Identifiers	NCT04337372 Unique Protocol ID: IRB202000756-N Secondary IDs: 1R21HD102715-01, 5R21HD102715-02
Brief Title:	Infant Shared Book Reading
Official Title:	Parent-infant Learning Dynamics During Early Shared Book Reading
	Date of last IRB approval: 2/11/22

UF | Institutional Review Board
UNIVERSITY of FLORIDA

INFORMED CONSENT FORM
to Participate in Research, and

AUTHORIZATION
to Collect, Use, and Disclose Protected Health Information (PHI)

Title of this study: Parent-infant learning dynamics during early shared book reading

Researchers: Lisa S. Scott, Ph.D., Andreas Keil, Ph.D.

You are being asked to participate in a research study.

Before you agree to take part in this study, Dr. Scott or Dr. Keil or his/her representative will tell you:

- **Why the study is being done and what will happen to you if you take part in the study:**

  You and your infant are invited to participate in a study of how infants learn to recognize faces and objects through shared book-reading. This study will help us understand how brain areas involved in visual recognition develop. You and your infant were selected as a possible participant in this study because he/she is between 5 and 12 months of age and either you or your infants' other parent indicated your interest in participating in developmental research. We ask that you read this form and ask any questions you may have before providing consent for your infant to participate in this study. Participation is entirely your choice.

  Prior to your first visit in the lab, you will be asked to complete a consent form for a questionnaire, and then asked to fill out the questionnaire, which is designed to provide us with demographic information about who has participated in our studies. This questionnaire includes two sections including questions about your child's sex, race and ethnicity as well as questions about the demographics of your family. A third section will include questions about your infant's communication, socialization, and motor abilities. This information is voluntary and confidential to the extent provided by law. Some of these questions may make some people uncomfortable; but you are free to leave any question blank.

  During the first visit to the lab, you and your infant will read a book while both wearing head-mounted eye-trackers. This is very similar to wearing a pair of glasses. We will video and audio record you both as you read the book. On the second visit, you and your child will be asked to look at photos of faces or objects presented with or without sounds while we measure both of your brain activity using EEG in two different tasks.

  To record brain electrical activity, a net with recording sensors is placed on your and your infant's head. In order to help the electrodes accurately measure your and your infant's brain activity, we will soak this sensor net in an electrolyte solution. The

solution contains distilled water, potassium chloride (salt), and baby shampoo. Recording EEG simply picks up the brain activity that is naturally emitted from the scalp and is non-invasive. If you baby does not like wearing the net or is too tired to complete the tasks you may be asked to return to the laboratory for an additional visit. You will be asked at the end of this consent form for permission to take photos and videos of you and your child to be used for academic/educational purposes.

During the study, your infant will be seated on your lap or in a high chair. You will be present and near your infant at all times during each session. If your infant fusses or cries and does not wish to look at the pictures, we will stop the test. If, at any point or for any reason, you wish to stop the test please feel free to advise us to stop. Approximately 360 participants will be invited to participate in this research study. We may invite you back for future studies if you are interested.

You will be asked to fill out a Databrary Release Form. This is an optional form, which if signed, will allow researchers from the Brain, Cognition and Development Lab to upload you and your infant's electrophysiological data, eye-tracking data, and questionnaire responses to the secure, web-based data library. All uploaded data will be de-identified prior to upload and participants must consent to their data being included. Although data will be de-identified, images of infants and their parents may be included in the video data. Making video/audio available on Databrary increases the risk that you or your infants may be identified even though there are no names associated with any files. You have the option of excluding your videos at any time. Videos uploaded to Databrary will be viewable and downloadable to authorized users who have been granted secure access. Only researchers with Principal Investigator status from institutions with Institutional Review Boards or similar review entities, or researchers affiliated with Principal Investigators, will be authorized for access.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

- **How long you will be in the study:**

  This study is separated into two sessions, each lasting approximately 45 minutes

- **How many people will be in the study:**

  Approximately 360 participants

- **The possible foreseeable risks, discomforts, and benefits of this research:**

  There are no direct benefits of being in this study.

