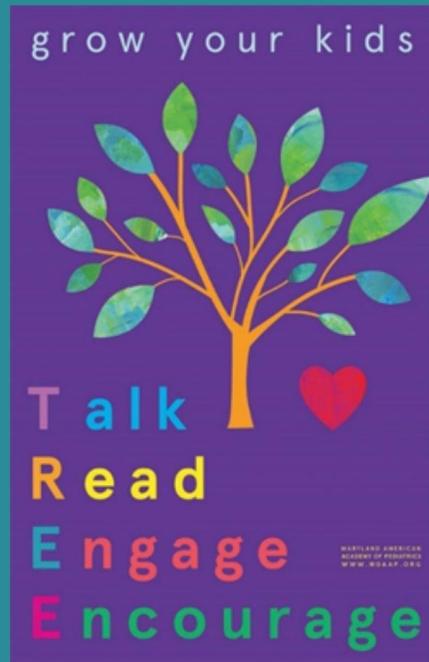


The TREEHOUSE Program



Review Guide

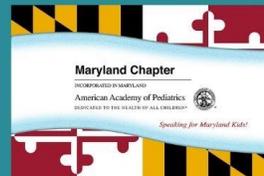


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Recruiting Caregivers

Caregivers will participate in the study for 8 to 11 months. Caregivers are eligible for participation in the study if the following criteria are met:

- child is no older than 9 months at the onset of their participation in TREEHOUSE
- caregiver has legal custody and is a primary caregiver to the child
- caregiver takes the child to a pediatric care provider who is participating in the TREEHOUSE program
- caregiver speaks English fluently
- caregivers do **not** have to enroll in the study in order to receive a developmental coaching session

Caregivers will be recruited in the following ways:

1. They will be approached by their pediatric provider during their 6-month well child checkup to receive a 9-month developmental coaching telehealth appointment
2. Or, they will be approached by their pediatric provider at other interactions (e.g. appointments other than their 6-month well child checkup between 6 and 9 months)

Refer to the recruitment script to guide your discussion using the IRB approved language for recruitment. You will tell caregivers about the opportunity to receive the developmental coaching sessions and that they will complete two surveys through the TREEHOUSE program (Appendix A).

Caregivers may access the survey through a QR code on the information sheet (Appendix B). Caregivers may also be sent the Qualtrics link to complete the survey via email.

Obtaining Consent

When inviting the caregiver to participate, it is important to keep in mind the following:

- caregivers will not be pressured or coerced as participation is voluntary
- participation is not related to care they will receive in their pediatric clinic – not agreeing to participate in data collection does not impact care or prevent them from getting developmental coaching
- caregiver should be reminded that they may stop at any time

Providers will confirm caregiver’s consent to participate in the TREEHOUSE program by verbal consent and by providing caregivers an information sheet (Appendix B). Caregivers will be directed to follow the link through the QR code at the end of the information sheet to complete the baseline survey. At the beginning of the survey caregivers will verify their consent by selecting “yes” that they agree to participate in the TREEHOUSE study.

Providers are asked to notify the University of Maryland research team with the child’s initials, DOB and caregiver email as well as the date of the upcoming coaching session if available by sending an email to Heather Whitty at heather.whitty@ssw.umaryland.edu

Developmental Coaching Sessions

After you have recruited a caregiver and obtained their verbal consent to participate, it is recommended that these appointments are scheduled with the caregiver before they leave the office or complete a telehealth visit if they do not have an in-person visit. The first developmental coaching session is to be conducted at 9 months and the second developmental coaching session is to be conducted at 15 months.

Please follow the procedures to send the caregiver the link to the video conferencing software used in your office that is HIPAA compliant (e.g doxy.me, Zoom)

Caregiver Surveys

After you have recruited a caregiver to participate, instruct them to fill out the baseline survey. This needs to be completed **before** their first scheduled developmental coaching session at 9 months. The weblink to the baseline survey is available via a QR code on the information sheet that is to be provided to the caregiver. Providers may ask caregivers to share their contact information with the UMB team to engage in data collection if caregivers have not completed their first survey at least 1 week before their first scheduled developmental coaching session.

- For reference, the weblink for the TREEHOUSE baseline caregiver survey is available here: https://umaryland.az1.qualtrics.com/jfe/form/SV_427fUDZnw6MV2gC

The UMB team will engage caregivers to complete the second and final survey through the contact method they indicated they desired on the baseline survey (e.g. phone, email, text). If caregivers are difficult to engage in follow-up data collection, the UMB team may contact the TREEHOUSE provider for assistance in reaching the caregiver. The survey should be completed **after** the second developmental coaching session at 15 months.

- For reference, the weblink for the TREEHOUSE follow-up caregiver survey is available here: https://umaryland.az1.qualtrics.com/jfe/form/SV_5hlibnXODYfkq98

Gift cards

Overall, a maximum of \$20 worth of electronic gift cards will be given to participants over two surveys. At baseline (before the 9-month developmental coaching session) caregivers will be given a \$10 electronic gift card as reimbursement for their completion of the baseline survey. At follow-up, caregivers will be given a \$10 electronic gift card as reimbursement for their participation in the follow-up survey.

Providers should direct caregivers to look in their email for an email from Tango Card, which is the gift card purveyor used by UMB.

Appendix A. TREEHOUSE Caregiver Recruitment Script

Pediatric providers say the following during the 6 month well child encounter or other pediatric encounter before 9 months.

I am working with trainers at the MDAAP to learn and collaborate on a project called the TREEHOUSE program. As part of the program, I am offering “developmental coaching” telehealth appointments with families who have older babies. I would like to invite you to take part in this program by agreeing to schedule a telehealth appointment when your baby is 9 and 15 months to learn more about healthy developmental for you and your baby. These sessions are meant to be fun and interactive and because it is a telehealth appointment, it can occur in your baby’s home environment. I am inviting you to participate because you are a patient here (***state name of medical practice where you are recruiting***) and have a child between 6 and 8 months of age. Would you be willing to spend a few minutes to learn about this study?

- ***If they say yes, continue below:***

Thank you for being willing to learn more about the study. Participation in this study is completely voluntary. If you agree, I would also need your permission to share

your name and email with researchers at the University of Maryland School of Social Work. They would like to get your information about your thoughts on the program, feelings about our pediatric practice, and your activities with your child. This is totally confidential, and your answers will never be shared with our practice. The questionnaires will be sent to you using a weblink. The web-based survey will take approximately 15-20 minutes to complete. You will be sent an electronic gift card as a thank you for your time after you have completed the survey and attended the developmental coaching appointment. You will be sent a follow-up survey to complete after the 15-month developmental coaching appointment. All of your information will be kept confidential, and your privacy will be maintained.

- *If they say No AT ANY TIME, thank them and move on.*

If they have additional questions, answer the questions about the study using information from the consent form including purpose of the research study, procedures, and privacy and confidentiality. Refer to Dr. Candelaria for additional questions: 410-706-6332

Appendix B: TREEHOUSE CAREGIVER INFORMATION SHEET
(THIS CONSENT FORM ALSO APPEARS AS A SEPARATE FILE ON THE
TREEHOUSE WEBSITE SO THAT YOU CAN COPY IT AND HAND IT OUT TO
FAMILIES INTERESTED IN PARTICIPATING IN THE TREEHOUSE STUDY)



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:

