

**Informed Consent for Participation in Research:**  
**Participant**

**Project Title:** Preventing Parental Opioid and/or Methamphetamine Addiction within DHS-Involved Families: FAIR

**Principal Investigator:** Lisa Saldana, Ph.D.,  
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**What is the purpose of the project?**

This project, part of the Families Actively Improving Relationships (FAIR) programs, aims to help families who are involved with the Oregon Department of Human Services (ODHS; Child Welfare or Self-Sufficiency) in building and maintaining positive relationships, and understanding how choices can influence family health (e.g., physical, mental, and educational health; substance misuse). The researcher in charge of this project is Dr. Lisa Saldana. The National Institute on Drug Abuse (NIDA) is paying for this project.

This project is a research study to help us understand if the FAIR program can be helpful for different types of families involved in ODHS. To learn about the families who participate in FAIR and how the program is working, we will collect information about the parents who choose to participate. This will include information about their health, relationships, and other parts of their lives. This study is interested in comparing the PRE-FAIR program to other services referred by ODHS.

Everyone in the project will be put in one of two groups. One group will get usual ODHS case management and service referrals. The other group will get the PRE-FAIR program with ODHS case management. You will be put in one of these groups randomly, which means there is a 50/50 chance of the group to which you are assigned. Neither you nor your caseworker will be able to choose the group. This is part of the research design.

**Do you want to participate?**

It is your decision to be in the project. Before you decide, you need to know the risks and benefits. You should also know what we will ask you to do. Please take your time to read this form. The form explains the project. A staff member also will explain the project and answer your questions. If you take part in the project, this will not help or hurt your case with ODHS. If you do not take part in the project, this also will not help or hurt your case with ODHS. There are no negative results for choosing not to be in the project or for quitting the project.

If you agree to be in this project, you will sign this description and consent form. When you sign the consent form, you “give consent.” This means that you agree to be in the project. It also means that you understand what we will ask you to do. You can change your mind at any time and withdraw consent. **Please review this consent form carefully.** Staff will answer any questions you have before you sign these forms.

After you sign this consent form, we will conduct the first interview. When that is complete, you will be assigned to one of two groups. One group is Usual Services and the other group is PRE-FAIR. The assignment will be random, which means that it will be like flipping a coin. The randomization will tell you if you will be in the PRE-FAIR program or referred back for other services by ODHS. You will be in the research project with interviews regardless of which condition you are in. The research project is separate from participating in the PRE-FAIR program or other services.

**What will we ask you to do if you choose to be in the project?**

We will ask you to do six face to face interviews over two years. We also will ask you to do 14 brief monthly phone calls. You can decide each time if you want to do the interview or not. The details of each visit are listed in the chart on the next page.

Interviews	How long	What will happen	How much paid
<b>In person</b> 1 <sup>st</sup> interview (“Baseline”) 4-months 8-months 12-months 18-months 24-months	About 2 hours	Face to Face Interview.  Urinalysis	\$100 gift card Each Interview
<b>Monthly Phone Calls</b> Months 1 through 17 (excluding in-person interview months)	About 20 minutes	Phone Interview	\$20 gift card Each phone call

The face to face interview covers many topics. There will be some demographic questions, such as ethnicity, income and employment and education history. We will ask about your thoughts about parenting, your history of using substances, any services that you are receiving, and about your mental health. The phone interview covers similar topics, but is much shorter. All answers will be entered into a secure computer.

For the face to face interviews, the team will work with you to pick times and places that make it easy for you to participate. That might be in your home, a restaurant or other public place, or another private office space. If an in-person interview is not feasible, we might ask to do your interview using virtual technology (i.e., video chat).

**What other types of information will the project collect?**

This project collects information in different ways. We will ask you questions in-person and over the phone or internet. You will answer questions and we will put your answers on paper or in a computer. We will collect urinalysis (UA). (If you are incarcerated at the time of an assessment, you will not be required to provide a sample for a UA.) We also will collect information from ODHS and Oregon Health Authority (OHA) about your history of medical and related services received, hotline reports, out of home placements of your child(ren), and case disposition. This is data that we will collect directly from ODHS and OHA. They will provide us with data for all of the parents who participate in the project whether or not they receive PRE-FAIR.

