

University of California, San Diego
Consent to Act as a Research Subject

STUDY TITLE

Self-Directed Physical Activity Tracking (SDPAT): Understanding Use and Implications of Wearable Activity Devices.

Who is conducting the study, why you have been asked to participate, how you were selected, and what is the approximate number of participants in the study?

Ernesto Ramirez, MS, a student in the Department of Family and Preventive Medicine within the School of Medicine, is conducting a research study to find out how people use physical activity tracking devices. You have been asked to participate in this study because you expressed interest in participating and you meet the study criteria. There will be approximately thirty (30) participants in this study.

Why is this study being done?

The purpose of this study is to examine how individuals engage with and use their physical activity tracking device and the data the device gathers in their everyday life. Additionally, this study is seeking to use a combination of subjective and objective data to explore and define the types of individuals who use physical activity tracking devices.

Who is funding this study?

This study is being funded as part of the Health Data Exploration Project in the Center for Wireless and Population Health Systems at the University of California, San Diego. This study is being funded by the Robert Wood Johnson Foundation.

What will happen to you in this study ?

If you agree to be in this study, you will be asked to participate in all of the following activities:

- **Interview (part one)** – During the first part of the interview you will be asked to answer questions about your demographic background, your thoughts and feelings about your physical activity, and about your past physical activity behavior.
- **Interview (part two)** – During the second part of the interview you will be asked about your experiences with your Fitbit device. This will include questions about your daily usage, your thoughts and emotions related to your use of the device and its mobile/web applications, and how you think about the information it collects.
- **Fitbit Data Authorization** – You will be asked to authorize the research staff to access and download your historical Fitbit data. This authorization will not require you to give your password or other personal information to the research staff. You will be directed to secure system (Fitabase) that will allow you to sign in with your Fitbit login and authorize the research staff to download your data. After you complete the interview described above the research staff will delete your authorization so that any data you collect after you complete the interview will not be collected. Research staff will access and download the following data gathered from your Fitbit account:
 - **Daily steps total**
 - **Measured steps per minutes**

- **Estimated energy expenditure**
- **Distance moved**
- **Minutes of vigorous activity**
- **Minutes of moderate activity**
- **Minutes of light activity**
- **Minutes of sedentary time**
- **Sleep length, quality, and movement**

What is involved with the Fitabase Authorization?

In order to access your Fitbit data you will be asked to authorize a third party, FitabaseServices, owned and operated by Small Steps Labs LLC, via an online form. Fitabase is a research platform that collects data from internet connected consumer activity devices. In order to authorize Fitabase to collect and store your Fitbit data you will connect Fitabase to your Fitbit account. This is done in order to gather you historical information for quantitative analysis of your physical activity. Fitabase, upon your authorization, will collect:

- Personal details added to your Fitbit user account, such as height, weight, gender, and age.
- Information sent wirelessly from your Fitbit product to the service and that is stored in your Fitbit user account.
- Information that was added manually to the Fitbit service and is stored in your Fitbit user account.
- Accounts of when a you elected to share data from your Fitbit user account with others.
- GPS route and location data for saved activities
- Minute-level data reported by devices including:
 - Number of steps taken
 - Calories burned
 - Intensity of movement metrics
 - Sleep data and times of awakening
 - Weight
 - Body fat percentage
 - Heart rate
 - Any manually reported food or exercise information provided to Fittbit.com.

Your Fitbit username and password will not be accessed, viewed, or stored by Fitabase, Small Steps Labs, LLC, or any study personnel.

When you authorize Fitabase to access and store your Fitbit data you are agreeing to the Terms of Use and Privacy Policy set by Fitabase. A copy of those Terms of Use and Privacy Policy will be given to you. We ask that you review both the Terms of Use and Privacy Policy before agreeing to participate in this study. If you have any questions about your privacy and the Fitabase system please contact the Principle Investigator, Ernesto Ramirez, at erramirez@ucsd.edu or (480) 225-0002.

If you decide to forgo participation in any of the above activities (Interview Part One, Interview Part Two, or the Fitbit Data Authorization) you will be removed from the study and any data contributed will be deleted or destroyed.

Human Research Protections Program UC San Diego	
Approved	
Current Approval:	05/05/2015
Do not use after	05/03/2016

How much time will each study procedure take, what is your total time commitment, and how long will the study last?

The activities will be completed during a phone call or web-based interview session using Skype or another online video-calling system. In total the above procedures will take a total of 1.5 hours. The first part of the interview including survey questions will take approximately 30-45 minutes. The second part of the interview that asks about Fitbit specific thoughts and emotions will last approximately 45 minutes. The Fitbit authorization will take approximately 5 minutes.

What risks are associated with this study?

