

Informed Consent for Participation in Research:
Participant

Project Title: Disrupting Social Determinants of Health to Improve Substance Use and Mental Health Outcomes for Parents in Rural Regions

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What is the purpose of the project?

This project is a research study to help us understand how Just Care for Families (Just Care) can best meet families' basic needs for health and wellness. To learn about the families who participate in Just Care 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. Everyone in the project will participate in the Just Care program.

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 or have someone read it to you. 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 have one. If you do not take part in the project, this also will not help or hurt your case with ODHS, if you have one. 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.

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

We will ask you to do three face-to-face interviews over 18-months. We also will ask you to complete check-ins every week using a specially designed app. You can decide each time if you want to do the interview or not. The details of each visit are listed in the chart below.

| Interviews | How Long | What Will Happen | How Much Paid |
|--|---------------|--|--|
| Face to Face 1 st interview ("Baseline") 9-months 18-months | About 3 hours | Face-to-Face Interview Urinalysis | \$100 gift card each interview |
| Weekly App Check-ins Weekly for 18-months | <10 minutes | Asked to answer questions in an app. | \$10 gift card each week responded (paid weekly) |

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, and about your mental health. All answers will be entered into a secure computer. The weekly check-ins will ask about your current status or concerns regarding life needs, such as housing and employment. These check-ins will be completed using a specially designed, secure app. If you do not have access to a device for the app, someone can call you on a landline to ask you the questions.

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).

Compensation payments totaling \$600 or more in a calendar year may be considered taxable income. In the event that you reach this limit, we will collect a W-9 form from you. This form will be submitted to Chestnut Accounting who will then mail you a 1099 and submit one to the Internal Revenue Service (IRS). Please keep this in mind when filing your taxes.

What other types of information will the project collect?

This project collects information in different ways. We will ask you questions in-person and through the internet. You will answer questions and we will put your answers in a computer or on paper, depending on your comfort. 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 will ask your clinician if certain topics came up during your meetings. 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 history will include two to four years after entry to the study. This is data that we will collect directly from ODHS and OHA.

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 online 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, you will receive services from a Just Care Clinic.

Just Care is a program designed for parents with children of any age. Just Care supports parents by strengthening their parenting skills, providing mental health and substance misuse support, and connecting parents to services in their community. Just Care 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 Just Care team:

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

Just Care focuses on four major components:

- Parenting skills training
- Substance misuse prevention
- Mental health treatment
- System navigation, building community, and assistance with basic needs including additional supports for housing, education, employment, physical healthcare, child welfare, and probationary expectations.

Just Care services are estimated to take 9 months to complete.

How long is the project?

The project is planned to last for five years, from September 2022 until September 2027. You will be asked to be in 1½ of the 5 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 250 parents will be in this project. Many of these families have had contact with ODHS and/or have been identified as benefiting 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 also can 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 Just Care services and decide to quit the research project, you do not need to quit your Just Care services. You also can quit your Just Care 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 consent form for reference.
- You are free to ask questions about the project at any time. You may contact the Principal Investigator, Dr. Lisa Saldana (541-915-6614). 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 the person in charge of protecting your rights, 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 store all information in safe, locked areas.
- We use a number instead of your name on all the information about you that we study and analyze.
- 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 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 also are 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 Just Care 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 Just Care 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 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 a 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, especially those 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.

What will be done with the information we collect for this project?

We will use information from this project for research and education only. Study staff will protect you so no one can connect your answers with you as an individual. Any personal information that could identify you will be removed or changed before any data files or results are shared. This is referred to as using “de-identified” data. Your de-identified data will be protected. We follow laws that protect the use of your health and personal information.

Your de-identified data will be used in the following ways:

- The data will be analyzed to understand how substance use and mental health problems can be prevented.
- We will share the results of the project in papers, books, and presentations.
- To allow for future research, your de-identified data will be stored and maintained indefinitely in a National Institute of Health (NIH)-approved data repository, in compliance with NIH requirements for sharing data that are collected with NIH funding. You will not be informed of the details of any specific research that might be conducted using your de-identifiable information.
- NIH requires that we share de-identified data through secure databases so that others also can learn from this research (see <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-013.html>). Therefore, your answers to surveys may be shared with other researchers through a data file. Before the data files are given to anyone else for research, we will remove your name and other information that could identify you. These data files will only have a research ID attached. Your personal information will not be made public. Any information that can identify you will be kept separate from the data files. Only the Principal Investigator and study staff who need to contact you will have access to your name and contact information. This information will be kept in a secure file. Any written reports or presentations shared with the public only will talk about groups of people and not individuals.

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.