RUTGERS HEALTH
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Mindfulness Oriented Recovery Enhancement for Chronic Pain and Opioid Relapse

NCT04491968

Version: July 1, 2022

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CONSENT TO TAKE PART IN A RESEARCH STUDY

TITLE OF STUDY: Mindfulness Oriented Recovery Enhancement as an Adjunct to Methadone Treatment for Opioid Use and Chronic Pain Management

Principal Investigator: Nina Cooperman, PsyD

STUDY SUMMARY: This consent form is part of an informed consent process for a research study and it will provide information that will help you decide whether you want to take part in this study. It is your choice to take part or not.

The **purpose of the research** is to: Evaluate the effectiveness of a novel intervention, Mindfulness Oriented Recovery Enhancement (MORE), on opioid use disorder (OUD) patients with pain who are in recovery or receiving methadone maintenance treatment (MMT). You may participate in this intervention through video conferencing or phone.

If you take part in the research, you will be asked to: 1) Complete three assessments, over the phone, through video conferencing, or in-person at your clinic or other safe and private location in the community (e.g, a library, coffee shop, or park), that will include questions or assessments about your methadone treatment, pain severity, drug use, and cognitive, mental, and physical health. Once the consent has been completed and you are deemed eligible for the study, a baseline assessment will be conducted over your own phone, video conference, or in-person followed by a phone, video conference, or in-person assessment in approximately two months, and approximately four months. Each assessment will last approximately one to two hours. An android tablet with a data plan will be provided to you in case you need a device to help you complete the assessments.
2) Complete assessments on a computer or tablet that will assess your self-control, thinking process, and visual perception. These assessments will take about 45 minutes to complete and occur during baseline assessment and approximately two months from baseline assessment.
3) Complete two daily assessments for about the next four months on your own smartphone, computer, or tablet or by android tablet that will be provided to you. The assessments will include questions about your current mood, pain intensity, and substance use at the moment, and will take you about three minutes or less to complete. You also be asked to complete a brief assessment on your smartphone, computer, or tablet if you experience a strong craving or a drug relapse. The assessment will take about three minutes or less and ask about your circumstances before and during the craving or relapse.
4) Take a urine or saliva test to screen for drugs that you may have used, recently (at initial assessment and approximately two and four months from initial assessment).
5) Provide permission to access information about you from the methadone maintenance treatment (MMT) clinic you attend and permission for us to provide information relevant to your care to your clinic.
6) If you are placed in the treatment group, you will be required to participate in eight, weekly, two-hour group sessions over 8-weeks. Each session will include approximately 7 participants from your methadone clinic and will be conducted online through video or phone

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conferencing. You will be provided with an Android tablet with a data plan to help you access video conferencing and complete assessments. If you have your own phone, computer, or tablet, you may use your own device, if you choose to do so. All group sessions will be audio or video recorded so that the research team can make sure that you are receiving the intervention as planned.

In sum, your time in the study will include three, one to two hour, assessments and two 45-minute assessments over approximately the next four months, and, if you are placed in the treatment group, eight two-hour group video or phone sessions.

Possible harms or burdens of participating in this study: You may experience discomfort about answering some questions, since they deal with sensitive issues. However, you need not answer any questions you don't feel comfortable with. Also, there is the very rare chance that someone other than the researchers may get access to the information you give us. However, we will take very strong precautions to ensure your information stays safe.

Possible benefits of participating in this study: The benefit of this study is that the intervention may help you cope with pain and prevent future drug use. However, it is possible that you may not receive any direct benefit from taking part in this study.

An alternative to taking part in the research study: Your alternative to taking part in the research study is not to take part in it.

The information in this consent form will provide more details about the research study and what will be asked of you if you choose to take part in it. If you have any questions now or during the study, if you choose to take part, you should feel free to ask them and should expect to be given answers you completely understand. After your questions have been answered and you wish to take part in the research study, you will be asked to sign this consent form. You are not giving up any of your legal rights by agreeing to take part in this research or by signing this consent form.

Who is conducting this research study?

Dr. Nina Cooperman from the Department of Psychiatry at Robert Wood Johnson Medical School in New Brunswick, New Jersey is the Principal Investigator of this research study. A Principal Investigator has the overall responsibility for the conduct of the research. However, there are often other individuals who are part of the research team.

