Mount Sinai Beth Israel

# Informed Consent Document

# Emergency Department Initiated Oral Naltrexone for Patients with Moderate to Severe Alcohol Use Disorder: A Pilot Feasibility Study

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**NCT04817410**
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**STUDY INFORMATION:**

**Study Title: Emergency Department Initiated Oral Naltrexone for Patients with Moderate to Severe Alcohol Use Disorder: A Pilot Feasibility Study**

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**SUMMARY OF THIS RESEARCH STUDY:**

In medicine there are many unanswered questions. A research study is when scientists try to answer a question about something that we don't know enough about. Participation in a research study may or may not directly help you or others. Participation is entirely voluntary. It is completely up to you whether or not you take part. You can also change your mind at any time and it will not affect your ability to get medical care within the Mount Sinai Health System.

The purpose of this research study is improve how we identify Emergency Department patients that have a problem with alcohol (alcohol use disorder or AUD). For Emergency Department subjects with moderate or severe alcohol use disorder we want to see if performing a brief counseling intervention in addition to starting subjects on a FDA approved medication for alcohol use disorder while still in the Emergency Department will increase the likelihood that they will be engaged in comprehensive addiction care at 14 and 30 days after their Emergency Department Visit.

The medication being used in this study, oral naltrexone, is a standard medication used to treat alcohol use disorder but it is normally started in out-patient clinics. Oral naltrexone has been shown to decrease the cravings for alcohol and reduce daily alcohol intake.

In this study, subjects will receive a brief counseling session and be started on oral naltrexone while in the Emergency Department. All subjects will receive a referral to an out-patient addiction medicine clinic for continued treatment. We will also access your mental health and addiction medicine records.

If you choose to participate, here is what to expect:

<u>While in the Emergency Department</u>

- You will be asked to complete a series of questionnaires
- You will be asked to provide a urine for drug and pregnancy testing
- You will be asked to provide a blood specimen to check your liver function
- You will receive a brief counseling session about your alcohol use



- You will be started on oral naltrexone, a medicine to decrease your craving for alcohol
- You will receive a referral to an out-patient addiction medicine clinic

At 14 and 30 days after your Emergency Department Visit

- You will be asked to complete a series of questionnaires

Daily on days 1 to 30 after your Emergency Department Visit

- You will be asked about your daily alcohol intake and craving for alcohol

The main risks to you are from the oral naltrexone. This medication can cause mild side effects including dizziness, nausea, headache and/or fatigue. The other risk if you choose to participate is loss of confidentiality.

You may also benefit from participation in this research by receiving counseling and medication that can help decrease your use of and craving for alcohol. Instead of participating in this research, you may receive the same counseling and the same medication (oral naltrexone) from an addiction medicine provider in a clinic. Both the counseling and medication being studied are considered standard treatment options for subjects with alcohol use disorder.

If you choose to participate you will be compensated for your time and inconvenience. All treatments and interventions being provided to you as part of this study will be billed to your insurance, except for the first 14-days of oral naltrexone which we will give you for at no cost.

If you are interested in learning more about this study, please continue to read below.

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**PARTICIPATION IN THIS RESEARCH STUDY:**

This research study will be fully explained to you by a member of the study team. Feel free to ask all the questions you want before you make a decision about whether or not to participate. Any new information that develops during this research study that might make you change your mind about participating will be given to you promptly.

You may qualify to take part in this research study because you are being treated in the Emergency Department and have moderate to severe alcohol use disorder.

Funds for conducting this research are provided by Mount Sinai.

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

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**LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE:**

Your participation in this research study is expected to last 30 days.
The number of people expected to take part in this research study is 30.

**DESCRIPTION OF WHAT'S INVOLVED:**

If you agree to participate in this research study, the following information describes what may be involved.

- Your screening and enrollment visit (day 0) will take place in the Emergency Department at Mount Sinai Beth Israel today. We will try and schedule your 14 and 30 day follow-up assessments at the same time as your addiction medicine clinic appointment which will take place at Mount Sinai Beth Israel Addiction Institute. If we are able to schedule your follow-up visit at the same time as your 14 and 30 day assessment, we will perform the follow-up assessments at that visit. If we are not able to schedule your addiction medicine follow-up at 14 and 30 days from your Emergency Department visit your follow-up assessments will occur over the phone.

- What happens at each study visit is listed below.

<u>While in the Emergency Department</u>
- You will be asked to complete a series of questionnaires
- You will be asked to provide a urine specimen for drug and pregnancy testing
- You will be asked to provide 1 teaspoon of blood to check your liver function
- You will receive a brief counseling session about your alcohol use
- You will be given naltrexone, a medication used to treat your alcohol use disorder
- You will receive a referral to an out-patient addiction medicine clinic

Completing all the study assessments will take approximately 1 hour.

<u>At 14 and 30 days after your Emergency Department Visit</u>
- You will be asked to complete a series of questionnaires

Completing all the study assessments at the day 14 and 30 follow-up will take approximately 30 minutes.

<u>Daily on days 1 to 30 after your Emergency Department Visit</u>
- You will be asked about your daily alcohol intake and craving for alcohol.

Completing the daily alcohol and craving assessment will take approximately 5 minutes.

- The results of your liver function tests will be disclosed to you either during your Emergency Department visit, if they are available, or at your first scheduled follow-up.

- As part of this study we will also access your mental health and addiction medicine treatment records

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**USE OF YOUR DATA AND/OR SPECIMENS:**

The private information and/or samples collected as part of this research will never be used or shared for future research, even if the identifiable information is removed.

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**YOUR RESPONSIBILITIES IF YOU TAKE PART IN THIS RESEARCH:**

If you decide to take part in this research study you will be responsible for the following things:

- Provide accurate locator information so we can re-contact you
- Take your medication as directed by the study team
- Complete all your study assessments on time
- Attend your study visit appointments as scheduled

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**COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:**

Taking part in this research study may lead to added costs to you. The costs of your addiction medicine clinic visits and any clinical care you receive as a result of those visits will be billed to you or your insurance company.

If you agree to take part in this research study, for your time and effort, we will pay you $50 for your enrollment visit and $50 for each of your follow-up assessments at 14 and 30 days. We will also pay you $5 for each daily assessment of alcohol use and craving you complete. If you complete all daily assessments and follow-up visits you will receive $290. You will receive this compensation through a reloadable debit card, which will be provided to you at the time of your Emergency Department visit. This 'reloadable' card is NOT anonymous. For these cards, we would register you with the vendor of the debit cards, Greenphire ClinCard (MasterCard) by providing your name, address, and date of birth (DOB). This card can be used as a credit card OR as an ATM card. You would be able withdraw money from a bank through an ATM machine. Please note that banks may charge a fee for using their ATM machine. If you lose the card, you can contact Greenphire ClinCard and have the card replaced. Please read the information sheet that comes with the card for more information.

Payments will be uploaded after each follow-up assessment (14 and 30 days).



Tax law may require the Mount Sinai Finance Department to report the amount of payment you receive from Mount Sinai to the Internal Revenue Service (IRS) or other agencies, as applicable. Generally, this reporting would take place if you receive payments that equal $600 or more from Mount Sinai in a calendar year. You would be responsible for the payment of any tax that may be due.

**POSSIBLE BENEFITS:**

It is important to know that you may not get any benefit from taking part in this research. Others may not benefit either. However, possible benefits may be a decrease in alcohol use as a result of the counseling and medication that you are given.

**REASONABLY FORESEEABLE RISKS AND DISCOMFORTS:**

The major risk to you is from the naltrexone. The side effects from oral naltrexone tend to be minor and can include dizziness, nausea, headache and/or fatigue. There is also the possibility of a loss of private information; this risk always exists, but there are procedures in place to minimize the risk.

You may also feel uncomfortable answering some of the personal questions asked of you in the assessments. If you feel uncomfortable answering these questions you can always choose not to answer them.

There is also the risk of the blood draw. The risks of a blood draw include pain, bruising, and the slight possibility of infection at the place where the needle goes in. Some people feel dizzy or may faint during or after a blood draw.

There could also be social risks to you, for example, a damage to your reputation that could happen if people found out about your alcohol problem. This could result in discrimination.

There could also be economic risks to you. The standard clinical care that you receive as part of your addiction medicine follow-up will be billed to you or your insurance. You will be responsible for costs that are not covered by your insurance.

**OTHER POSSIBLE OPTIONS TO CONSIDER:**

You may decide not to take part in this research study without any penalty. The choice is totally up to you.

Instead of being in this research study, your choices may include:

- Receiving a referral to an addiction medicine provider.



**IN CASE OF INJURY DURING THIS RESEARCH STUDY:**

If you believe that you have suffered an injury related to this research as a participant in this study, you should contact the Principal Investigator.

If you are injured or made sick from taking part in this research study, medical care will be provided. Generally, this care will be billed to you or your insurance in the ordinary manner and you will be responsible for all treatment costs not covered by your insurance, including deductibles, co-payments and coinsurance. This does not prevent you from seeking payment for injury related to malpractice or negligence. Contact the investigator for more information.

