



Consent for Research Participation

Title: Remote Supporting Early Learning (rSEAL) Study

Sponsor: Eunice Kennedy Shriver National Institute of Child Health & Human Development (NICHD)

Researcher(s): Shannon Peake, Ph.D., University of Oregon

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peake@uoregon.edu

You are being asked to participate in a research study. The box below highlights key information about this research for you to consider when making a decision whether or not to participate. Carefully consider this information and the more detailed information provided below the box. Please ask questions about any of the information you do not understand before you decide whether to participate.

Key Information for You to Consider

- **Voluntary Consent.** You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to participate or discontinue participation.
- **Purpose.** The purpose of this research is to help determine the best ways to support families with their healthy development remotely.
- **Duration.** It is expected that your participation will last 10 months. In that time period there will be three total research sections: one before you begin the parenting program, one immediately after program completion (which will last about 10 weeks), and one 6 months after completion of the parenting program. The 10 weekly program sessions will be about 30-minutes each and each of the three research sections will take about 2 hours to complete.
- **Procedures and Activities.** You will be asked to participate in either the Filming Interactions to Nurture Development (FIND) or the Healthy Toddler Program (HTP). Both programs include 10 web-based sessions with a trained coach. They will include surveys and a video recording task over Zoom. There will also be an at-home audio recording task during each research section, as well as hair collection.
- **Risks.** There is a possibility that your information may be seen by someone who should not. Your confidentiality will be protected by using a code to de-identify the information you provide.
- **Benefits.** Caregivers have expressed that they enjoy working with coaches and that it has given them more confidence in their abilities as caregivers.
- **Alternatives.** Participation is voluntary. There are many ways to learn caregiving skills. Feel free to ask if you would like to learn about other options available to you and your family.

How long will I be in this research?

We expect that your participation will last for 10 months.

**What happens if I agree to participate in this research?**

All surveys will be completed in your own home on your own devices. You will be asked to fill out surveys that ask about things like your personality, your attitudes toward parenting, or your stress levels. Because we are interested in determining the best ways to support families with their healthy development, some of the survey questions may ask you about potentially sensitive events in your past, including traumatic experiences. You may opt out of answering any individual questions that make you uncomfortable, and all of your answers will be kept strictly confidential. We will also record a video of you and your child playing together as you normally would during each of the three research sections via Zoom. These videos will be coded to help us learn more about the program. A small sample of yours and your child's hair will be collected if you opt in. Additionally, if you opt in, we will mail you an audio-recording device (LENA) and the LENA Diary Log to fill out at home. The LENA device will record from a pocket inside of a special vest we'll give to your child, and he/she will wear it throughout the day for 2 days. We will ask you to mail it back in between each wave, and we will provide paid mailing service. Participants' zip codes will be collected as well. The smallest unit of mapping will occur at the zip code level, and appropriate aggregations to the county level or higher will be done when necessary. Data that is mapped is de-identified and maps will be either choropleth (i.e. zip code forms the shape and is colored appropriately to represent count/frequency data) or locations identified from the centroids of zip codes (i.e. distances, spatial relationships etc. will be calculated/mapped by identifying the most central point in the zip code region).

Once you have completed the first research section, you will be contacted by a trained coach to begin either the FIND program or HTP program. You will be randomly assigned to one of the two programs and will not be able to choose which one you participate in. Both programs were originally designed to be delivered as a home-visiting program but have been adapted to be delivered as web-based sessions.

Filming Interactions to Nurture Development (FIND) is a video coaching program, designed by Dr. Phil Fisher and colleagues, for parents and other caregivers of young children. It uses video to show you your strengths as a caregiver. During FIND sessions, the coach will take video recordings of you and your child doing everyday activities and showing you edited clips of moments when you are supporting your child's development. The video recordings will be sent electronically through a secure method to a film editor at UO. For training purposes, video from the coaching sessions will also be shared with a FIND consultant at UO. There will be 10 sessions total, each lasting about 30-minutes.

