Justice Community Opioid Innovation Network (JCOIN)
Coordination & Translation Center

Fostering MAT Use in Justice Populations

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IRB APPROVED
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INFORMED CONSENT DOCUMENT
AGREEMENT TO BE IN A RESEARCH STUDY
Staff Consent

TITLE:	Fostering MAT Use in Justice Populations
PROTOCOL NO.:	None WIRB® Protocol #20200548 2019-1473
SPONSOR:	National Institute on Drug Abuse with National Institutes of Health
INVESTIGATOR:	Todd Molfenter, PhD University of Wisconsin – Madison 1513 University Avenue, Mechanical Engineering Building Rm 4103 Madison, Wisconsin 53706 United States
STUDY-RELATED PHONE NUMBER(S):	608-262-4378 608-262-1685 414-899-4324 (24 hours)

Invitation

We invite you to take part in a two-year research study about fostering MAT (Medication Addiction Treatment) use in justice populations. We are inviting your organization because you are a jail system or a community-based provider that works with justice involved populations and are interested in increasing the use of MAT with individuals in jails as well as post-incarceration that have opioid use disorder.

The purpose of this consent form is to give you the information you need to decide whether to be in the study. Ask questions about anything in this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study. This process is called "informed consent."

What is the purpose this study?

The purpose of this research study is to test two implementation interventions being applied to MOUD (Medications for Opioid Use Disorder) dissemination and implementation in justice settings for justice-involved populations: NIATx Coaching (focused on organization) and the Extension for Community Healthcare Outcomes (ECHO) model (focused on prescriber). NIATx Coaches provide expertise in MOUD implementation and organizational change to help treatment organizations/jails make, sustain, and spread MOUD. The ECHO platform focuses on the clinical provider side by connecting the primary care provider with expert MOUD prescribers to promote high-quality MOUD practices. This will be the first trial that assesses the comparative effectiveness of these approaches overall, and in justice settings.

This study is being done by the University of Wisconsin-Madison (UW-Madison) and George Mason University. A total of 48 sites nationally will participate in this study.

THIS IS AN IMPORTANT DOCUMENT - KEEP FOR FUTURE REFERENCE

VERSION CONTROL

Funding for this study is provided by the National Institute on Drug Abuse (NIDA) with the National Institutes of Health (NIH).

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

What is involved in study participation?

If your organization has decided to participate in the study and you have been identified to be the Executive Sponsor, Change Leader or a part of the Change Team, the researchers will ask you to;

1) Participate in the implementation and utilization of the NIATx Coaching Model. Half of the sites will also ask for their physicians/prescribers to participate in ECHO.
    a. You/Your organization will be randomly assigned to one of four study arms with 12 sites being in each arm that will include;
        i. High-Dose NIATx Coaching & ECHO
        ii. Low-Dose NIATx Coaching & ECHO
        iii. High-Dose NIATx Coaching Only
        iv. Low-Dose NIATx Coaching Only

2) Description of Interventions
    a. NIATx Coaching: NIATx provides each participating site/staff with a NIATx Coach who is an expert in MOUD implementation and organizational change and will help the organization adopt, implement, and increase the use of MOUD. Coaches help the sites think through key issues, offer process improvement training, and suggest changes.
    b. ECHO Model: ECHO connects MOUD prescribers and experts with primary care providers/prescribers and medical teams to promote high-quality MOUD practices. ECHO is provided monthly through videoconferences. Experienced MOUD prescribers address topics such as counseling strategies, urine test interpretation, and transitioning from buprenorphine, naltrexone and methadone.

3) Throughout the two years of the study, based on your role, you will be asked to complete 2-3 surveys/interviews. You may skip any question on the survey and/or during the phone interview that you do not wish to answer.
    a. *Executive Sponsor*: Complete an Organizational Survey by phone interview on behalf of your organization prior to start of study. Data to be gathered include; operational characteristics, present status MOUD slots and use, clinicians using MOUD, organizational readiness for MOUD, and likelihood of MOUD sustainability. Executive Sponsor will also be asked to complete organizational surveys at month 12 and month 24.
    b. *Change Leader and Change Team*: Will be asked to complete Staff Surveys at baseline, month 12 and month 24 of the study.
    c. *Prescribers (Physicians) on the Change Team*: Prescribers will also be asked to complete a short Physician Survey on attitudes toward MOU at baseline, month 12, and month 24.
    d. In addition, the research team will conduct qualitative phone interviews at baseline and at 12 months with the *Change Leader* at 24 randomly selected sites.

