UNIVERSITY OF OREGON

12132019.029

A Substance Use Adaptation of Fathering Through Change

July 8, 2021

Research Plan

IMPORTANT: When completing this outline, please use the **Research Plan Guidance** for the content necessary to develop a comprehensive yet succinct Research Plan. Using the guidance to complete this outline will help facilitate timely IRB review.

Study Title: An Adaptation of Fathering Through Change for Fathers receiving Treatment for Substance Use Disorders

Protocol Number: 12132019.029

Principal Investigator: Camille Cioffi

A. Introduction and Background

It is well documented that children exposed to parental drug use are at greater risk for maladjustment, deviant peer affiliation, and substance use initiation. Parents living with Opioid Use Disorder (OUD) are at high risk for incarceration, family disruptions, health problems, and financial hardship However, research on drug abuse with men has largely neglected the role of fathering, parenting roles and parenting status for these men. Moreover, our understanding of the unique impacts of opioid misuse on fathering behaviors is even more limited than our knowledge base for mothers. The majority of extant research has been conducted on mothers, although there is evidence that more fathers than mothers enter into drug abuse treatment.

Existing opioid research suggests there are marked parenting differences for fathers and mothers who misuse opioids. Compared to mothers, fathers are more likely to be misusing opioids when they first become a parent, and compared to fathers without a substance use disorder, fathers with OUD exhibit more concerning parenting behaviors and report other limitations that may impact their children. For parenting specifically, compared to fathers without OUD, OUD fathers report lower parental efficacy, engage in fewer positive parenting behaviors such as consistency and positive involvement, and report less satisfaction with the parenting role compared to mothers. Fathers who misuse opioids also report greater prevalence of violence towards their child's mother both over the course of the relationship and report greater violence perpetrated against them by their child's mother.

Within the preventive intervention and treatment research, fathers are vastly underrepresented in studies of parent training relative to mothers, with only a handful of studies including father-related outcomes. Less is known about fathers who do or do not misuse opioids, or what mechanisms are unique to opioid use that interfere with effective parenting. The goal of this pilot is to better understand the unique, specific, influence of opioid misuse on compromised fathering behaviors, and further, how misuse uniquely affects the process of intervention uptake. We will use Fathering Through Change, an evidence-based parenting intervention which has been found to be efficacious for positive changes in fathering mediated by changes in pare parenting efficacy and fathering identity.

B. Specific Aims/Study Objectives

Aim 1: Document Baseline Differences Among Opioid Misusing and Non-Opioid Using (other substance using) Fathers and Child Functioning (note, we are recruiting from substance use treatment centers and substance use related pages on social media so some fathers use opioids while others do not just by nature of who attends treatment)

Aim 2: Understand how Opioid Misuse is related to treatment outcomes and whether the intervention shows promise for this population

C. Methods, Materials and Analysis

This study will include two procedures; Procedure 1 is for the intervention study and Procedure 2 is for the baseline study.

Procedure 1 for the intervention study is a randomized-control trial of the Fathering Through Change (FTC) intervention. Our goal is to recruit up to 120 participants and randomly assign them to either intervention or control. Treatment centers throughout the state of Oregon will help to facilitate recruitment. They will do outreach to men currently receiving treatment services and to men who have received treatment from the respective treatment centers in the past. Individuals who receive communication from a treatment center may also share that information with their peers in recovery. Those individuals will also be welcome to participate if they meet the inclusion/exclusion criteria. The clinician does not have to be vetted by in order to provide services for men currently receiving treatment since they are not an employee of any treatment center and have been vetted by the University of Oregon. Additionally, the study will recruit participants by advertising on social media websites, specifically Facebook and Reddit. Public account pages will be made on each platform to advertise the current study. The recruitment flyer and posted text (see “Fathering Through Change (FTC) Intervention Research Study.pdf” and “Facebook or reddit example posting.docx” will be posted on both platforms. For Facebook, the flyer and posted text will be posted to groups related to heroin/opioid/substance use recovery and parenting. For Reddit, a similar process will occur, such that the flyer and posted text will be posted to "communities" that relate to heroin/opioid/substance use recovery and parenting in recovery. In addition to the flyer and posted text, contact information will be shared that can connect interested individuals with affiliated research personnel. All individuals expressing interest in the study will be directed to contact the project coordinator to complete the eligibility screener.

