Consent To Participate In Research

Please complete the survey below.

Thank you!

Early Social Comm. Environment and Brain Development in Infants

Principal Investigator (s): Meghan Swanson, PhD

UTD IRB: 19-100

The University of Texas at Dallas

CONSENT TO PARTICIPATE IN RESEARCH

Title of Research Project: Early Social Communication Environment and Brain Development in Infants

Investigators:	Contact Number
Principal Investigator: Meghan Swanson, Ph.D.	972-883-2058

Key Information: This study investigates how parents communicate with their young children, and how young children develop. Families will enter the study when infants are 6-months old and exit the study when they are 24-months old. Families will participate in three visits that will either be virtual or in-person. Virtual visits will be at 6-months and possibly 12-months. These visits will include phone interviews, parent questionnaires, and home language recordings. In-person visits will be at possibly 12-months and 24 months. These visits will include lab assessments and MRI scans of infants while they are taking a nap.

Purpose: The purpose of this research study is to increase our understanding of how caregiver speech supports brain development and language developments in infants.

Description of Study: To determine study eligibility, parents will complete screening questionnaires about their pregnancy, childbirth, family medical history, and infant sleep patterns. We will also ask questions to ensure MRI is safe for your infant. Families who participate in this study will complete home language audio samples when infants are 6, 9, 12, 15, and 24 months of age. Children will wear a small recorder that records what the child says and hears during the day. We are interested in how much caregivers talk to infants and less interested in what words are being said. To use the recorder, caregivers will turn it on in the morning and the child will wear it throughout the day. The recorder is worn using a tee-shirt designed to hold the recorder. When language samples have been completed, caregivers will return the recorders at the next lab visit or using pre-paid postage envelopes.

Families will also participate in virtual visits when infants are 6 months of age. During the virtual visit, parents will be asked to complete questionnaires about their infant's development. Parents can choose to not answer a question for any reason. The visit at 12-months will be either virtual or in-person (described below), depending on the status of in-person research at UTD.

Families will also participate in lab visits when infants are 12, and 24 months of age. During the lab visit, parents will be asked to complete questionnaires about their infant's development. Many of these questionnaires may be filled out online before, during, or after the lab visit. Parents can choose to not answer a question for any reason. During the lab visit, we will collect information that is similar to what is collected as part of a standard daycare program assessment. The assessments replicate common experiences in daily life, like a child playing when a parent or other person is around, or a child cleaning up after playing. During these visits, your child will also watch several short videos on a computer. An eye tracker attached to the computer will collect information on what your child is looking at while watching the videos. Portions of the lab visit will be videotaped.

At 12 and 24 months infants will participate in an MRI scan at the UTD Center for BrainHealth Imaging Center. MRI scans do not use radiation and are considered safe. Children will lie on a sliding table that will slowly move them into a large cylinder which is inside a large magnet. The scanner makes a loud, machine-like noise. Children and anyone else in the scanning room will be required to wear ear protection (e.g., earplugs and/or headphones). Children will lay motionless for up to 70 minutes. Children will be scanned while they are naturally sleeping (no sedatives will be used).

Number of Participants: If your child is in this study they will be one of approximately '40 participants.

Inclusion Criteria: To participate in this study infants are required to: have been born at gestational age 37-42 week, and have a birth weight that is appropriate for their gestational age.

Exclusion Criteria: To participate in this study infants may not: be adopted; have 1st-degree relatives with autism, intellectual disability, schizophrenia, or bipolar disorder; have a significant medical illness or developmental delay, or significant medical and/or genetic conditions; have contradiction for MRI or abnormality seen in previous imaging; have a history of significant perinatal or postnatal adversity.

Length of Study: Families will enter the study when infants are 6-moths old and exit the study when infants are 24-months old. Virtual visits will take approximately 45-60 minutes (at 6-months and possibly 12-months). Lab visits (at possibly 12 months, and 24 months) will take approximately 2 hours to complete. The MRI (at possibly 12 months, and 24 months) scan will take approximately 1.5-2 hours to complete. Parent questionnaires will take approximately 2-3 hours to complete.

