Official Title(s):

"Rural Families Affected by Opioid Use: An Online Parenting Intervention"

and

"Supplement to Prevention Research Center: Parenting Among Women Who are Opioid Users, Project 2"

Clinical Trials Registration Number: NCT05180487

Document: Primary Consent Form

Date: 5-13-2024

UNIVERSITY OF OREGON

Consent for Research Participation

Title:	**Parenting Young Children Study**
Sponsor:	National Institute on Drug Abuse (NIDA)
Researcher(s):	Elizabeth Stormshak, Ph.D., John Seeley, Ph.D, Leslie Leve, Ph.D. (University of Oregon)
Researcher Contact Info:	Project Coordinator: Allison Caruthers phone: 503-412-3770 email: ascaru@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 study is to learn about what parents with young children in Oregon are experiencing, what services and support they are receiving, and provide parenting support through a smartphone-based program called the Family Check-Up Online (FCU Online). Half of parents will be randomly assigned to receive the FCU Online and support from a Family Consultant over phone, text or Zoom, and half of parents will receive the FCU Online one- year later.
- **Duration.** It is expected that your participation will last approximately 10 to 11 hours spread across 1 year.
- **Procedures and Activities.** You will be invited to participate in the following activities:
    - Phone interviews or Self-administered surveys- Four private phone interviews/surveys: at the beginning of the study, 3- months later, 6- months later, and 1-year later that each take between 1 and 1.5 hours to complete. The interviews/surveys will ask about you, your feelings, your health, your family, and parenting your child. You will be paid $75 for each interview/ survey, and that can be paid by check or electronic gift card to Amazon.
    - Interview or Survey Completion Bonus: If you complete an interview or return your survey within 2 weeks of the initial scheduling phone call in which project staff go over the informed consent document, you will be eligible for a quick completion bonus in the amount of $25. This bonus can be paid by check or electronic gift card to Amazon.
  - FCU Online- You will be invited to use the FCU Online on your smartphone to think about parenting and practice new skills. The five topics covered include wellness and self-care, parenting and substance use, positive parenting, proactive parenting, and rules and limit setting. You can expect to spend about 40 minutes a week using the FCU Online. You will either access the FCU Online at the beginning of your study participation, or one year from now depending on how you are randomly assigned.
  - Phone support from a Family Consultant- Half of families will be randomly selected to receive support from a Family Consultant who will offer guidance on the FCU Online through phone calls, text, or Zoom check-ins. Families in this group will complete check-in

appointments with a Family Consultant for each of the 5 topics in the FCU Online. Each check-in will take approximately 20 minutes and will be video or audio recorded.
  - EARS tool- You may opt into downloading the EARS application, which examines how information collected through your mobile phone is related to mental health for an additional $25. If you are interested in hearing more, the recruiter will give more details after reviewing this consent form.

In summary, you may earn up to $400 for participation for doing interviews/ surveys, using the FCU Online, and receiving the quick completion bonuses (when eligible), or up to $425 if you choose to also participate in the EARS portion of the study.

- **Risks.** Some of the foreseeable risks or discomforts of your participation include feeling uncomfortable answering some questions in the phone interview/survey. You can choose not to respond to questions in the interview/survey. There is also a risk that your private information could be revealed. However, we take precautions to guard against this.
- **Benefits**. Some of the benefits that may be expected include enjoying thinking about parenting and practicing new skills. You may enjoy engaging with the FCU O program and making goals for yourself.
- **Alternatives.** Participation is voluntary and the only alternative is to not participate.

Who is conducting this research?

The researcher(s) Elizabeth Stormshak, Ph.D., and John Seeley, Ph.D. from University of Oregon are asking for your consent to this research. The study is funded by the National Institutes of Health.

The PI, Beth Stormshak, is founder of Northwest Prevention Science, Inc., a for-profit entity that provides consultation and training services on the Family Check Up. Research on the Family Check Up may contribute to and inform the services Dr. Stormshak provides through Northwest Prevention Science, Inc. As a result, Dr. Stormshak and Northwest Prevention Science, Inc. may financially benefit from this research. Questions about this may be directed to Dr. Stormshak.

Why is this research being done?

The purpose of this study is to evaluate a smartphone-based program for parents with young children. The program relies on the Family Check-Up (FCU), a family-based intervention that has been used in schools, in homes, and at the University of Oregon Prevention Science Institute for the past 25 years. Recently the FCU was developed to be delivered online with coaching. This study will deliver the FCU as a smartphone telehealth program to parents with young children in Oregon along with coaching.

You are being asked to participate because you have a child between the ages of 18-months and 5 years old.About 400 people will take part in the study. Phone interviews will be offered, and you may opt to have interviews conducted via HIPAA-compliant Zoom or to answer questions on your own in a survey format.

What happens to the information collected for this research?

Information collected from this study will be used to help us ensure our smartphone-based program is easy for parents to use, and a helpful resource for dealing with some of the stress that comes with parenting young children. Your interview/survey responses will be kept private, and video and audio recordings of check-in sessions will be kept private and stored on a secure server.

Your interview/survey responses and opinions are kept private and only reported in summary. No names will be used in any summaries of the study findings. Data from this study will be securely stored locally at UO before being de-identified and submitted to a centralized data repository for the Center on Parenting and Opioids (CPO) and HEAL Prevention Coordinating Center (HPCC). Deidentified study data means that all personal information about you (such as name, address, birthdate and phone number) is removed and replaced with a code number. Sharing your deidentified study data helps researchers learn new and important things about health more quickly than before.

During and after the study, the study researchers will send deidentified study data about your health and behavior to the centralized repository, which will be hosted by the University of Oregon (UO), Oregon Health and Sciences University (OHSU), HEAL Prevention Coordinating Center (HPCC), or the National Institute on Drug Abuse (NIDA) which is a branch of the National Institutes of Health (NIH). Other researchers across the world can then request your deidentified study data for other research. Every researcher (and institutions to which they belong) who requests your deidentified study data must promise to keep your data safe and promise not to try to learn your identity. Experts at the UO, OHSU and HPCC who know how to keep your data safe will review each request carefully to reduce risks to your privacy. You will not be contacted directly by other researchers about the study data you contributed to the CPO repository.

In addition, your deidentified data may be shared with additional investigators for future research studies without additional informed consent from you or your legally authorized representative.

Sharing your study data does have some risks, although these risks are rare. Your study data could be accidentally shared with an unauthorized person who may attempt to learn your identity. The study researchers will make every attempt to protect your identity.

How will my privacy and data confidentiality be protected?

Your interviews/surveys are given unique study ID numbers, so your name is not linked to your responses. Research records, including your consent form and the key linking identifiable information to your unique study ID number, will be retained for five years through the end of the study, and will be destroyed at the end of the study.

Despite taking steps to protect your privacy, we can never fully guarantee your privacy will be protected.

We will take measures to protect the security of all your personal information including storing consent forms, interviews/surveys collected via Qualtrics, and video and audio recordings of any sessions with Family Consultants on our secure server. Staff conducting phone interviews or Zoom interviews are trained to protect participant privacy. Data stored on our server is password protected and access will be limited to authorized staff. Despite these precautions to protect the confidentiality of your information, we can never fully guarantee confidentiality of all study information.

Individuals and organization that conduct or monitor this research may be permitted access to and inspect the research records. This may include access to your consent form or audio recording. These individuals and organizations include: The Institutional Review Board (IRB) that reviewed this research.

The research team includes individuals who are mandatory reporters. If the research team has reasonable cause to suspect abuse or neglect of a child or adult, a report may be required under Oregon State Law. In such a case, the research team may be obligated to breach confidentiality and may be required to disclose personal information.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

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.

Will I be paid for participating in this research?

In this study, you may be paid up to $425 **if you complete all components**:

- Payment 1: $100 for the initial phone interview/survey *and* opting into EARS or $75 for the initial phone interview and opting out of EARS. Payment will be sent after interview/survey completion.
- Payments 2-4: $75 after completing each additional phone interview/survey (3- month, 6-month, and 1-year). Payment will be sent after interview/ survey completion.
- Quick Completion Bonus: $25 for completing your interview/survey within two weeks of receiving it (Initial, 3- month, 6-month, and 1-year). Payment will be sent after interview/ survey completion, for a total of up to $100.

If you complete each activity, you may earn $425 for your time. If you do not complete an activity, you will not receive this amount. You can decide if you would like to receive payment by check in the mail or an electronic gift card to Amazon.

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:

Project Coordinator: Allison Caruthers
phone: 503-412-3770
email: ascaru@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

STATEMENT OF CONSENT

I have had the opportunity to consider the study information presented to me. 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 signing this form, I am providing my consent to participate in this study. I understand that I am not waiving any legal rights, and that I will receive an emailed copy of this consent form once I sign and return it. I understand that if my ability to consent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Research Participant Name:_____

Date:_____

Official Title(s):

"Rural Families Affected by Opioid Use: An Online Parenting Intervention"

and

"Supplement to Prevention Research Center: Parenting Among Women Who are Opioid Users, Project 2"

Clinical Trials Registration Number: NCT05180487

Document: Consent Form to use EARS Tool

Date: 5-13-2024

UNIVERSITY OF OREGON

Consent for Research Participation

Title: **EARS Tool - Parenting Young Children Study**

Sponsor: National Institute on Drug Abuse (NIDA)

Researcher(s): Elizabeth Stormshak, Ph.D., John Seeley, Ph.D, Leslie Leve, Ph.D. (University of Oregon)

Researcher Contact Info: Project Coordinator: Allison Caruthers phone: 503-412- 3770 email: ascaru@uoregon.edu

You have consented to the Parenting Young Children Study and are being asked to participate in an optional portion of the 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**. It is up to you whether you choose to participate in the EARS research activity 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 in EARS. Your decision will not affect your status in the Parenting Young Children Study.

- **Purpose**. Most of the information we collect from you in the Parenting Young Children study is gathered through interviews: you answer questions about yourself and your own behavior. If you choose to participate in the EARS research activity, you would allow us the opportunity to observe mood-related behavior in a more naturalistic manner. The EARS mobile application collects passive data from your mobile phone related to mental health, such as sleep-wake patterns, the frequency with which you leave your home, the frequency and duration of phone calls, and the emotional tone of the information you type into your phone, including, but not limited to, all text messages, emails, text entered when making social media posts, and text entered when using other apps. The only words that the keyboard does not collect are those typed into secure fields, like passwords or credit card information. These data, combined with your interview data, will help us better understand how well the Family Check-Up Online works to improve parent mood.

- **Duration.** It is expected that your participation in EARS will last approximately 3 months.

- **Procedures and Activities.** You will be invited to:
  - Install EARS, a mobile app developed for iPhone and Android at The Center for Digital Mental Health at the University of Oregon. Once the app is installed, you will use your phone as you normally would for three months. During this time, we will collect several types of data from your phone, including keyboard data, geolocation, and phone usage. At the end of the three months, you will be instructed to delete the app from your phone. You will be reminded to do so at the time of your 3-month follow up interview for the Parenting Young Children study.
  - Give a Daily Status Report: Each day during this 3-month period you will be asked to briefly rate how you feel parenting has been going over the past day. Opening the application to

answer this question helps make sure the application stays active on your phone. If you decide not to answer this question, we ask that you try to at least open the application to keep it running.

If you decide to participate in the EARS research activity, you will receive $25. You will be paid for EARS after your baseline phone interview has been completed.

- **Risks.** Some of the foreseeable risks or discomforts of your participation include feeling uncomfortable answering the daily question. You can choose not to respond to this question. There is also a risk that your private data collected by EARS could be revealed. However, we take precautions to guard against this, such as: assigning a set of unique IDs to your data instead of associating it with your name; encrypting mobile phone data during transmission to a secure cloud service; deleting EARS data from your phone's memory after transmission to the cloud; and protecting stored data in the cloud with 256-bit AES encryption.

  Data collected from you during this study may eventually be shared with other researchers for scientific purposes; however, these data will not contain any identifying information that would allow others to link the data to you. When the results of this research are published or discussed at conferences, absolutely no information will be included that would reveal your identity.

- **Benefits**. There are no known direct benefits to you for using the EARS tool. However, it is hoped that information gained from this study will help scientists better understand the effects of the Family Check Up Online on the mental health of parents of young children.

- **Alternatives.** Participation is voluntary and the only alternative is to not participate.

Who is conducting this research?

The researcher(s) Elizabeth Stormshak, Ph.D., and John Seeley, Ph.D. from University of Oregon are asking for your consent to this research. University of Oregon is partnering with Healthy Start and New Day for this study. The study is funded by the National Institutes of Health.

The PI, Beth Stormshak, is founder of Northwest Prevention Science, Inc., a for-profit entity that provides consultation and training services on the Family Check Up. Research on the Family Check Up may contribute to and inform the services Dr. Stormshak provides through Northwest Prevention Science, Inc. As a result, Dr. Stormshak and Northwest Prevention Science, Inc. may financially benefit from this research. Questions about this may be directed to Dr. Stormshak.

Nick Allen, a co-investigator on this project, is founder of Ksana Health, Inc., a for-profit entity that provides software for research, including the EARS program that will be used in this study. Research on the EARS tool may contribute to and inform the services Dr. Allen provides through Ksana Health, Inc. and the commercialization of the EARS technology. As a result, Dr. Allen and Ksana Health, Inc. may financially benefit from this research. Questions about this may be directed to Dr. Allen.

What happens if I agree to participate in this research?

Participants who choose to participate in the EARS activity will have the following information collected via the EARS application:

- *Keyboard Data.* A keyboard logger collects text input across all applications on the mobile phone. The logger will install a specialized keyboard on the phone, which collects every word that you type into your phone, including SMS, social media, searches, and emails. The only words that the keyboard does not

collect are those typed into secure fields, like passwords. The output that is generated includes a time, date, and GPS stamp for each entry. Keyboard data will not be monitored in real time, and therefore we would not be able to intervene and manage any risks if you include information about harm to self or others. Moreover, computer algorithms, and not humans, will conduct the analysis of keyboard data.

- *Geolocation.* EARS will collect the variation in your day-to-day geographical location. This includes assessing the amount of time spent at home compared to other locations each day.
- *Phone Usage*. EARS will also collect different aspects of phone usage, including application usage time, call statistics (duration and frequency), and motion sensing data. We will collect the frequency and duration of each application usage, as well as the total time that your screen is in use per day.
- *Daily Status Report.* In order to keep the application running in the background, users will get a single question pushed to their phone each day at 11 AM ("How effective do you feel as a parent today?"). Without this question, your mobile operating system will often close the application to conserve memory, which prevents the application from collecting any more data until it is opened again.

The EARS tool should have minimal impact on your day-to-day experience with your mobile phone. Once installation is complete, the only difference you should notice is the custom keyboard for iOS. All other data is collected in the background with no user interaction. You should not notice much impact on your phone's memory usage or battery life, either. In order to reduce to impact of the app on the battery life of your phone, motion sensing data will only be collected every 15 minutes (if Android) or once a user moves above a given threshold (if iOS). When possible, GPS will get location data from known Wi-Fi points rather than satellite. In addition, most Cloud uploads will be scheduled late at night when the phone is usually plugged in, and when the device is connected to a Wi-Fi network. Early testing on a range of phones indicated the tool consumed no more than 15% of the battery over a 16-hour period. Battery usage for both versions is continually monitored and improved by the EARS development team.

What happens to the information collected for this research?

Information collected for this research will be used to help us better understand how well the Family Check-Up Online works to improve parent mood.

Data collected from the EARS app are kept private and only reported in summary. No names will be used in any summaries of the study findings. Data from this study will be securely stored locally at UO before being de-identified and submitted to a centralized data repository for the Center on Parenting and Opioids (CPO) and HEAL Prevention Coordinating Center (HPCC). Deidentified study data means that all personal information about you (such as name, address, birthdate, and phone number) is removed and replaced with a code number. Sharing your deidentified study data helps researchers learn new and important things about health more quickly than before.

