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Principal Investigators: Jeremy Jones, Ph.D.
Influents Innovations
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Informed Consent for Participation in Fathering in Recovery Study

Study Title: Fathering in Recovery
Principal Investigator: Dr. Jeremy Jones
Sponsor: NIDA 1R43DA052949-01

We are inviting you to take part in a research study. You do not have to be in the study if you do not want to. You can also decide to be in the study now and change your mind later.

We want everyone in the study to understand what it is about. We are developing and providing a helpful parenting program for fathers who are in recovery from opioid misuse. Parenting help for fathers is lacking in general. Rarely do fathers get specific parenting supports or classes and there are very few available programs for fathers in recovery from substance use. Previous research has shown that parenting support is helpful and fathers often want more support. The goal of this project is to develop and test a web-based program meant for fathers in recovery.

If you take part in this study, we will ask you to participate by using the online Fathering in Recovery (FIR) program over a 5-week period. You will also complete some surveys.

- You will need to have access to a computer, tablet, or cell phone with texting/video viewing capabilities to participate.

- Your participation will include responding to brief texts/emails from our study team.

- You will be asked to fill out two surveys. The first survey will happen after you consent to participate, the second survey will happen 5 weeks later. Surveys will include questions about parenting your child, your mental health, and substance use. Surveys will be completed on your personal computer, tablet, or cell phone. You can decline to answer any of the questions.

- You will receive up to $200 for participation in the study.

Risks and What Will Be Done to Reduce the Risks

There are some possible risks involved for participants, including:

1. There is the possible risk of loss of privacy**.** All records obtained from participants will be kept in locked file cabinets in locked rooms. Computer-based information regarding participant information will be password protected and kept in locked rooms. All data that is collected will be de-identified, meaning no names will be associated with the data. Project staff are trained and experienced with confidentiality, including data collection, data management, and reporting procedures. Data recycling is arranged through a contracted, bonded recycler.

2. There is an exception to maintaining confidentiality if project staff learn the participant is in danger of being hurt or hurting someone else. If evidence of child abuse is encountered at any time during any contacts, staff at the appropriate government agency will be contacted and arrangements for further evaluation will be made immediately. We will disclose to the responsible authorities only information we receive from participants about intended harm to potential victims. Project staff are mandatory reporters so it is their responsibility to inform authorities and to protect the well-being of potential victims.

Benefits to You

1. You may or may not benefit from participating in this research. You may enjoy the opportunity to reflect on your life experiences. You may see improvements in your parenting skills, and in your relationship with your child and your child's other parent.

2. You will be contributing to research on providing fathering supports to individuals in recovery from substance use.

We plan to make the results of this study public, but we will not include your name or provide other identifying information.

We would like you to ask us questions if there is anything about the study that you do not understand. You can call us at 541-484-2123 or email FIR@influentsin.com.

You can also contact the Office for the Protection of Human Subjects with any concerns that you have about your rights or welfare as a study participant. This office can be reached at (541) 484-2123 or by email at kathryn@ori.org.

There are additional details to consider about the study if you are interested on the following pages.

Informed Consent for Participation in Parenting in Recovery

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STUDY DETAILS

WHAT IS THE PURPOSE OF THIS RESEARCH STUDY?

You are invited to participate in a research study which could greatly improve our understanding of effective interventions for fathers with opioid use disorder. This study is being conducted by Jeremy Jones, Ph.D. of Influents Innovations in Eugene, Oregon and is funded by The National Institute on Drug Abuse 1R43DA052949-01. We want everyone in the study to understand what it is about. Please read this form and ask any questions you may have before agreeing to participate in the study.

WHAT WILL YOU BE ASKED TO DO IN THIS RESEARCH STUDY?

If you decide to participate, you will be asked to use the online Fathering in Recovery (FIR) program, and complete some surveys over a 5-week period. Your participation may include responding to texts from our study team, and notifications from the FIR program. You will receive a total of up to $200 for participation in the study - $75 after completing the first survey and program introduction in week 1, and $125 after completing the program and the second survey in week 5. We estimate your participation in the study will take about 2-4 hours.