Participation in this study may involve some added risks or discomforts. These include the following:

1. A potential for the loss of confidentiality. We will attempt to employ the following procedures to maintain confidentiality:
 - a. We will not record your name or link identifiable information to the data. After conducting the interview, we will transcribe the audio recording and remove any personally identifiable information from the transcript.
 - b. Research data will be stored electronically on a laptop computer in an encrypted file or stored electronically on a secure server in an encrypted file with password protection. The audio recordings will also be stored in a secure location; then transcribed as soon as possible and erased within six (6) months of the end of the study.
 - c. We will keep your contact information for no more than 6 months after conducting the interview. Your contact information will not be linked to the interview recording or transcript and will be stored separately.
 - d. The researchers intend to keep the anonymized research data in a repository indefinitely. Other researchers may have access to the data for future research. Any data shared with other researchers will not include your name or other personal identifying information.
 - e. To ensure the confidentiality of data and participant information, all study participants will be de-identified and will receive a study identification number, which will be used for data tracking. Data collected over the phone, via web-based calls, in-person, and through Fitabase will be transferred to a study database on a secure server at UCSD. All files containing identifiable information, including the linked file with participant's name, contact information, and study ID number will be stored in locked cabinets. Only key study personnel will have access to the password-protected database.

2. Research records may be reviewed by the UCSD Institutional Review Board.

3. The possible risks and/or discomforts associated with the procedures described in this study include anxiety, embarrassment, and invasion of privacy.

4. As we will be conducting interviews to inquire about physical activity behavior and experiences there is a possibility that you will become embarrassed or may not be comfortable answering questions. You may experience shame, remorse, or discomfort due to recalling previous behaviors such as the inability to meet goals or periods of low activity. We will attempt to mitigate potential psychological distress due to boredom, feelings of discomfort, or other psychological discomfort by creating an open and inviting dialogue with you during the

survey and interview process. You may stop at any time and resume the interview (if desired) at a future time. You may also refuse to answer any interview or survey question. Doing so will not affect your eligibility to participate in this study.

5. There is a risk that employees of the Fitabase service may access your Fitbit data, including information you post or add to your Fitbit account. This data is only associated with your unique study identifier. Additionally your data will be deleted from the Fitabase system (both online and backup servers) at the completion of this study. Fitabase also employs robust security and encryption. For more details please read the Fitabase Security and Privacy Information sheet provided to you.

Because this is a research study, there may also be some unknown risks that are currently unforeseeable. You will be informed of any significant new findings.

Will my data be shared with others?

Yes, the data you contribute to this study will be retained and made available to other researchers and entities interested in understanding Fitbit data, physical activity measurement device use, or other similar research questions. Only anonymized transcripts, surveys, and matched and anonymized Fitbit data will be retained and made available to others. Any data shared with other researchers and other entities will not include your name or other personal identifying information.

Will I be able to access the data I contribute to this study?

You will be contacted via email after the principal investigator, Ernesto Ramirez, completes the study in order to return a copy of the data you contributed to this research study. This will include a copy of your transcribed interview (parts one and two), and copy of your Fitbit data. Ernesto Ramirez will also make himself available for a phone call or web video conference for at least 30 minutes upon returning a copy of your data in order to answer questions about your data and the study findings. **You are not required to take part in this post-study call if you are not interested.**

Data collected during the course of this study and returned to you are not for treatment or diagnosis, and data findings will only reflect your physical activity levels. Questions regarding your physical activity status should be discussed with a physician.

What are the alternatives to participating in this study?

The alternative to participation in this study is to not participate.

What benefits can be reasonably expected?

There may or may not be any direct benefit to you from participating this study. The investigator, however, may learn more about how individuals use and experience self-directed physical activity measurement and society may benefit from this knowledge. The results of this research have the potential to generate new methods for understanding physical activity behavior and the role of technology for understanding and impacting health behaviors. There is the potential that this research will inform future generations of devices and applications that may positively impact you as well as many future users of similar devices and applications.



Can you choose to not participate or withdraw from the study without penalty or loss of benefits?

Participation in research is entirely voluntary. You may refuse to participate or withdraw or refuse to answer specific questions in an interview or on a questionnaire at any time without penalty or loss of benefits to which you are entitled. If you decide that you no longer wish to continue in this study, you will be required to contact the Principle Investigator, Ernesto Ramirez, at erramirez@ucsd.edu or (480) 225-0002.

You will be told if any important new information is found during the course of this study that may affect your wanting to continue.

Can you be withdrawn from the study without your consent?

The PI may remove you from the study without your consent if the PI feels it is in your best interest or the best interest of the study. You may also be withdrawn from the study if you do not follow the instructions given you by the study personnel.

Will you be compensated for participating in this study?

You will not be compensated for participation.

Are there any costs associated with participating in this study?

There will be no cost to you for participating in this study.

What if you are injured as a direct result of being in this study?

If you are injured as a direct result of participation in this research, the University of California will provide any medical care you need to treat those injuries. The University will not provide any other form of compensation to you if you are injured. You may call the Human Research Protections Program Office at (858) 657-5100 for more information about this, to inquire about your rights as a research subject or to report research-related problems.

Who can you call if you have questions?

Ernesto Ramirez, MS has explained this study to you and answered your questions. If you have other questions or research-related problems, you may reach Ernesto Ramirez at 480-225-0002.

You may call the Human Research Protections Program Office at (858) 657-5100 to inquire about your rights as a research subject or to report research-related problems.

Your Signature and Consent

You have received a copy of this consent document.

You agree to participate.

Subject's signature

Date

Human Research Protections Program	
UC San Diego	
Approved	
Current Approval:	05/05/2015
Do not use after	05/03/2016