

CONSENT TO PARTICIPATE IN RESEARCH

Dartmouth College

User Study using mobile health (mHealth) devices

You are being asked to participate in a research study. Your participation is voluntary.

Your decision whether or not to participate will have no effect on your academic standing or job status if you are student or employee of XXX. Please ask questions if there is anything you do not understand.

What is the purpose of this study ?

The purpose of the study is to

1. test the feasibility of a method to automatically connect two mHealth devices to each other, and
2. gather minimal data about your activities using an accelerometer in an mHealth device.

What does this study involve ?

The length of time of your participation in this study is 10 days.

You will carry one or two mHealth devices, including a Fitbit, at all times. A Fitbit is a device that you can clip onto your clothes or carry in your pocket, to calculate the number of steps that you take and the calories you burn and which you can wear on your wrist when you sleep, to measure sleep quality. The Fitbit will send data to the Fitbit website every 15 minutes, if you are near the dock station which we will provide. We will download the data from the website and present it to you on a website which we create.

We will also gather data about your physical activities using a second, "accelerometer" device; you must carry the accelerometer in a secured location by the waist (e.g., a pants pocket) for three days. You should carry the accelerometer from the time you leave your room in the morning to the "end" of your day, whether it be dinnertime or when you go to your room to sleep. The accelerometer should be otherwise left alone as long as it is secured and safely worn.

You should take the devices off before a shower or a swim, since they are not waterproof.

You must return the devices at the end of the study.

Are there any benefits from participating in this study ?

You may benefit from participating in this study. The device (Fitbit) will record data about your activities, which may help you if you are interested in losing weight or becoming more fit. After three days, we will give you the opportunity to share the collected information with your family and friends, so that they can help motivate you to achieve your health goals. Your

participation will also help us learn the feasibility of our approach that allows future mHealth devices to connect to each other automatically, which would be useful if you were to use more than one mHealth device to monitor your health.

What are your options if you do not want to take part in this study?

Participation is voluntary; hence you can withdraw from the study at any time. Please do not sign the consent form if you do not want to take part in the study.

If you take part in this study, what activities will be done only for research purposes?

If you take part in this study, the following activities will be done only for research purposes: You will carry two devices at all times and one of them, the Fitbit, will record your level of physical activity. The accelerometer in this device will record only your motion.

What are the risks involved with being enrolled in this study ?

Your first name will be collected at the start of the study, to make the website user-friendly. One device, the Fitbit, will record data about your level of physical activity throughout the day, and later upload it to the vendor's servers and to our own password- controlled website.

Other important items you should know:

- **Withdrawal from the study:** You may choose to stop your participation in this study at any time; if so, you must return the devices. Your decision to stop your participation will have no effect on your academic standing or job status if you are a student or employee of Dartmouth College.
- **Number of participants:** We expect XX participants to enroll in this study.
- **Funding:** The XXX provides funding to XXX for this research.
- **Devices:** You are required to return both devices at the end of the study.

How will your privacy be protected?

The information will be collected by the accelerometer in the mHealth devices. Accelerometers collect information about your movements, specifically the level of activity but not location or type of activity.

Efforts will be made to protect the identities of the participants and the confidentiality of the research data used in this study, such as:

We will collect only your first name, which we will use to add a welcome message to make the web interface more appealing. The data collected using Fitbit will be uploaded to the fitbit.com database. The Fitbit privacy policy (<http://www.fitbit.com/privacy>) states that the information will not be sold or rented to anyone. Other than Fitbit, only the researchers working on the project will have access to the collected data. Your name will be removed from our records at the end of the study. All research data will be stored on secure computers, and hard copies

(including this consent form) will be stored in the researcher's office in a locked filing cabinet when not in use.

Research data may be shared with officials of XXX and others involved in the oversight of this study as permitted by law. Research data may be obtained by a court order or other legal process.

What about the costs of this study ?

There is no cost to participate but if you fail to return the mHealth devices at the end of the study you will be required to reimburse XXX for the cost of the devices.

Will you be paid to participate in this study ?

Yes, you will be paid \$X each day you carry both devices. You will be paid an additional \$X each day you remember to upload the Fitbit data. You will be paid an additional \$X every day if you wear the Fitbit for at least XX hours that day (including when you sleep).

Whom should you call with questions about this study?

Questions or concerns about this study may be directed to the researcher in charge of this study: Call us at XXX or email XXX.

If you have questions, concerns, or suggestions about human research at XXX, you may call the Office of the Committee for the Protection of Human Subjects at XXX during normal business hours.

CONSENT

I have read the above information about *User Study using mHealth devices* and have been given an opportunity to ask questions. I agree to participate in this study and I have been given a copy of this signed consent document for my own records.

Participant's Signature and Date / PRINTED NAME

Researcher or Designee Signature and Date PRINTED NAME