INFORMED CONSENT FORM

Official Title: Randomized, Placebo-Controlled Trial of Extended-Release Naltrexone and Monthly Extended-Release Buprenorphine for Cocaine Use Disorder (CURB-2)

NCT number: NCT05262270

Document date: 11-21-24

PART-2

Consent and Authorization to be part of a Research Study
To be conducted at
Icahn School of Medicine at Mount Sinai

Study Site Information:

Study site(s): Icahn School of Medicine at Mount Sinai

Principal Investigator (Lead Researcher): Keren Bachi, PhD

Physical Address: 1399 Park Ave, Suite 3-330, New York NY 10029 and/or 1425 Madison Ave., Fifth FL, room L5-24, New York NY 10029

Mailing Address: Keren Bachi, 1399 Park Ave, Suite 3-330 New York NY 10029

Phone: (212) 585-4669 or (212) 585-4672

Who is conducting the study? Keren Bachi, an Assistant Professor at the Icahn School of Medicine at Mount Sinai is the Lead Researcher conducting the study at the Icahn School of Medicine at Mount Sinai. The PI's email address is keren.bachi@mssm.edu and phone number is (212) 585-4669.

This information sheet will describe any information that you are required to know and is specific to the Icahn School of Medicine at Mount Sinai. You will be given Part 1 of the informed consent document that will describe the purpose of the study and what will be done. You may talk to the researchers about this study if you have any questions.

Conflict of Interest
Researchers sometimes get paid for consulting or doing work for companies that produce drugs, biologics or medical devices. If you have questions regarding industry relationships, you are encouraged to talk to the Lead Researcher or visit our website at http://icahn.mssm.edu/ where Mount Sinai publicly discloses the industry relationships of our faculty.

Site-specific Procedures and Risks

Not applicable.

Compensation

You will be compensated for your participation in this study. This compensation is for your time and to help with travel, parking, and other costs involved with you participating. You will be given a round-trip MetroCard for local travel after every study visit, in the event that a MetroCard is not available, the value of a round-trip MetroCard will be added to a physical plastic debit card.

You will be issued a physical plastic debit card that your funds are loaded onto and can be used at your discretion. When a visit is completed, funds will be approved and loaded onto your physical card. The funds will be available within 1 business day and can be used at your discretion. In order to assign a physical card to you and load funds onto the card, your name, address, and date of birth is required. Registration is restricted to those 18 years and older.

The amount will be based on **completed** assessments. For the schedule of compensation for each **COMPLETED** assessment, please refer to Part 1 of the consent form.

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 happens 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.

Costs – Will taking part in this study cost anything?

Study participants will be provided with study medication and study related procedures at no cost to them or their insurance.

The sponsor will provide the study drug/device at no cost during this study. At the end of your participation, you must return all unused study drug/device to the researcher (if applicable).

What if a research-related injury occurs?

The researchers have taken steps to minimize the known or expected risks. However, you may still experience problems or side effects, even though the researchers are careful to avoid them. In the event of a research-related injury or if you experience an adverse reaction, please immediately contact the research team. See the section "Contact Information" for phone numbers and additional information. You may also need to tell your regular doctors.

If you are injured or made sick from taking part in this research study, medical care will be provided. This care may be billed to you or your insurance. Depending on the circumstances, this care may be provided at no cost to you. The research team has no plans to give you money if you are injured. The Lead Researcher can provide you with more information.

Neither the University of Texas Southwestern Medical Center, affiliates, or the Icahn School of Medicine at Mount Sinai have a program to pay you if you are hurt or have other bad results from being in the study. If you sign this form, you do not give up your right to seek additional compensation if you are harmed as a result of being in this study.

Additional information about your local site:

As part of this study, some of your private and/or protected health information will be obtained, used, and shared with your permission. There is a Federal Health Insurance Portability and Accountability Act (HIPAA) that makes sure this is done correctly and safely.

