

COMBINED CONSENT/ASSENT TO TAKE PART IN RESEARCH

TeenLife: A Study of Health Behaviors in Teens

Principal Investigator: XXX

Introduction: You are being asked to take part in a research study. Taking part in research is voluntary.

The term "You" in this form may refer to enrolling your child in this study. You are being asked to take part in this study because you are teen aged 14 to 18. Your decision whether or not to take part will not influence your future medical care, academic standing, or job status. Please ask questions if there is anything about this study you do not understand.

What is the purpose of this study?

The purpose of the study is to learn about daily health behaviors and self-regulation in teens. The daily health behaviors that we are studying include sleep, physical activity, substance use, heart rate, stress, and mood. This project will help us learn more about how teens' health behaviors and self-regulation change from day to day, and help us to create new interventions to improve teens' health.

Will you benefit from taking part in this study?

You will not personally benefit from being in this research study. We hope to gather information that may help people in the future.

What does this study involve?

Your participation in this study may last up to 4 weeks. After this initial visit, all participation is completed from home. There are three research assessments in this study.

Assessment 1

The initial assessment will include an interview and filling out questionnaires.

Assessment 2

The second research assessment will last 2 weeks.

1. We will install a program on your smartphone that will do the following:

- This program will share with us data from the sensors on your phone including:
 - Physical activity

- Location

- Sounds

- ◆ We will not record intelligible speech. With your consent we will record 3-second samples every 5 minutes to determine if there is any human conversation or if there is silence. This amount of audio is not enough to detect any information about a conversation. You have the option of turning off this feature.

- At any time, you can turn off this program so that it does not share your activity, location, or sound data with us

Data from the smartphone is recorded in the internal memory and will be transmitted to our secure server via wifi connections each night.

The program on the phone will not give you or anyone else access to your data or information during the study.

At the end of this assessment the program and any associated data will be removed from your phone and stored on secure workstations at XXX.

2. We will also provide you with a wristband with sensors and ask you to wear this wristband, except for when it needs to be charged. The sensors on the wristband measure:

- i. Sleep

- ii. Heart Rate

- iii. Galvanic skin response (very small changes in sweat on your skin)

You can remove or turn off the wristband as needed if there is a time you do not want the wristband to collect data

Data from the wristband is recorded in the internal memory and will be transmitted to your phone and then to our secure server via wifi connections each night. At the end of this assessment any data on the wristband will be removed and deleted from the wristband and this data will be stored on secure servers at XXX.

3. We will send you text notifications to complete brief surveys 5 times per day about health behaviors and self-regulation, including:

- a. The program will signal you throughout the day 4 times and then 1 more time at the end of the day
- b. You are not required to respond to every signal and can ignore signals that occur at a time when you do not want to answer

You will answer questions using an online survey system. The text notification will include a link to the survey. You can request to stop or take a break from the surveys at any time.

Assessment 3

After completing assessment 2, you will be asked to complete a final assessment. This assessment is a brief online survey about your experiences in this study.

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

The alternative option is to not take part in this study.

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

All the activities described in this consent form are being done only for research purposes.

What are the risks involved with taking part in this study?

Possible risks of participating in this study include risks related to boredom or having to answer questions that you find upsetting. Another potential risk is that people may find out that you are in this study or other information about you. We will keep your forms in a locked file cabinet. We will keep electronic data in password protected and encrypted servers. We won't use your name on the files. Only people who work on the study will see your forms and we won't give out your name unless you tell us we can. The only other time we would give others information about you is if we were worried about your safety or the safety of others.

These problems might happen to you. Some problems might happen that the researchers don't know about. It is important to let the researchers know if there is anything that you don't like about the research study right away. Sometimes things that bother one person don't bother another person at all, so you need to let us know when something is bothering you.

Other important items you should know:

- **Leaving the study:**

You may choose to stop taking part in this study at any time for any reason without penalty.

- **New Information:** New information related to this research will be made known to you when it becomes available. This may affect your decision to stay in this study.

- **Funding:** XXX is the sponsor of this research.

- **Number of people in this study:** We expect up to XX people to enroll in this study.

How will your privacy be protected?

We will collect information about your health including physical health, mental health, and your daily health behaviors and activities, including:

1. physical activity
2. sleep
3. location
4. social interactions
5. substance use
6. managing your thoughts and feelings
7. stress
8. mood
9. heart rate

Data collected for this study will be maintained indefinitely.

