

CONSENT FORM FOR: SMALL TALK STORY COUNTY

This form describes a research project. It has information to help you decide whether or not you wish to participate. Research studies include only people who choose to take part—your participation is completely voluntary. Please discuss any questions you have about the study or about this form with the project staff before deciding to participate.

Who is conducting this study?

This study is being conducted by Constance Beecher, Iowa State University.

Why am I invited to participate in this study?

You are being asked to take part in this study because you are a parent of a child aged 0-30 months.

What is the purpose of this study?

The purpose of this study is to pilot-test a "plug and play" intervention package called LENA Start that has been designed to be implemented in the community to help parents learn to talk and read more with their children.

What will I be asked to do?

If you agree to participate, you will be asked to sign up for and consent to the following research activities. Your participation will last for approximately 14 weeks. While enrolled in the project you may:

- Be randomly assigned to start the program right away, or be assigned to the wait-list and start the program during the next session.
- Attend an orientation followed by 13 weekly Small Talk (or LENA Start, or parent education) sessions, each lasting about 60-90 minutes. If you are accepted and start the program, you will attend sessions as scheduled, or arrange a makeup session if you have to miss a session.
- Attend (or make up) all the first 4 sessions and at least 5 of the next 9 sessions.
- Turn in at least 9 LENA recordings, plus a practice recording.
- Use a small, lightweight LENA recorder that your child wears for one full day (at least 10 hours) each week (after each session), using special clothing. Recordings are done to generate information. They cannot and will not be listened to, and will be deleted after they are processed. Your child and people around your child will be recorded during recording days.
- Be asked to fill out a survey asking for basic demographic information about you and your family at the beginning of the program, and another survey at the end of the study, with questions about how you liked the program and asking for your opinion about future studies. We anticipate this will take less than 5 minutes.
- Be asked to complete a questionnaire about child development (the SPEAK) at the beginning and end of the program. We anticipate this will take around 10-15 minutes.

- Be asked to complete the Developmental Snapshot. The Snapshot is done 4 times during class sessions 1,5, 9 & 13 during classtime.
- Be invited to take part in a focus group, discussing your experiences in the program. This will be audio taped for transcription.
- Possibly be observed and video-taped reading with your child at the start of your participation and right after completing the program, for a total of two occasions. This will take place at the site of your class, and be approximately 5 minutes.

What are the possible risks or discomforts and benefits of my participation?

Risks or Discomforts— If you choose to participate, you will have to complete at least 9 full-day LENA recordings. Although these recordings will not be listened to, and will be deleted, some families may feel uncomfortable being recorded in the home. Be aware that the program takes place in the library, so you may be observed attending the program.

You might also feel uncomfortable answering some of the question about what your child does or about your knowledge of child development, and you can choose not to answer any question you feel uncomfortable with.

Benefits—You will receive information on how to help your baby develop language and learning skills. Research suggests that children whose parents use the kind of language tips you will learn have better academic outcomes. You will learn how much you talk to your baby and strategies to increase the amount of language your baby hears.

How will the information I provide be used?

The information you provide will be used to inform the effectiveness and delivery of this intervention program across the state of Iowa.

What measures will be taken to ensure the confidentiality of the data or to protect my privacy?

Records identifying participants will be kept as confidential as possible while following laws and regulations. Records will not be made publicly available. However, auditing departments of Iowa State University and the ISU Institutional Review Board (a committee that reviews and approves research studies with human subjects) may see and/or copy study records for quality assurance and analysis. These records may contain private information.

To ensure confidentiality to the extent permitted by law, the following measures will be taken:

- All records (weekly surveys, consent forms, LENA data) will be kept in a locked filing cabinet in a locked office at the Small Talk office (Ames Public Library) or the University.
- Names will be taken off of data and replaced with I.D. codes, with only research staff having access to the name and codes. This will be kept on a computer with password protection.
- Any articles or reports will not use private identifying information, only group information.
- If we video tape you reading with your child, the video will only be viewed by the research team, and recordings will be stored on our secure server.
- You can opt out of receiving texts from the LENA system.

- LENA Recordings will be deleted after the program processes the information, and will never be listened to. Only the number of words, number of exchanges and amount of electronic sound are retained.
- LENA information and program attendance will be shared with the LENA Foundation. Scores from the SPEAK, basic demographic information, and LENA scores will be shared with the University of Chicago for the purpose of validating the assessment. All data will be de-identified before sharing – no names will be used. Your address, email and phone number are entered into the LENA system, and before any information is shared with LENA, your first and last name will be replaced with a code consisting of your first name and a number. You will be provided with a printed copy of LENA's attached LENA privacy, terms and conditions document.

Will I incur any costs from participating or will I be compensated?

You may have costs from participating in this study if you agree to receiving text messages. Text messages will be sent to your personal phone. If you receive text messages, you will pay for the text messages according to your personal phone plan. You will be compensated with a \$100 gift card for participating in this study.

The \$100 gift card will be given at the end of the study. Should you choose to withdraw before the end of the study, you will receive a gift card in a prorated amount of \$10 per recording week for completing the recordings and required content (such as the Snapshot, Observations and Satisfaction survey), plus \$10 total, \$5 for each for the pre and post SPEAK survey completed. Therefore 9 recording weeks x 10= \$90 plus \$10 for surveys is \$100.

You will need to complete a form to receive payment, which will include providing your social security number. Please know that payments may be subject to tax withholding requirements, which vary depending upon whether you are a legal resident of the U.S. or another country. If required, taxes will be withheld from the payment you receive.

What are my rights as a human research participant?

Participating in this study is completely voluntary. You may choose not to take part in the study or to stop participating at any time, for any reason, without penalty or negative consequences.

If you have any questions *about the rights of research subjects or research-related injury*, please contact the IRB Administrator, (515) 294-4566, IRB@iastate.edu, or Director, (515) 294-3115, Office for Responsible Research, Iowa State University, Ames, Iowa 50011.

Whom can I call if I have questions about the study?

You are encouraged to ask questions at any time during this study. For further information, please contact Dr. Constance Beecher at cbeecher@iastate.edu or 515-294-4512

Consent and Authorization Provisions

Your checking the “yes” box below indicates that you voluntarily agree to participate in this study, that the study has been explained to you, that you have been given the time to read the document and that your questions have been satisfactorily answered. This also indicates that you

give your permission for your child to participate in the study as well. You will receive a copy of the written informed consent prior to your participation in the study.

Do you understand the statements above and freely consent to participate in the study?

- Yes
- No

Participant's Name

Please type your child's name