to develop and test the web interface. At the onset of the project, they will be invited to participate in an idea-building session in order to develop specific guidelines for web interface development. Idea-building sessions are one of the nominal group techniques that are used to structure small group meetings in such a way that individual judgments can be effectively pooled. Typically, four steps are involved: 1) silent generation of ideas; 2) group recording of ideas; 3) serial discussion of ideas; and, 4) voting to order the ideas as to their salience. Idea writing is particularly helpful in developing general ideas into more specific ideas using group interaction. This is also a four-step process: 1) organization into small groups; 2) initial written response; 3) written interaction; and, 4) analyses and report. Idea writing is an attractive technique because the group produces a written product. Analyses of the idea-building data includes recording, transcription, and examination of the data for emergent themes. The information from these sessions will be used for several purposes: 1) to define the form and content of final data that the web interface will provide, 2) to develop a system of notifications or alarms for specific metabolic and behavioral values, such as blood pressure that is too high or physical activity that is too low as discussed in the previous paragraph, 3) define important pathways within the data that health practitioners will need to navigate easily and 4) to ensure web interface user friendliness, accuracy and appeal. Ideas will also be generated on use of the web interface to develop interventions for the targeted groups immediately and in the future.

The Research Team

The following members of the research team will conduct the Human Subjects research:

Donna Spruijt-Metz, PhD is Associate Professor of Preventive Medicine at the University of California Keck School of Medicine. Her research focuses on human motivation and pediatric obesity. She brings expertise in pediatric obesity in minority youth, stress in youth, insulin resistance, the pubertal decline in physical activity and measurement of physical activity. She has been funded by NIH since 2001. Dr Spruijt-Metz will serve as PI and will oversee and manage all aspects of the proposed study through collaboration with the co-investigators listed below and other project staff and trainees.

Murali Annavaram, PhD is an Assistant Professor in the Electrical Engineering department USC. His research focuses on privacy in mobile environments and energy efficient computation. Dr Annavaram has extensive experience with mobile device architecture and programming. He will supervise the development of mobile software that integrates and collects data from all the external sensors with mobile phones. He will also be responsible for the energy efficient storage and transfer of sensor data from mobile phones to backend servers.

Shrikanth S. Narayanan, PhD is the Andrew Viterbi Professor of Engineering. He brings expertise in human-centric mulitmodal signal processing, essential for handling the proposed measurements through the proposed wireless body area network, as well as in the design of advanced interactive systems for children. His research interest include developing sensors to register and interpret emotion. Narayanan will be responsible for designing multi-modal signal processing methods for combining the signals from the heterogeneous sensors. He will also be responsible for sensor data integrity and improving the signal to noise ratio in sensor data.

Gisele Ragusa, PhD is an Associate Professor and the Director of the Center for Outcomes Research and Evaluation in USC's Rossier School of Education with a joint appointment in USC's Viterbi School of Engineering, Division of Engineering Education. Her research focuses on using case studies in teacher education, measuring teacher efficacy in urban settings (science teacher efficacy) , content area literacy development in K-12 students, beginning teacher induction, health and science literacy, engineering education, assessment and measurement and training of K-12 science teachers using university based laboratory settings. Ragusa will work together with Spruijt-Metz to develop and execute all aspects of evaluation for this project

The following members of the research team will be involved in sensor/website development only:

Gaurav Sukhatme, PhD is the co-director of the USC Robotics Research Laboratory and the director of the USC Robotic Embedded Systems Laboratory. His research interests are in multi-robot systems and sensor/actuator networks. He is a Co-PI on the Center for Embedded Networked Sensing, an NSF Science and Technology Center. He will be responsible for determining body orientation, step detection and stride length estimation based on accelerometer data. Given his expertise in deploying sensor networks in the field, Sukhatme will also manage any sensor modification to work within the context of the newly developed wireless body area sensor network.

Urbashi Mitra, PhD is Professor in the USC Viterbi School Department of Electrical Engineering. She has significant expertise in detection theory, estimation theory, and statistical inference which is central to the translation of engineering measures into useable information for intervention design. Her current areas of research include wireless communications and sensor networks. She will be responsible for creating adaptive sampling methods to determine the optimal selection of sensors with the goal of prolonging the lifetime of the wireless body area sensor network. Mitra will determine the optimal placement of sensor nodes for both sensing accuracy and high wireless communication fidelity. She will also determine the signaling methods to be used by the Bluetooth devices on the sensors to communicate with the N95 cellphones.

Nenad Medvidovic, PhD is Associate Professor in the USC Computer Science Department. Medvidovic brings expertise in software systems engineering. In particular, he is a pioneer in the area of software architectures, with applications to resource-constrained, mobile, and embedded systems. He will be responsible for data storage management and providing web interface to data access.

4. Evaluation plan

4.1 The evaluation plan for this project has four primary objectives: (1) To provide useful information related to the useability of the web interface both formatively (so adaptations can be made throughout implementation) and summatively; (2) To provide useful information about the processes used to carry out the project's research activities (3) To test the mobile biomonitoring suite validity against existing gold standard monitors in a controlled observation laboratory situation and; (4) To provide information about the adolescent satisfaction with the mobile biosensors.

4.2 Research Team and Advisory Group (MDs) Participation Evaluation: To evaluate the effectiveness and participant satisfaction of both the research and design effort, two evaluative surveys have been created. These surveys use a 7-point Likert-type scale. The evaluator research team participation; a) satisfaction with the web interface, b) their receptivity to the collaborative approach of technology design and development and c) their beliefs regarding how the products will affect adolescent health care. An electronic platform will be used to deliver the surveys. Because surveys cannot always provide the level of detail needed to make project decisions and do not typically reveal useful ancillary qualitative information, the evaluator will follow up each survey and exam with in-depth interviews with key scientists (PI and Co-PI).

4.3 Adolescent User Evaluation: Child participant evaluative data will include measures of procedural understanding, a measure of user satisfaction, and a measure of health monitoring. These measures include a Pre and Post Test procedure inventory, a satisfaction survey, and a calibration of health status collected from the technological devices.

4.4 Evaluation Matrix. The following table provides a description of all summative assessment measures across participant groups.

Table 2- Metric Comparisons/Descriptions of Formative and Summative Measures

Metric/description	Research Team	Adolescent Users	Advisory Group	Timeframe
1. Pre/Post Use Device Procedure Inventory- a 4 point multiple choice type questionnaire to assess student knowledge of how to use the technology device (pre and post use of device)		✓		At start and end of the Project
2. User Satisfaction Survey- A 7 point Likert type survey for all device users- measures satisfaction and usability with using the device		✓		Once Annually Years 1 and 2
3. Lab-based device monitoring sub-study measure- A subgroup of users will attend the PI's lab and will be monitored and observed to test the mobile biomonitoring suite validity against existing gold standard monitors in a controlled observation laboratory situation		✓		Once During Year 1
4. Research Team Perception of Team Effectiveness Survey- A 7 point survey related to the research team's perception of collaborative research processes	✓			At Completion of Project
5. Research Team Device Success Survey- A 7 point Likert type scale survey provides information about how the research team believes that the device is functioning.	✓			At Completion of Project
6. PI/Co-PI interviews: A depth measure of the project successes and challenges.	✓			At Completion of Project

7. Health practitioner advisory group device success inventory- measures the doctor's advisory groups' usability of the data obtained from the device			✓	Once Annually Years 1 and 2

4.5 Analysis of Measures: In order to evaluate the effectiveness of the project, the project evaluator (Ragusa) will collect data (listed in Table 2 above) related to project aims and evaluation objectives. Rigorous analyses of the evaluation data will be performed to measure the projects' success. Quantitative measures (surveys, concept inventories, comparisons of mobile biosensors to state-of-the-art sensors and observation) will be analyzed using SPSS (version 17). Descriptive statistics in the form of means and standard deviations of all quantitative variables will be tabulated and presented. Reliability coefficients will be examined for the various measures in the evaluation data sets including the various subscales from the satisfaction and success surveys, the pre and post-test measures for the device users (adolescents) as applicable. Factor analysis procedures will be used to examine the underlying structure of the various measures, as applicable. Correlational procedures will be used to explore the relationships among the variables and their associated measures, and regression and multivariate techniques will be used to model relationships between variables. Qualitative measures (interview transcripts) will be analyzed using a digital analyzer tool, Hyperresearch (version 2.7) with coding schemas for analysis aligned to quantitative survey and concept inventory subscales. Hyperresearch attempts to "quantify" qualitative data through coding procedures resulting in frequency output tables. Quantitative data will be compared with qualitative data by comparing coding results (frequency counts) to statistical analyses of the quantitative data sources. The analyses will be accomplished at the close of both the first and second project year. Statistical comparisons across the two years will be accomplished to demonstrate project success.