Possible Risks: There is minimal risk associated with participating in this research study. If infants or caregivers become tired, a break will be provided. If they become uncomfortable, we will cease procedures. Participants can refuse to participate in any part of the assessment. Participants will be informed about new research that provides additional information about risks or that may influence their decision to continue participation in this research.

Risk of Breach of Confidentiality: There is a risk that the confidentiality of your data may be breached. When data is stored electronically, there is also a risk of breach of computer security. According to the Texas Mandatory Reporting Law, any individual with knowledge of child abuse must report it to appropriate authorities. As such, confidentiality is not applicable if child abuse is detected.

Psychological Stress: Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions, take a break, or stop your participation in this study at any time. If these questions are upsetting in any way, we encourage you to discuss this with a trained professional or contact 1-800-273-TALK (8255).

MRI Brain Scan: MRI has no radiation and there is no known risk from MRI scans unless children have certain existing conditions (such as metal clips from prior surgery). These will be explored fully prior to scanning using an MRI screening form. The MRI will not be done if one of these conditions are identified. Children will be sleeping during the scan so there is little risk of infants experiencing anxiety or discomfort while in the scanner. There is a chance the scan reveals a major and clinically significant abnormality. If this happens you will be referred to the appropriate care provider.

Cognitive/Behavioral Assessment: There is no risk from the behavioral and cognitive assessments we plan to do with your child. There is a chance that we will identify a previously unrecognized condition. If any other medical conditions are detected during the course of the evaluation or during the period of follow up in the study, you will be referred to the appropriate care provider.

Eye tracking: Eye trackers are non-invasive, and there is no known risk from eye-tracking. During eye tracking, we will watch for how tired, alert, or anxious your child is and provide breaks when necessary. Eye trackers use light emissions that are not harmful to the human eye. However, if your child has ever had a seizure or has been diagnosed with epilepsy, they will be ineligible to participate due to an increased risk for photosensitive epileptic episodes.

Adult Consent

1) Check the statement that matches your choice

◯ My child has epilepsy or has had a seizure
◯ My child has never had epilepsy or seizures

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Loss of Confidentiality: Any time information is collected; there is a potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

Possible Benefits to the Participant: Generally speaking, research is designed to benefit society through new knowledge. You will receive reports of your child's development; this may be a benefit.

Alternatives to Participation: You and your child may choose to not participate in this study.

Payments to Participate: Your child will receive a maximum payment of $420.00 for participation in this research study. Families will be compensated $50.00 for completing the home language sample at 6, 9, 12, 15, and 24 months. Families will be compensated $50.00 for completing each virtual visit 6 months, and possibly 12 months. Families will be compensated $50.00 for completing each lab visit (includes MRI brain scan) at possibly 12 months and 24 months, plus $10 for any travel costs. There are no additional funds available to pay lost time away from work and other activities, lost wages, or child care expenses. UTD is required to send to the IRS a Form 1099-MISC if the amount paid to any one participant reaches $600. Participants will be responsible for any taxed assessed on compensation.

How Will Payments Be Made? You will be issued a UT-Dallas Greenphire ClinCard, which can be used as a credit or debit card. You will also receive instructions on how to use the card. In order to receive the Clincard, you will be asked to provide your date of birth and mailing address.

Research Results: All families will be provided a report describing their child's development. Families will be notified if the cognitive/behavioral assessments reveal an illness, or if the MRI reveals a major and clinically meaningful abnormality.

Voluntary Participation: All individuals have the right to agree or refuse to participate in this study. Individuals who consent to participate also have the right to change their minds while at any time during the experimental procedure. Your child may tell the investigator that they no longer wish to participate. Refusal or withdrawal of participation will not involve any penalty or loss of benefits to which non-participants are entitled. Refusal to participate will not affect participants' legal rights or the quality of services they may wish to receive at UT Dallas or UTD affiliate centers (e.g., Center for BrainHealth, Callier Center for Communication Disorders).

Records of Participation in this Research:

Information Stored at the University of Texas at Dallas: All of the information participants provide to investigators as part of this research will be protected and held in confidence within the limits of the law and institutional regulation. Participant personal information will be stored in RippleTM, a secure web application designed for the sorting and management of personally identifying information of research participants. Participant data will be kept separately and we will use a unique study identifier (and not your name) for all data. We will use recordings, video recordings, eye-tracking data, and paper/electronic information. All data will be stored on secure and encrypted servers and computers. Paper copies of data will be stored in locked filing cabinets behind locked doors. Access to data (both electronic and paper) will be limited to study personnel who have completed the necessary training in human subjects research and the responsible conduct of research.

Video recording: Video recordings of lab visits will be used for the rating of behaviors by members of the research team. You can request to have the video recording of lab visits stopped at any time. Video data will be stored on secure and encrypted servers and computers, with a file name that uses a unique study identifier.

Audio Recording: During the course of this study you will complete home language samples using LENA speech recorders that are worn by the child using a shirt with a pocket. Upon request, we will delete any home language sample. Home language sample audio data will be stored on secure and encrypted servers and computers, with a file name that uses a unique study identifier.

2)	Check the option that best matches your choice	◯ OK to video record me and/or my child during the lab visit ◯ Not OK to video record me and/or my child during the lab visit
3)	Check the option that best matches your choice:	◯ OK to audio record me and/ or my child during the study ◯ Not OK to audio record me and/ or my child during the study

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Identifiable Private Information: Private information that can be used to identify your child will be removed from the data collected in the course of this study. After such removal, the de-identified data could be used by Investigators for future research studies or distributed to another investigator for future research studies without additional informed consent.

Information Available to Others: Members and associated staff of the Institutional Review Board (IRB) of The University of Texas at Dallas may review the records of your participation in this research. An IRB is a group of people who are responsible for assuring the community that the rights of participants in research are respected. A representative of the UTD IRB may contact you to gather information about your participation in this research. If you wish, you may refuse to answer questions the representative of the IRB may ask.

De-identified data from home language samples, including short snippets of adult or child speech, may be shared with outside investigators. These snippets will be screened to ensure they do not include private information prior to sharing. It is highly unlikely that any participant could be identified from a given snippet since they are so short (e.g., single words), randomly selected, and anonymized.

Publications Associated with this Research: The results of this research may appear in publications but individual participants will not be identified.

Contact People:

You and your child have the right to ask, and have answered, any questions you may have about this research. If you want more information about this research, you should contact the researchers listed on the first page of this form.

All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you or your child has questions or concerns about your child's rights as a research subject, or if you would like to obtain the information or offer input, you may contact:

The University of Texas at Dallas Institutional Review Board 972-883-4579

UTD Office of Research

Adult Consent

4) Check the option that best matches your choice

- ◯ OK to share audio recordings of me and/or my child with other investigators
- ◯ Not OK to share audio recordings me and/or my child with other investigators

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Parent's Agreement

A parent's signature indicates that they have read, or listened to, the information provided above and that they have received answers to their questions. The signature also indicates that they have freely decided to participate in this research and that they know they have not given up any of their legal rights.

5) Printed Name of Research Participant (Child) _____

6) Printed name of the research staff who reviewed the consent form with you _____

7) Printed Name of Parent or Legal Guardian _____

8) Signature of Parent or Legal Guardian _____

9) Date _____

Parental Consent

The following questions are designed to ensure that the consent process adequately addressed the goals of the research study and what will be involved in order for you to participate.

10) 1. What is the main goal of this study?

- ◯ To increase our understanding of how caregiver speech supports brain development and language development in infants
- ◯ To increase our understanding of how infants choose to communicate
- ◯ To increase our understanding of infants' attachment to their caregivers in the first two years of life

11) 2. If you agree to participate, what will your experience be like during the study?

- ◯ I will bring my child to a medical facility where they will participate in a number of physical and medical examinations.
- ◯ I will answer questions about myself, my child, and my family. While at home my child will wear a small recorder. My child will participate in play-based lab assessments and MRI brain scans
- ◯ I will observe my child during play and take notes which I will give to researchers.

12) 3. What should you do if you no longer want to participate in the study?

- ◯ Nothing, continue to participate until study is complete.
- ◯ Nothing, stop communicating with research staff.
- ◯ Notify the research staff or PI of the study that I no longer want to participate. I will not be penalized in any way for withdrawing from the study.