All eligible and consented participants for Procedure 1 will be invited to take three sets of surveys using Qualtrics or RedCap. IP address tracking will be enabled for all surveys in effort to increase security measures and reduce fraudulent survey submissions. First at baseline (pre); second, at 6-weeks later (post); and lastly, at 4 months from baseline (follow-up). Surveys will be conducted online on the participants electronic device and will be formatted for administration on a computer, tablet, or smartphone. Surveys will assess the parent-child relationship, child behavior, parent mental health, parent substance use, intervention knowledge gained and satisfaction, and participant context. The baseline questionnaire will take approximately 95 minutes. The post questionnaire will take approximately 90 minutes. The follow-up questionnaire will take approximate 90 minutes.

These are the steps for participation:

1. Treatment center sends out text messages and emails to current and past male clients. They will not send out text messages and emails to current in-patient clients because these clients do not have access reliable access to technology (not allowed to use it). The text message will contain information to contact the study team. Formal recruitment will occur when the potential participant reaches out to the study team via phone or email. For Facebook and Reddit recruitment, the project coordinator will post the recruitment flyer to groups and communities on both platforms. All interested individuals will contact the project coordinator and complete the formal recruitment process including the eligibility screener.

    See **Text Messages** document.

2. For both Procedure 1 and Procedure 2, the study team will respond to interested participants with an enrollment text from a google voice number or study specific email. They will first ask screening questions to determine eligibility. If a participant is eligible, they will provide a link to the electronic survey.

See **Text Messages** document.

3. The first page of the survey will take participants to a screener to ensure they are eligible to participate. We will screen for past 18 month (Procedure 1) and 36 month (Procedure 2) abstinence from illicit substance use (For Procedure 1, must have less than an 18 months of abstinence from illicit substances. For Procedure 2, must have less than a 36 months of abstinence from illicit substances), child in appropriate age range and at least two hours per week spent with child. Regarding Procedures 1 and 2, participants who are ineligible will be taken to the end of the survey and will not receive follow-up. Participants who are eligible will complete the informed consent process electronically. After consenting, they will take the baseline questionnaire survey. In the baseline survey, we will include a questionnaire related to the psychological and parenting consequences of COVID-19 (see "Measures Overview_8_31_20.docx") to better understand the impacts of COVID-19 on fathers' parenting, ability to care for their child(ren), distress, and potential substance use cravings and use.

4. For both Procedures 1 and 2, during the survey, they will provide their contact information so that they can receive either an electronic gift card or check in the mail, depending on their preference as an incentive. This information will also be used to provide them with study materials, reach out for follow-up surveys (Procedure 1), and link participant data overtime (Procedure 1).

5. For Procedure 1, once they have completed the questionnaire, they will receive a follow-up text message and email (at least one method depending on information given) within one week to welcome them to the study. Different messages will be provided depending on whether a participant is assigned to the control or intervention group. Random assignment will occur using a random number generator in batches of 10 (up to 100 pre-determined for eligible participants- assigned at the time of enrollment) to ensure the design is balanced if our sample size is smaller than expected.

6. For Procedure 1, the PI will provide videos to the participant on a weekly basis for 6 weeks. The participant will have the opportunity to take a brief knowledge test after watching each video to earn an additional $5 per knowledge test completed. The PI will schedule appointment for the coach to call via text or email with participants.

See **Text Messages** document.

7. For Procedure 1, the clinician will call participants at the designated appointment time using a google voice number at week 1, week 3, and week 5. Since these are just opportunities to check-in, if a participant misses their appointment, they will have the opportunity to check-in again. However, this will be the participants responsibility- the PI will not make another attempt to schedule a coaching call. If the participant asks to check-in via text instead, the clinician may also use the google voice number to check-in via text using the same script. Please note that the coaching calls document is a loose script and may be adapted by the clinician. The clinician is responsible for providing notes after each call, but calls will not be recorded.

See **Coaching Calls** document.

8. See **Text Message** document for a full overview of when participants will be contacted for each component of the study and what content will be provided.

Procedure 1:

Control (approx. 40 fathers)	Intervention Condition (approx. 40 fathers)
Services as Usual:	All Services as Usual PLUS

Current or previous substance use disorder treatment Medication Assisted Treatment (if applicable) Some Parenting Coaching if still in treatment	Fathering Through Change Intervention: 6 weekly video clips, texted to their phone, approximately 5-15 minutes per week with a follow-up knowledge quiz (see **Text Message** document) Opportunities for three 20 minute check-ins with a clinician (Jones) who is not affiliated with any treatment center Will receive a certificate of completion

Procedure 2 for recruiting participants only for the baseline survey:

For Procedure 2 interested individuals will text or email "I'm Interested" to the study phone number or email. The project coordinator will complete the eligibility screener and, if eligible to participate, send the eligible indidivudal the link to the Qualtrics survey. If eligible to participate, the survey will continue to inform the eligible individual to review the consent form (see "Informed Consent_Baseline only_A6.docx"). Once consent is completed, the participant will complete the baseline survey that includes the same questionnaires from the previously approved baseline survey of the intervention study. Participants will have the opportunity at the end of the Qualtrics survey to indicate if they consent to be re-contacted for future research studies; in effort to potentially enroll them in the intervention study (Procedure 1). Participants will be compensated $50 for completing the baseline survey.

Procedure 2 will recruit participants through both social media and treatment center outreach.
Treatment centers previously contacted for Procedure 1 will be contacted via email (see "email template for treatment centers_baseline.docx") to send them a flyer (see "Baseline only FTC flyer.pdf").For social media, we will recruit participants by advertising on social media websites, specifically Facebook and Reddit. Public account pages will be made on each platform to advertise the current study. The recruitment flyer and posted text (see "baseline only FTC flyer.pdf" and social media template_baseline.docx") will be posted on both platforms. For Facebook, the flyer and posted text will be posted to groups related to heroin/opioid/substance use recovery and parenting. For Reddit, a similar process will occur, such that the flyer and posted text will be posted to "communities" that relate to heroin/opioid/substance use recovery and parenting in recovery.
In effort to reduce fraudulent survey submissions anticipated from posting our study on social media platforms, three actions will be taken: 1) we will remove the compensation option "giftcard by text" and prompted "if receiving mail is a problem for you check this box" followed by the option to indicate, "I don't have a mailing address. Please follow-up with me", 2) implement IP address restrictions on the Qualtrics survey settings, and 3) add three fill in the blank attention checks to assess for fraudulent and bot responses (see "example attention check questions.docx").

Analysis Plan The research does not involve any procedures typically used in a biomedical/clinical setting and/or administration of medications. To address aims, we will use quantitative analyses including, *t*-tests, 2 x 2 ANCOVAs and MANOVAs, for test of mediation and moderation we will specify structural equation path models. Identifiable information will be collected but data will be reported anonymously. Research will be disseminated at conferences and through scientific journals, and press releases. Findings will also be shared through outlets deemed appropriate by the larger center this study is a part of (noted in the funding and sponsorship form).

D. Research Population & Recruitment Methods

Procedure 1 (Intervention Study): The participant population are fathers who are in recovery from substance use disorders and have been abstinent from illicit substances for less than 18 months. Participants must be over the age of 18 years old. Our primary intervention target is fathers with opioid use disorder and efforts will be made to prioritize fathers who have specifically misused opioids in the past.

Fathers are eligible to participate if:

1. They identify as being in recovery and have been abstinent from illicit substances for at least 1 day and less than 18 months.

2. They have parenting responsibilities for a child between the ages of 3-16 who they spend at least 2 hours per week with.