During and after the study, the study researchers will send deidentified study data about your health and behavior to the centralized repository, which will be hosted by the University of Oregon (UO), Oregon Health and Sciences University (OHSU), HEAL Prevention Coordinating Center (HPCC), or the National Institute on Drug Abuse (NIDA) which is a branch of the National Institutes of Health (NIH). Other researchers across the world can then request your deidentified study data for other research. Every researcher (and institutions to which they belong) who requests your deidentified study data must promise to keep your data safe and promise not to try to learn your identity. Experts at the UO, OHSU, and HPCC who know how to keep your data safe will review each request carefully to reduce risks to your privacy. You will not be contacted directly by other researchers about the study data you contributed to the CPO repository.

In addition, your deidentified data may be shared with additional investigators for future research studies without additional informed consent from you or your legally authorized representative.

Sharing your study data does have some risks, although these risks are rare. Your study data could be accidentally shared with an unauthorized person who may attempt to learn your identity. However, the study researchers will make every attempt to protect your identity.

How will my privacy and data confidentiality be protected?

Although data collection of this type may raise privacy concerns because of the sensitivity of mobile phone data, the EARS team has a highly skilled team of programmers and data scientists whose job it is to ensure the privacy of your data. Only staff associated with this research project will have access to your data. A set of unique IDs will connect your mobile phone data to data collected from other sources. Your name and contact information will not be connected to your data and will be kept in locked, password-protected databases at the University of Oregon and will only be accessible to key staff members who need to contact you. Research records, including your consent form and the key linking identifiable information to your unique study ID number, will be retained for five years, through the end of the study, and will be destroyed at the end of the study. All of your mobile phone data and survey responses will be encrypted (locked) after being uploaded to a secure cloud service (AWS) for storage and processing. The upload process uses secure methods as well, so your data is protected in transfer. Therefore, although it is technically possible that your private information could be lost or stolen (as with any research study), this is very unlikely because your data is transferred, stored, and accessed in an extremely secure manner.

The keyboard that we install on your phone will collect all types of text that you input, except for passwords, which it will never collect. In fact, anything typed into a "secure field" (passwords and credit card numbers) will not be collected. However, this means that we may collect other personal information that you type into your phone, such as names and addresses. We will not share this information with anyone outside of the research team.

Data collected by the app will be removed from the phone daily. However, we recommend that you add a passcode to open your phone if you do not already use one. This will help prevent the data on your phone from being stolen.

The Encryption protocol for data collected using the EARS tool will be as follows:

> When transmitting the data to the Amazon cloud service (AWS), the EARS tool uses the latest version of TLS available (TLS 1.2 or greater) to connect to the server, meaning all data in transit are encrypted using the industry standard for encrypting data travelling between networks. After transmission to the Cloud, the EARS tool then deletes the data from the phone's memory. Upon upload to AWS, the data are then protected by Amazon's Server Side encryption, which uses 256-bit AES encryption. Upon completion of or withdrawal from the study, a participant's uninstallation of the EARS tool automatically deletes all EARS data still residing on the phone.

Data collected from you during this study may eventually be shared with other researchers for scientific purposes only; however, these data will not contain any identifying information that would allow others to link the data to you. When the results of this research are published or discussed at conferences, absolutely no information will be included that would reveal your identity.

Be aware that the research team includes individuals who are mandatory reporters. If the research team has reasonable cause to suspect abuse or neglect of a child or adult, a report may be required under Oregon State Law. In such a case, the research team may be obligated to breach confidentiality and may be required to disclose personal information.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or

suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

What if I want to stop participating in this research?

If you choose to participate in the EARS research activity, you may discontinue participation at any time. If you wish to discontinue EARS, we ask you to contact us so we can make sure that the tool is completely uninstalled from your phone. At that time, you can let us know whether it is okay for us to keep the data we already have, or whether you want us to destroy it.

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:

Project Coordinator: Allison Caruthers
phone: 503-412-3770
email: ascaru@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

STATEMENT OF CONSENT

I have had the opportunity to consider the study information presented to me. 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 I am not waiving any legal rights and that I will received a copy of this consent form once I sign and return it. I understand that if my ability to consent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

I consent to install the EARS tool on my phone and to have data collected as described above.

Research Participant Name _____

Date:_____