Reading Bees: Randomized Trial of an App-Based Approach to Reading (SHARE/STEP) and Screen Time Guidance for Parents of Infants During Pediatric Clinic Visits

The following is a short summary of this study to help you decide whether to be a participant in it. More detailed information about the study is listed later in this form. This document does not replace the discussion you should have with the research team about this study including having any questions or concerns answered.

Investigator: *John Hutton, M.S. M.D.*

Contact Info: *513-636-6721*

Industry Protocol #: *2021-0635*

Funding: *National Institute of Health*

Parents/Guardians: You have the option of having your child join this research study. This is a parental permission form. It explains this research study. If you decide that your child can be in this study, you will sign this form to show that you agree. If you sign this form, you will receive a signed copy for your records.

Reason for the study:

The main reason for this research study is to look at differences in how information about reading and screen time are provided to parents of infants (0-12 months-old) during clinic visits.

This study is led by **Dr. John S. Hutton, MS MD,** a pediatrician at the Cincinnati Children's Hospital Reading and Literacy Discovery Center. Dr. Hutton is responsible for the supervision of this research, and is the author of children's books used in the study. While Dr. Hutton is the author, he does not profit from sales of these books. If you have questions about this, you are welcome to speak with him.

Procedures:

You and your child will be in this study for approximately 12 months, involving 3 visits that are the same as usual recommended checkups for your child. No extra visits are required. The first part of the study happens today during this visit. At the first visit (today), you will be asked some questions about yourself, such as your age, education, and income, contact information (phone and email), history of reading difficulties in the family, and thoughts about reading and screen time with your baby at home. These will take around 5-7 minutes.

You will then be randomly assigned to one of two groups, which will determine how information related to reading and screen time is shared with you at this visit. There is nothing about you or your baby that will influence which group you are assigned to. It is not yet known which way is most helpful, which is the purpose of the study. Depending on your group assignment, if you agree to participate you may receive up to 2 brief informational text messages per month via your smartphone. No response to these is required.

The next part happens at a regularly scheduled checkup visit to this clinic when your baby is 6-months old, and the last at a regularly scheduled checkup visit when your baby is 12-months old. At your child's 6-month and 12-month checkup visits, a member of our study team will ask some survey questions involving reading and screen time routines with your baby at home, your baby's language development, and impression and use of informational materials shared with you today. Each part of the study takes 10-15 minutes.

More detailed information about the study procedures can be found under ***"(Detailed Procedures)"***

Risks to Participate:

Reading and limiting screen time are healthy practices, and so there are no true risks to this study. The only discomfort is the time and effort spent answering questions, and possibly extra time at your doctor visit, though we will try our best to not let this happen.

Benefits to Participate:

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include receiving information about reading with your baby, which other studies suggest is helpful to promote healthy development. You may receive new children's books to read with your child at home.

Findings of this study will help develop methods for pediatricians and other providers to share information with families, which we hope will improve child health outcomes.

Other Options:

Participation in research is completely voluntary. Your decision to participate or not to participate will not affect the care you or your child receive.

Your alternative to participating in this research study is to not participate.

Cost to Participate:

There are no costs for you for participating in this study.

Payment:

If you agree to take part in this research study, we will pay you $10 for your time and effort after each study visit (today, 6-months, 12-months). This payment will be in the form of a reloadable debit card (ClinCard). We will give you a handout that will explain how to use the card. Because you are being paid for your participation, Cincinnati Children's is required by the Internal Revenue Service (IRS) to collect and use your social security number (SSN) or taxpayer identification number (TIN) to track the amount of money that we pay. You will need to complete a Federal W-9 form for this income tax reporting. This form requires your Social Security number. This form will be given to the

Cincinnati Children's business office. It will not be kept as part of your child's study chart. If you move, you will need to complete another W-9 with an updated address.

Additional Study Information:

The following is more detailed information about this study in addition to the Key Information.

If I have Questions or would like to know about:

Who to talk to…	**You can call …**	**At …**
• Emergencies • General study questions • Research-related injuries • Any research concerns or complaints	**Dr. John Hutton** **(Primary Investigator)**	Phone: 513-636-6721
• Emergencies • General study questions • Research-related injuries • Any research concerns or complaints	**Chelsie Edwards** **Lead Study Coordinator**	Phone: 513-517-1256
• Your child's rights as a research participant	**Institutional Review Board** This is a group of scientists and community members who make sure research meets legal and ethical standards.	Phone: (513) 636-8039

Total number of participants:

We expect about **186** parents and their babies will be in this study (83 in each of 2 groups).

Detailed Procedures:

A. Today, after you sign this consent form, you will be asked some questions about yourself, such as your age, education, and income, contact information (phone and email), history of reading difficulties in the family, and thoughts about reading and screen time with your baby at home. These will take around **5-7 minutes**.

   1. You will then be randomly assigned to one of two groups, which will determine how information related to reading and screen time is shared with you at this visit. There is nothing about you or your baby that will

influence which group you are assigned to. It is not yet known which way is most helpful, which is the purpose of the study.