What is protected health information (PHI)?
PHI is the combination of two things:

1. PHI contains information that identifies you. It will be used to contact you and link you to your health information, like name, date of birth, medical record number, and address.
2. PHI also contains health information, including information about your mental and physical health from your visits to doctors or hospitals, or from study visits.

Every time you visit a hospital or your doctor, PHI is created and recorded in your medical record by your healthcare providers. In the same way, the PHI created as part of this study will be linked to who you are and your medical information.

<u>What PHI is collected and used in this research study, and might also be shared with others?</u>
As part of this research project, the research team at the hospital(s) involved in the research will collect your name, address, telephone/fax numbers, birthdate, e-mail, social security number for payment purposes, medical records number. The researchers will also get information from your medical record.

During the study the researchers will gather information by:

- Completing the tests, procedures, questionnaires and interviews explained in the description section of this consent.
- Reviewing genetic tests
- Reviewing mental health records
- Reviewing alcohol and/or substance abuse records

Why is your PHI being used?

Researchers need the information that identifies you so they can contact you during the study. They need your health information and the results of any tests and procedures being collected as part of this study to answer the questions posed in the study. The purpose of the study is discussed earlier in this consent form. Before researchers analyze the data, they remove any information that would let others know who you are or that you took part in the study. If researchers publish or present study results at scientific meetings, lectures, or other events, their presentations would not include any information that would let others know who you are, unless you give separate permission to do so.

The Lead Researcher may also use and share the results of these tests and procedures with other healthcare providers at Mount Sinai who are involved in your care or treatment. 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 Mount Sinai Program for the Protection of Human Subjects is responsible for overseeing research on human participants 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.
- If the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.

Who, outside Mount Sinai, might receive your PHI?

As part of the study, the Lead Researcher, research team and others in the Mount Sinai workforce may disclose your PHI, 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 Lead Researcher.)

- The Sponsor (Dr. Trivedi) and the Funding Agency (NIDA). The Sponsor includes any people, entities, groups or companies working for or with the Sponsor or owned by the Sponsor. The Sponsor will receive written reports about your participation in the research. The Sponsor may look at your health information to assure the quality of the information used in the research.
- The Research offices at the University of Texas Southwestern Medical Center.
- The members of the local study team.
- Indivior and Alkermes, the companies that make the study medications.
- The following collaborators at other institutions that are involved with the study: University of California, Los Angeles, and UT Health San Antonio.
- DSMB/DSMC, the committee that checks the study data on an ongoing basis, to determine if the study should be stopped for any reason.
- The Institutional Review Board (IRB), Human Research Protection Program Office and the Compliance Office of the University of Texas Southwestern Medical Center, and other groups that oversee how research studies are carried out.

- The Food and Drug Administration (FDA) and other U.S. and international governmental regulatory agencies involved in overseeing drug or device research.
- The United States Department of Health and Human Services and the Office of Human Research Protection.
- Representatives of domestic and foreign governmental and regulatory agencies may be granted direct access to your health information for oversight, compliance activities, and determination of approval for new medicines, devices, or procedures.

Parts of your PHI may be photocopied and sent to a central location, or it may be transmitted electronically, such as by e-mail or fax. The groups receiving your health information may not be obligated to keep it private. They may pass information on to other groups or individuals not named here.

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 Lead Researcher 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 (IRB) 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, a contract research organization, may 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, OHRP, 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. OHRP and FDA are authorized to remove information with identifiers if necessary to complete their task. By signing this document, you are authorizing this access. The results of this research may be published. However, your name and other identifying information will be kept confidential.

For how long will Mount Sinai be able to use or disclose your PHI?
This permission to use your personal health information expires when the research ends, and all required study monitoring is over.

Will you be able to access your records?
During your participation in this study, you will not be able to access your medical records. This is done to prevent the knowledge of study results from affecting the reliability of the study. Your information will be available should an emergency arise that would require your treating physician to know this information to best treat you. You will have access to your medical record and any study information that is part of that record when the study is over or earlier, if possible. The research team is not required to release research information to you that is not part of your medical record.

