

## **STUDY INFORMATION SHEET:**

### **Parent and Caregiver Experiences with Pediatric Primary Care**

#### **What is this study?**

You are being invited to participate in an interview with members of our study team at [SITE] and the Yale School of Medicine about your experiences during your recent visit to your child's doctor's office, especially how you felt about conversations around your child's growth and healthy behaviors. The interview will take about 30-45 minutes and will happen by video chat or over the phone. It will be audio-recorded. We will also connect your responses to information in your child's electronic health records, like demographics and their growth information from their most recent visit. After you complete the interview, you will receive a \$50 electronic gift card to thank you for your time.

We do not expect any risks for those who participate in this study. One potential risk associated with this study is loss of confidentiality. It is also possible that some questions during the interview could make you uncomfortable. You can always choose not to answer a question or choose to stop the interview at any time.

We do not expect you to have any benefits from participating. What we learn from this study could help us better understand how to improve the experiences of families during primary care visits.

#### **Why me?**

We are inviting you to participate because you are the parent or caregiver of a child who was recently seen at the doctor's office at one of the study sites.

#### **Do I have to participate?**

The decision of whether to participate in this study is completely up to you. You can also change your mind at any time. Whatever choice you make will not have any effect on your relationship with your doctor's office or [SITE].

#### **How will you keep my data safe?**

Only the researchers involved in this study and those responsible for research oversight will have access to the information you provide. The interview will be done by one of our team members at Yale, so your information will be shared with them so they can contact you.

The interview will be conducted over videochat or phone. Notes about the interview discussion will be handwritten, and the interview will be recorded. Recordings will be sent to be professionally transcribed by a trusted, Yale-approved service provider and the audio recordings will be saved on a secure server at the Yale School of Medicine for three years after the completion of the study. When we discuss or publish the results of the research, we will not use your name or any other information that could identify you. We may share your responses with other researchers for future studies, but we would not use your name or any other identifiers. Because your identifying information would be removed, we would not ask for your permission for this sharing.

#### **Who is funding the research?**

This work is supported by funding from the National Institutes of Health (grant # 1R01MD014853). This study was reviewed and approved by the Yale University Human Research Protection Program.

**What Information Will You Collect About Me in this Study?**

The information we are asking to use and share is called “Protected Health Information.” It is protected by a federal law called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). In general, we cannot use or share your health information for research without your permission. If you want, we can give you more information about the Privacy Rule. Also, if you have any questions about the Privacy Rule and your rights, you can speak to Yale Privacy Officer at 203-432-5919.

The specific information about you and your health that we will collect, use, and share includes:

- Research study records
- Medical records from your visits to your pediatrician.

**How will you use and share my information?**

We will use your information to conduct the study described in this consent form.

We may share your information with:

- The U.S. Department of Health and Human Services (DHHS) agencies
- Representatives from Yale University, the Yale Human Research Protection Program and the Institutional Review Board (the committee that reviews, approves, and monitors research on human participants), who are responsible for ensuring research compliance. These individuals are required to keep all information confidential.
- The Principal Investigator
- Co-Investigators and other investigators
- Study Coordinator and Members of the Research Team
- Data and Safety Monitoring Boards and others authorized to monitor the conduct of the Study

We will do our best to make sure your information stays private. But, if we share information with people who do not have to follow the Privacy Rule, your information will no longer be protected by the Privacy Rule. Let us know if you have questions about this. However, to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

**Why must I agree to the use of my information?**

By giving permission for the use of your health information, you will allow researchers to use and disclose your information described above for this research study. This is to ensure that the information related to this research is available to all parties who may need it for research purposes. You always have the right to review and copy your health information in your medical record.

A description of this clinical trial will be available on ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

**What if I change my mind?**

The authorization to use and disclose your health information collected during your participation in this study will never expire. However, you may withdraw or take away your permission at any time. You may withdraw your permission by telling the study staff or by writing to Dr Mona Sharifi (mona.sharifi@yale.edu) at the Yale School of Medicine, New Haven, CT 06520.

If you withdraw your permission, you will not be able to stay in this interview study but the care you get from your doctor outside this study will not change. No new health information identifying you will be gathered after the date you withdraw. Information that has already been collected may still be

used and given to others until the end of the research study to ensure the integrity of the study and/or study oversight.

### **Certificate of Confidentiality**

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

### **Contact us**

Please feel free to ask us any questions that you have. If you have any questions about this study, you may contact Emily Finn at the Yale School of Medicine, at e.finn@yale.edu or the lead investigator at [SITE], [NAME], at [PHONE NUMBER] or email at [EMAIL ADDRESS]. If you would like to talk with someone other than the researchers to discuss problems or concerns, to discuss situations in the event that a member of the research team is not available, or to discuss your rights as a research participant, you may contact the Yale University Human Subjects Committee, 203-785-4688, human.subjects@yale.edu. This research study has also been approved by [local IRB]. If you would prefer to discuss your questions with the IRB at [SITE], please contact the IRB Office at [PHONE NUMBER].