Department of Nutritional Sciences

CONSENT FORM

BaseMetrics: A Mobile Health-tracking App for OSU Employees

IMPACT OF COVID-19 ON THIS STUDY

Although temporarily paused due to COVID-19, this study has been permitted to resume.
At the present time, there is increased risk of COVID-19 exposure with all activities located outside of your personal residence. However, the researchers are committed to strong measures to lessen risk of COVID-19 spread during your participation in this study.

Should you choose to participate in this study, the following steps will be taken to decrease risk of COVID-19 spread:

- All participants will be screened via telephone prior to attending the laboratory.
- Temperature checks will be conducted on all researchers and participants upon entering the laboratory.
- All individuals will apply hand sanitizer and wear a mask upon entering the laboratory. Researchers will wear a mask, gloves and a laboratory coat.
- If you participate, you will be the only participant in the laboratory and there will never be more than 2 investigators in the laboratory with you.
- As much as possible, individuals in the laboratory will be at least 6 feet apart.
- Investigators will wash their hands or apply hand sanitizer before and after every procedure during your assessment.
- Prior to your arrival in the laboratory, all surfaces that you will contact will be disinfected. This will be repeated after each participant leaves the laboratory. We will also disinfect equipment after each specific test/procedure.

Background Information

You are invited to be in a research study of a new health-tracking mobile app called Base Metrics. You were selected as a possible participant because you are an employee of Oklahoma State University (OSU). We ask that you read this form and ask any questions you may have before agreeing to be in the study. Your participation is entirely voluntary.

To be eligible to participate in this study, you must:

- Be an employee of OSU
- Be age 30-64 years
- Own and use a smartphone (iOS or Android)
- Own and regularly wear a physical activity tracker (such as Fitbit, Garmin, Apple Watch, etc.)

You are not eligible to participate if:

- You have been diagnosed with a chronic condition that could impact your study results or behavior during the study period (such as, but not limited to, heart disease, cancer, or type 2 diabetes)
- You have a pacemaker or other electrical implant

This study is being conducted by: Christina Sciarrillo, Bryant Keirns, and Kara Poindexter of the Department of Nutritional Sciences, under the direction of Dr. Sam Emerson of the Department of Nutritional Sciences, Dr. Bridget Miller of the School of Community Health Sciences, Counseling and Counseling Psychology, and Jai Rajendran of the OSU Technology Development Center.

Procedures

***Overview of Study*:** If you participate in this study, you will be required to make at least 3 visits to the laboratory, separated by 12 weeks. In the first visit, we will also conduct a fasting metabolic measurement via needle stick, you will complete questionnaires, we will measure height, weight, body composition, and blood pressure, and lastly we will conduct a risk factor consultation. Then, you will be randomly assigned to either have access to the Base Metrics mobile app for 12 weeks, or have no access to the Base Metrics app. Halfway through the study (i.e. 6 weeks later), you will return to the lab to complete the same questionnaires as the first visit (except health history) and to measure body composition and blood pressure. At the end of

12 weeks (i.e. 6 weeks after the mid-study assessment), you will return to the laboratory to complete all of the same measurements as the first session (including needle stick and metabolic assessment).

***Specific Procedures*:**

Blood pressure: We will measure your blood pressure using an automatic cuff on the upper-arm 2-3 times.

Body composition and weight: We will measure your body composition using a Seca mBCA 514. The Seca uses a non-invasive technique called bio-electrical impedance analysis (BIA), which works by sending a small, insensible electrical current through your body and measuring the flow resistance of the electrical current based on different tissues. The Seca also has a weight scale integrated into the system, so we will measure weight simultaneously.

Physical activity and sleep data: At the beginning and the end of the study, we will ask you to provide certain physical activity and sleep data (including steps, exercise sessions, and sleep time) for a 7-day period. This data will be recorded in hard copy format (in other words, we will not request access to all of your physical activity and sleep data).

Phlebotomy (single needle sticks) and metabolic measurement: A 21-gauge needle will be used to draw blood from a forearm vein at the two study visits. We will draw approximately 4 mL of blood each time. Therefore, we will draw a total of ~8 mL of blood. These blood samples will be analyzed for standard metabolic risk markers (cholesterol, glucose, HDL, LDL, triglycerides).

Questionnaires: You will complete questionnaires related to health history, diet, physical activity, health literacy, self-efficacy, and intention to change behavior.