5. Plan for further investigation and acquisition for future funding

5a. Current funding

- Annavaram, Medvidovic, Narayanan, Mitra, Sukhatme and Spruijt-Metz currently have a small 54 thousand dollar pilot grant from Qualcomm to establish wireless communication links between a preliminary subset of sensors and the N95 Nokia cell phone. This work is near completion and the team will be pursuing further funding from Qualcomm, in particular to pursue the development of sensors that would be able interpret stress levels and emotional data using multiple cues including galvanic skin response, heart rate, and explicit vocal or gestural cues.

5b. Future plans for investigation and acquisition of funding

- The PI of this project, Spruijt-Metz, along with Narayan and several researchers from the USC Departments of Medicine and Geography (Wolch, Curtis and others) recently submitted a proposal to the Robert Wood Johnson Foundation entitled: *Places to Play: The Shifting Emotional Geographies of Minority Girls Growing Up*. This grant combines synchronous recording of accelerometry, galvanic skin response and geographic positioning, with state-of-the-art metabolic data including Frequently Sampled Intraveneous Glucose Tolerance Tests, measures of leptin, ghrelin, adiponectin and other hormones and inflammatory markers. This data will be layered onto existing Geographical Information Systems data and used to understand physical activity etiology and outcomes in minority females aged 9-11. Funding decisions are expected in September.
- Spruijt-Metz and the abovementioned team plan an October 5th submission to the NIH mechanism Reducing Health Disparities Among Minority and Underserved Children (R01) PA-07-392 to conduct a longitudinal study mirroring the *Places to Play* study mentioned above. We will study the longitudinal mutual influences of behavior, physiological parameters and the environment as minority girls traverse puberty through biosensing and intensive psychosocial and physiological measurement.
- Urbashi head up an application for an NSF Cyber-Enabled Discovery and Innovation grant, letter of intent due September 30th, 2008, which will support a 5 year research program specific to the engineering questions posed by mobile device biomonitoring, and include the development of more sensitive and accurate accelerometers.
- Spruijt-Metz is also spearheading an October 5th grant application with Annavaram, Medvidovic, Narayanan, Mitra, and Sukhatme to the NIH mechanism Bioengineering and Obesity (R01) PA-07-354

that will expand on the current proposal to include Mobile Device Biomonitoring of markers of emotion and include an interface to provide information to youth and parents as well as health professionals.

Timeline

	Oct	Nov	Dec	Jan	Feb	March	April	May	June	July	August	Sept
Year 1	Development of Mobile Software Suite		IN LAB TESTING OF FIRST SUITE		IN LAB Testing and refining of Mobile Software Suite				FREE LIVING Data collection (staggered wear for 3 non-contiguous 1-week periods)			
	Focus groups with AA and Hisp youth, periodic testing of Elements of the Mobile Software Suite				Development of algorithms for data analyses						Year-end evaluation	
					Development of secure web interface for data upload							
	Convene advisory group, initial Idea building sessions				Development of web interface							
								Reconvene youth advisory group to refine Mobile software suite				
Year 2	Continued staggered data collection					Data analysis						
	Finalization of algorithms for data analyses					Preparation of articles for peer reviewed journals						
						Grant writing						
	Reconvene health professional advisory group, refine web interface					Ongoing evaluation activities						

6.1 Protection of Human Subjects

6.1.1 Risks to Human Subjects

a. Human Subjects Involvement and Characteristics: 50 healthy African American and Hispanic youth (50% female, aged 12-17 years) will participate in this project in the following capacities: 1) an advisory group of 10 youth, 2) 20 youth to wear the biomonitors in our laboratories and 3) 20 youth to wear the biomonitors free-living and provide data and feedback. Inclusion criteria is self-identification as either Hispanic or African American, between the ages of 12-17, and without any disabilities that would disallow wear of sensors and normal physical activity. We focus on African American and Hispanic youth because they are at high risk for obesity and related diseases, and are an underserved and understudied population. 10 adult health practitioners will be asked to complete interviews in groups and to provide feedback on website development.

b. Sources of Materials: Data sources will include interview data (recorded), data collected by sensors (mobile phone, GPS, accelerometry, galvanic skin response, blood pressure and glucose levels, sleep and physical activity). Only specified health care providers and the research team will have access to this data.

c. Potential Risks: The risks of this research are minimal and include loss of privacy, possible discomfort while wearing the sensors.