WHAT ARE THE RISKS AND WHAT WILL BE DONE TO REDUCE THE RISKS?

There are some possible risks involved for participants. These are:

- There is the possible risk of loss of privacy and confidentiality**.** All records obtained from participants will be kept in locked file cabinets in locked rooms. Computer-based information regarding participant information will be password protected and kept in locked rooms. All data that is reported will be de-identified, meaning no names will be associated with the data. Project staff are trained and experienced with confidentiality, including data collection, data management, and reporting procedures. Data recycling is arranged through a contracted, bonded recycler.

- There is an exception to maintaining confidentiality if project staff learn the participant is in danger of being hurt or hurting someone else. If evidence of child abuse is encountered at any time during any contacts, staff at the appropriate government agency will be contacted and arrangements for further evaluation will be made immediately. We will disclose to the responsible authorities only information we receive from participants about intended harm to potential victims. Project staff are mandatory reporters so it is their responsibility to inform authorities and to protect the well-being of potential victims.

- The risks or discomforts of participating in this research include psychological risks such as feeling uncomfortable with the questions asked in surveys or feeling uncomfortable watching videos about parenting. All participants may request discontinuation of any procedure at any time if they experience undue distress. Should participants experience an adverse reaction to the assessments and require medical or psychological assistance, project staff will be prepared to evaluate the situation and, if necessary, make appropriate referrals. Referrals are made to low-cost, high-quality service agencies in the participant's local area when possible.

- We have a "Certificate of Confidentiality" which is a legal assurance from the federal government, which will help us protect your privacy. In rare cases, identifiable records could be subpoenaed. If this happens, Influents innovations' lawyer will work with the courts to protect your privacy. We will not give information to anyone unless you provide a signed release telling us to do so, or unless we have reason to suspect: 1) abuse, neglect, or endangerment of a child or elder; 2) or that anyone is in immediate danger of seriously hurting himself/herself or someone else. In these situations, we may have to make a report to the appropriate authorities.

Storage & Future Use of Your Information

We will retain the information you provide us with in this study. It is possible that we will conduct similar studies in the future. We would like your permission to use the information you provide us without having to ask you again. We will only use your information in other studies about parenting, substance use, and recovery. We will remove your name and any other information that identifies you before we use it in a new study or share it with other researchers. There is still a small chance that someone could figure out that the information is about you.

WHAT ARE THE BENEFITS OF THIS STUDY?

- There are some benefits to taking part in this research study. The information gained could greatly improve our understanding of effective interventions for fathers in recovery. Because this study will use a web-based mobile platform, the public health potential for reaching a large population is high.

- Fathers and their children may benefit from improved parenting skills, improved health, and reduction in the risk factors associated with early-onset problem behavior, and substance abuse in adolescence. Further, fathers in the intervention will continue to receive any other services that would have typically been provided to them while concurrently participating in our intervention, therefore our intervention will not take away from other treatment services.

DO YOU HAVE A RIGHT TO WITHDRAW FROM THE PROJECT?

Your participation is entirely voluntary and your decision whether to participate will involve no penalty or loss of benefits you might otherwise receive. If you decide to participate, you can later change your mind and stop participating any time without penalty. Participation in this research study or your withdrawal from the study has no impact on other services or treatments that you are participating in.

If you have questions about the research at any time, or if you have a visual or other impairment and require this material in another format, please call 541-484-2123 or email us at FIR@influentsin.com. If you have questions about your rights as a research subject and/or research-related injury, call the Office for the Protection of Human Subjects, Oregon Research Institute, (541) 484-2123. ORI's TDD number is 800-735-2900. You will be emailed a copy of this form to keep.

WHAT DOES MY SIGNATURE ON THIS CONSENT FORM MEAN?

Your signature below indicates that you (1) have read and understand the information provided above, (2) that you willingly agree to participate, (3) that you may withdraw your consent at any time and stop participating at any time without penalty, and (4) acknowledge that you will receive a copy of this consent form.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov . This website will not include information that can identify you. At most, the website will include a summary of the research results. You can search this website at any time.