

TREEHOUSE STUDY CAREGIVER INFORMATION SHEET



RESEARCH CONSENT FORM AND HIPAA AUTHORIZATION

Protocol Title: The TREEHOUSE Program

Study No.: HP-00097453

Principal Investigator: *Margo Candelaria, PhD, Research Principal Investigator, 410-706-6332*

Sponsor: Healthy Tomorrows Partnerships for Children Program (HTPCP), Maternal & Child Health Bureau (MCHB), Health Resources and Services Administration (HRSA)

CONCISE SUMMARY:

- The purpose of this study is to examine how children (who receive care with an enrolled pediatric provider in Maryland) and their caregivers interact with each other, and how pediatric providers work with caregivers and talk to them about engaging with their children. We are also interested in how caregivers feel about the care provided by their pediatric provider. You will engage with the pediatrician in two telehealth developmental coaching appointments. Participation is voluntary.
- If you agree to participate you will be asked to fill out surveys about yourself, your child and your pediatric care. You will be asked to do that now and again when your child is 16 months old. It should take about 15-20 minutes to complete the questionnaires. There is a risk of feeling discomfort related to sharing information about yourself or your practices with families.
- If you are interested in learning more about this study, please continue to read below.

PURPOSE OF STUDY

- The purpose of this study is to examine how children (who receive care with an enrolled pediatric provider in Maryland) and their caregivers interact with each other, and how pediatric providers work with caregivers and talk to them about engaging with their children. We are also interested in how caregivers feel about the care provided by their pediatric provider. You will engage with the pediatrician in two telehealth developmental coaching appointments.
- You are being asked to participate in this study because you bring your young child to a pediatrician in Maryland for health care.

- We are expecting to enroll 450 participants in this study over 5 years. Six to 10 caregivers will be enrolled from your pediatrician's office, in addition to 24-40 caregivers from other pediatric offices in your cohort from other pediatric offices in Maryland. This 6-month cycle will continue until February 2026.

PROCEDURES

- You will participate in two developmental coaching telehealth appointments with your pediatric provider. Data collection will occur two times; before you complete the first appointment at 9 months, and the second data collection period will occur after the second appointment when your child is between 15 and 16 months. You will complete the questionnaires through a web-based survey.
- We will reach out to you in approximately 6 months for a second round of data collection, after your 15 month developmental coaching telehealth appointment is completed. We will contact you through your preferred contact method (e.g. phone, email, text) to complete a web-based survey.

WHAT ARE MY RESPONSIBILITIES IF I TAKE PART IN THIS RESEARCH?

If you take part in this research, you will be responsible for engaging with your pediatric provider in two developmental coaching sessions and completing two surveys through a web-based link (one before your first appointment and the second after your second appointment).

POTENTIAL RISKS/DISCOMFORTS:

- Health risks or discomforts anticipated in this study are rare.
- If you feel uncomfortable answering any questions you can skip those questions or stop at any time.
- Your information will be kept confidential and no information about you or your family will be shared with anyone outside the study team. Loss of confidentiality will be minimized by using a secure web-based survey that directly enter your responses into. Electronic data will be password-protected.
- The only time there would be a breach in confidentiality is if you spontaneously indicate that there is a risk of harm to yourself or others.
- There is a potential risk of loss of privacy. This risk will be mitigated by ensuring that the caregiver is approached by the provider when in a private exam room for recruitment.

POTENTIAL BENEFITS

- You will not benefit directly from your participation in this study. However, you will be helping us learn about pediatric provider practices and families' experiences.

ALTERNATIVES TO PARTICIPATION

- This is not a treatment study. Your alternative is to not take part. If you choose not to take part, your healthcare at University of Maryland, Baltimore will not be affected.

COSTS TO PARTICIPANTS

- It will not cost you anything to take part in this study.

PAYMENT TO PARTICIPANTS

- In exchange for your participation you will receive an electronic gift card after you attend the first developmental coaching appointment and complete the first survey. If you complete the second developmental coaching appointment and complete the second survey you will receive another electronic gift card.

CONFIDENTIALITY AND ACCESS TO RECORDS

- All of your information, including research study and medical records, will be kept confidential and kept limited to those on the research team.
- Any information you share will be connected to a unique ID number and will not be connected to your name.
- The only people who will access your study data are the research evaluation team members. Your pediatric providers will not have access to your questionnaire data.
- The data from the study may be published. However, you will not be identified by name. People designated from the institutions where the study is being conducted and people from the sponsor's organization will be allowed to inspect sections of your medical and research records related to the study. Everyone using study information will work to keep your personal information confidential. Your personal information will not be given out unless required by law.
- Efforts will be made to limit your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

RIGHT TO WITHDRAW

- Your participation in this study is voluntary. You do not have to take part in this research. You are free to withdraw at any time. Refusal to take part or to stop taking part in the study will involve no penalty or loss of benefits to which you are otherwise entitled. If you decide to stop taking part, or if you have questions, concerns, or complaints, or if you need to report a medical injury related to the research, please contact the investigator Margo Candelaria, Ph.D., mcandelaria@ssw.umaryland.edu, #410-706-6332.
- There are no adverse consequences of your decision to withdraw from the research.
- If you are an employee or student, your employment status or academic standing at UMB will not be affected by your participation or non-participation in this study

CAN I BE REMOVED FROM THE RESEARCH?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include failure to follow instructions of the research staff, or research staff decide that the research study is no longer in your best interest. The sponsor can also end the research study early. The study staff will tell you about this and you will have the chance to ask questions if this were to happen.

UNIVERSITY STATEMENT CONCERNING RESEARCH RISKS

The University is committed to providing participants in its research all rights due them under State and federal law. You give up none of your legal rights by signing this consent form or by participating in the research project. This research has been reviewed and approved by the Institutional Review Board (IRB). Please call the Institutional Review Board (IRB) if you have questions about your rights as a research participant.

The research described in this consent form has been classified as minimal risk by the IRB of the University of Maryland, Baltimore (UMB). The IRB is a group of scientists, physicians, experts, and other persons. The IRB's membership includes persons who are not affiliated with UMB and persons who do not conduct research projects. The IRB's decision that the research is minimal risk does not mean that the research is risk-free. You are assuming risks of injury as a result of research participation, as discussed in the consent form.

If you are harmed as a result of the negligence of a researcher, you can make a claim for compensation. If you have questions, concerns, complaints, or believe you have been harmed through participation in this research study as a result of researcher negligence, you can contact members of the IRB or the staff of the Human Research Protections Office (HRPO) to ask questions, discuss problems or concerns, obtain information, or offer input about your rights as a research participant. The contact information for the IRB and the HRPO is:

University of Maryland Baltimore
Human Research Protections Office
620 W. Lexington Street, Second Floor
Baltimore, MD 21201
410-706-5037

Please follow this QR code to complete the first survey:

