CONSENT TO PARTICIPATE IN RESEARCH

XXXX

User Study using mobile health (mHealth) devices

You are being asked to participate in a <u>research study</u>. Your participation is <u>voluntary</u>.

Your decision whether or not to participate will have no effect on your academic standing or job status if you are a student or employee of XXXX. 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,
- 2. gather minimal data about your activities using an accelerometer in an mHealth device, and
- 3. allow you to share the collected information with acquaintances and thus increase the benefits to you.

What does this study involve?

You have been carrying an mHealth sensing device called a Fitbit at all times for the past three days. The Fitbit has been sending data to the Fitbit website every 15 minutes, when you were near the dock station which we provided. We downloaded the data from the website and presented it to you on the website which we created. Now you should share the collected information with at least three other people of your choice. Please choose at least one family member and two friends. You can also share some information with the public on your public profile. You can decide what information to share with your acquaintances and the public. Sharing information with family and friends gives them an opportunity to be part of your effort to lose weight or get fit. At the end of the study, you can keep the collected information. If you choose to continue with the study, we will require the email addresses of the individuals, including at least one family member and two friends you have chosen to share the collected information with.

You may choose to leave the study if you feel uncomfortable sharing your information with others.

Are there any benefits from participating in this study?

Yes. The device will record information about your physical activities. This information will help you in your effort to lose weight or become fit. Now we give you the opportunity to share the collected information with your family and friends, so that they can motivate you to achieve your health goals.

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

You can choose to withdraw from the study, in which case you will be compensated for participating in the study for the past three days.

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 the mHealth device (Fitbit) at all times and record information about your level of physical activity. The accelerometer in the device will record only your motion. A summary of this information will be shared daily with people chosen by you, at a level of detail selected by you.

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

The only risk is sharing of information about your physical activities. We will collect your first name, which will be revealed to the individuals you have chosen to share your information with. Your name will be removed from our records at the end of the study. The data collected using Fitbit will be uploaded to the fitbit.com database and to our password-protected website. Other than Fitbit, the researchers working on the project, you, the individuals chosen by you will have access to the collected data; however, we will also prepare a version of the data to be publicly available on our website (at a level of detail selected by you).

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 Fitbit device. 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 XXXX.

- Number of participants: We expect XX participants to enroll in this study here.
- Funding: XXXX provides funding to XXXX for this research.
- You must return the Fitbit device to the researchers at the end of the study.

How will your privacy be protected?

Information is collected by the accelerometer in the Fitbit device. Accelerometers collect only information about your movements, that is, your level of physical activity.

Efforts will be made to protect the identities of the participants and the confidentiality of the research data used in this study. The Fitbit privacy policy (http://www.fitbit.com/privacy) states that the information uploaded to its database will not be sold or rented to anyone.

We will collect only your first name, to add a welcome message to make the web interface more appealing. Even though your name will be revealed to these individuals along with your collected information, it will be removed from our records at the end of the study. You can decide what information to share with your acquaintances and the public. Apart from you, the individuals you choose and those who have the link to your public profile, only researchers working on the project will have access to the data. All such 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.

The individuals you choose to share your information with will be required to login to access your information. Thus, your information will be password-protected and cannot be accessed by unauthorized parties.

Research data may be shared with officials of XXXX, XXXX, 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 Fitbit device at the end of the study, you will be required to reimburse XXXX for the device.

Will you be paid to participate in this study?

Yes, you will be paid \$XX each day you remember to upload the data and you share your information with at least three people. You will be paid an additional \$XX each day you wear the Fitbit for at least 20 hours, and another \$XX each day you answer all the questions we ask in the daily email and on our website.

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-XXX-XXXX or email.

If you have questions, concerns, or suggestions about human research at XXXX, you may call the Office of the Committee for the Protection of Human Subjects at XXX-XXXA 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 I	Date	PRINTED NAME