2. Next, I (the research coordinator) will share information about reading and screen time using whatever materials are involved with your group assignment, which may take up to **5 minutes**.
3. Depending on your group assignment, if you agree to participate you may receive up to 2 brief informational text messages per month via your smartphone. No response to these is required.
4. No matter which group you are assigned to, you will be sent two reminders by text message 3 days and 1 day before your child's 6-month and 12-month checkup visits so that a research coordinator can meet you at the clinic. These will include a prompt to confirm if you are able to make this appointment or need to reschedule. These will also include a reminder for you to come to this visit if possible so that we can collect all information from the same parent. No personal information will be shared in these messages, and we will not contact you for any other reason.

B. At your child's 6-month and 12-month checkup visits, a member of our study team will ask some survey questions involving reading and screen time routines with your baby at home, your baby's language development, and impression and use of informational materials shared with you today. These should take around **15 minutes**.

C. At the 6-month and 12-month checkup visit, you may be asked to complete video recordings in a private area of the clinic. These are designed to measure interactions between parents and their infants. The videos will be taken using an iPad positioned to record you and your baby. Only study staff will see these and they won't be shared in any way. The purpose is to learn more about how you and your baby interact at this age. These are not intended to judge your parenting or your baby's development and no one will contact you about them. You will also receive an extra $15, per recording, if you decide to participate in this part of the study. A total of **80** parents and their infants will be in this part of the study (40 in each of 2 groups) on a first-come, first-served basis. If you are interested, we will provide more information at your child's 6-month visit.

Change of Mind/Study Withdrawal:

Your participation in this study is **voluntary**. Your decision whether or not to participate will not result in any loss of benefits from your doctor or CCHMC.

If you decide to take part in the research study, you are free to drop out at any time. Leaving the study will not result in any loss of benefits to you.

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 loss of funding.

If you stop being in the research, data already collected may not be removed from the study database.

Privacy:

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete privacy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

Samples and/or data collected for or generated from this study could be shared and used for future research. Samples and /or data may be shared with other collaborators at Cincinnati Children's and possibly with outside collaborators, who may be at another institution or for-profit company.

If information that could identify you is removed from your information or samples collected during this research, that information or those samples could be stored and used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

The study doctor will tell you if they find out about new information from this or other studies that may affect your or your child's health, safety or your willingness for your child to stay in this study.

AUTHORIZATION FOR USE/DISCLOSURE OF HEALTH INFORMATION FOR RESEARCH

To be in this research study you must also give your permission (or authorization) to use and disclose (or share) your "protected health information" (called PHI for short).

What protected health information will be used and shared during this study?

Cincinnati Children's Hospital Medical Center (Cincinnati Children's) will need to use and share your PHI as part of this study. This PHI will come from:

- Your child's medical records from Cincinnati Children's Hospital.

The types of information that will be used and shared from these records include:

- Scheduled appointment times for 6-month and 12-month checkup visits.

Who will share, receive and/or use your protected health information in this study?

- Staff at all the research study sites (including Cincinnati Children's)
- Personnel who provide services to you as part of this study
- The members of the Cincinnati Children's Institutional Review Board and staff of the Office of Research Compliance and Regulatory Affairs.

How will you know that your PHI is not misused?

People that receive your PHI as part of the research are generally limited in how they can use your PHI. In addition, most people who receive your PHI are also required by federal privacy laws to protect your PHI. However, some people that may receive your PHI may not be required to protect it and may share the information with others without your permission, if permitted by the laws that apply to them.

Can you change your mind?

You may choose to withdraw your permission at any time. A withdrawal of your permission to use and share your PHI would also include a withdrawal from participation in the research study. If you wish to withdraw your permission to use and share PHI you need to notify the study doctor, listed on the first page of this document, in writing. Your request will be effective immediately and no new PHI about you will be used or shared. The only exceptions are (1) any use or sharing of PHI that has already occurred or was in process prior to you withdrawing your permission and (2) any use or sharing that is needed to maintain the integrity of the research.

Will this permission expire?

Your permission will expire at the end of the study. If the study involves the creation or maintenance of a research database repository, this authorization will not expire.

Will your child's other medical care be impacted?

By signing this document you agree for child to participate in this research study and give permission to Cincinnati Children's Hospital to use and share your PHI for the purpose of this research study. If you refuse to sign this document you will not be able to participate in the study. However, your rights concerning treatment <u>not</u> related to this study, payment for services, enrollment in a health plan or eligibility of benefits will not be affected.

SIGNATURES

The research team has discussed this study with you and answered all of your questions. Like any research, the researchers cannot predict exactly what will happen. Once you have had enough time to consider whether you should participate in this research you will document your permission by signature below.

You will receive a copy of this signed document for your records.

Opt-in for text message appointment reminders: ❑ Yes ❑ No

_____
Printed Name of Research Participant (Parent or Legally Authorized Representative*)

_____ _____
Signature of Research Participant Indicating Consent or Assent Date

_____ _____
Signature of Parent or Legally Authorized Representative* Date

_____
* If signed by a legally authorized representative, a description of such representative's authority must be provided

_____ _____
Signature of Individual Obtaining Consent Date