

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

#### PARENTAL PERMISSION/YOUTH ASSENT FORM

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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

(In this consent document, "You" refers to "your child".)

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Luis Santiago PROJECT MANAGER WHY IS THIS STUDY BEING DONE?

this form.

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 of mobile devices. We hope to develop new tools that may be helpful in preventing and treating adolescent childhood obesity. You are invited as a possible participant because you are Latino and/or African American between 12 and 17 years old. A total of 50 Hispanic and African American youth will be asked to participate in this 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, two or three groups involved in the study. All three groups will 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: The Youth Advisory Team**

You may be invited to participate in the initial advisory group that will be retained throughout the first phases of the study to periodically visit our laboratory and test-run the sensors. This group will also take part in ideabuilding sessions to ensure that sensors will be attractive and wearable, and to test the ease of using our mobile software suites. This group will meet 4-6 times, and meetings will last for approximately 2-3 hours. All meetings will be audio/videotaped.

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#### **Group 2: Testing KNOWME NETWORKS in the laboratory**

After the advisory team has helped us to develop the mobile sensor suites, you may be invited to participate in laboratory testing of the mobile software suite. Group 2 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 4-5 visits to our physical activity laboratories, and the visits will last about 3 hours. During the 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, for example, we want to know if you think it is comfortable, easy to wear and easy to use. All visits will be audio/videotaped.

## **Group 3: 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 and to find ways to encourage teens to wear the sensors. Data collected from these weeks of wear will be analyzed and the results will show where and when children like yourself are active and when they are stressed.

### 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 secret and 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 not let any of the other children see your child's height and weight measurements.

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 help other children become more active, fit and healthy. This may also help health care professionals find ways to prevent and treat childhood obesity.

#### **WHAT OTHER OPTIONS ARE THERE?**

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

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#### 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 that is made up of professionals and community members who review and monitor 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 free of charge and you will be reimbursed for any travel expenses that you might have.

## 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 \$30 and some study paraphernalia such as t-shirts and water bottles with the study name and USC and study logo.

## WHAT HAPPENS IF YOU 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 study is closed.

# 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.

As a parent or legal guardian, you are free to withdraw your consent and to discontinue your child's participation in this study at any time. Your decision whether or not to allow your child to take part will not affect your child's current or future care at this institution. You are not giving up any legal claims or rights. Your child has the right to withdraw from the study even if you would want him/her to continue.

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#### 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 child's 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 child's 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 PHOTOGRAPHED

| MY PHOTOGR  | APH MAY BE      | TAKEN.                         |              |             |  |
|---|-----------------|--------------------------------|--------------|-------------|--|
| Yes   | No              | Initials                       |              |             |  |
| MY PHOTOGR<br>MATERIALS A                         |                 | E USED IN RESEARCH PF<br>TUDY. | RESENTATIONS | AND PRINTED |  |
| Yes   | No              | Initials                       | <del></del>  |             |  |
| MY PHOTOGRAPH MAY BE POSTED ON THE STUDY WEBSITE. |                 |                                |              |             |  |
| Yes   | No              | Initials                       |              |             |  |
| AGREEMENT:  |                 |                                |              |             |  |
| If your child agrees to                           | participate, ha | ave your child sign here.      |              |             |  |
| Name of Child                                     |                 | Child's Signature              | Date         | Time        |  |
| Name of Parent/Legal                              | Guardian        | 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.

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| Name of Witness                                  | Signature  | Date Signed                |          |
|--|--|----------------------------|----------|
| parent/legal guardian and                        | ed the research to the researd<br>answered all questions. I be<br>this informed consent and free | elieve that he/she underst | ands the |
| Name of Investigator/Persobtaining Informed Cons | •  | ure Date                   | Time     |

Study ID: HS-08-00635 Valid From: 5/21/2013 To: 5/20/2014

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