
Consent for Research Participation

Research Study Title: Diet, Physical Activity, and Sleep Habits Study
Researcher(s): Grace Hawkins, University of Tennessee, Knoxville
Hollie Raynor, PhD, RD, LDN, University of Tennessee, Knoxville

Why am I being asked to be in this research study?

We are asking you to be in this research study because you are an adult between the ages of 18 and 35 years, taking classes and/or working, and able to engage in physical activity.

What is this research study about?

The purpose of the study is to observe the diet, physical activity, and sleep habits of young adults.

How long will I be in the research study?

If you agree to be in this study, your participation will last 8 to 14 days and will involve one session at the beginning, one session at the end, and 7 online surveys.

What will happen if I say “Yes, I want to be in this research study”?

If you agree to be in this study, we will ask you to come to the Healthy Eating and Activity Laboratory (HEAL) for 1, 60-minute first session and 1, 30-minute final session. At the first session, your height, weight, and body composition will be measured. You will be asked to complete questions about your demographic information (age, race, education, etc.) and you will complete a survey about your typical sleep habits. You will be given a Body Media Armband, along with instructions for care and use and a charging cord, to wear every day and night over the next week. You will also receive instructions on how to complete an online survey on daily activities and how to complete 3 days of food records. After a week of taking the survey on daily activities, you will return for your final session. At this session, you will return the armband, charging cord, and food records. You will receive feedback on your diet, physical activity, and sleep habits via email within two weeks of completing your participation.

The daily surveys, which will take no more than 5 minutes to complete, about your typical activities will be emailed to you each morning. The surveys should be completed each day by 3 pm. If you do not complete the survey by 2 pm, you will receive a reminder email. You will be asked to wear the Armband for at least 23 hours each day. This means wearing the Armband while sleeping and during the day. Do not wear the Armband when engaging in water activities (bathing or swimming). You will be asked to complete the food records on three consecutive days, two weekdays and one weekend day. It will take about 20 minutes to complete each day of the food record. The daily surveys, armband, and food records will need to be collected during the same week.

What happens if I say “No, I do not want to be in this research study”?

Being in this study is up to you. You can say no now or leave the study later. Either way, your decision won't affect your relationship with the researchers or the University of Tennessee.

What happens if I say “Yes” but change my mind later?

Even if you decide to be in the study now, you can change your mind and stop at any time.

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IRB APPROVAL DATE: 07/23/2019

IRB EXPIRATION DATE: 05/01/2020

Participant Initials _____

If you decide to stop before the study is completed, you may contact the HEAL at 865-974-0752 to let us know you would no longer like to participate. You can then schedule a time to return the armband and charging cord. Any of your information already collected for the research study will be returned to you if you request it.

Are there any possible risks to me?

Possible risks of this research study are considered minimal. It is possible that someone could find out you were in this study or see your study information, but we believe this risk is small because of the procedures we use to protect your information. The confidentiality procedures are described later in this form. You may be allergic to the metal in the Armband, but you have been phone screened on this criterion.

Are there any benefits to being in this research study?

We do not expect you to benefit from being in this study. Your participation may help us to learn more about the diet, physical activity, and sleep habits of young adults. We hope the knowledge gained from this study will benefit others in the future.

Who can see or use the information collected for this research study?

We will protect the confidentiality of your information by storing it securely. Only persons conducting the study will have access to your information unless you specifically give permission in writing to do so otherwise.

If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information or what information came from you. Although it is unlikely, there are times when others may need to see the information that we collect about you. These include:

- People at the University of Tennessee, Knoxville who oversee research to make sure it is conducted properly.
- Government agencies (such as the Office for Human Research Protections in the U.S. Department of Health and Human Services), and others responsible for watching over the safety, effectiveness, and conduct of the research.
- If a law or court requires us to share the information, we would have to follow that law or final court ruling.
- A description of this study will be posted on a public website, <http://ClinicalTrials.gov>, and summary results of this study will be posted on this website at the conclusion of the research. No information that can identify you will be posted.

What will happen to my information after this study is over?

Your research information may be used for future research studies or shared with other researchers for use in future research studies without obtaining additional informed consent from you. If this happens, all of your identifiable information will be removed before any future use or distribution to other researchers.

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Will I be paid for being in this research study?

If you complete all procedures in this study, you will receive a \$25 Amazon gift card at your final session. You will not receive any payment if you withdraw from the study before completing all of the activities.

What else do I need to know?

We may need to stop your participation in the study without your consent if you no longer meet the study's eligibility requirements.

The University of Tennessee does not automatically pay for medical claims or give other compensation for injuries or other problems.

Who can answer my questions about this research study?

If you have questions or concerns about this study, or have experienced a research related problem or injury, contact the researchers:

Grace Hawkins
229 Jessie Harris Building
The University of Tennessee, Knoxville
Knoxville, TN 37996-1920
Phone: (865) 974-0752

Dr. Hollie Raynor
301B Jessie Harris Building
The University of Tennessee, Knoxville
Knoxville, TN 37996-1920
Phone: (865) 974-6259

For questions or concerns about your rights or to speak with someone other than the research team about the study, please contact:

Institutional Review Board
The University of Tennessee, Knoxville
1534 White Avenue
Blount Hall, Room 408
Knoxville, TN 37996-1529
Phone: 865-974-7697
Email: utkirb@utk.edu

STATEMENT OF CONSENT

I have read this form and the research study has been explained to me. I have been given the chance to ask questions and my questions have been answered. If I have more questions, I have been told who to contact. By signing this document, I am agreeing to be in this study. I will receive a copy of this document after I sign it.

Name of Adult Participant

Signature of Adult Participant

Date

Researcher Signature (to be completed at time of informed consent)

I have explained the study to the participant and answered all of his/her questions. I believe that he/she understands the information described in this consent form and freely consents to be in the study.

Name of Research Team Member

Signature of Research Team Member
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