There are some potential risks if you take part in this study. Though no adverse reactions have been observed in the past, there is a remote risk of allergic reaction to the potassium chloride (salt) and baby shampoo solution that is used in the recording

procedure. No serious reactions have been observed, though a few participants have found the solution to be mildly itchy (< 1%).

Due to the flickering nature of the stimuli there is a potential risk for individuals with Photo Sensitive Epilepsy (PSE). PSE is a form of epilepsy in which seizures are triggered by visual stimuli that form patterns in time or space, such as flashing lights, bold, regular patterns, or regular moving patterns. If anyone in your infant's immediate family has a history of seizures or PSE, this may be an applicable potential risk and you should inform the researchers when asked.

There is a chance that your infant may become fatigued during testing. If your infant becomes consistently fussy we will end the testing session. There are no other known or suspected risks to participants beyond the risks encountered in daily living.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You have been informed that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. That is, if you give written consent for the release of information, we cannot withhold that information and we cannot hold responsibility for how that person may use your information.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances. If we learn about child abuse, elder abuse, or intent to harm yourself or others, we will report that information to appropriate authorities.

- **Alternatives to being in the study:**

  You do not have to be in this study if you do not want to. If you agree to be in the study, but later change your mind, you may drop out at any time. There are no penalties or consequences of any kind if you decide that you do not want to participate. You have the right to withdraw your consent or stop participating at any time. You have the right to refuse to answer any question(s) or participate in any procedure for any reason. Deciding not to participate will have no effect on benefits you receive from the Department of Psychology or the University of Florida.

- **How your study records will be maintained and who will have access:**

  To maintain the privacy of your infant's data, your infant will be assigned an arbitrary subject number, and your infant's data will be identified through that number, rather than being associated with his/her name or other identifying information. All information you provide us on the questionnaires is also confidential and will not be associated with any identifying information.

  The following procedures will be used to protect the confidentiality of your study records. First, all your study records will be kept in a locked filing cabinet in a locked room. Research records will be labeled with a code. A master key that links names and codes will be maintained in a separate and secure location. All electronic files containing identifiable information will be password protected and the computer that has the stored files will also be password protected to prevent access by unauthorized users. Only the members of the research staff will have access to the passwords. At the conclusion of the study, the researchers may publish their findings. Information will be presented in summary format and neither you nor your infant will be identified in any publications or presentations.

- **If it will cost you anything to take part in this study:**

  It will not cost you anything to participate in this study. You will receive $20 for participation for both visits to the laboratory, you will receive $10 during the first visit and $10 during your second visit. In addition, your baby will receive a small toy at the conclusion of the study. If you choose to withdraw before the conclusion of this study you will receive payment for the session(s) you and your infant attended.

- **When or if you may be told about new findings which may affect your willingness to keep taking part in this study:**

  We will may you aware of any new findings and what will be happening during both visits.

If you agree to participate in this study, you will be given a signed copy of this document.

You may contact Dr. Lisa Scott at (352) 273-2125 at any time if you have questions about the research or if you think that you have been hurt by the research.

You may contact the Institutional Review Board at the University of Florida Health Science Center at (352) 273-9600 if you have questions about your rights as a research subject or what to do if you are injured.

You may choose not to be in this study, or you may quit being in the study at any time and there will be no penalty and no loss of any benefits you are entitled to.

If you agree to participate in this study, Dr. Lisa Scott will create, collect, and use private information about you and your health. This information is called protected health information or PHI. In order to do this, the Principal Investigator needs your authorization.

More specifically, the following information may be collected, used, and shared with others:

- Name
- Telephone number
- Full face photographic image
- Email address
- Dates
- Geographic subdivision smaller than a state or the first three digits of a zip code

This information will be stored in locked filing cabinets or in secure computer servers with security passwords.

Your PHI may be collected, used, and shared with others for the following study-related purpose(s):

- Names and demographic information will be used to contact you regarding participation
- Photo/video/audio will be recorded during eye-tracking task to be analyzed for parent-child interactions during book-reading

Once this information is collected, it becomes part of the research record for this study.