Dr. Cooperman may be reached at 732-235-4341. Her office is at 317 George Street, Suite 105, New Brunswick, NJ 08901.

Dr. Cooperman or another member of the study team will also be asked to sign this informed consent. You will be given an extra copy of this consent form for your records.

The sponsor of the study is the National Institute of Health (NIH): National Center for Complementary and Integrative Health (NCCIH) and the National Institute on Drug Abuse (NIDA).

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Why is this study being done?

This study is being conducted to compare the impact of a novel intervention, Mindfulness Oriented Recovery Enhancement (MORE), delivered by phone or video conferencing, plus methadone treatment, to methadone treatment alone among people who have chronic pain and are in methadone treatment for a opioid use disorder. To do this, we will compare pain, drug use, and other experiences and behaviors among study participants who are randomly assigned to receive MORE plus methadone treatment to people who are randomly assigned to receive only methadone treatment.

Who may take part in this study and who may not?

We are looking for people to take part in the study who speak English, are at least 18 years of age, and have experienced at least a mild level of pain that is not related to cancer for a duration of 3 months or longer. We also want to enroll people who will be available to participate in an intervention for 8-weeks and to conduct research interviews over the course of approximately the next four months. You are not eligible to participate in the study if you have cognitive impairment or active psychosis, are at risk for suicide, unable to attend phone or video group sessions for 8 weeks, if necessary, or participated in formal mindfulness training within the past 5 years (e.g., formal mindfulness class for eight weeks or more).

Why have I been asked to take part in this study?

You have been invited to take part in this study because you are currently receiving methadone maintenance treatment (MMT) for opioid use disorder (OUD) and are experiencing moderate levels of pain.

How long will the study take and how many subjects will take part?

We will enroll approximately 170 participants in the study. Your participation in this study will last approximately four months from initial assessment. The entire study will last for two years.

What will I be asked to do if I take part in this study?

If you decide to take part in the study, we will ask you to:
1) Complete 3 assessments, by phone or video conference, or in-person that will include questions or assessments about your methadone treatment, pain severity, drug use, and cognitive, mental, and physical health. The assessments will be over the phone or video conference, or in-person and will last approximately one to two hours, each. The initial assessment will occur within the next week or two and then again in approximately two months and four months. You will be provided with an Android tablet and unlimited data plan, at no cost to you, to help you complete assessments and participate in video conferencing. If you have your own smartphone, tablet, or computer, you may complete the assessments on your own device, if you choose.

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2) Complete two assessments on a computer or tablet that will assess your self-control, thinking process, and visual perception. These assessments will take about 45 minutes to complete and occur during initial assessment and approximately two months from the initial assessment.
3) Complete two daily assessments during the next four months on a tablet with a data plan that will be provided to you, at no cost to you, or your own smartphone or tablet. The assessments will include questions about your current mood, pain intensity, and substance use at the moment, and will take you about three minutes or less to complete. You will also be asked to complete a brief assessment on your smartphone or tablet if you experience a strong craving or use drugs. The assessment will take about three minutes or less and ask about your circumstances before and during the craving or relapse. We may contact you to obtain information on your drug use on days that you miss completing the daily assessments yourself.
4) Take a urine or saliva test to screen for drugs that you may have used, recently, at each assessment (at the initial assessment and approximately two and four months from the initial assessment). You will be mailed a urine or saliva test prior to the assessment appointment. At the time of the assessment, you will be instructed on how to administer the test and will be instructed to show the research assistant the results on the video conference or tell the research assistant the results over the phone. Alternatively, this can be done in-person at your clinic or another safe and private location in the community (e.g., library, coffee shop, or park). Drug test results, whether positive or negative, will not be shared with anyone, including your methadone clinic, without your written consent.
5) Provide permission to access information about you from the methadone maintenance treatment (MMT) clinic you attend and permission for us to provide information relevant to your care to your clinic.
6) You will be assigned a number, and a computer will randomly determine if, based on your number, you will receive the MORE intervention or if you will continue your treatment, as usual, at your clinic. If you are randomly assigned to receive that MORE intervention, you will receive your usual care at the methadone clinic, plus, you will be required to participate in eight, weekly, two-hour group online video or phone sessions, from your home, over 8-weeks. Each session will include approximately 7 participants from your methadone clinic and will be conducted online through video conferencing or phone. You can use the tablet and data plan that will provided to you or your own computer, tablet, or phone to access the intervention session. All group sessions will be audio or video recorded so that the research team can make sure that you are receiving the intervention as planned. If you are not randomly assigned to receive the MORE intervention, you will receive only your usual care at the methadone clinic. All study participants will be followed for 16 weeks.