3. They speak English.

4. They are 18 and older.

The project coordinator will complete the eligibility screener via text message or phone call. Individuals will be asked to describe their recovery and family situation to the project coordinator through open ended questions. Individuals will be excluded if they do not meet eligibility criteria, or if they deny answering questions about their recovery and family situation. Individuals will be excluded if they cannot speak English because they will not be able to understand intervention content and will not be able to participate in surveys. Father's must have potential to have some contact following treatment since the intervention is targeted at improving parenting skills. Fathers of children younger than 3 or older than 16 will be excluded because the intervention is not suitable for children outside of the age range 3-16.

The total number of participants will not exceed 80 for procedure 1. Our goal is to recruit approximately 40 fathers to the intervention condition and 40 fathers to the control condition. This will provide enough data to compare effectiveness between condition and also to examine the effects of different substances on intervention outcomes. We expect these numbers may be less due to COVID-19.

The PI or a research assistant will recruit participants. If a research assistant recruits participants, they will be trained by the PI to use the **Text Message** script. See the Text Message document for screening procedures. Language and device access will not be specifically screened for, because participants would only be able to contact the study team if they read the delivered text which was in English and could respond to the questions we are asking. We believe asking this question would place an unnecessary burden on participants.

The individuals who will recruit participants have not and will not provide treatment or care to the prospective participants.

The clinician also has a role in intervention development. The clinician will not have access to the data to diminish undue influence.

There are no costs to the participant or third party.

Participants will receive $25 for the baseline questionnaire, $50 for the post questionnaire, and $75 for the follow-up questionnaire. Participants in the intervention condition will also receive $5 per knowledge quiz they complete (up to a total of $30). Participants in the intervention condition will receive a certificate of completion indicating the number of video session completed (as indicated by the number of knowledge tests completed) and the number of coaching calls participated in. Participants will be given the choice to receive either a check in the mail or electronic gift card following each survey. Individuals participating in the intervention will receive a lump sum for all knowledge tests they completed at the end of the intervention and will similarly be given the choice to either receive an electronic gift card or check in the mail.

Participants will be texted after they complete the baseline survey and before they receive the Week 1 texts, "You have the opportunity to receive additional cash incentive: if you refer someone to the study who is

eligible to participate, you will receive an additional $5 incentive. You can refer up to two people. Make sure to instruct the referred individual to provide your name when they take the survey in order to receive incentive. Importantly, you will only receive the $5 incentive if the person you referred meets eligibility criteria. Feel free to contact the research team with questions or request for details regarding eligibility requirements, (458) 215-1034." (see “Text Messages” script). Participants will only receive the incentive payment(s) if the person(s) they refer is deemed eligible for participation.

Participants will have the opportunity to communicate if they were referred by someone within the baseline survey in Qualtrics. We will add a display logic question: "Did someone refer you to participate in this study?" If so, "What is the name of the person who referred you?" (see “Baseline_referral questions.docx”). We will cross-check the identified name in our database to document referral and initiate reimbursement. Participants will have the opportunity to communicate how they heard about the research study within the baseline surveys in Qualtrics for Procedures 1 and 2. We will add a fill in the blank question, “how did you hear about this study?” to track how participants learned about the current study they are engaged in. In attempt to reduce bias: 1) each participant will be limited to two verified recommendations, 2) only the first 20 participants will be provided this option to refer someone to the study.

Participants are being incentivized more at the post and follow-up surveys to improve the likelihood of longitudinal data collection.

Procedure 2 (Baseline Only Survey): The participant population are fathers who are in recovery from substance use disorders and have been abstinent from illicit substances for less than 3 years (36 months). Participants must be over the age of 18 years old. Our primary intervention target is fathers with opioid use disorder and efforts will be made to prioritize fathers who have specifically misused opioids in the past.

Fathers are eligible to participate if:

1. They identify as being in recovery and have been abstinent from illicit substances for at least 1 day and less than 3 years (36 months).

2. They have parenting responsibilities for a child between the ages of 3-16 who they spend at least 2 hours per week with.

3. They speak English.

4. They are 18 and older.

The total number of participants will not exceed 120 for the baseline only survey. This number includes the participants who also participated in procedure 1 so we would recruit 120-number recruited for procedure 1. We anticipate that recruitment is finished for procedure 1 and we have enrolled only 41 subjects, thus, we expect that no more than 79 participants will be recruited for the baseline only survey.