Do you need to give us permission to obtain, use or share your PHI?
NO! If you decide not to let the research team obtain, use or share your PHI, 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?
If you decide to stop being in the study, please contact the Lead Researcher or the research staff.
The research team may ask you whether they can continue to collect information from your medical record. You will also have to decide if you wish to limit the continued use of the information collected during the study. Under US privacy laws you may also withdraw your permission for the researchers to use and share any of

your protected information for research, but you must do so in writing to the Lead Researcher at the address on the first page.

Even if you withdraw your permission, the Lead Researcher may still use the information that was already collected, but only to complete this research study. Your health information may still be used or shared after you withdraw your authorization if you have an adverse event (a bad effect) from taking part in the research study.

If you have not already received it, you will also be given The Hospital's Notice of Privacy Practices that contains more information about how The Hospital uses and discloses your PHI.

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, where possible, Mount Sinai has entered into agreements with those who will receive your information to continue to protect your confidentiality.

If researchers are reviewing your medical records or asking questions about your medical history or conditions, it is possible that they may learn information related to your HIV status. If that is the case, the following information concerns you. If researchers are not reviewing your medical records or asking questions about your medical history or conditions, then you may ignore the following section.

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.

The Genetic Information Nondiscrimination Act (GINA) is a federal law that will protect you in the following ways:

- Health insurance companies and group plans may not request genetic information from this research;
- Health insurance companies and group plans may not use your genetic information when making decisions regarding your eligibility or premiums;
- Employers with 15 or more employees may not use your genetic information when deciding to hire, promote, or fire you or when setting the terms of your employment.

GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination based on an already-diagnosed genetic condition or disease.

Any further disclosure of genetic test results or information derived from genetic tests to persons or organizations not named on the informed consent shall require the further informed consent of the participant. Family members of an individual who provided a stored tissue sample will not be contacted for clinical, research, or other purposes without consent of the participant.

What happens to information collected about me?

The following information explains how your medical and health records and the research data collected about you for the study may be used and disclosed.

Regulatory authorities, such as the Food and Drug Administration, as well as members of the ethics committee/institutional review board ("IRB"), employees at the study site, representatives of the Sponsor (Dr. Trivedi), and representatives of the funding agency (NIDA) may review your medical records to verify study procedures and/or data without violating your confidentiality, to the extent permitted by the applicable laws and regulations. By signing this consent form, you are authorizing such access.

Researchers will keep your personal medical records and a list that links each participant's name to his or her code number for at least 15 years.

After your encoded Protected Health Information is disclosed to the Sponsor and Funding Agency, the results of the study may be reanalyzed later and may be combined with the results of other studies. The Funding Agency and people who work with the Funding Agency may use the results of this study for other research purposes, including:

- Reviewing the safety or effectiveness of the study medication and other products or therapies;
- Evaluating other products or therapies for patients;
- Developing a better understanding of disease; and
- Improving the design of future clinical trials

You are participating in a multi-site research study and your information may also be shared with researchers at associated sites for purposes of data analysis. Your records will be kept by the Sponsor and Funding Agency for as long as necessary. During that time, they will be kept confidential to the extent permitted by law.

De-identified data (which cannot be used to identify you) from this study will be available to researchers on another website, https://datashare.nida.nih.gov/ after the study is complete and the data analyzed. The primary outcome(s) publication for the full study will also be included along with study underlying primary data in the data share repository, and it will also be deposited in PubMed Central http://www.pubmedcentral.nih.gov/. These websites will not include information that can identify you. You can view these websites at any time.

The results of the study may be published in a medical book or journal or presented at meetings for educational purposes. If the results of the study are published, you will not be personally identified, and your identity will not be disclosed.

By signing this form, you are permitting direct access to and use of your medical records and information by the individuals and entities identified above for the purposes described. These entities may post information on your medical records regarding the medications you are taking.

