

Appendix J: Student/Teenager Assent Form for ActiviTeen Continued Study Participation

RTI International Investigators

Robert Furberg Ph.D.
Sonia Grego Ph.D.
Alexa Ortiz MSN

RTI International

RTI International, is a not for profit research company based in Research Triangle Park, North Carolina.

About ActiviTeen

ActiviTeen is an investigative research study. The purpose of this study is to demonstrate the ability to collect data about physical activity through consumer wearable devices (e.g. Fitbit). This approach offers the benefit of collecting data on devices that people typically purchase for their own use. Doing this allows us to achieve long-term data on physical activity levels that are an important contributor to health and well-being. You are one of up to 45 teenage students between the ages of 13 to 17 that RTI will recruit for an additional three month data collection period.

Participation

Students continuing to participate in ActiviTeen will not receive extra credit and participation will not impact their academic standing.

If participating, you will continue to wear the provided Fitbit Zip during the study's additional three month period. As a result, each participant will need to continue use of their personal smart phone with internet access to sync their Fitbit to their de-identified Fitbit account once every 3-4 days. The Fitbit, when worn, will passively monitor your activity. We will request that participants continue to wear the device on the right side of their hip, attached to their belt or pocket, every day throughout the study. No further surveys will be administered at any point during the three month data collection period.

Voluntary Participation

You may choose whether or not you would like to participate. Participation in this study is voluntary and can be stopped or refused at any time by either you or your parent/guardian.

Data Collection

Each Fitbit Zip will continue to be connected to an individually assigned RTI email account. Your name will not be associated with this email account. You will not be responsible for checking the RTI assigned email account and the email account will not be a method of communication with project staff at RTI. This email account continues to allow RTI staff to collect your de-identified movement data from your de-identified online Fitbit account. This will require you to keep the previously downloaded Fitbit app on your smartphone for the remainder of the data collection period.

RTI will monitor the online account for the additional three month period. You will continue to have access to your data via the Fitbit app. However, the Fitbit app is not secure and it is not encrypted. Anyone who has access to your phone may also have access to your collected data. During the study, do not enter any additional information (such as food intake or water consumption) beyond what the Fitbit Zip will automatically collect (activity level and step count). RTI will collect step count and activity level (i.e. mildly active, moderately active, intensely active, etc.) based upon your steps per minute. All data collected throughout the study will be de-identified, meaning no names will be associated with your data. Re-calibration of your Fitbit Zip is not

required; however, your Fitbit account will continue to have the following information: your gender, your height, your weight, and your birth year.

All participants will be permitted to keep their Fitbit Zip devices as a thank you for their participation. A decision to leave the study at any time does not impact your ability to keep the device. Once you leave the study, the distributed Fitbit Zip will no longer be connected to an RTI assigned ID or email account.

Risks

Within the Fitbit Product manual (obtainable at: http://help.fitbit.com/resource/manual_zip_en_US), Fitbit lists the following risks

- Heed all warnings
- Follow all instructions
- Do not attempt to open the tracker. Substances contained in this product and/or its battery may damage the environment and/or human health if handled and disposed of improperly.
- Do not tamper with your Zip.
- Do not use abrasive cleaners to clean your Zip.
- Do not place your Zip in a Dishwasher, Washing Machine or Dryer.
- Do not expose your Zip to extremely high or low temperatures.
- Do not use your Zip in a sauna or steam room.
- Do not leave your Zip in direct sunlight for an extended period of time.
- Do not leave your Zip near open flames.
- Do not dispose of your Zip in a fire. The battery could explode.
- Do not attempt to disassemble your Zip, it does not contain serviceable components.
- Never allow children to play with the Zip; the small components may be a choking hazard!

Benefits

There are no direct benefits to you; however, by participating you will help us develop a better understanding of the feasibility and processes for passive data collection using wearable devices.

Confidentiality

All collected data will be kept confidential. We will not connect your name to the survey completed before or after the four week data collection period or any activity-based information. RTI International will not retain your name or email address.

Questions

If you have any questions about this study, you may contact Alexa Ortiz at amortiz@rti.org. If you have any questions about your rights as a study participant, you may contact RTI's Office of Research Protection at 1(866)-214-2043. This is a toll-free number.

An overview of ActiTeen was previously distributed to your parent/guardian by Research Triangle High School and they have been provided with the same contact information if study concerns arise.

By signing below, you are giving assent for your participation in the research described above. Please sign only if:

- ✓ You read the information about the research described in this assent form, and

✓ You have had all of your questions answered fully.

You will be given a copy of this form to keep.

By signing below, I agree to participate in this research study:

Student's Name: _____
(Print your name here)

Date: _____

Signature: _____
(Sign your name here)

Date: _____