Similar procedures for virtual recruitment from procedure 1 will be followed in the event of virtual recruitment for procedure 2. For procedure 2, the project team may travel to treatment centers to complete the eligibility screener and offer the chance to complete the survey in person via an iPad. Treatment centers will allow the research team to be present on site, and will provide an indoor or outdoor space that allow for sufficient spacing and privacy to mitigate risks associated with COVID-19 transmission and loss of privacy. The treatment centers will let fathers know that the study team is on site and fathers will voluntarily approach the study team in a location where the study team is not able to see treatment center attendees to mitigate HIPAA privacy concerns. We will work with treatment centers who consent to in-person recruitment to determine the best process to talk with clients while on site. This might vary based on the type of treatment center. For example, the Methadone clinic has people coming and going regularly, thus

the option to set up a booth might be an effective strategy to be visibly available to anyone walking through. Another example is that outpatient treatment centers might allow us to be present on site before or after groups. For inpatient treatment centers, they might want us to visit during meal times to talk with individuals while they are eating and discuss the research study opportunity. A member of the project team (the PI, RA/Project Coordinator, or Co-I) will use the in-person recruitment script (see "in person recruitment script.docx") provide the participant with an iPad to facilitate the informed consent process and research survey. If we do not have enough iPads at any point, we will encourage individuals to complete the survey on their phone or mobile device. We will have paper copies of the survey as back up if needed or preferred by individuals. All paper copies will be stored in a locked cabinet within a locked room that only the PI has access to. All paper copies will be double-entered for quality assurance. A member of the project team will provide the participant with their incentive upon completion of the survey. Tabling to recruit participants may also happen virtually, if preferred by treatment centers. For virtual tabling, a research assistant will attend online group meetings, with permission from the treatment center, to present the opportunity to participate to clients. Treatment center staff will provide the study flyer to clients and interested individuals will be instructed to contact the study email or phone number. Virtually tabling will occur using secure wifi and using a link provided by the treatment center or the research assistant's HIPAA protected zoom account.

For in person recruitment, all safety protocols will be followed in accordance with the University of Oregon's Stage 1 and 2 Research Activities protocol. The Stage 1 and 2 form will be completed and submitted separately.

Participants who complete procedure 2 (the baseline only survey) will be compensated $50 via check or gift card in the mail, sent electronically or provided in-person if research is conducted in-person. If participants do not have a mailing address, they will have the opportunity to indicate as such and provide a phone number for the project coordinator to follow-up.

E. Informed Consent Process

Informed consent for Procedure 1 and Procedure 2 will be collected electronically. Individuals will consent to participate at the beginning of the survey by clicking that they consent to participate after reading the consent form and by typing their name and the date "(type name and date:_____)" . They will also complete a consent quiz to check for understanding. Incorrect answers will be followed up with the correct answer and then participants will be permitted to proceed. Participants will be provided a copy of the informed consent using the same process they select for receiving payment (email, mail, or in-person).

This research will not involve minors or individuals of diminished capacity given the requirements of treatment centers. The research was designed the research to only solicit anonymous information about children from the fathers to avoid having to engage children in the research.

We are requesting a waiver of documentation of informed consent. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

There will not be any deception.

The investigators will post a copy of the consent form as required and will use the study's established registration at clinicaltrails.gov to post the document within the required timeframe.

F. Provisions for Participant Privacy and Data Confidentiality

1. Privacy

During the intervention, it will be up to participants to disclose vulnerable information about their previous experiences with parenting. It will be their choice to disclose such information during coaching calls however, in services as usual, they would disclose similar parenting information.

To promote protection of privacy \ during coaching calls there will be a designated time decided on by the participant when the coach will call. The coach will not disclose that the participant is a research study when the call is made in case someone else answers the participant's phone.

Regarding privacy protections for mailing payments to Procedure 2 participants, return envelopes will be labeled with "University of Oregon Prevention Science Institute" without a reference to the study and in the check note, "CPO Pilot 2". The envelopes and checks issued for payments will not include the study title nor other information on outward facing materials that would indicate the participant is in recovery.

