

Client Informed Consent Form

Study Title: Medication-Assisted Treatment for Opioid Use Disorders (MAT Study)

Study #: N/A

Sponsor: Centers for Disease Control and Prevention (CDC)

Principal Investigator:

Laura Dunlap

RTI

3040 E. Cornwallis Rd. Durham, NC 27709

Telephone Number: (800) 957-6483

After Office Hours: (919) 599-9771

When reading this form, please note that the words “you” and “your” refer to the person in the study rather than to a parent/guardian who might sign this form on behalf of the person in the study.

WHY IS THIS STUDY BEING DONE?

Please be aware: Answering questions in this study has risks. It is possible that your answers may be given to certain authorities. This is discussed in more detail later in this form.

There are nearly 2.4 million people with in the United States who are addicted to opioids. About half of these people receive some form of opioid addiction treatment. There are very few studies, though, that help people suffering from opioid addiction and their doctors decide among different treatment options. Not only are there different medications and treatment approaches, different people respond differently to the same treatments. We want to learn why different treatments work well for some people and not as well for others. Is it something about the person, about the treatment, about the treatment provider, or a combination of these?

The goal of this study is to see how well opioid addition treatment works in real-world settings. You are being asked to participate in this study because you have started treatment for your opioid addiction. We hope to identify factors that influence how well a person does in treatment. This research will inform national policy, advance clinical practice, and ultimately improve treatment for people like yourself.

WHO IS CONDUCTING THIS STUDY?

The MAT Study is being conducted by RTI International, a research organization in Research Triangle Park, North Carolina. RTI's work on this study is funded by The Centers for Disease Control and Prevention (CDC), the leading national public health institute of the United States.

Neither RTI nor CDC is offering you any treatment. While we are working with your opioid addiction treatment provider to identify study participants, the MAT Study is totally separate from your treatment. Your decision to participate or not participate in the MAT Study will not affect your treatment in any way.

HOW MANY PEOPLE ARE TAKING PART IN THIS STUDY?

Approximately 3,560 men and women aged 18 or older from across the United States are expected to participate.

WHAT DO I NEED TO DO TO BE PART OF THE STUDY?

We ask you to complete a **Baseline Client Questionnaire** now which will last between 45 and 60 minutes. If you agree, we will provide a study laptop where you will privately read and answer a series of questions about aspects of your life. You can skip any question that you do not know the answer to or do not want to answer. These results are for research purposes only. The healthcare staff where you receive your opioid addiction treatment will never see your responses on the questionnaires you complete. Your answers will never be associated with your name.

We ask that you complete two **short Check-In Questionnaires** (about 20-30 minutes) in about 3 months and again in about 6 months. The Check-In Questionnaires are similar to the first questionnaire except much shorter. The Check-in Questionnaires may be completed online using your own computer. If you prefer, a RTI staff member will meet with you and provide a laptop on which you can complete the questionnaires. We are available to meet at your convenience including evenings and weekends. Check-ins may also be conducted over the telephone at your request. You will be asked to complete these questionnaires even if you are no longer receiving treatment.

We ask that you complete two **Follow-up Client Questionnaires**, one in about 12 months and another in about 24 months. These questionnaires are similar to the Baseline Questionnaire and take about 40-50 minutes to complete. The follow-up questionnaires may be completed online using your own laptop or a study laptop. If you chose to use a study laptop, we will meet you at a convenient time and location. The times include evenings and weekends. The location may be at your home or at another mutually agreeable location, for example, a library. We will make every effort to pick a time that is convenient for you and location where you are comfortable. You will be asked to complete these questionnaires even if you are no longer receiving treatment.

The health professionals providing your opioid addiction treatment will be asked several times during your treatment to report on medication you receive to treat your opioid addiction and provide information about your adherence to your addiction treatment program and results of drug screens. This is your personal health information and we must have your consent to use it for research purposes.

Study staff may access publicly available records for you, for example, Vital Records about births and deaths. This information will be used exclusively for research purposes. Public data may also be accessed to see if you have a new phone number or address. You and your data will never be personally identified in any research results.

WHAT TYPES OF QUESTIONS WILL YOU ASK ON THE QUESTIONNAIRES?

