

UT Austin IRB Approved
Protocol Number: 2019-09-0080

Approved: 10/16/2019

Title of the Project: Project LIBRA

Principal Investigator: Dr. Aprile Benner, Associate Professor, University of Texas at Austin

Parental Permission for Child Participation in Research

Invitation to be Part of a Research Study

We would like to invite your child to be part of a research study. This permission form will help you decide whether or not to allow your child to participate in the study. Feel free to ask if anything is not clear in this consent document.

What is the study about and why are we doing it?

Teenagers experience many different positive and negative interactions everyday with teachers, parents, friends, and others they encounter in their daily lives. These experiences can cause a number of different emotions and physical reactions. The goal of this project is to learn more about teenagers' daily lives and how their positive and negative experiences influence their well-being. We will be using many methods that assess aspects of health, social and emotional well-being, and academic and educational experiences. We are also interested in understanding how COVID-19 is impacting adolescents' daily lives.

What will happen if your child takes part in this study?

If you choose to allow your child to participate, your child will be asked to complete a general survey three different times throughout the project.

You can also choose if you would like your child to:

- o Complete 1-3 rounds of daily mini-surveys; each round lasts 14-days
- Wear an activity sensor throughout the day and while sleeping for 14 days.
- o <u>Provide health data (height, weight, blood pressure, waist circumference, blood spots, saliva samples).</u>
- o Provide information on phone use/GPS location.
- o Participate in 1 or 2 interviews over the study period.

During the study period, we will be scheduling periodic home visits or virtual zoom meetings in which research assistants will train your child on how to complete the daily mini-surveys, use the activity sensor, and how to provide the saliva samples.

If completing daily mini-surveys diaries, the surveys can be completed on any device that has internet connectivity (phone, laptop, etc); nightly reminders will be sent via email and text.

If using the activity sensors, the activity sensors being used in this study are the Fitbit Charge 3, an E4 wristband, and an OURA ring. Each of these sensors are designed to track daily activity,

heart rate, and sleep quality. If your child is assigned to wear the E4 activity sensor they will be provided with a laptop; every evening, your child will upload data from their E4 wristband onto the laptop. You and your child will not be responsible if the activity sensors are lost, stolen, or damaged.

If providing saliva samples, your child will be asked to drool into a vial through a straw 4 times a day for three days. From the saliva samples, we will assess stress and inflammation. If providing dried blood spots, this method for collecting blood involves pricking the person's finger with a small lancet; drops of blood are collected on a piece of filter paper. From the blood spots, we will assess stress, inflammation, and metabolic functioning.

If participating in an interview, interviews will take place via an online phone, chat, or video system (e.g., Zoom) and will be audio-recorded. If providing information on the phone usage and GPS location, your child will be asked to upload an associated data app onto their phone. No one outside the research team will know this information belongs to your child.

How long will your child be in this study and how many children will be in the study?

This study will occur over the next two years, and 760 adolescents will be enrolled in the study.

What risks and discomforts might your child experience from being in this study?

Your child may feel temporary feelings of discomfort (e.g., loneliness, sadness, anxiety) that may come with thinking about stressful events that occurred throughout the day and with having measures such as blood pressure, height, weight, waist circumference, and blood spots taken. Your child may also feel temporary physical discomfort (e.g., itchiness, annoyance) from wearing the activity sensor and having their finger pricked, or they may experience dry mouth if providing saliva samples.

The researchers will let you know about any significant new findings (such as additional risks or discomforts) that might make you change your mind about allowing your child to participate in this study.

How could your child benefit from this study?

Your child might benefit from being in this study because he/she will be engaged in the research process and may learn more about his/her health and habits through the use of the activity sensor. Your child may also appreciate that they are being listened to by researchers.

What will happen to the samples and/or data we collect from your child?

The data will be analyzed to better understand how daily life experiences impact health. Any information we collect will remain confidential and will not be shared with anyone outside of the research team. Upon final analysis, audio-recordings, saliva, and blood spots will be destroyed.

How will we protect your child's information?

This study is confidential. Any reports from this study will not be linked back to your child in any way. Your child will be assigned an ID number, and this number (rather than your child's name) will appear on all study materials. If it becomes necessary for the Institutional Review Board to review the study records, information that can be linked to your child will be protected to the extent permitted by law. Your child's research records will not be released without your consent unless required by law or a court order. The data resulting from your child's participation may be made available to other researchers in the future for research purposes not detailed within this consent form. In these cases, the data will contain no identifying information that could associate it with your child, or with your child's participation in any study.

If the research staff should observe or otherwise learn of child or elder abuse while visiting your child, confidentiality will be broken. We are required by law to report child or elder abuse to relevant agencies (Child Protective Services or the Texas Department of Family and Protective Services). If this situation occurs, then confidentiality will be broken.

What will happen to the information we collect about your child after the study is over?

Your child's name and other information that can directly identify them will be deleted from the research data collected as part of the project.

How will we compensate your child for being part of the study?

As a participant in this study, your child will receive \$25 for each survey completed. In addition, your child could also receive the following compensation:

- \$50 for completing daily mini-surveys, wearing activity sensor for 14-days, providing health data (height, weight, blood pressure, waist circumference, blood spots, saliva samples), and providing information on phone use/GPS location
- \$35 for participating in a 30-60 minute interview

Your Child's Participation in this Study is Voluntary

Taking part in this research study is voluntary. You or your child may decline to participate or stop participating at any time.

The decision to participate will not affect your or your child's relationship with The University of Texas at Austin or your child's school. You and your child will not lose any benefits or rights you already had if you decide not to participate. Even if you decide to allow your child to be part of this study now, you may change your mind and stop at any time. Your child does not have to answer any questions they do not want to answer. If you decide to withdraw your child from the study before it is completed, you may do so.

Contact Information for the Study Team and Questions about the Research

If you have any questions about this research, you may contact:

Dr. Aprile Benner Phone: (512) 232 1964

Email: abenner@prc.utexas.edu

Contact Information for Questions about Your Rights as a Research Participant

If you have questions about your rights or your child's rights as a research participant, or wish to obtain information, ask questions, or discuss any concerns about this study with someone other than the researcher(s), please contact the following:

The University of Texas at Austin Institutional Review Board

Phone: 512-232-1543

Email: irb@austin.utexas.edu

Please reference study number 2019-09-0080.

Your Permission

By signing this document, you are agreeing to allow your child to be in this study. Make sure you understand what the study is about before you sign. We will give you a copy of this document for your records. We will keep a copy with the study records. If you have any questions about the study after you sign this document, you can contact the study team using the information provided above.

I understand what the study is about and my questions so far have been answered. I agree to allow my child take part in this study.

Printed Subject Name

Signature of Parent or Legal Guardian	Date
Signature of Person Obtaining Consent	Date

The main component of this study is the general survey. Below is a list of the additional parts of the study. Please mark an X on any additional part of the study you **<u>DO NOT</u>** want your child to complete:

Interviews

14-day mini-surveys

14-day wearing of an activity sensor (e.g., Fitbit, E4, Oura ring)

3-day saliva samples

Provision of blood spots

Provision of other health data (height, weight, waist circumference, pulse, blood pressure)

Cell phone/GPS monitoring