What are the risks and/or discomforts I might experience if I take part in this study?

Because this study involves asking you questions and/or participating in group therapy sessions, there are no medical risks to your participation. You may feel uncomfortable about answering some questions, since they deal with sensitive issues. However, you need not answer any questions you don't feel comfortable with. If you feel uncomfortable with a question, you can skip that question or withdraw from the study altogether. If you decide to quit at any time before you have finished the questionnaire, your answers will not be recorded.

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There is also a very rare chance that someone other than the researchers may get access to the information you give us. Since the assessments will be administered using technology, there is possible risk of data being intercepted. However, as we describe in greater detail below, we have never had this happen with any of our studies and we take very strong precautions to ensure your information stays safe.

Are there any benefits to me if I choose to take part in this study?

The benefits of taking part in this study may help you cope with pain and prevent future drug use. However, it is possible that you may not receive any direct benefit from taking part in this study.

What are my alternatives if I do not want to take part in this study?

Your alternative is not to take part in this study and continue with your usual care at the clinic.

How will I know if new information is learned that may affect whether I am willing to stay in the study?

During the course of the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

Will there be any cost to me to take part in this study?

There will not be any cost to you to take part in the study other than the time you spend answering the survey questions and/or partaking in group therapy sessions.

Will I be paid to take part in this study?

You will receive gift cards, by standard mail or email, according to the following schedule:

- $30.00 after first questionnaire and drug screen assessment
- $40.00 after two-month questionnaire and drug screen assessment (about two months from baseline assessment)
- $50.00 after four-month questionnaire and drug screen assessment (about four months from baseline assessment)
- After your first assessment session and your two-month assessment session you will receive an additional $20 gift card if you complete the computer assessments.
- After your four-month assessment visit you will receive a gift card for $20 if you complete 10-25% of daily assessments, $30 if you complete 26-50% of daily assessments, $40 if you complete 51-85% of daily assessments, and $50 if you complete 86-100% of the daily assessments).
- If you are assigned to receive the MORE intervention, you will receive a $5 gift card after each session that you participate in.

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How will information about me be kept private or confidential?

All of your answers to the survey questions will be identified by a number, not your name. Your name, phone number, address or any other identifying information will never be stored with your study question answers. All identifying information written on paper forms will be stored in locked filing cabinets in locked offices, and only research staff will have access to these cabinets. All identifying information that is kept on the computer will be stored in files that are separate from your answers to the survey questions. We will keep all computer files on the secure Rutgers server and research staff will need a password in order to open these files. Only Rutgers research staff will know what this password is.

No data that you provide will be stored on the technology that you use for the study. All survey information you provide on the phone, computer, or tablet will only have an ID code and not your name and will be sent through and stored by secure web applications called Qualtrics or REDCap. Your information will be encrypted for security and received and stored by the secure Qualtrics or REDCap system that is designed to protect confidential health information. All computer task results and information will be stored on the Inquisit system that uses the same technology used by online shopping and banking web sites to protect sensitive information transmitted over the web.

Although we will make all efforts to keep your personal information and research record confidential, confidentiality may be broken if the research staff determines that you are a danger to yourself or others or a child is being abused or neglected.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require, such as laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from

willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Center for Complementary and Integrative Health (NCCIH) and the National Institute on Drug Abuse (NIDA) which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document such as answers to survey assessments, biospecimen results, and information about you provided from your methadone maintenance treatment (MMT) clinic.

What will happen if I do not wish to take part in the study or if I later decide not to stay in the study?

It is your choice whether to take part in the research. You may choose to take part, not to take part or you may change your mind and withdraw from the study at any time.

If you do not want to enter the study or decide to stop taking part, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to Dr. Cooperman. Her address is 317 George Street, Suite 105, New Brunswick, NJ 08901.

Who can I call if I have questions?

If you have questions about taking part in this study, you can call Dr. Cooperman at 732-235-4341.