**ENDING PARTICIPATION IN THE RESEARCH STUDY:**

You may stop taking part in this research study at any time without any penalty. This will not affect your ability to receive medical care at any of the Mount Sinai Health System hospitals or to receive any benefits to which you are otherwise entitled.

If you decide to stop being in the research study, please contact the Principal Investigator or the research staff. Stopping the naltrexone should not result in any negative consequences.

Withdrawal without your consent: The study doctor, the sponsor, or the institution may stop your involvement in this research study at any time without your consent. This may be because the research study is being stopped, the instructions of the study team have not been followed, the investigator believes it is in your best interest, or for any other reason. If specimens or data have been stored as part of the research study, they too can be destroyed without your consent.

**CONTACT INFORMATION:**

If you have any questions, concerns, or complaints at any time about this research, or you think the research has harmed you, please contact the office of the research team and/or the Principal Investigator at phone number 212-420-2652 or the study team at 347-346-3288.

If you experience an emergency during your participation in this research call 911 or go to the emergency room.

This research has been reviewed and approved by an Institutional Review Board. You may reach a representative of the Program for Protection of Human Subjects at the Icahn School of Medicine at Mount Sinai at telephone number (212) 824-8200 during standard work hours for any of the reasons listed below. This office will direct your call to the right person within the Mount Sinai Health System:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.

- You are not comfortable talking to the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

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**DISCLOSURE OF FINANCIAL INTERESTS:**

Sometimes, physicians/researchers receive payments for consulting or similar work performed for industry. Effective September 2014, Mount Sinai reviews only payments to an individual totaling more than $5,000 a year per entity when determining potential conflicts of interest. If you have questions regarding industry relationships, we encourage you to talk your physician/researcher or visit our website at http://icahn.mssm.edu/ where Mount Sinai publicly discloses the industry relationships of our faculty.

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**MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION:**

As you take part in this research project it will be necessary for the research team and others to use and share some of your private protected health information. Consistent with the federal Health Insurance Portability and Accountability Act (HIPAA), we are asking your permission to receive, use and share that information.

What protected health information is collected and used in this study, and might also be shared with others?

As part of this research project, the research team at the hospital(s) involved in the research will collect your name, address, telephone number, e-mail address, date of birth, medical record number, and information in your electronic medical record related to your addiction medicine treatment.

The researchers will also get information from your medical record. This could include information about your alcohol use disorder treatment including hospital admissions and out-patient treatment.

During the study the researchers will gather information by:

- Taking a medical history (includes current and past medications or therapies, illnesses, conditions or symptoms, family medical history, allergies, etc.)
- Doing a physical examination that generally also includes blood pressure reading, heart rate, breathing rate and temperature
- Completing the tests, procedures, questionnaires and interviews explained in the description section of this consent
- Reviewing HIV-related information, which includes any information indicating that you have had an HIV related test, or have HIV infection, HIV related illness or AIDS, or any information which could indicate that you have been potentially exposed to HIV
- Reviewing mental health records
- Reviewing alcohol and/or substance abuse records

Why is your protected health information being used?

Your personal contact information is important to be able to contact you during the study. Your health information and the results of any tests and procedures being collected as part of this research study will be used for the purpose of this study as explained earlier in this consent form. The results of this study could be published or presented at scientific meetings, lectures, or other events, but would not include any information that would let others know who you are, unless you give separate permission to do so.

The Principal Investigator may also use and share the results of these tests and procedures to treat you in collaboration with others in the Mount Sinai Health System.

The research team and other authorized members of The Mount Sinai Health System ("Mount Sinai") workforce may use and share your information to ensure that the research meets legal, institutional or accreditation requirements. For example, the School's Program for the Protection of Human Subjects is responsible for overseeing research on human subjects, and may need to see your information. If you receive any payments for taking part in this study, the Mount Sinai Finance Department may need your name, address, social security number, payment amount, and related information for tax reporting purposes. I*f the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.*

Who, outside Mount Sinai, might receive your protected health information?
As part of the study, the Principal Investigator, study team and others in the Mount Sinai workforce may disclose your protected health information, including the results of the research study tests and procedures, to the following people or organizations: (It is possible that there may be changes to the list during this research study; you may request an up-to-date list at any time by contacting the Principal Investigator.)

- The United States Department of Health and Human Services and the Office of Human Research Protection.