The Healthy Toddler Program (HTP) is a home visiting curriculum program adapted from the Partners for a Healthy Baby program, which was created by Florida State University's Center for Prevention & Early Intervention Policy. A coach will alternate between information sessions about specific areas of child development, and observation sessions where the coach will observe you and your child engaging in free play and then discussing your experience interacting with your child. HTP will also include 10 sessions, each lasting about 30-minutes.

We will tell you about any new information that may affect your willingness to continue participation in this research.

What happens to the information collected for this research?

Information collected for this research will be used to help determine the best ways to support families with their healthy development remotely. We may share results and data with other education or research centers for scientific, educational, or instructional purposes. We will not use names or other personal information when we share project results or data.

Identifiers might be removed from identifiable private information collected in this research. After removal of identifiers, the information may be used for future research or distributed to another investigator for future research without obtaining additional consent. The only data that will not be deidentified and shared externally are



the videos collected, which are only to be used internally to rSEAL staff, or if a supplemental video release consent is signed, may be shared within the SNAP lab for further research endeavors.

A description of this clinical trial will be available on <http://www.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.

How will my privacy and data confidentiality be protected?

We will take measures to protect the security of all your personal information. Every member of the project team has agreed to protect your confidentiality. The information you provide will be given a unique code that will be used as a de-identifier, and will therefore be kept private. Only members of the project team will know that you are participating in this study. However, the research team includes individuals who are mandatory reporters and legally required to take steps to keep everyone safe. Therefore, if the research team has a reasonable cause to suspect abuse or neglect of a child or adult, a report may be required under Oregon State Law. We may have to share confidential information with others if we believe that you, your child, or someone else has been hurt or is at risk of being hurt; if information has been subpoenaed by the court; or for other emergencies.

To ensure confidentiality, all files and records pertaining to your participation in the project are stored securely. All project team members sign confidentiality agreements, and nobody outside of the project team has access to these records. You have the right to review your records. If you wish to do so, contact a member of the research staff.

All video recordings will be kept strictly confidential and will be labeled in an anonymous fashion. The video recordings will be deleted when the study ends unless you provide additional permission on a different consent form. By signing this consent form, you are giving your consent for video recordings to be viewed by persons connected to this project only. Additional permissions for the videos to be used outside of the project team would need to be given by you on a different consent form.

Hair samples we collect from you and your child will be labeled in an anonymous fashion and used for this study only. The hair will be destroyed while it is being analyzed.

Individuals and organizations that conduct or monitor this research may be permitted access to and inspect the research records. This may include access to your private information. These individuals and organizations include the Institutional Review Board (IRB) that reviewed this research and the National Institute of Health.

All audio recordings through the LENA device will be kept strictly confidential and labeled in an anonymous fashion. The audio recordings will be deleted when the study ends unless you provide additional permission on a different consent form. For those who choose to do the LENA task, by signing this consent form, you are giving your consent for the audio recordings to be heard and transcribed by research personnel only. The LENA device may capture background noises and voices, which may make it possible that these recordings contain personal and sensitive information of other individuals. Any identifiable information inadvertently recorded will be removed.

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.



What if I want to stop participating in this research?

Taking part in this research study is your decision. Your participation in this study is voluntary. You do not have to take part in this study, but if you do, you can stop at any time. You have the right to choose not to participate in any study activity or completely withdraw from continued participation at any point in this study without penalty or loss of benefits to which you are otherwise entitled. Your decision whether or not to participate will not affect your relationship with the researchers or the University of Oregon.

If you decide to withdraw yourself from the study, you may request to have your information removed from the research. Information stored by computer will be permanently deleted. Information collected by paper will be destroyed.

There are many ways to learn parenting skills. Talk to project staff to learn about other options available to you and your family.

Will I be paid for participating in this research?