If you have questions about your rights as a research subject, you can call the IRB Director at: New Brunswick/Piscataway HealthSci IRB (732)235-9806 or the Rutgers Human Subjects Protection Program at (973)972-1149 in Newark or (732)235-8578 in New Brunswick.

PERMISSION (AUTHORIZATION) TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY

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The next few paragraphs tell you about how investigators want to use and share identifiable health information from your medical record in this research. Your information will only be used as described here or as allowed or required by law. If you sign this consent form, you agree to let the investigators use your identifiable health information in the research and share it with others as described below. Ask questions if there is something you do not understand.

What is the purpose of the research and how will my information be used?

You are being invited to take part in this research study which is described at the beginning of this form. The purpose of collecting and using your health information for this study is to help investigators answer the questions that are being asked in the research.

What information about me will be used?

- Medical, psychiatric, and drug use history or treatment
- Medications prescribed and prescriptions filled
- Laboratory/diagnostic tests
- Psychological and cognitive testing, surveys or questionnaires
- Physical symptoms and health
- Information about the medical, psychiatric, substance abuse treatment, and other social services you receive during the study
- Your contact information

Who may use, share or receive my information?

The research team may use or share your information collected or created for this study with the following people and institutions:

- Rutgers University investigators and staff involved in the study
- Non-Rutgers investigators on the study team (Eric Garland, Ph.D and Adam Hanley, PhD at the University of Utah)
- Members of the study Data Safety Monitoring Board
- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services
- The National Institute of Health (NIH): National Center for Complementary and Integrative Health (NCCIH) and National Institute on Drug Abuse.

Those persons or organizations that receive your information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, if permitted by the laws governing them.

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Study results will be reported at conferences and published in peer-reviewed journals. Identities will not be reviewed or revealed in published or presented data.

If you are in the intervention group, notes about the study group sessions will be a part of your clinic record; however, your study data that is identified by only an ID code will not be included in your clinic record.

Will I be able to review my research record while the research is ongoing?

No. We are not able to share information in the research records with you until the study is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research study.

Do I have to give my permission?

No. You do not have to permit use of your information. But, if you do not give permission, you cannot take part in this study. (Saying no does not stop you from getting medical care or other benefits you are eligible for outside of this study.)

If I say yes now, can I change my mind and take away my permission later?
Yes. You may change your mind and not allow the continued use of your information (and to stop taking part in the study) at any time. If you take away permission, your information will no longer be used or shared in the study, but we will not be able to take back information that has already been used or shared with others. If you say yes now but change your mind later for use of your information in the research, you must write to the researcher and tell her of your decision: You should write to Dr. Cooperman at 317 George Street, Suite 105, New Brunswick, NJ 08901.

How long will my permission last?

There is no set date when your permission will end. Your health information may be studied for many years.

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AGREEMENT TO PARTICIPATE

Subject Consent:

I have read this entire consent form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form and this study have been answered. I agree to take part in this study.

Subject Name (Print):_____

Subject Signature:_____ Date:_____

Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed all the important details about the study including all of the information contained in this consent form.

Investigator/Person Obtaining Consent (Print):_____

Signature:_____ Date: _____

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Who may take part in this study and who may not?

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Why have I been asked to take part in this study?

You have been invited to take part in this study because you are currently receiving methadone maintenance treatment (MMT) for opioid use disorder (OUD) and are experiencing moderate levels of pain.

How long will the study take and how many subjects will take part?

We will enroll approximately 170 participants in the study. Your participation in this study will last approximately four months from initial assessment. The entire study will last for two years.

