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Mobile Device Biomonitoring to Prevent and Treat Obesity in Underserved Minority Youth: *The KNOWME NETWORKS study*

INFORMED CONSENT

Principal Investigator: Donna Spruijt-Metz, M.F.A., PhD
Department of Preventive Medicine, Tel: 626 457-6631

Donna Spruijt-Metz, PhD
Principal Investigator

Murali Annavaram, PhD
Co- Investigator

Shri Narayanan, PhD
Co- Investigator

Mitra Urbashi, PhD
Co- Investigator

Gaurav Sukhatme, PhD
Co- Investigator

Nenad Medvidovic, PhD
Co- Investigator

Giselle Ragusa, PhD
Co- Investigator

Luis Santiago
PROJECT MANAGER

University of
Southern California
1000 S. Fremont Ave.
Unit 8
Alhambra, CA
91803-8800
Tel: 626-457-4071
Fax: 626 457 6633

We invite you to take part in a research study. Please take as much time as you need to read the consent form. You may also decide to discuss it with your family or friends. You may find some of the language difficult to understand. If so, please ask questions. If you decide to participate, you will be asked to sign this form.

WHY IS THIS STUDY BEING DONE?

This study is about developing mobile sensors that can measure physical activity, sleep, heart rate, and other physical and emotional reactions. The sensors need to be strong enough, comfortable enough and easy to use so that children would enjoy wearing and using them.

The purpose of this study is to measure physical activity with the use mobile devices to develop new tools for minority adolescent childhood obesity prevention and treatment. A total of 30 adults will be recruited to assist in technology development and testing in the study.

WHAT IS INVOLVED IN THE STUDY?

Interviews and laboratory visits will take place at the USC HSC Alhambra Campus, 1000 S. Fremont Ave., Alhambra, CA 91803 or at the USC Viterbi School of Engineering, Hughes Aircraft Electrical Engineering Center, 3740 McClintock, Los Angeles, CA 90089.

You may be asked to participate in one or two groups involved in the study. Both groups may have their height and weight measured during the process. Your picture may be taken to use for research presentations, printed materials about the study, or for posting on the study website.

Group 1: Testing KNOWME NETWORKS in the laboratory

Group 1 will visit both the Health Science Campus and the Main Campus physical activity laboratories to test out the mobile software suites. We anticipate that this group will pay 4-7 visits to our physical activity laboratories, and the visits will last about 3 hours. During the

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visits, we will ask you to wear the sensors and perform daily activities such as walking, folding laundry, walking on a treadmill, watching a movie, etc. We will ask you about your experience using the mobile sensor suite - we want to know if you think it is comfortable, easy to wear and easy to use. All visits may be audio/videotaped.

Group 2: Testing KNOWME NETWORKS in the field

Once the software and hardware are ready to be used, you may be asked to participate in the development phase. You will wear wireless sensors all day long during your regular activities to measure physical activity, blood pressure, sleep, heart rate, galvanic skin response (slight changes that are happening all the time in your skin's ability to conduct electricity) and blood glucose levels. The information is sent to a mobile phone wirelessly for three periods of one week (7 days). After each period, you will be asked to participate in brief individual interviews and surveys to find out about ease of wear. Data collected from these weeks of wear will be used for the remaining data analysis and web presentation phases of the study.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

You may feel uncomfortable or embarrassed about filling out personal information on the surveys or answering some of the interview questions. To help you feel as comfortable as possible, we will keep your information private. You may skip any questions you do not want to answer. You may also stop filling out the survey at any time.

You might feel uncomfortable or embarrassed having your height and weight measured. To help you feel as comfortable as possible, we will keep your height and weight measurements private.

The study will work to make the mobile software suites as comfortable to wear as possible during the times in which data is being gathered.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART IN THIS STUDY?