2. Data Disposition

Identifiable participant information will be collected in Qualtrics or RedCap during each survey Following data collection, identifiable data will be removed, and a unique identifier assigned for all analyses. The clinician will only be given the participants first name and phone number to maintain confidentiality. 3.

3. Confidentiality

The only individuals with access to identifiable participant information on Qualtrics or RedCap will be the PI and advisor. The code and key will be retained in a locked file on the Prevention Science Institute (at University of Oregon) server with permissions granted to only Cioffi and DeGarmo.

Participant identities will not be disclosed as a result of this research.

Storage of data will be stored electronically on a private server and will be directly uploaded only while using secure wifi. If the data must be transferred, they will be transferred using a secure client server. Only the PI and advisor will have access to the data. Students may be granted access to the data after signing a data use agreement, in order to complete analyses. Records will be kept for up to 3 years after the study has been completed.

Participants will be informed that researchers are mandatory reporters and are required by law to report a situation if they have reasonable cause to believe that any person with whom they come into contact has abused a child.

Research funded by NIH automatically has a Certificate of Confidentiality associated with it. This is added protection against forced disclosure of research information in circumstances of subpoena.

Sharing data

This research study is part of a larger set of related studies being conducted by the Center on Parenting and Opioids (CPO; cpo.uoregon.edu), a National Center co-located at UO's Prevention Science Institute (PSI), UO's Center for Translational Neuroscience (CTN) and Oregon Health and Sciences University (OHSU). The research at CPO is funded by an award from the National Institute on Drug Abuse (NIDA).

De-identified data collected as part of the current protocol will be shared to a central data repository maintained by CPO. The repository will house de-identified data collected from all research projects within CPO. Data will be coded with a unique identifier that cannot be linked to any identifiable information. The repository is encrypted, and password protected behind firewalls. This expectation for data sharing is in accordance with guidelines from national funding agencies (e.g., see NIH Data Sharing Policy here:

http://grants.nih.gov/grants/policy/data_sharing/index.htm). Therefore, we will ask participants to consent to sharing their de-identified data to the data repository created and managed by CPO.

G. Potential Research Risks or Discomforts to Participants

Information risks, psychological risks, and social risks may occur as the result of participating in this study. Information risks include loss of privacy and/or breach of confidentiality. Since data will be collected using only private wifi (except when participants are not connected to secure wifi) and will be stored on a secure server, it is unlikely that loss of privacy will occur. A breach of confidentiality may occur if the clinician discloses identifiable participant information. The clinician will be asked sign a confidentiality agreement before providing services.

Psychological risks may occur such as guilt or loss of self-esteem while receiving or not receiving parenting intervention services. It is likely that both the treatment as usual and the treatment conditions will improve fathers' sense of responsibility without inducing guilt and improve self-esteem but not everyone receives treatment uniformly. Participants will be encouraged to seek services if they are in need of additional support. The clinician will be responsible for providing these resources as part of the services they provide to the study.

Social risks may occur as a result of receiving services in the participant's home (i.e. watching videos and phone coaching calls- no one will physically be in the participants home). Specifically, participants might feel uncomfortable engaging in the intervention if they do not have a private space to participate.

All risks will be communicated in the informed consent process.

The protocol involves intervention. The intervention includes watching videos that have been used for prior research studies with divorced and separated fathers. It also includes on-on-one parenting coaching with a clinician who is a trained clinician. This research does not pose any additional risk over the services provided as usual since fathers in treatment also receive services aimed at improving parenting via phone as part of standard practice at treatment centers (not as part of the proposed intervention).