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2) Complete two assessments on a computer or tablet that will assess your self-control, thinking process, and visual perception. These assessments will take about 45 minutes to complete and occur during initial assessment and approximately two months from the initial assessment.
3) Complete two daily assessments during the next four months on a tablet with a data plan that will be provided to you, at no cost to you, or your own smartphone or tablet. The assessments will include questions about your current mood, pain intensity, and substance use at the moment, and will take you about three minutes or less to complete. You will also be asked to complete a brief assessment on your smartphone or tablet if you experience a strong craving or use drugs. The assessment will take about three minutes or less and ask about your circumstances before and during the craving or relapse. We may contact you to obtain information on your drug use on days that you miss completing the daily assessments yourself.
4) Take a urine or saliva test to screen for drugs that you may have used, recently, at each assessment (at the initial assessment and approximately two and four months from the initial assessment). You will be mailed a urine or saliva test prior to the assessment appointment. At the time of the assessment, you will be instructed on how to administer the test and will be instructed to show the research assistant the results on the video conference or tell the research assistant the results over the phone. Alternatively, this can be done in-person at your clinic or another safe and private location in the community (e.g., library, coffee shop, or park). Drug test results, whether positive or negative, will not be shared with anyone, including your methadone clinic, without your written consent.
5) Provide permission to access information about you from the methadone maintenance treatment (MMT) clinic you attend and permission for us to provide information relevant to your care to your clinic.
6) You will be assigned a number, and a computer will randomly determine if, based on your number, you will receive the MORE intervention or if you will continue your treatment, as usual, at your clinic. If you are randomly assigned to receive that MORE intervention, you will receive your usual care at the methadone clinic, plus, you will be required to participate in eight, weekly, two-hour group online video or phone sessions, from your home, over 8-weeks. Each session will include approximately 7 participants from your methadone clinic and will be conducted online through video conferencing or phone. You can use the tablet and data plan that will provided to you or your own computer, tablet, or phone to access the intervention session. All group sessions will be audio or video recorded so that the research team can make sure that you are receiving the intervention as planned. If you are not randomly assigned to receive the MORE intervention, you will receive only your usual care at the methadone clinic. All study participants will be followed for 16 weeks.

What are the risks and/or discomforts I might experience if I take part in this study?

Because this study involves asking you questions and/or participating in group therapy sessions, there are no medical risks to your participation. You may feel uncomfortable about answering some questions, since they deal with sensitive issues. However, you need not answer any questions you don't feel comfortable with. If you feel uncomfortable with a question, you can skip that question or withdraw from the study altogether. If you decide to quit at any time before you have finished the questionnaire, your answers will not be recorded.

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There is also a very rare chance that someone other than the researchers may get access to the information you give us. Since the assessments will be administered using technology, there is possible risk of data being intercepted. However, as we describe in greater detail below, we have never had this happen with any of our studies and we take very strong precautions to ensure your information stays safe.

Are there any benefits to me if I choose to take part in this study?

The benefits of taking part in this study may help you cope with pain and prevent future drug use. However, it is possible that you may not receive any direct benefit from taking part in this study.

What are my alternatives if I do not want to take part in this study?

Your alternative is not to take part in this study and continue with your usual care at the clinic.

How will I know if new information is learned that may affect whether I am willing to stay in the study?

During the course of the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

Will there be any cost to me to take part in this study?

There will not be any cost to you to take part in the study other than the time you spend answering the survey questions and/or partaking in group therapy sessions.

Will I be paid to take part in this study?

You will receive gift cards, by standard mail or email, according to the following schedule:

- $30.00 after first questionnaire and drug screen assessment
- $40.00 after two-month questionnaire and drug screen assessment (about two months from baseline assessment)
- $50.00 after four-month questionnaire and drug screen assessment (about four months from baseline assessment)
- After your first assessment session and your two-month assessment session you will receive an additional $20 gift card if you complete the computer assessments.
- After your four-month assessment visit you will receive a gift card for $20 if you complete 10-25% of daily assessments, $30 if you complete 26-50% of daily assessments, $40 if you complete 51-85% of daily assessments, and $50 if you complete 86-100% of the daily assessments).
- If you are assigned to receive the MORE intervention, you will receive a $5 gift card after each session that you participate in.

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How will information about me be kept private or confidential?

All of your answers to the survey questions will be identified by a number, not your name. Your name, phone number, address or any other identifying information will never be stored with your study question answers. All identifying information written on paper forms will be stored in locked filing cabinets in locked offices, and only research staff will have access to these cabinets. All identifying information that is kept on the computer will be stored in files that are separate from your answers to the survey questions. We will keep all computer files on the secure Rutgers server and research staff will need a password in order to open these files. Only Rutgers research staff will know what this password is.

