Provider Focus Group
Participant Informed Consent

Study Title: Medication-Assisted Treatment for Opioid Use Disorders (MAT Study)
Study #: N/A
Sponsor: Centers for Disease Control and Prevention (CDC)

Principal Investigator:
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Introduction
You are being asked to participate in a research study. Before you decide if you want to take part in this study, you need to read this Informed Consent Form so that you understand what the study is about and what you will be asked to do. This form also tells you who can be in the study, the risks and benefits of the study, how we will protect your information, and who you can call if you have questions.

You are encouraged to ask the Principal Investigator or study team to explain anything you don't understand before you make your decision.

Purpose
The Medication Assisted Treatment (MAT) Study is a research study funded by the sponsor, the Centers for Disease Control and Prevention (CDC). The study is being conducted by RTI International, a research organization located in Research Triangle Park, North Carolina. The purpose of this study is to aid the CDC in assessing the comparative effectiveness of the different medication assistant therapies (MAT) and non-MAT counselling for opioid use disorder treatment. You are one of about 81 people selected from among over 40 medical/counseling facilities that are participating in the MAT Study.

Procedures
If you agree to participate, you will be asked to take part in a telephone conference call with seven to nine of your colleagues from medical/counseling facilities that are participating in the MAT Study. Participants in the focus group will only be identified by first name or other label of their choice. The group will discuss:

- experiences and challenges in providing MAT for opioid use disorder (OUD),
- practice environment and organizational structure, and
- barriers and facilitators to treating OUD clients.

Your participation in the focus group discussion will take about 90 minutes. All your responses will be held confidentially and used only for research purposes. Your responses will be audio recorded if all the participants in the group agree to allow audio recording. You can still take part in the focus group even if you do not want the discussion to be recorded. You will be able to indicate your choice regarding audio recording of the focus group at the end of this form.

Alternatives
Your alternative is to not participate in this focus group discussion.

Possible Risks or Discomforts
Your participation is voluntary. You may contribute to the discussion or not at your choice. While we will keep all the conversations as confidential as possible, it is possible that other participants in the group will reveal information that you gave during the focus group discussion. Please keep this mind during the discussion. If the discussion is recorded, it is also possible that people who hear the recording will recognize your voice.
We are required to disclose suspected child abuse and neglect or threats of harm to self or others.
You will be informed in a timely manner if new information becomes available that may be relevant to your willingness to continue participation in the focus group discussion.

Your Benefits
There are no direct benefits to you for participating in this focus group discussion. We hope that information from this study will help those suffering from opioid dependence by creating new and additional opportunities for opioid treatment in the future.

Incentives
You will be given $150 for your participation in this group.

Costs
Taking part in this focus group discussion will not involve any costs to you.

Confidentiality
Many precautions have been taken to protect your privacy and keep the information you provide (including the audio recordings, if applicable) as confidential as possible. The study team uses computer security measures to protect your data. Your data are encrypted and stored on password-protected systems. Generally, only study team members may access your data.

Personal information like your name, address, telephone number, email address, and social security number, will be stored separately from the information you provide. No one at your facility will be told what you say. Your name will be replaced with a number when we transcribe the data from our interview. If the results of this study are presented in reports, at scientific meetings, or published in scientific journals, no information will be included that could identify you or your answers personally.

In addition, we are seeking a Certificate of Confidentiality from the United States Government. Certificates are issued by the Department of Health and Human Services (HHS) to researchers to help protect the privacy of people enrolled in sensitive, health-related research. With this Certificate we cannot be forced to release information that may identify you, even by court subpoena, in any federal, state or local civil, criminal, administrative, legislative, or other proceeding. The Certificate allows us to refuse to release any information that may identify you, with the following exceptions:
This Certificate cannot be used to turn down a demand for information from the United States Government for the purpose of auditing or evaluating federally funded projects. A Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this project. If you provide written permission for release of research information to an insurer, employer, or other person, the study team cannot use the Certificate to withhold your information.

The certificate will NOT be used to prevent disclosure of suspected child abuse and

neglect or threats of harm to self or others.

To learn more, please see this website: http://grants.nih.gov/grants/policy/coc/index.htm

Your Rights

Your decision to take part in this research study is completely voluntary. You do not have to take part in this focus group discussion. You can also refuse any part of the study and you can stop participating at any time. There will be no penalty or loss of benefits that you are otherwise entitled to. You can refuse to answer any question.

If you decide to participate and later change your mind, you will not be contacted again or asked for further information.

