

Parent Consent

We invite you to participate in a research study being conducted by investigators from Washington University in St. Louis. You are being asked to participate in this research study because you are enrolled in Parents as Teachers (PAT). The purpose of the study is to evaluate the standard Parents as Teachers lessons plus additional lessons about how families can live healthy and active lives while reaching a healthy weight (HEALTH program). We hope to determine if the new lessons help change the way people eat and/or their activity level. The National Institutes of Health is funding this research study.

If you agree to participate, there will be two parts of the study:

Part 1: We will collect measurements including your height, weight, waist circumference, and blood pressure. You will then take a survey that will ask you questions about topics such as physical activity, the foods you normally eat, and your overall opinion of the lessons. The data collections will take place now, 12 months from now, and again 24 months from now. At the first data collection only, the survey will include questions about sociodemographic data, such as age, marital status, and number of children. Each data collection will take approximately 60-75 minutes to complete. You are free to skip any questions that you prefer not to answer. All data collections will take place at your house, in an alternate, private location (e.g., library, doctor's office), online or over the phone. We will provide materials for you to complete data collection. We will provide a scale for you to measure your weight. If it is possible, we will also provide a blood pressure cuff to measure your blood pressure and a tape measure to measure your waist circumference. If we are not able to provide the blood pressure cuff or tape measure, we will not ask you to complete these parts of data collection. Please use only materials from the research team to complete your measures. A member of the research team will help you with all parts of the process.

Part 2: The lessons will be delivered for 2 years via routine home visits and telephone calls with parent educators. Parent educators at some sites will be trained in the HEALTH program. These sites will be assigned at random. If your parent educator is not trained in the HEALTH program, you will receive PAT as usual. During home visits, discussions are related to child development, parenting topics, and information about healthy living and active lifestyles, if your parent educators were trained in the HEALTH program. Fun parent-child activities will also take place during home visits.

One aspect of this study involves making audio recordings of you. Your parent educator will audio record during home visits to make sure the information in each lesson is covered. Only members of the study team have access to these

FOR IRB USE ONLY
IRB ID #: 201810157
APPROVAL DATE: 10/05/20
RELEASED DATE: 10/05/20
EXPIRATION DATE: N/A

audio recordings. All recordings will be destroyed when the study is finished. You may still be included in the study without being recorded.

As part of this study, we are obtaining data from you. We would like to use this data for studies going on right now as well as studies that are conducted in the future. These studies may provide additional information that will be helpful in understanding healthy lifestyle programs. It is unlikely that what we learn from these studies will have a direct benefit to you. There are no plans to provide financial compensation to you for use of your data. By allowing us to use your data you give up any property rights you may have in the data. We may also ask PAT to share the data it has collected about your family.

If you change your mind and do not want us to store and use your data for future research, you should contact the research team member identified at the bottom of this document. The data will no longer be used for research purposes. However, if some research with your data has already been completed, the information from that research may still be used. Also, if the data has been shared with other researchers it might not be possible to withdraw the data to the extent it has been shared.

This part of the study is optional and you can still do the rest of the study if you don't do this.

If you do not wish to participate in this study, you may tell the study team or parent educator that you are not interested. Approximately 504 people will take part in this study at Washington University.

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

You might feel stress and anxiety when describing personal information regarding your weight and lifestyle. You may be asked sensitive questions. You may choose not to answer any question with which you feel uncomfortable. Please note that although you may tell us sensitive information, we have been trained on confidentiality and are required by law to keep this information private. One risk of participating in this study is that confidential information about you may be accidentally disclosed. We will use our best efforts to keep the information about you secure.

You may or may not benefit from being in this study. However, we hope that others may benefit in the future from what we learn as a result of this study.

You will not have any costs for being in this research study.

You will be paid for being in this research study. You will be given a \$30 gift card at each data collection (today, 12 months later, and 24 months later). You will need to provide your social security number (SSN) in order for us to pay you. If your social security number is obtained for payment purposes only, it will not be retained for research purposes. You may choose to participate without being paid if you do not wish to provide your SSN for this purpose. If you should withdraw at any point, you may keep any gift cards you've already been given, but will not receive any future gift cards.

We will keep the information you provide confidential by conducting the data collections in a private area. The research team will enter your data online using a unique ID. The record that links these IDs to your information will be encrypted and stored on a secure server. Data will be stored in an encrypted format on a secure server. Any hard copy information will be kept in a locked cabinet in a locked office. However, federal regulatory agencies and Washington University, including the Washington University Institutional Review Board (a committee that reviews and approves research studies) and the Human Research Protection Office may inspect and copy records pertaining to this research. If we write a report about this study we will do so in such a way that you cannot be identified.

To further protect your privacy, this research is covered by a Certificate of Confidentiality from the federal government. This means that the researchers can refuse to disclose information that may identify you in any legal or court proceeding or to anyone who is not connected with the research except if:

- there is a law that requires disclosure, such as to report child abuse and neglect, or harm to self or others;
- you give permission to disclose your information, including as described in this consent form; or
- it is used for other scientific research allowed by federal law.

You have the right to share your information or involvement in this study with anyone at any time. You may also give the research team permission to disclose your information to a third party or any other person not connected with the research.

Your participation in this study is completely voluntary. You may choose not to take part at all. If you decide to participate in the study you may stop participating at any time. Any data that was collected as part of this study will remain as part of the study records and cannot be removed. If you decide not to take part in the study or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

If you do not wish to participate in this study or want to end your participation in the study, you may withdraw by telling the study team or your parent educator you are no longer interested in participating in the study. You will not be

FOR IRB USE ONLY
IRB ID #: 201810157
APPROVAL DATE: 10/05/20
RELEASED DATE: 10/05/20
EXPIRATION DATE: N/A

penalized or lose any benefits for which you otherwise qualify. Should contact with you be lost during the course of the two years, we will attempt to contact you by asking your parent educator for your current contact information (phone number, etc.).

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Cindy Schwarz, (314) 935-3063. If you feel you have been harmed from being in the study, please contact: Dr. Rachel Tabak, (314) 935-0153. If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office at 660 South Euclid Avenue, Campus Box 8089, St. Louis, MO 63110, 1-(800)-438-0445 or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, <http://hrpo.wustl.edu>. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

Thank you very much for your consideration of this research study.