Each questionnaire will cover some basic information about you (for example, age, gender, race, education), your mental and physical health, and your health behaviors. We will ask about the treatment(s) you receive for your opioid addiction over a three-year window. We will ask about medications you receive to treat your opioid addiction. We will ask about your use of opioids outside of a doctor's care as well as your use of illicit drugs. We will ask about any times you were arrested or convicted, if any, your employment, and your housing situation. We will ask questions about any childhood trauma or abuse you may have experienced.

You will not be asked to complete any medical tests or procedures as part of the study.

All your answers will be held confidentially and used only for research purposes. Your answers will be combined with the answers of about 3,560 other people who complete these questionnaires. You will complete the questionnaire in private on a computer. Once you start the questionnaire, you may skip any question. You can also end your participation in the study for any reason. This study has been reviewed by the Quorum Review Board for ethical protection of human subjects.

WILL I GET INCENTIVES?

You will be given the incentive for each questionnaire when you finish. You will get \$40 for the Baseline Client Questionnaire, \$20 for each Check-In Questionnaire (\$40 total), and \$50 for each the Follow-up Client Questionnaires (\$100 total). If the RTI staff member is present, he/she will hand you your gift card personally. If you complete your questionnaire online without a RTI staff member present, you will have a link to an electronic gift card.

DO I HAVE TO BE IN THIS STUDY? CAN I STOP BEING IN THE STUDY?

Your participation in this research study is voluntary. You also can refuse any part of the study, and you can withdraw from the study at any time. There will be no penalty or loss of benefits that you are otherwise entitled to. Please let an RTI staff member know if you want to stop participating in the study.

While we are working with your opioid addiction treatment provider to identify study subjects, the MAT Study is totally separate from your opioid addiction treatment. Your decision to participate (or not participate) in the MAT Study will not affect your addiction treatment in any way. Your decision to continue your treatment (or end it) does not affect your participation in the MAT Study in any way.

The principal investigator may end your participation in the study if she believes it is in your best interest; for example, if you repeatedly seem upset by the questions, repeatedly do not complete entire questionnaires, or the study is stopped. If you choose to leave the study, the study will still be able to use the information you have already provided.

WHAT ARE THE SIDE EFFECTS OR RISKS FOR BEING IN THIS STUDY?

It is possible that some of the questions may make you feel uncomfortable or upset. **You can refuse to answer any question** or may take a break at any time during the questionnaire.

In addition to the risks and discomforts listed here, there may be uncommon or previously unknown risks. You should report any problems you experience to the Principal Investigator or RTI staff member. You will be informed in a timely manner if new information becomes available that may be relevant to continued participation in the study.

IS MY DATA CONFIDENTIAL?

The study team is doing everything possible to see that does not happen, but this cannot be fully guaranteed. There is always risk of loss of confidentiality, however we are taking several steps to protect your confidentiality. First, the study team uses computer security measures to protect your data. Your data are encrypted and stored on password-protected systems. Only study team members may access your data. Second, your personal healthcare provider(s) will not have access to your data. Personal information like your name, address, telephone number, email address, and social security number, will be stored separately from your questionnaire answers and the data your provider gives us. The data files with your questionnaire answers will not include your name or any personally identifying information. All your data will be as confidential as possible and used only for statistical purposes. If the results of this study are presented at scientific meetings or published in scientific journals, no information will be included that could identify 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. However, none of the questionnaires ask about perpetration of child abuse or 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>

ARE THERE BENEFITS TO BEING IN THIS STUDY?

There are no direct benefits. We hope that information from this study will help those suffering from opioid dependence by creating new and additional opportunities for opioid treatment.

WHOM DO I CALL IF I HAVE FURTHER QUESTIONS?

In the event of an emergency, dial 911 immediately. If you require health care, contact your healthcare provider.

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.

ARE YOU WILLING TO PARTICIPATE?

If you agree to participate in the MAT Study, please sign at the end of this form.

Your consent also means that 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.

This MAT Study is **completely separate** from the treatment you receive for your opioid addiction. Your alternative is not to be in the MAT Study. If you decide not to participate, your continued participation in any treatment for opioid addiction will not be affected.

If you agree to participate, the RTI staff member will collect your contact information and ask you to sign this form. We will request your Social Security Number. Your SSN will be used exclusively to help us locate you if you become lost-to-follow-up. We will also use it to check Vital Records for you (records of births and deaths).