By signing this document, you also give permission to the researchers to disclose the study results to the Sponsor, the Funding Agency, and representatives of the Sponsor or Funding Agency. The study results will not contain information that directly identifies you. The Sponsor will prevent those that do not need to access the results from viewing the results. Neither the Sponsor nor the Funding Agency will attempt to identify the study participant.

In addition to being used to complete this research study, your personal information (such as, name, address, date of birth, social security number), study data, and samples (blood, tissue, urine, saliva, or any other body matter.) may also be used and shared for additional (future) research. Before anything is shared, all of your identifying personal information will be removed and it will be replaced with a code. Researchers are not planning on giving you the details of any of this future research nor the results. That means that a research project might be done that you would not consent to if provided with the details of that research project. If you

do not want any future research to be done with your data and/or samples, even with your identity removed, please do not sign this consent form or take part in the study.

To do more powerful research, it is helpful for researchers to share data and/or samples from the people they study. They do this by putting data and/or samples into a repository. A repository is where something is stored safely for a specified period of time. Data and/or samples from one study may be stored in a repository along with data and/or samples from other studies. Sample repositories are commonly called biobanks, while data repositories are commonly called databases. Researchers can then use the data and/or samples from multiple studies to learn even more about health and disease. If you agree to take part in this study, some of your genetic and health information might be placed into one or more scientific databases, but they will not share your direct identifiers (for example, name, address, date of birth). These databases are maintained by either Icahn School of Medicine at Mount Sinai, another institution, the federal government, or private companies. Any researcher who wants to do a study using data and/or samples from the repository must apply for permission. There are different ways of reviewing such requests. Researchers with an approved study may be able to see and use your data, along with that from many other people. Researchers may use your samples for genetic sequencing and other experimental testing. Researchers will always have a duty to protect your privacy and to keep your information confidential, but there are always risks associated with data and/or sample collection and sharing. They are described in more detail in Part 1 of this consent form.

HIV Testing
As part of this research study, your blood will be tested for evidence of HIV, the virus that causes AIDS. People can get HIV through unprotected sexual contact with someone who has HIV, and through contact with blood (as in sharing needles including for piercing, tattooing, and injecting drugs). People who are pregnant with HIV infections can transmit HIV to their infants during pregnancy, delivery or while breastfeeding. There are treatments for HIV/AIDS that can help people stay healthy. People with HIV/AIDS can adopt safe practices to protect uninfected and infected people in their lives from getting HIV or getting infected with a different strain of HIV.

By law, positive test results for HIV/AIDS (as well as other communicable diseases such as hepatitis B, hepatitis C, and syphilis) are reported to the NYS Department of Health so they can study how people get and transmit the disease and notify sexual or needle-sharing partners they may have been exposed. If you wish to be tested anonymously for HIV/AIDS, the research team can refer you to a public testing center. New York State law protects the confidentiality of HIV test results and other related information. It is illegal to discriminate against a person based on their HIV status and services are available to help if this happens. If you decide to not get tested for HIV or any other infectious disease, you can still participate in this study.

Reproductive Risks (continued from Consent #1):
As previously mentioned, participants of childbearing potential: You should not become pregnant while taking part in this study because the research team does not know how the study drugs/procedures could affect a fetus, if a participant becomes pregnant during the study.

In addition, there are concerns for sexually active individuals: Drugs can be found in semen and alter sperm. Since you are taking part in a study using experimental drugs or treatments, it is recommended that 1) you use a condom, 2) you do not get a partner pregnant or expose them to semen, and 3) you do not donate semen. These recommendations apply both while you are taking the study drug, and for 4 months after you stop taking the study drug. This is because levels of the study drug may be present in the sperm and/or semen even after you stop taking the study drug. You are encouraged to tell your partner(s) and/or their doctor(s) that you are participating in this clinical trial.

Contact Information – Who can you contact if you have questions, concerns, comments, or complaints?

