

Informed Consent for Participation in Research:
Parent/Guardian

Project Title: Testing Implementation Strategies to Scale-up a Multicomponent Continuum of Service Intervention for Families Involved in Systems with Parental Opioid and Methamphetamine Use

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What is the purpose of the project?

This project is a research study to help us develop a program designed for parents with substance use disorder who are involved with or at-risk for involvement with child welfare Oregon Department of Human Services (ODHS). The program is called Just Care for Families. The project will help us understand the needs of parents living in rural Oregon communities, if the Just Care for Families program can help meet those needs, and if the use of a mobile App can help increase access to care. We will collect information about the parents who choose to participate. This will include information about their health, relationships, child welfare involvement, and other parts of their lives.

Do you want your youth to participate?

Your youth will be asked to participate in one of four ways depending on the county they live in and the year of the project. All participants will be compensated for their time (described below). Your youth is being asked to participate by (check one):

- ☐ (1) completing weekly digital surveys and 5 interviews over 18-months.
- ☐ (2) completing weekly digital surveys and 5 interviews over 18-months and enrolling in the Just Care for Families program.
- ☐ (3) completing weekly digital surveys and 5 interviews over 18-months, enrolling in the Just Care for Families program, and using the Just Care App as part of their treatment.
- ☐ (4) completing weekly digital surveys and 5 interviews over 18-months, enrolling in the Just Care for Families program, and using the Just Care App as part of their treatment with information from the App communicated directly to their Just Care treatment team.

It is your and your youth's decision to be in the project. Before you decide, you need to know the risks and benefits. You also should know what we will ask your youth 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 your youth takes part in the project, this will not help or hurt their case with ODHS, if they have one. If they do not take part in the project, this also will not help or hurt their case with ODHS, if they have one. Your and your youth's decision to be in the project does not help or hurt their ability to receive Just Care for Families services in their county if they are being offered. There are no negative results for choosing not to be in the project or for quitting the project.

If you agree for your youth 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 for your youth to be in the project. It also means that you understand what we will ask them 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 with your youth.

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

We will ask participants to do a total of 5 interviews over 18 months. This includes 3 face-to-face interviews and 2 virtual interviews. We also will ask your youth to complete check-ins every week using an online survey that they can receive as a text or email. Participants can decide each time if they want to answer the questions or not. Participants can choose to answer some questions and not others.

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 2 hours	Face-to-Face Interview Urinalysis	\$100 gift card each interview
Virtual (Zoom) or phone 4-months 14-months	About 2 hours	Virtual (Zoom) Interview or phone call	\$100 gift card each interview
Weekly App Check-ins Weekly for 18-months	<10 minutes	Asked to answer questions in survey sent to your youth.	\$10 gift card each week responded (paid weekly)

The face-to-face and virtual interviews cover many topics. There will be some demographic questions, such as ethnicity, income and employment, and education history. We will ask about participants' thoughts about parenting, their history of using substances, and about their mental health. All answers will be entered into a secure computer. The weekly check-ins will ask about participants current status or concerns regarding life needs, such as housing and employment. These check-ins will be texted or emailed to participants through an online survey. If participants are not able to complete check-ins by text or email, the questions can be read to them over the phone.

For the face-to-face interviews, the team will work with participants to pick times and places that make it easy for them to participate. That might be in their 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 their interview using virtual technology (i.e., video chat) or phone.

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

What other types of information will the project collect?

This project collects information in different ways. We will ask participants questions in-person, by phone, and through the internet. They will answer questions, and we will put their answers in a computer or on paper, depending on their comfort. We will collect urinalysis (UA; if participants are incarcerated at the time of an assessment, they will not be asked to provide a sample for a UA). We also will collect information from ODHS and Oregon Health Authority (OHA) about their history of medical and related services received, hotline reports, out of home placements of their 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 the participant during and after the project, we also may:

- collect the names and phone numbers of others close to them with their consent

- visit their last known residence
- search public records like the telephone directory and internet resources such as online directories and social media sites to try to find them

What else might your youth be asked to do?

For participants in conditions 2, 3, or 4 only. Your youth is in condition [].

If your youth agrees to be in the study, you will receive services from a Just Care Clinic.

Just Care for Families is a program designed for parents with children under the age of 18. 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 your youth may spend time with their 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 6 major components:

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

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

For participants in conditions 3 and 4 only. Your youth is in condition [].

Just Care App

- As part of your youth's participation in Just Care for Families, they will have access to a Just Care App. They will be asked to download the App to their smartphone, tablet, or desktop computer. There is no charge for downloading or using the App. Once participants have the App, they will be able to keep it as long as they like. The information participants enter into the App will be stored securely on a HIPAA secure server. This information will include information about participants' mood, needs, treatment goals, and activities to meet their goals.