You may not receive any direct benefit from taking part in this study. However, this study could help you decide to become more physically active. The surveys and interviews also could help you to think about reasons why you should exercise. The information learned from this study could provide health care professionals with tools to identify risks before children become obese, as well as tools to develop interventions to prevent and treat childhood obesity.

WHAT OTHER OPTIONS ARE THERE?

An alternative would be to not take part in this study.

WILL YOUR INFORMATION BE KEPT PRIVATE?

The investigator and the Institutional Review Board (IRB) will keep your records for this study private as far as the law allows. The IRB is a research review board reviews and monitors research studies to protect the rights and welfare of research participants. We may publish the information from this study in journals or present it at meetings. If we do, we will not use your name.

All your information will be kept secret and private. Each participant will have an ID code number. The ID code number, not your name, will be used on all surveys, interview forms and data collected by sensor. If someone were to see your data, they would not see your name. The researchers at USC will keep all of the data in a locked filing cabinet or secure servers. When data is entered into a computer, the computer file will be protected with a password. The only people who will be able to see the surveys or computer files will be the researchers at USC.

WHAT ARE THE COSTS?

There are no costs to participate in the study. All materials and activities will be given to you free of charge.

ARE THERE ANY PAYMENTS TO YOU FOR TAKING PART IN THE STUDY?

To thank you for your time and participation in this study, you will receive study paraphernalia such as t-shirts and water bottles with the study name and USC and study logo.

WHAT HAPPENS IF I GET INJURED OR NEED EMERGENCY CARE?

If you feel you have been injured by taking part in the study, please contact the investigator.

UNDER WHAT CIRCUMSTANCES CAN YOUR PARTICIPATION BE TERMINATED?

You may be removed from the study if you do not follow the investigator's instructions or if the sponsor closes the study.

WHAT ARE YOUR RIGHTS AS A PARTICIPANT, AND WHAT WILL HAPPEN IF YOU DECIDE NOT TO PARTICIPATE?

Your participation in this research study is voluntary. You can decide to stop a test at any time. You can decide not to do a test at all.

WHOM DO YOU CALL IF YOU HAVE QUESTIONS OR CONCERNS?

You may contact Dr. Spruijt-Metz at (626) 457-6631 with any questions, concerns or complaints about the research or your participation in this study. If you have questions, concerns, or complaints about the research and are unable to contact the research

team, or if you want to talk to someone independent of the research team, please contact the Institutional Review Board (IRB) Office at 323-223-2340 between the hours of 8:00 AM and 4:00 PM. (Fax: 323-224-8389 or email at irb@usc.edu). If you have any questions about your rights as a research participant, please also contact the Institutional Review Board office at the LAC+USC Medical Center, General Hospital Suite 4700, 1200 North State Street, Los Angeles, CA 90033.

You will get a copy of this consent form.

CONSENT TO BE PHOTOPGRAPHED

MY PHOTOGRAPH MAY BE TAKEN.

Yes_____ No_____ Initials_____

MY PHOTOGRAPH MAY BE USED IN RESEARCH PRESENTATIONS AND PRINTED MATERIALS ABOUT THE STUDY.

Yes_____ No_____ Initials_____

MY PHOTOGRAPH MAY BE POSTED ON THE STUDY WEBSITE.

Yes_____ No_____ Initials_____

AGREEMENT:

I have read the information provided above. I have been given a chance to ask questions. All my questions were answered. I have decided to sign this form in order to take part in this study.

Name of Research Participant Signature Date Time

If informed consent is obtained using the Short Form method (oral translation of this document in a language understood by the participant combined with the written Short Form in the participant's language), the witness must sign and date the informed consent below. A witness signature is required ONLY when the Short Form method is used. If you are not using the Short Form method to obtain consent, no witness is needed and you may leave this signature line blank.

Name of Witness Signature Date Signed

I have personally explained the research to the research participant and answered all questions. I believe he/she understands the information described in this informed consent and freely consents to participate.

Name of Investigator/Person Obtaining Informed Consent	Signature	Date	Time