Mobile app usage: If you are randomized to have access to the Base Metrics mobile app, we will help you download the app on your mobile device (smartphone) and explain how to use it. For the 12-week intervention period, the degree and manner in which you use the app is up to you. In other words, there are no minimum requirements for app usage during the 12-week study. The app is intended to help you track and understand your risk factor values. If you are randomly assigned to the control group (no Base Metrics app access), you will simply need to return 12 weeks later for a follow-up assessment.

Risk Factor Consultation: During the first appointment, a researcher will review your risk factor results with you. This consultation will simply consist of the researcher presenting to you the recommended levels for each risk marker, as well as your personal results. The researcher presenting your results is not a physician and therefore not qualified to make clinical recommendations. Furthermore, no physicians will review the results of these tests, as the researchers are not using this test to make a diagnosis. We will only present your results to you alongside the recommended levels.

Participation in the study involves the following time commitment:

Pre-Study Session: ~1 hour
Mid-Study Session: ~30 minutes
Post-Study Session: ~45 minutes
Total Time Commitment for the Study in the Laboratory: ~2.25 hours

Biospecimen Sampling for Research:

We will be collecting blood samples to measure metabolic markers in circulation. However, these blood samples will be analyzed immediately upon extraction and will never be stored. Blood samples will be discarded and destroyed after use.

Information or specimens collected from you will not be used for future research studies or shared with other researchers for future research.

Risks and Benefits of being in the Study

The only foreseeable risks involved in this study are related to phlebotomy (single needle sticks). Risks of phlebotomy include slight pain/discomfort upon needle insertion, and potential redness and bruising at the site of the insertion. A blood draw may lead to lightheadedness or fainting in some individuals. In order to minimize these risks, we will wipe the site of the blood draw with alcohol to disinfect the area, use disposable sterile needles and tubes to collect blood, and apply pressure to the site following the blood draw to minimize bruising. In order to assist with the offset of these risks, we are utilizing the most participant-friendly procedures possible to address our research aims: we are conducting the minimal amount of needle sticks and drawing the minimal amount of blood. In case of injury or illness resulting from this study, emergency medical treatment

will be available through transportation to the nearby student health center or hospital. However, this outcome is highly unlikely. No funds have been set aside by Oklahoma State University to compensate you in the event of illness or injury.

The benefits to participation are: your risk factor results (both from study visits) will be shared with you. Some individuals find this personal health information very interesting. However, we cannot guarantee or promise that you will find this study or its associated information beneficial.

Compensation

You will receive no payment for participating in this study.

Confidentiality

The information that you give in the study will be handled confidentially. Your information will be assigned a code number. Your name will not be used in any report.

We will collect your information through paper surveys and metabolic assessments. Paper surveys and data sheets will be stored in a locked filing cabinet in a locked laboratory. Data will be stored electronically on a password-protected program on a password-protected laptop that does not leave the locked laboratory, and backed up on an encrypted and password-protected external hard drive. This informed consent form will be kept for 3 years after the study is complete, and then it will be destroyed. Your data collected as part of this research project, will not be used or distributed for future research studies.

It is unlikely, but possible, that others, such as the FDA, responsible for research oversight may require us to share the information you give us from the study to ensure that the research was conducted safely and appropriately. We will only share your information if law or policy requires us to do so.

Voluntary Nature of the Study

Your participation in this research is voluntary. There is no penalty for refusal to participate, and you are free to withdraw your consent and participation in this project at any time. The alternative is to not participate. On the questionnaires, you can skip any questions that make you uncomfortable and can stop at any time.

Contacts and Questions

The Institutional Review Board (IRB) for the protection of human research participants at Oklahoma State University has reviewed and approved this study. If you have questions about the research study itself, please contact the Principal Investigator at 405-744-2303, sam.emerson@okstate.edu. If you have questions about your rights as a research volunteer or would simply like to speak with someone other than the research team about concerns regarding this study, please contact the IRB at (405) 744-3377 or irb@okstate.edu. All reports or correspondence will be kept confidential.

You will be given a copy of this information to keep for your records.

Statement of Consent

I have read the above information. I have had the opportunity to ask questions and have my questions answered. I consent to participate in the study.

Indicate Yes or No:

I give consent to be contacted for follow-up in this study or future similar studies:
___Yes ___No

Signature:_____ Date: _____

Signature of Investigator:_____ Date: _____