For participants in condition 4 only. Your youth is in condition [].

Just Care App and Treatment Feedback

- The information that participants enter in the App will be made available to the Just Care treatment team. This information will be used in their treatment planning.

How long is the project?

The project is planned to last for five years, from September 2025 until September 2030. Your youth will be asked to be in 1½ of the 5 years of this project. If we receive more funding, we may invite them to stay in for a longer period. Being part of this project one year does not mean they have to be in the project in future years.

Who else will take part?

About 254 parents will be in this project. Many of these families have had contact with ODHS or other family-related systems/organizations.

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

Sometimes your youth or project staff might feel that they need other help. We can provide information or contacts for other services. We also can help participants make phone calls to other services to set up an appointment.

What are your youth's rights as a participant in this project?

Your youth has certain rights while they are in this project. These rights help protect them.

- They can decide to be in the project or not. It is voluntary and always their choice.
- They can change their mind about being in this project at any time. If they decide to quit the project, there will be no negative results of any kind.
- If they are receiving Just Care services and decide to quit the research project, they do not need to quit their Just Care services. They also can quit their Just Care services and stay in the research project.
- They 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 the participant to answer them honestly, but if there are some questions they do not want to answer, they may skip them and move on to other questions.
- They also have the right not to do other parts of the project, such as the urinalysis.
- You and your youth will get a copy of this consent form for reference.
- They are free to ask questions about the project at any time. They may contact the Principal Investigator, Dr. Lisa Saldana (541-915-6614). They can talk to someone outside the project about questions or concerns about the project. They can also ask about their rights as a participant. This person is the person in charge of protecting their rights, Dr. Ralph Weisheit, at 309-451-7855.

How will your youth's privacy (or confidentiality) be protected?

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

- We store all information in safe, locked areas.
- We use a number instead of their name on all the information about them 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 participants' privacy. Only a small number of them will see your youth's information. In some cases, the National Institute on Drug Abuse (NIDA), that

is/are responsible for and funding this project might see information about participants as part of their review of our project. They also are required to protect participants' privacy.

- To help us protect participants' 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 your youth from choosing to give information about themselves or their participation in this project. Also, if someone learns about your youth's participation and gets their consent to receive Just Care for Families project information about them, 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 the participants answers with anyone without their permission. We will not share anyone else's answers with the participant, including answers from your family members.

Are there times when we will share information about your youth?

Yes, these are called "exceptions to confidentiality." Project staff will keep all of the participant's information private, except in the following cases. These cases are those where the safety of the participant 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 the participant or someone they know has plans to hurt themselves, we will contact Dr. Saldana, who oversees the project. She might ask to speak to you or the participant and might suggest additional services. If the participant or someone they 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 the participant to identify if they have a caseworker to notify to establish a safety plan. If they do not, we will collaborate with them to notify the ODHS reporting line.

What are the possible risks to your youth as a participant in the project?

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

- We collect personal information about them. Although we follow the privacy procedures described earlier, there is the chance that someone who should not see their information might see it.

- They might feel uncomfortable with some parts of the project. For example, some questions we ask are personal. Or they might feel uncomfortable with urinalysis. They are free to say “no” to any part.
- If they participate in this project, they might not be able to be in another Chestnut Health Systems project.
- If they participate in this project, the research team might not be able to hire them in the future. Also, if they participate in this project, the research team might not be able to hire family members or those close to them.

If you or your youth 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 your youth as a participant?

The information from this project will help us understand more about the types of treatments that help families, especially those who are involved in the ODHS system. This information will be used to help develop methods for implementing the Just Care program and make it available to others. Your youth 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 your youth 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 your youth so no one can connect their answers with them as an individual. Any personal information that could identify them will be removed or changed before any data files or results are shared. This is referred to as using “de-identified” data. Their de-identified data will be protected. We follow laws that protect the use of their health and personal information.

Their 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.
- The National Institutes of Health (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 youth’s 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 their name and other information that could identify them. These data files will only have a research ID attached. Their personal information will not be made public. Any information that can identify them will be kept separate from the data files. Only the Principal Investigator and study staff who need to contact them will have access to their 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. Your youth will not be informed of the details of any specific research that might be conducted using their de-identifiable information.

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

I hereby ____ agree / ____ do not agree (check one) to allow my youth 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 my youth has questions or concerns, they can contact one of the persons listed above.

Parent/Guardian (please print)

Parent/Guardian (signature)

Date

Verbal consent given ☐

Participant (please print)

Witness (signature)

Date

____ Ineligible ____ Refused (Reason: _____)

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