We are careful to protect the identities of the people in this study. We also keep the information collected for this study secure and confidential. We will not disclose any information you provide without written permission. All teen responses and data are kept strictly confidential and we will not share answers on questionnaires or data with your parents. However, if we are concerned about your safety related to child abuse or self-harm, or safety of another person, we may need to contact the appropriate authorities.

We keep your records and all electronic data in locked files and rooms. We use an ID number on files and data, and not your name. Our computer files are password protected and data is stored on encrypted servers.

To further help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The confidentiality Certificate is issued to protect the investigators on this study from being forced to tell people that are not connected with this study about your participation in the study, even under a subpoena (a written order issued by the courts to appear). The protection offered by the Confidentiality Certificate does not stop us from voluntarily reporting information about suspected or known sexual, physical, or other abuse of a child or older person, or a subject's threats of violence to self or others. If any member of the research team is given such information, he or she will make a report to the appropriate authorities.

Even when a Confidentiality Certificate is in place, you and your family members must still continue to actively protect your own privacy. If you voluntarily give your written consent to anyone to receive information about your participation in this research, then we may not use the confidentiality Certificate to withhold this information.

The results of this study may eventually be published and information may be exchanged between medical investigators, but research subject confidentiality will be maintained.

Who may use or see your health information?

By signing this form, you allow the research team to use your health information and give it to others involved in the research. The research team includes the study director plus others working on this study at XXX and elsewhere.

The information collected for this study may be used by researchers or officials of the following institutions.

◆ XXX

◆ XXX

◆ XXX

Some of the information used in this study, called Protected Health Information ("PHI"), is protected by federal privacy laws. By signing this consent form, you give your permission to have your PHI collected, used and disclosed for purposes of this study. After the study staff discloses your PHI to others, it could be re-disclosed and no longer protected by federal privacy laws.

Your permission to use your health information for this study will not end until the study is completed. During this study, you and others who take part in the study may not have access to the study data. You may ask for study data once the study is over.

What if you decide not to give permission to use and share your personal health information?

If you do not allow use of your health information for this study, you may not take part in this study.

If you choose to stop taking part in this study, you may cancel permission for the use of your health information. You should let the researcher know if you want to cancel your permission. The study team will assist you in putting your wishes in writing. Information collected for the study before your permission is cancelled will continue to be used in the research.

Whom should you call about this study?

If you have questions about this study or need to report a study related injury, you can call your doctor or the research director for this study: XXX toll free at xxx-xxx-xxxx during normal business hours.

If XXX is not available, other members of the research staff will be available to answer your questions during normal business hours.

If you have questions, concerns, complaints, or suggestions about human research at XXX, you may call xxx-xxx-xxxx during normal business hours.

If you agree to take part in this study and you sign this consent form, you are not giving up any of your legal rights.

What about the costs of this study?

The assessments conducted in this study are provided at no cost. We will not pay for treatment of any physical or mental health problems during your participation in the study. You will be responsible for the costs associated with your transportation to and from the initial visit.

Will you be paid to take part in this study?

You will receive payment if you complete the initial (assessment 1) and exit (assessment 3) assessments.

1. \$XX for completing the initial assessment
2. \$XX for completing the exit assessment.

You can also earn incentives for completing assessment 2, the 2-week assessment.

3. You can earn \$x for each completed daily assessment (maximum earning of \$xx per day and \$xx in x weeks)
4. You can also earn up to \$xx based on the percent of time that you provide data from your smartphone and wristband for the passive assessment

The money earned will be deposited to a personal prepaid MasterCard which we will provide to you.

Your name, address, and social security number will be given to an office at XXX that arranges for payments and reports payments to the IRS. If you do not provide a social security number, no payment can be made. This office sometimes checks to make sure that social security and numbers and names match.

CONSENT

I have read the above information about **TeenLife: A Study of Health Behaviors in Teens** and have been given time to ask questions. I agree to take part in this study and I will be given a copy of this signed consent form.

Consent of adolescent (**if age 18**) and Date

PRINTED NAME

Researcher or Designee Signature and Date

PRINTED NAME

ASSENT for ages 14-17

I have explained to this child what taking part in this study will involve and have answered any questions that he or she has asked.

Researcher or Designee Signature and Date

PRINTED NAME

Assent of minor (age **14-17**) and Date

PRINTED NAME

Legally Authorized Representative (Parent/legal guardian) and Date

PRINTED NAME