In almost all disclosures outside of Mount Sinai, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier. Some records and information disclosed may be identified with a unique code number. The Principal Investigator will ensure that the key to the code will be kept in a locked file, or will be securely stored electronically. The code will not be used to link the information back to you without your permission, unless the Institutional Review Board allows it after determining that there would be minimal risk to your privacy. The Certificate of Confidentiality obtained from the Department of Health and Human Services will not be used to prevent disclosure to local authorities of child abuse and neglect, or harm to self or others. It is possible that a sponsor or their representatives, a data coordinating office, or a contract research organization, will come to inspect your records. Even if those records are identifiable when inspected, the information leaving the institution will be stripped of direct identifiers. Additionally, *the Office of Human Subjects Protection (OHRP) of the Department of Health and Human Services as well as the Food and Drug Administration (FDA) will be granted direct access to your medical records for verification of the research procedures and data. They are authorized to remove information with identifiers if necessary*



*to complete their task. By signing this document you are authorizing this access.* We may publish the results of this research. However, we will keep your name and other identifying information confidential.

For how long will Mount Sinai be able to use or disclose your protected health information?
Your authorization for use of your protected health information for this specific study does not expire.

Will you be able to access your records?
During your participation in this study, you will have access to your medical record and any study information that is part of that record. The investigator is not required to release to you research information that is not part of your medical record.

Do you need to give us permission to obtain, use or share your health information?
NO! If you decide not to let us obtain, use or share your health information you should not sign this form, and you will not be allowed to volunteer in the research study. If you do not sign, it will not affect your treatment, payment or enrollment in any health plans or affect your eligibility for benefits.

Can you change your mind?
You may withdraw your permission for the use and disclosure of any of your protected information for research, but you must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your permission, the Principal Investigator for the research study may still use your protected information that was already collected if that information is necessary to complete the study. Your health information may still be used or shared after you withdraw your authorization if you should have an adverse event (a bad effect) from being in the study. If you withdraw your permission to use your protected health information for research that means you will also be withdrawn from the research study, but standard medical care and any other benefits to which you are entitled will not be affected. You can also tell us you want to withdraw from the research study at any time without canceling the Authorization to use your data.

It is important for you to understand that once information is disclosed to others outside Mount Sinai, the information may be re-disclosed and will no longer be covered by the federal privacy protection regulations. However, even if your information will no longer be protected by federal regulations, where possible, Mount Sinai has entered into agreements with those who will receive your information to continue to protect your confidentiality.

If as part of this research project your medical records are being reviewed, or a medical history is being taken, it is possible that HIV-related information may be revealed to the researchers. If that is the case, the following information concerns you. If this research does not involve any review of medical records or questions about your medical history or conditions, then the following section may be ignored.

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**Notice Concerning HIV-Related Information**

If you are authorizing the release of HIV-related information, you should be aware that the recipient(s) is (are) prohibited from re-disclosing any HIV-related information without your authorization unless permitted to do so under federal or state law. You also have a right to request a list of people who may receive or use



your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights at (888) 392-3644 or the New York City Commission on Human Rights at (212) 306-5070. These agencies are responsible for protecting your rights.

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Certificate of Confidentiality:

To further protect your privacy, the researchers have obtained a Certificate of Confidentiality from the Department of Health and Human Services. This is intended to ensure that your identity as a participant in this research study will not have to be disclosed as a result from a subpoena, for the purpose of identifying you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings other than to the FDA or OHRP as identified above.

The research staff will not share any of your research information or biospecimens with anyone who is not a member of the research team, including any family members or friends, other than to those identified above. However, you should know that if we learn that you or someone else is threatened with serious harm, such as a child or an elderly person being abused, the investigators may notify the appropriate authorities if necessary to protect you or others. A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. This means that you and your family must also actively protect your own privacy. If an insurer or employer learns about your research participation, and you agree that they can have your research information, then the researchers may not use the Certificate of Confidentiality to keep this information from them.

**ADULT PARTICIPANT:**
Your signature below documents your permission to take part in this research and to the use and disclosure of your protected health information. A signed and dated copy will be given to you.

| _____ | _____ | _____ |
|---|---|---|
| Signature of subject | Printed Name of Subject | Date |

**PERSON EXPLAINING STUDY AND OBTAINING CONSENT:**

| _____ | _____ | _____ | _____ |
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| Signature of consent delegate | Printed Name of consent delegate | Date | Time |

**WITNESS SECTION:**
*When a witness is required to observe the consent process, it should be documented below (for example, when subject is illiterate, visually impaired, or this document accompanies a short form consent).*

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

| _____ | _____ | _____ | _____ |
|---|---|---|---|
| Signature of Witness | Printed Name of Witness | Date | Time |