To stay in contact with you during and after the project, we also may:

- collect the names and phone numbers of others close to you with your consent.
- search public records like the telephone directory and internet resources such as on-line directories and social media sites to try to find you.

**What else might you be asked to do?**

If you agree to be in the study and are randomly selected for the PRE-FAIR group, you will receive services from a PRE-FAIR Clinic.

FAIR is a program designed for parents with children of any age. FAIR supports parents by strengthening their parenting skills, providing mental health and substance misuse support, and connecting parents to services in their community. FAIR is a home and community-based program that allows for flexibility in meeting times and places. Sessions occur in the places where you may spend time with your child(ren), such as at home, school, and playgrounds. Sometimes sessions also occur on the phone or with video chat.

The FAIR team:

- Works with parents to help them achieve treatment goals they set for themselves.
- Communicates with ODHS to understand what treatment goals ODHS expects.
- Helps parents work toward meeting those goals in addition to your personal goals.
- Will work with you to pick times and places that make it easy for you to participate.
- Is available 24/7 for on-call support and ongoing engagement.
- Is staffed with qualified mental health and substance abuse providers.

FAIR focuses on four major components:

- Parenting skills training
- Substance misuse prevention
- Mental health treatment
- Resource building and additional supports for housing, education, employment, physical healthcare, child welfare, and probationary expectations.

PRE-FAIR services are estimated to take 4 to 6 months to complete.

### **How long is the project?**

The project is planned to last for four years, from September 2020 until September 2024. You will be asked to be in 2 of the 4 years of this project. If we receive more funding, we may invite you to stay in for a longer period. Being part of this project one year does not mean you have to be in the project in future years.

### **Who else will take part?**

About 240 parents will be in this project. All of the families have had contact with ODHS and have been identified as benefitting from additional services and supports.

### **What happens if you need more or different services/treatment?**

Sometimes you or project staff might feel that you need other help. We can give you information or contacts for other services. We can also help you make phone calls to other services to set up an appointment.

### **What are your rights as a participant in this project?**

You have certain rights while you are in this project. These rights help protect you.

- You can decide to be in the project or not. It is voluntary and always your choice.
- You can change your mind about being in this project at any time. If you decide to quit the project, there will be no negative results of any kind.
- If you are receiving FAIR services and decide to quit the research project, you do not need to quit your FAIR services. You also can quit your FAIR services and stay in the research project.
- You can skip or not answer any question. Some questions might be personal or sensitive. They are important to the project so that we understand the families that we work with and can make sure that treatment covers their needs. We would like you to answer them honestly, but if there are some questions you do not want to answer, you may skip them and move on to other questions.
- You also have the right not to do other parts of the project such as the urinalysis.
- You will get a copy of this Project Description and the Consent Form(s).
- You are free to ask questions about the project at any time. You may contact the Principal Investigator, Dr. Lisa Saldana (541-915-6614), or the Project Manager, Rafael Robles (458-243-7939).
- You can talk to someone outside the project about questions or concerns about the project. You can also ask about your rights as a participant. This person is Dr. Ralph Weisheit, at 309-451-7855.

### **How will your privacy (or confidentiality) be protected?**

We will do all we can to keep everything about you and your family completely private. Here are the ways that we will protect your privacy.

- We use a number instead of your name on all the information about you that we study and analyze.
- We store all information in safe, locked areas.
- We study information from everyone in the project as a group, not as individuals. When we share project results, we will not identify any one person. We will not use names or other personal information.
- We train all staff members to protect your privacy. Only a small number of them will see your information. In some cases, the National Institute on Drug Abuse (NIDA), that is/are responsible for and funding this project might see information about you as part of their review of our project. They are also required to protect your privacy.
- To help us protect your privacy, we have a Certificate of Confidentiality from the National Institute on Drug Abuse (NIDA).