If you stop participating in this study, the Principal Investigator and study team will still be able to use your information that they have already collected.

Your Questions

You can ask questions about the study at any time. You can call the Principal Investigator or study team at any time if you have any concerns or complaints. You should call the Principal Investigator or study team at the phone number listed on page 1 of this form if you have questions about the study procedures, study costs (if any), or study payment (if any).
Quorum Review reviewed this study. Quorum Review is a group of people who review research studies to protect the rights and welfare of research participants. Review by Quorum Review does not mean that the study is without risks. If you have questions about your rights as a research participant, if you are not able to resolve your concerns with the Principal Investigator or study team, if you have a complaint, or if you have general questions about what it means to be in a research study, you can call Quorum Review or visit the Quorum Review website at www.quorumreview.com.

Quorum Review is located in Seattle, Washington.
Office hours are 8:00 AM to 5:00 PM Pacific Time, Monday through Friday.
Ask to speak with a Research Participant Liaison at 888-776-9115 (toll free).

Are You Willing to Participate?

If you agree to participate in the MAT Study as a provider focus group participant, please sign at the end of this form.

If you agree, we may contact you in the future for additional studies. You do not have to agree to being contacted in the future to take part in this study, and you may withdraw your permission for future contact at any time. If you do not want to participate in this study, we thank you for considering being a participant.

HIPAA AUTHORIZATION

This section explains who will use and share your health information if you agree to take part in this focus group discussion. You must authorize this use and sharing of your information by signing this form or you cannot be in this study. You can still be in the main part of the study even if you do not authorize the use and sharing of your information for the optional future contact part of the study. The Principal Investigator and study staff will collect, use, and share health information about you, including any information needed to do this study, as described in this form, and other identifying information about you, such as your name, address, phone number, or social security number. Your information may be used and shared with these people for the following purposes:

- The Principal Investigator and study staff to conduct this research.
- The sponsor, The Centers for Disease Control and Prevention (CDC); people who work with or for the sponsor; and other researchers involved in this study. These people will use your information to review the study, and to check the results of the study.
- Others required by law to review the quality and safety of research, including the U.S. Food and Drug Administration (FDA), Department of Health and Human Services, Office for Human Research Protections, other government agencies in the United States and other countries, and Quorum Review.

After your information is shared with the people and groups listed above, the law may not require them to protect the privacy of your information. To maintain the integrity of this research, you might not have access to any health information developed as part of this study until it is completed. At
that point, you generally would have access to your health information. This authorization to use and share your information expires in 50 years. You may withdraw your authorization at any time but you must let the Principal Investigator know in writing. You should send your written withdrawal notice to the address on page 1 of this form. If you withdraw your authorization, your participation in this study will end and the study personnel will stop collecting information from you for the focus group. You can cancel your authorization for the optional future contact part of the study and remain in the main study. Information about you collected before you cancel this authorization may continue to be used and shared by the CDC following your cancellation of this Authorization.

_____ _____
Signature of Participant Date

Your Statement
I have read the above information. I have been given the opportunity to ask questions, and my questions have been answered to my satisfaction. By signing this form, I voluntarily consent to participate in the research study. I understand that I may withdraw from this study at any time without penalty or loss of benefits to which I am otherwise entitled. I am also authorizing the collection, use, and disclosure of my personal health information as described above. I understand that I will not lose any of my legal rights as a research subject by signing this consent form. I will be given a copy of this signed consent form. I hereby elect to participate in this research study.

Please keep a copy of this form in a safe place in case you need to refer to it later concerning your rights and responsibilities as a research participant.

Optional Future Contact
I read earlier that if I agree, I may be contacted in the future regarding additional studies. **I understand that this future contact is optional. My decision regarding the optional activity will not affect my participation in the main study.**
I have decided that (please initial one line):
_____ Yes, I agree to be contacted in the future regarding additional studies.
_____ No, I do not agree to this future contact. I may still be in the main study.

Audio Recordings
Do you wish the focus group discussion to be recorded? You can say no and still participate in the discussion. The discussion will only be recorded if all participants agree to allow audio recording.

Initial below beside only one option:
_____Yes, I agree that the focus group discussion may be recorded.
_____No, I do not agree to the focus group discussion being recorded.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

YOU WILL BE GIVEN A COPY OF THIS CONSENT FORM TO KEEP.
I attest that the individual providing consent had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to participation in this study.

_____
Printed Name of Person Explaining Consent

_____ _____
Signature of Person Explaining Consent Date