6.1.2 Adequacy of Protection Against Risks

a. Recruitment and Informed Consent: The recruitment process will be conducted at churches, schools and over the phone. Home visits will be paid when requested. The Project Manager and ethnically diverse staff members will explain the study to the teens and their parents at the recruitment sites and over the phone. Parental consent and adolescent assent will be obtained prior to admission to the study. Both forms will include a complete description of the study and will include a telephone number for parents and students to call if they have questions.

b. Protections Against Risk: Confidentiality. Every effort will be made to maintain the confidentiality of participant data for this study by the investigator and the Institutional Review Board (IRB) to the extent permitted by law. Only group information without personal identifiers will be included when submitting manuscripts for publication. Information about the participant will not be shared with other family members without the subject/guardian's permission. All information gathered from these studies will be treated as a medical record with the same degree of confidentiality. The website that will be used to upload, analyze and display data will be extremely secure, however only identifiers and no names will be used on the website. One document that links names with identifiers will be kept by the PI in a locked cabinet. Discomfort: If the sensors are not comfortable, the research team will make every effort to adjust them. Participants can stop participation at any time.

6.1.3 Potential Benefits of the Proposed Research to Human Subjects and Others

The protential benefits of this research to participants is minimal. They might learn something about their own health and health-related behaviors. The potential benefits of this research to others is high. The systems developed in this research could lead to new and effective ways to monitor health and behavior of underserved, at-risk minority youth.

6.1.4 Importance of the Knowledge to be Gained: This research will help us to develop ways to prevent and treat obesity in minority populations through the development of novel mobile biomonitoring systems that allow real-time monitoring of behavior and metabolism that creates the opportunity for highly individualized, culturally and developmentally appropriate feedback and intervention. This system will contribute to our understanding of how behaviors track through time, influence physical health, and are influenced by the built enviroment.

6.2 Inclusion of Women and Minorities: This project focuses on African American and Hispanic youth (male and female), a population at high risk for obesity and related disorders and diseases.

Targeted/Planned Enrollment Tables

Study Title: **Mobile Device Biomonitoring to Prevent and Treat Obesity in Underserved Minority Youth**

Total Planned Enrollment: 60

TARGETED/PLANNED ENROLLMENT: 60			
Ethnic Category	Sex/Gender		
	Females	Males	Total
Hispanic or Latino	14	14	28
Not Hispanic or Latino	31	31	62
Ethnic Category: Total of All Subjects *	45	45	90
Racial Categories			
American Indian/Alaska Native			
Asian	2	2	4
Native Hawaiian or Other Pacific Islander			
Black or African American	16	15	31
White	28	27	55
Racial Categories: Total of All Subjects *	46	44	90

6.4 Inclusion of Children: This study focuses on biomonitoring of African American and Hispanic youth 12-17 years of age, populations at high risk for obesity and related diseases who are understudied and often have inadequate access to health care. The Principal Investigator has all been closely involved in clinical research with African American and Latino populations as well as school-based research in Southern California for many years.

6.5 Data and Safety Monitoring Plan

Data and safety monitoring will be the responsibility of the Principal Investigator and the university's Institutional Review Board (IRB). The Principal Investigator will implement and monitor procedures to ensure that each participant provides informed consent and that each respondent's data remains confidential. Data will be uploaded to a secure website and stored in as password-protected files accessible only to the investigators, and participating health professionals. In the database, respondents will be identified only by an ID code number, not by their names or addresses. The list linking respondents' names with their ID codes will be stored in a separate file with a separate password. All original paper surveys will be stored in locked file cabinets. In the case of a breach of confidentiality the Principal Investigator will report the event to the IRB and the appropriate NIH officials, and appropriate procedural changes will be implemented to prevent future breaches.

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