No data that you provide will be stored on the technology that you use for the study. All survey information you provide on the phone, computer, or tablet will only have an ID code and not your name and will be sent through and stored by secure web applications called Qualtrics or REDCap. Your information will be encrypted for security and received and stored by the secure Qualtrics or REDCap system that is designed to protect confidential health information. All computer task results and information will be stored on the Inquisit system that uses the same technology used by online shopping and banking web sites to protect sensitive information transmitted over the web.

Although we will make all efforts to keep your personal information and research record confidential, confidentiality may be broken if the research staff determines that you are a danger to yourself or others or a child is being abused or neglected.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require, such as laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from

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willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Center for Complementary and Integrative Health (NCCIH) and the National Institute on Drug Abuse (NIDA) which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document such as answers to survey assessments, biospecimen results, and information about you provided from your methadone maintenance treatment (MMT) clinic.

What will happen if I do not wish to take part in the study or if I later decide not to stay in the study?

It is your choice whether to take part in the research. You may choose to take part, not to take part or you may change your mind and withdraw from the study at any time.

If you do not want to enter the study or decide to stop taking part, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to Dr. Cooperman. Her address is 317 George Street, Suite 105, New Brunswick, NJ 08901.

Who can I call if I have questions?

If you have questions about taking part in this study, you can call Dr. Cooperman at 732-235-4341.

If you have questions about your rights as a research subject, you can call the IRB Director at: New Brunswick/Piscataway HealthSci IRB (732)235-9806 or the Rutgers Human Subjects Protection Program at (973)972-1149 in Newark or (732)235-8578 in New Brunswick.

PERMISSION (AUTHORIZATION) TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY

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The next few paragraphs tell you about how investigators want to use and share identifiable health information from your medical record in this research. Your information will only be used as described here or as allowed or required by law. If you sign this consent form, you agree to let the investigators use your identifiable health information in the research and share it with others as described below. Ask questions if there is something you do not understand.

What is the purpose of the research and how will my information be used?

You are being invited to take part in this research study which is described at the beginning of this form. The purpose of collecting and using your health information for this study is to help investigators answer the questions that are being asked in the research.

What information about me will be used?

- Medical, psychiatric, and drug use history or treatment
- Medications prescribed and prescriptions filled
- Laboratory/diagnostic tests
- Psychological and cognitive testing, surveys or questionnaires
- Physical symptoms and health
- Information about the medical, psychiatric, substance abuse treatment, and other social services you receive during the study
- Your contact information

Who may use, share or receive my information?

The research team may use or share your information collected or created for this study with the following people and institutions:

- Rutgers University investigators and staff involved in the study
- Non-Rutgers investigators on the study team (Eric Garland, Ph.D and Adam Hanley, PhD at the University of Utah)
- Members of the study Data Safety Monitoring Board
- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services
- The National Institute of Health (NIH): National Center for Complementary and Integrative Health (NCCIH) and National Institute on Drug Abuse.

Those persons or organizations that receive your information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, if permitted by the laws governing them.

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Study results will be reported at conferences and published in peer-reviewed journals. Identities will not be reviewed or revealed in published or presented data.

If you are in the intervention group, notes about the study group sessions will be a part of your clinic record; however, your study data that is identified by only an ID code will not be included in your clinic record.

Will I be able to review my research record while the research is ongoing?

No. We are not able to share information in the research records with you until the study is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research study.

Do I have to give my permission?

No. You do not have to permit use of your information. But, if you do not give permission, you cannot take part in this study. (Saying no does not stop you from getting medical care or other benefits you are eligible for outside of this study.)

If I say yes now, can I change my mind and take away my permission later?
Yes. You may change your mind and not allow the continued use of your information (and to stop taking part in the study) at any time. If you take away permission, your information will no longer be used or shared in the study, but we will not be able to take back information that has already been used or shared with others. If you say yes now but change your mind later for use of your information in the research, you must write to the researcher and tell her of your decision: You should write to Dr. Cooperman at 317 George Street, Suite 105, New Brunswick, NJ 08901.

How long will my permission last?

There is no set date when your permission will end. Your health information may be studied for many years.

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AGREEMENT TO PARTICIPATE

Subject Consent:

I have read this entire consent form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form and this study have been answered. I agree to take part in this study.

Subject Name (Print):_____

Subject Signature:_____ Date:_____

Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed all the important details about the study including all of the information contained in this consent form.

Investigator/Person Obtaining Consent (Print):_____

Signature:_____ Date: _____