Only certain people have the legal right to collect, use and share your research records, and they will protect the privacy and security of these records to the extent the law allows. These people include:

- the study Principal Investigators, Dr. Lisa Scott and Dr. Andreas Keil and research staff associated with this project.
- other professionals at the University of Florida or Shands Hospital that provide study-related treatment or procedures
- University of Florida Institutional Review Board (IRB; an IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research).

Your PHI may be shared with:

- Sponsor
- United States and foreign governmental agencies who are responsible for overseeing research, such as the Food and Drug Administration, the Department of Health and Human Services, and the Office of Human Research Protections
- Government agencies who are responsible for overseeing public health concerns such as the Centers for Disease Control and federal, state and local health departments

Otherwise, your research records will not be released without your permission unless required by law or a court order. It is possible that once this information is shared with authorized persons, it could be shared by the persons or agencies who receive it and it would no longer be protected by the federal medical privacy law.

Your PHI will be used and shared with others until the end of the study (or alternative).

Once this research study is completed, any information that could identify you **might** be removed from any identifiable private information or identifiable biospecimens collected and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

You are not required to sign this consent and authorization to allow researchers to collect, use and share your PHI. Your refusal to sign will not affect your treatment, payment, enrollment, or eligibility for any benefits outside this research study. However, you cannot participate in this research unless you sign this consent and authorization.

You have the right to review and copy your protected health information. However, we can make this available only after the study is finished.

You can revoke your authorization at any time before, during, or after your participation in this study. If you revoke it, no new information will be collected about you, but information that was already collected may still be used and shared with others if the researchers have relied on it to complete the research. You can revoke your authorization by giving a written request with your signature on it to the Principal Investigator.

Signing this document means that the research study, including the above information, has been described to you orally and/or that you have read this document, and you voluntarily agree to take part.

Consent to be Photographed and Video Recorded

With your permission, you will have the following done during this research (check all that apply):

☐ photographed ☐ video recorded

Your name or personal information will not be identified on the photograph(s) or recordings, and confidentiality will be strictly maintained. However, when these photograph(s) or video recordings are shown or heard, others may be able to identify you.

The Principal Investigator (PI) of this study, Dr. Lisa Scott, or her successor, will keep the photograph(s) and video recordings in a locked cabinet, in a folder on a password protected computer server drive, or as an encrypted electronic file. These photograph(s) and video recordings will be shown under her direction to students, researchers, doctors, or other professionals and persons.

Please indicate under what conditions Dr. Lisa Scott has your permission to use the photograph(s) and video recordings, and sign and date below.

☐ The following will be **destroyed once the study is closed** (initial next to all that apply):

____ photograph(s) _____ video recording(s)

☐ As described in the Informed Consent Form, and for the purposes of **education at the University of Florida Health Science Center**. The PI may keep the following for an indefinite period of time in a locked file, in a password protected computer server drive, or as an encrypted electronic file (initial next to all that apply):

____ photograph(s) _____ video recording(s)

☐ As described in the Informed Consent Form; for the purposes of **education at the University of Florida Health Science Center; and for presentations at scientific meetings outside the University**. The PI may keep the following for an indefinite period of time in a locked file, in a password protected computer server drive, or as an encrypted electronic file (initial next to all that apply):

____ photograph(s) _____ video recording(s)

_____ _____

Signature Date

PARENT OR GUARDIAN PROVIDING VOLUNTARY CONSENT FOR CHILD

I have read this form and decided that my infant will participate in the project described above. The general purposes and particulars of the study as well as possible hazards and inconveniences have been explained to my satisfaction. I understand that I can withdraw him/her at any time.

_____ _____

Signature of Person Obtaining Consent Date

_____ _____

Consent and Authorization of Patient Date

PARENT OR GUARDIAN VOLUNTARY PERSONAL CONSENT

I have read this form and decided that I will participate in the project described above. The general purposes and particulars of the study as well as possible hazards and inconveniences have been explained to my satisfaction. I understand that I can withdraw at any time.

_____ _____

Signature of Person Obtaining Consent Date

_____ _____

Consent and Authorization of Patient Date