For taking part in this research, you may be paid up to a total of \$240. Compensation will be in the form of a gift card or mailed check— whichever you decide. If you decide to withdraw earlier in the study, you will be paid in accordance with the proportion of the survey completed. Your compensation will be broken down as follows:

- \$30 for completion of the pre-program surveys.
- \$50 for completion of the post-program surveys.
- \$70 for completion of the 6-month follow-up surveys.
- \$20 per wave of the study (\$60 total); pre-program, post-program, and the 6-month follow-up for mailing back the LENA device (*if eligible and opting in*)
- \$10 per wave of study (\$30 total); pre-program, post-program, and the 6-month follow-up for completing hair collection (*if eligible and opting in*)

For full completion of study tasks, participants will earn \$240. Compensation is only for the research activities; there is no compensation for the 10-session parenting program.

Please be aware, compensation for your participation in research may be considered taxable income. The University requires tracking for compensation that is paid to you; this may include your name and contact information. This information is stored confidentially and separate from research data. If you receive \$600 or more in a calendar year, you may be contacted to provide additional information (e.g. Social Security Number) for tax reporting purposes.

The 10-session program (either FIND or HTP) will be delivered to you at no cost, and neither you nor your insurance company will be billed for any costs associated with your participation in this research.

Who can answer my questions about this research?

If you have questions, concerns, or have experienced a research related injury, contact the research team at:

Shannon Peake, Ph.D.
541-600-4424
peake@uoregon.edu

or

Megan Carson
541-357-9462
mcarson2@uoregon.edu



An Institutional Review Board ("IRB") is overseeing this research. An IRB is a group of people who perform independent review of research studies to ensure the rights and welfare of participants are protected. UO Research Compliance Services is the office that supports the IRB. If you have questions about your rights or wish to speak with someone other than the research team, you may contact:

Research Compliance Services
5237 University of Oregon
Eugene, OR 97403-5237
(541) 346-2510

Authorization for Audiovisual Recording

Filming you and your child is an important part of this study. If you are assigned to participate in the FIND program, the FIND team will not share your FIND video with anyone outside of the project team without getting your permission first. This is also true of videos we record of you and your child during the research sections.

I hereby authorize the study team to make audio/visual recording of me and of my family for the purpose of:

- Supervision and case consultation
- Coding of caregiver-child interaction
- Use in services and support
- Training of new project team members

I understand that:

- This release will be valid indefinitely, unless withdrawn.
- I may refuse to sign a copy of this release.
- I may request a copy of this release.
- I may revoke or restrict this release at any time.

Upon written notice, I may have all of the audiovisual recordings erased and/or restrict their use to one or more of the above stated purposes.

I understand that all audiovisual recordings are available for viewing by me.

Signature: _____ Date: _____

Name (Please type): _____

STATEMENT OF CONSENT

I have had the opportunity to read and consider the information in this form. I have asked any questions necessary to make a decision about my participation. I understand that I can ask additional questions throughout my participation.

I understand that by typing my name below, I volunteer to participate in this research. I understand that I am not waiving any legal rights. I have been provided with a copy of this consent form. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

By typing my full name below, I consent to participate in this study. I also confirm that I am legally authorized to provide permission for the child listed below to participate in the research.

Name of Adult Participant

Signature of Adult Participant

Date



Name of Child Participant

Your Relationship to This Child

Date

If you are assigned to the FIND program, you will receive video coaching in your home. Sometimes your other children may be in the house and may end up on camera. By completing the lines below, you consent for your additional child(ren) to be visible in the video recordings. You also confirm that you are legally authorized to provide permission for the child(ren) listed below to be visible in the video recordings.

Name of Child

Your Relationship to This Child

Date

Name of Child

Your Relationship to This Child

Date

Name of Child

Your Relationship to This Child

Date

SECTION BELOW FOR RESEARCH TEAM USE ONLY

Verification of Explanation

For the interviewer only:

By typing my name in the box below, I certify that I have read the consent script to the caregiver. I have answered all of their questions and he/she has agreed to take part in this project. I have written in the printed information above based on what the caregiver agreed to.

Researcher's Signature: _____ Date: _____