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. When you take the Client Questionnaires, the first page will briefly review the consent form and we ask that you agree by entering your initials.

HIPAA AUTHORIZATION

This section explains who will use and share your health information if you agree to be in this study. You must authorize this use and sharing of your information by signing this form or you cannot be in the 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 the study and other identifying information about you, such as your name, address, phone number, or social security number. The information used and shared will include:

- information from your medical records
- information collected about you during the research (such as your questionnaire responses)
- 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 the study will end and the study personnel will stop collecting information from you. If an adverse event occurs, your entire medical record may be reviewed. 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 (if an Adult) Or Parent/Guardian

Date

CONSENT/ASSENT TO PARTICIPATE

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 the principal investigator and study staff. 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 agreeing to the collection, use, and release 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 agree to participate in this research study.

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.

Printed Name of Participant

Signature of Participant (If an Adult)

Date

Signature of Participant (If a Minor)

Date

If participant does not have the legal capacity to consent to their participation:

I am the parent/guardian of the participant named above and I consent to his/her participation in this research study.

Printed Name of Parent/Guardian

Signature of Parent/Guardian

Date

I agree that the individual(s) providing consent/assent 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/Assent

Signature of Person Explaining Consent/Assent

Date

**Client Focus Group
Participant Informed Consent/Assent Form**

Study Title: Medication-Assisted Treatment for Opioid Use Disorders (MAT Study)

Study #: N/A

Sponsor: Centers for Disease Control and Prevention (CDC)

Principal Investigator:

Laura Dunlap

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Telephone Number: (800) 957-6483

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When reading this form, please note that the words “you” and “your” refer to the person in the study rather than to a parent/guardian who might sign this form on behalf of the person in the study.

Introduction

You are already taking part in the Medication Assisted Treatment (MAT) Study, sponsored by the Centers for Disease Control and Prevention (CDC). You are now being asked to participate in an optional part of this research study. Before you decide if you want to take part in this optional part of the study, you need to read this Informed Consent/Assent Form so that you understand what this part of the study is about and what you will be asked to do. This form also tells you who can be in this part of the study, the risks and benefits of this part 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 MAT Study is a research study funded by 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 clients selected from among over 40 medical/counseling facilities across the United States to take part in this optional part of the study.

Procedures

If you agree to participate, you will be asked to take part in a telephone conference call with seven to nine other persons who have participated in opioid use disorder (OUD) treatment and who are also taking part 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:

- use of drugs and how that use may have changed during treatment,
- drugs used when a relapse occurs,
- how you were introduced to opioids, and
- how you came to be in treatment.

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

This focus group discussion does not involve any treatment for your opioid use disorder. Your alternative is to not participate in this part of the study.

Possible Risks or Discomforts

It is possible that some of the subjects discussed during the focus group may make you feel uncomfortable or upset. 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 may reveal information that you say 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 \$40 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 involved in your care will be told what you say on this call. 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 optional part of the 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.

You can refuse to take part in this focus group discussion and continue to participate in the main part of the MAT Study. If you decide to participate and later change your mind, you will not be contacted again or asked for further information related to the focus group.

If you stop participating in this part of the 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 (which includes this focus group discussion) 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 this focus group discussion as part of the MAT Study, please sign at the end of this form.

If you do not want to participate in this part of the 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 part of the 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 this optional 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 optional part of the 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 optional part of the study will end and the study personnel will stop collecting information from you for the focus group. You can cancel your authorization for this optional 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 (if an Adult)
Or Parent/Guardian

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 focus group discussion. I understand that I may withdraw from this optional part of the 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 focus group discussion.

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 (**If an Adult**)

Date

Signature of Participant (**If a Minor**)

Date

If participant does not have the legal capacity to consent to their participation:
I am the parent/guardian of the participant named above and I consent to his/her participation in this focus group discussion.

Printed Name of Parent/Guardian

Signature of Parent/Guardian

Date

YOU WILL BE GIVEN A COPY OF THIS CONSENT FORM TO KEEP.

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

I agree that the individual(s) providing consent/assent had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to participation in this focus group discussion.

Printed Name of Person Explaining Consent/Assent

Signature of Person Explaining Consent/Assent

Date