

RESEARCH DESCRIPTION

The Pennsylvania State University

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Research Team: Dr. Saeed Abdullah, Sahiti Kunchay (Research Assistant and Developer)

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Telephone Number: 814-865-7177

IRB Number: STUDY00013672

This document gives you information about the research.

Whether or not participants take part in the study is up to them. Participants can choose not to take part. Participants can agree to take part and later change their mind. Participants' decision will not be held against them and there will be no penalty or loss of benefits to which they are entitled.

1. Why is this research study being done?

This research is being done to find out about substance use and other health behaviors. Approximately 80 people will take part in this research study at Penn State.

2. What will happen in this research study?

- 1) During the study period, participants will be asked to respond to survey prompts via an app on the Apple Watch for a two- or four-week period. These survey prompts will include questions about their experiences, substance use, and other health behaviors.
- 2) Additionally, we will collect the following data through Apple's HealthKit (<https://developer.apple.com/healthkit/>):
 - a. Heart rate
 - b. Physical Exercise Measures and Trends (Walking, Running, Stairs Climbed)
 - c. Step Count
 - d. Active Energy Burned
 - e. Basal Energy Burned
 - f. Exercise Time
 - g. Stand Time
 - h. Body Temperature
 - i. Walking metrics: Double support time, walking speed, walking step length
 - j. VO₂ Max
 - k. Sleep Data (Time spent awake, in bed, and sleeping)

All of this data will be collected through Apple's HealthKit API only after participants give the app permission to do so. Participants can change these permissions at any time through the Settings app or the Health app.

Users can choose which of the aforementioned data they want to share with the application. The application reads and stores only the data types that the user has given the app permission to access. This data is stored using Google's Firebase Database. Only the research staff from the study team at Penn State have access to this collected data, and appropriate data security measures (or security "rules") are in place to ensure that data can be collected through only registered participants and only authorized personnel can view the data.

The use of Firebase to store the de-identified data and Google's BigQuery to analyze the de-identified data is authorized by Penn State's IRB and Office of Information Security. Thus, these third-party applications have been reviewed by Penn State to adequately protect users' data and ensure privacy and security of uploaded data.

Following the study completion, the data is stored on ICDS servers, which is protected by a firewall. The data can only be accessed by research personnel within the Penn State network and will be additionally secured through 2 Factor Authentications.

- 3) We will also collect sensor data:
 - a. Location (collected every time movement > 100m is detected)
 - i. NOTE: Location data will only be collected after participants give the app permission to do so. Participants can change these permissions at any time through the Settings app.
- 4) At the end of the study period, participants will be asked to come in-person for the end of study visit. Participants will return the study device, and participate in a brief in-person interview about the usability of the device. The in-person interview will be audio-recorded.

Participants can decide at any time that they don't want to participate, and participating in this study is voluntary. They can also ask questions about the study and their participation at any time. During survey questionnaires, they can skip any question that they would prefer not to answer or indicate "Prefer not to say."

3. What are the risks and possible discomforts from being in this research study?

There is a risk of loss of confidentiality if participants' information or their identity is obtained by someone other than the research team, but precautions will be taken to prevent this from happening. The confidentiality of electronic data created by participants or by the researchers will be maintained as required by applicable law and to the degree permitted by the technology used. Absolute confidentiality cannot be guaranteed.

4. What are the possible benefits from being in this research study?

4a. What are the possible benefits to the participant?

Participants will not benefit from this research study.

4b. What are the possible benefits to others?

There are no direct benefits to others related to this survey. The information we gain from this research could help better understand health behaviors in order to improve existing interventions to promote health.

5. What other options are available instead of being in this research study?

Participants may decide not to participate in this research study.

6. How long will participants take part in this research study?

If they agree to take part, participants will be asked to participate for up to four weeks.

7. How will participants' privacy and confidentiality be protected if they decide to take part in this research study?

7a. What happens to the information collected for the research?

Data collected from participants' devices will be uploaded to Google's Firebase Database and subsequently moved to the servers provided by Penn State Institute for Computational and Data Sciences.

Efforts will be made to limit the use and sharing of participants' personal research information to people who have a need to review this information. Reasonable efforts will be made to keep the personal information in participants' research record private. However, absolute confidentiality

cannot be guaranteed. A list that matches participants' names with their code number will be kept in a password-protected file on a secure server accessible only to trained research personnel.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot disclose information that identifies participants to anyone not connected with the research. This protection also prevents this information from being used or disclosed for legal proceedings, such as being accessed through a court order. The Certificate of Confidentiality however does not prevent disclosures required by law, such as information about child abuse or neglect and harm to participants or others. Also, participants' information may be disclosed in accordance with any consent that the participants provide, including for their medical treatment or use in other research. For additional information ask the principal investigator or a member of the study team (sahiti@psu.edu or kunchay.sahiti@gmail.com) or contact the Office for Research Protections at (814) 865-1775.

In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

We will do our best to keep participation in this research study confidential to the extent permitted by law. However, it is possible that other people may find out about participation in this research study. For example, the following people/groups may check and copy records about this research.

- The Office for Human Research Protections in the U. S. Department of Health and Human Services
- The research study sponsor, The Penn State College of Information Sciences and Technology
- The Institutional Review Board (a committee that reviews and approves research studies) and Penn State's Office for Research Protections.

7b. What will happen to participants' research information and/or samples after the study is completed?

In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared. We may use participants' research information for future research studies or may share participants' information with other investigators here or at other institutions for future research without their additional informed consent. Future research may be similar to this study or completely different. Before we use or share participants' information we will remove any information that shows their identity.

De-identified research data will be kept indefinitely for future undetermined research.

8. What are the costs of taking part in this research study?

8a. What happens if participants are injured as a result of taking part in this research study?

In the unlikely event that participants become injured as a result of their participation in this study, medical care is available. It is the policy of this institution to provide neither financial compensation nor free medical treatment for research-related injury. By agreeing to participate in this study, participants are not waiving any rights that they have against The Pennsylvania State University for injury resulting from negligence of the University or its investigators.

9. Will participants be paid or receive credit to take part in this research study?

Participants will be paid according to an established compensation structure.

10. Who is paying for this research study?

Funds from the Penn State College of Information Sciences and Technology will be used to support this research.

11. What are participants rights if they take part in this research study?

Taking part in this research study is voluntary.

- Participants do not have to be in this research.
- If participants choose to be in this research, they have the right to stop at any time.
- If participants decide not to be in this research or if participants decide to stop at a later date, there will be no penalty or loss of benefits to which they are entitled.

The person in charge of the research study or the sponsor can remove participants from the research study without their approval. Possible reasons for removal include trying to participate in the study more than once.

12. If you have questions or concerns about this research study, whom should you call?

Please contact the research assistant associated with this research study, Sahiti Kunchay, at sahiti@psu.edu or kunchay.sahiti@gmail.com if you:

- Have questions, complaints or concerns about the iPhone or Apple Watch applications or development

Please call the head of the research study (principal investigator), Dr. Ashley Linden-Carmichael at 814-865-7177 if you:

- Have questions, complaints or concerns about the research, including questions about compensation.
- Believe you may have been harmed by being in the research study.

You may also contact the Office for Research Protections at (814) 865-1775, IRB-ORP@psu.edu if you:

- Have questions regarding your rights as a person in a research study.
- Have concerns, complaints, or general questions about the research.
- You may also call this number if you cannot reach the research team or wish to offer input or to talk to someone else about any concerns related to the research.