The funding agency required a Data Safety Monitoring Plan for this research at the time of funding proposal. A copy of the DSMP submitted to the funder is attached; however, it should be noted that there are some discrepancies due to the evolution of the project following proposal. The discrepancies are documented in a separate Memo to File. The key differences are that no information is being obtained from the treatment facilities, and the research no longer plans to include families and children as subjects. We are no longer excluding fathers of children with a developmental disability since children are not research subjects. Only fathers will participate. Additionally, our sample size is now 120 instead of 80. There will be three points of data collection rather than two. All other key components of the DSMP as proposed persist including the defined roles and responsibilities, procedures for monitoring site performance, procedures for monitoring data integrity, protecting confidentiality, and safety reporting and monitoring. Additionally, in the event of a crisis such as expressed elevated suicidality or intent to harm self or other, Jeremy Jones, who is currently receiving supervision to obtain licensure, will create a safety plan with the client (attached) and will make a referral to the appropriate agency such as the emergency department, back to the treatment center they are receiving services from if the client is currently receiving services, a local therapy center such as Options Counseling, or Child Welfare if warranted.

There is no established Data and Safety Monitoring Board/Committee (DSMB/C) as noted in the DSMP.

H. Potential Benefits of the Research

Individuals may receive benefits from participating in this research such as improvements in parenting skills and the opportunity to form relationships with other fathers who might have experienced similar situations.

As a result, relationships between the participant and his child may improve as well as the relationship between the participant and the child's other parent.

By participating in this research, the research team will be able to learn whether the intervention would be generally useful for fathers receiving drug and alcohol treatment.

I. Investigator Experience

The PI (Dr. Camille Cioffi) is a research associate at the Prevention Science Institute and Co-I part of the Center on Parenting and Opioids. She has experience volunteering with individuals with substance use disorder. She has provided support to the Environmental influences on Child Health Outcomes study (PI Leslie Leve) related to IRB submissions and the creation of survey materials. She has experience administering surveys to parents with low income as an undergraduate research assistant in the Developmental Sociobiology Lab (PI Jeffrey Measelle) and through her work as PI on the Voluntary Pregnancy Screening at Syringe Exchange study. Cioffi has extensive experience conducting in-person research related to COVID-19 testing as a Co-I on two federally funded grants to provide COVID-19 testing to Latinx communities and syringe exchange clients, respectively. She will ensure appropriate precautions are taken to prevent the transmission of SARS-CoV-2 infection while conducting research.

The co-investigator, Dr. Dave DeGarmo has led several randomized control trials including a randomized control trial of the Fathering Through Change intervention and other adaptions of Parent Management training for fathers. He is a researcher at the Prevention Science Institute and is the leader of the Data Science Core for the P50 Center as a whole. He provides mentorship to the PI.

The clinician, Dr. Jeremy Jones has a master's degree in Special Education and a doctorate in School Psychology and possesses in-depth experience providing evidence-based interventions for children and families. Dr. Jones has considerable expertise in parent training, having been certified as a Parent Management Training – Oregon (PMTO) Specialist, Coach, and Mentor. In addition, to providing direct intervention services, Dr. Jones has unique experience in conducting large scale (e.g. states and countries) implementations of Parent Management Training - Oregon (PMTO) across a variety of settings, including, child-welfare, community-based mental health systems, and schools over the past several years. Of particular importance for this project is that Dr. Jones specializes in working with fathers, and served as a Co-investigator and content expert on a recently completed SBIR (R44HD075499-02) where along with colleagues successfully adapted PMTO for recently divorced fathers and developed *Fathering Through Change*, an Internet-based program designed to be delivered through court systems. This study is an adaptation of the previous FTC program.

2. Roles and Research Duties

The PI or research assistance will consent participants and administer on-line surveys. The clinician will deliver the intervention.

The PI and faculty advisor will be responsible for data management, reporting, and science communication. The PI and faculty advisor will also be responsible for documenting program changes.

3. Training and Oversight

The clinician, Jeremy Jones has previous experience conducting similar parenting coaching intervention to those being used for this study. There is no certification for delivering the intervention however, on previous studies, Jones has demonstrated high adherence to the intervention principles. Training may be provided to graduate student research assistants or treatment center personnel by the clinician. If any trainees are used, they will be added to the protocol and will be part of the calls/delivery of the clinician coaching and will receive clinical supervision by their University department.

Graduate student research assistants will complete CITI training, and will be supervised by the PI. They will be responsible for the delivering the text message script and will review PI-participant text messaging records for training. The PI will review all text exchanges to ensure there are no ethical concerns and to provide feedback.