If you have questions now, feel free to ask us. If you have additional questions, concerns, comments, or complaints later or you wish to report a problem which may be related to this study please contact: keren.bachi@mssm.edu and (212) 585-4669.

Primary contact:
Keren Bachi, PhD can be reached at (212) 585-4669.

If primary is not available, contact
Christopher Kudrich, PA can be reached at (212) 585-4672.

To revoke authorization, you can mail your request to:
Keren Bachi
1399 Park Ave, Suite 3-330
New York NY 10029

Icahn School of Medicine at Mount Sinai IRB
Mailing Address:
One Gustave L. Levy Place
Box 1081
New York, NY 10029

This form is yours to keep.

Comprehension Quiz Questionnaire

CTN-0109: CURB-2
COMPREHENSION QUESTIONS

- My participation in this study is completely voluntary. ☐ True ☐ False
- Information about me will NOT be given to others under any circumstances. ☐ True ☐ False
- I will be asked to attend clinic visits 2 times per week during the 8-week medication phase. ☐ True ☐ False
- There are no risks or discomforts if I participate in this research study. ☐ True ☐ False
- If I do not participant in this study, there are other possible treatment options for me. ☐ True ☐ False
- The study doctor may end my participation in this research study to protect my health and safety, even if I would like to continue. ☐ True ☐ False
- I will receive compensation for my study participation. ☐ True ☐ False
- The EEG study procedure will be available across all study sites. ☐ True ☐ False

Research Consent & Authorization Signature Section
Signatures - Permission for specific study procedures

You will be given a copy of this consent form to keep.

Do you agree to let us collect a blood sample for NIDA genetic testing? *(Please initial either yes or no.)*

Yes Initials_____

No Initials_____

Do you agree to allow your blood samples stored at the UTSW Repository to be used for future genetic research? *(Please initial either yes or no.)*

Yes Initials_____

No Initials_____

If EEG is offered, do you agree to part-take in it? *(Please initial either yes or no or indicate if not applicable.)*

Yes Initials_____

No Initials_____

or

Not Applicable Initials_____

Do you agree to let us contact your other doctors about your participation in this study? *(Please initial either yes or no or indicate if not applicable.)*

Yes Initials_____

No Initials_____

or

Not Applicable Initials_____

Do you agree to be contacted for future studies if the researchers think you may qualify? *(Please initial either yes or no.)*

Yes Initials_____

No Initials_____

If you agree to participate in this research and agree to the use of your protected health information in this research, sign this section. You will be given a copy of Part 1 and Part 2 of this to keep. You do not waive any of your legal rights by signing this form.

SIGN THIS FORM ONLY IF THE FOLLOWING STATEMENTS ARE TRUE:

- You have read (or been read) the information provided above which is printed in English. This is a language that you read and understand.
- Your questions have been answered to your satisfaction about the research and about the collection, use and sharing of your protected health information.
- You have freely decided to participate in this research, or you are voluntarily giving your consent for another person to participate in this study because you believe this person would want to take part if able to make the decision and you believe it is in this person's best interest.
- You understand that a copy of the Part 1 and Part 2 signed consent document, information about this study, and the results of any test or procedure that may affect your medical care, may be included in your medical record. Information in your medical record will be available to health care providers and authorized persons including your insurance company.
- You authorize the collection, use and sharing of your protected health information (another person's protected health information) as described in this form.

Adult Signature Section

Printed Name of Participant	Signature of Participant	Date	Time AM PM
Printed Name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date	Time AM PM

Blind or Illiterate Signature Section *At the time of consent, also complete this section if consent is obtained from an individual who is unable to read and/or write but can otherwise communicate and/or comprehend English (e.g., blind, physically unable to write, etc.)*

Declaration of witness:

By signing below, I confirm I was present for the entire consent process. The method used for communication (e.g., verbal, written, etc.) with the participant was:

The specific means (e.g., verbal, written, etc.) by which the participant communicated agreement to participate was:

Printed Name of Witness	Signature of Witness	Date	Time AM PM