We can use the Certificate to legally refuse to give away any identifying information from the research project about any person. This is true even if a court of law asks for the information. This does not apply to records from the PRE-FAIR clinical team.

This Certificate does not stop you from choosing to give information about yourself or your participation in this project. Also, if someone learns about your participation and gets your consent to receive FAIR project information about you, we may not use the Certificate to withhold this information. This means that you and your family must also actively protect your own privacy.

- We will not share your answers with anyone without your permission. We will not share anyone else's answers with you, including answers from your family members.

### **Are there times when we will share information about you?**

Yes, these are called "exceptions to confidentiality." Project staff will keep all of your information private, except in the following cases. These cases are those where the safety of you or someone else is determined to be at risk. In these cases, unless there is imminent danger, the project staff will first contact Dr. Lisa Saldana who oversees the project. She will determine if the situation is an exception to confidentiality. Situations that might be considered an exception, even if we have a Certificate of Confidentiality, include:

- We might hear or see something that we think is abuse of a child. We might see or hear something that tells us that a child is in danger. Or we might learn that a child has witnessed violence (such as adults physically fighting in the home). In cases like these, we will take action to protect the child. We will talk to a child welfare agency and may talk to the child's caregivers.
- We might think that a child under age 18 is in immediate danger of trying to kill him or herself. We will tell the caregivers about these concerns. We also will give caregivers information about agencies that can help in such cases.
- We will report when we hear that someone plans to hurt themselves. If you or someone you know has plans to hurt themselves, we will contact Dr. Saldana who oversees the project. She might ask to speak to you and might suggest additional services. If you or someone you know is at imminent risk for hurting themselves, we might contact the authorities for safety.
- We will report when we hear that someone plans to hurt someone else. We will contact Dr. Saldana. She might determine that we should contact the authorities.
- We might learn that a participant has been using illegal or non-prescription substances through an urinalysis while caring for a child. We will work with you to identify if you have a caseworker to notify to establish a safety plan. We might need to notify the ODHS reporting line.

**What are the possible risks to you as a participant in the project?**

As a participant in this project, there are a few risks to you:

- We collect personal information about you. Although we follow the privacy procedures described earlier, there is the chance that someone who should not see your information might see it.
- You might feel uncomfortable with some parts of the project. For example, some questions we ask are personal. Or you might feel uncomfortable with urinalysis. You are free to say “no” to any part.
- If you participate in this project, you might not be able to be in another Chestnut Health Systems project.
- If you participate in this project, the research team might not be able to hire you in the future. Also, if you participate in this project, the research team might not be able to hire your family members or those close to you.

If you want to talk to someone about any of these risks, please let us know or contact one of the people listed above.

**What are the benefits to you as a participant?**

The information from this project might help us understand more about the types of treatments that help families who are involved in the ODHS system. This information might be used to help others. You can be part of this valuable project.

Many people find it helpful to think and talk about their lives and their families. Being in the project gives you a chance to do this.

I agree to take part in the study: The study has been explained to me. I had a chance to ask questions. I understand that I can choose not to answer any question and that I can take myself out of this study at any time. I can continue with my usual treatment even if I am not in the study. No one has made any promises about how the study will turn out. My personal information related to the study will be protected and kept private according to federal law. When my information is looked at for a required review or to protect my safety, my records will be protected by federal laws.

I hereby \_\_\_ agree / \_\_\_ do not agree (check one) to take part in the study that is described in this consent form. I have been given a copy of the consent form. I understand that if I have questions or concerns, I can contact one of the persons listed above.

Participant (please print)

Participant (signature)

Date

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Verbal consent given

Witness (signature)

Date

\_\_\_\_\_

\_\_\_\_\_

\_\_\_ Ineligible \_\_\_ Refused (Reason: \_\_\_\_\_)

This consent automatically expires 5 years from the date it is signed.