Is my permission voluntary and may I change my mind?

Your permission is voluntary. You may completely remove yourself from the study at any time. You also may choose to stop taking part or skip any questions that you do not feel comfortable answering.

Whether or not you decide to take part in the study, or if you choose to leave the study, your choice will not affect your employment status or any benefits you receive. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose any legal rights.

What are the risks of participation?

There is a risk that your information could become known to someone not involved in this study.

A member of this research team has a personal interest in or might profit financially from the results of this study. This is called a "conflict of interest." The University of Wisconsin-Madison manages conflicts of interest so that they do not affect study participants, or the quality of the data collected. We are telling you about the conflict of interest in case it affects whether you want to take part in this study.

Are there any benefits?

Being in this study may not provide a direct benefit. You may experience less work from improved organizational processes. From an organizational standpoint, having physicians and staff provide best-practice treatments may help the jail or community-based provider site you work with provide more comprehensive care to their substance-abusing population and reduce utilization of high-cost hospitalizations and emergency visits, rearrests and deaths.

Will I be compensated?

We will not pay you to take part in this study or pay for any out of pocket expenses related to your participation. However your organization/site will receive $2,000 compensation for study participation.

How will researchers keep my research information confidential?

We have strict rules to protect your personal information. We will limit who has access to your name, email address, phone number, and other information that can identify you. We will also store this information securely. We may publish and present what we learn from this study, but none of this information will identify you directly without your permission. Identifiers might be removed from the identifiable private information and after such removal, the information may be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you. The researchers have received a Certificate of Confidentiality from the government which will help protect the privacy of research subjects. The certificate protects against the involuntary release of information about subjects collected during the course of this research. The researchers involved in this study cannot be forced to disclose any information collected in this study in any legal proceedings.

However, you may choose to voluntarily disclose the protected information and this certificate does not prohibit such voluntary disclosure. Furthermore, the parties listed in the below section of this consent form may review the records under limited circumstances and this certificate does not prohibit such disclosure. We cannot promise complete confidentiality. Federal or state laws may permit or require us to show information to university or government officials and study sponsors.

Who at UW-Madison can use my information?

- Members of the research team
- Offices and committees responsible for the oversight of research

Who outside the UW-Madison may receive my information?

- U.S. Office for Human Research Protections
- The study sponsor, the National Institutes of Health (NIH)
- Collaborating researchers outside UW-Madison, including researchers at George Mason University

What if I have questions?

If you feel you have had a research-related issue or if you have any questions, concerns, or complaints about this study at any time, contact the Principal Investigator Todd Molfenter, PhD. at 608-262-1685 or 414-899-4324 (after hours). You can also contact the Study Coordinator, Jessica Vechinski at 608-262-4378.

This research is being overseen by an Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at (800) 562-4789, help@wirb.com if you have questions, concerns, or complaints that are not being answered by the research team.

Volunteering to be in the study

It is your choice if you want to be in the study. No one can force you to be in the study. You may choose not to be in this study or you may leave the study at any time without penalty or loss of benefits to which you are otherwise entitled. Your alternative is to not participate.

The investigator or IRB may take you out of the study without your permission, at any time, for the following reasons:

- If you do not follow the investigator's instructions
- If we find out you should not be in the study
- If the study is stopped
- If it becomes harmful to your health

If you leave the study, no more information about you will be collected for this study. However, all of the information you gave us before you left the study will still be used.

Agreement to participate in the research study

If you check the box below and complete the survey tools, it means that you:

- You have read this consent form.
- You have had a chance to ask questions about the research study, and the research team has answered your questions.
- You want to be in this study.

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You can keep a copy of this form if you download it as a PDF.