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

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PART-2

Consent and Authorization to be part of a Research Study
To be conducted at the University of Illinois at Chicago

Who is conducting the study?
Dr. Niranjan S. Karnik, MD, PhD, a Psychiatrist at the University of Illinois at Chicago (UIC) is the Principal Investigator conducting the study at UIC. The PI's email address is nkarnik@uic.edu and phone number is (312) 273-0185.

This information sheet will describe any information that you are required to know and is specific to UIC. 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.

Payment / Compensation

You will receive payment for your participation in the form of a prepaid debit card according to the payment table in Part 1 of the Informed Consent Document for each **completed** study visit. If you do not finish the study, you will be compensated for the visits you have completed. If you complete the study, you will receive up to a total of $1603.00. You will receive your payment on a prepaid debit card at the **COMPLETION/END** of each study visit. The amount of compensation you will receive at each visit will be based on **completed** assessments. Please see the schedule of compensation for each **COMPLETED** assessment. We may need to collect information about you including your name, address, date of birth, and social security number or Taxpayer Identification Number (TIN) in order to issue your compensation and for tax reporting purposes to the United States Internal Revenue Service (IRS). This information may be shared with a third-party solely for the purposes of compensation processing. All information will be stored in a secure fashion.

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

Please note that if you are on record as owing money to the State of Illinois, such as for back child support or a delinquent student loan, the payment may be applied to that debt.

An IRS Form 1099 will be sent to you if your total payments are $200 or more in a calendar year, unless it's a reimbursement.

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 free of charge 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?

If you get ill or injured from being in the study, UIC will help you get medical treatment. You should let the study doctor know right away that you are ill or injured. If you believe you have become ill or injured from this study, you should contact Dr. Niranjan Karnik, MD, PhD at telephone number (312) 273-0185. In the event that you experience an emergency related to your participation in the study, you should go to your nearest emergency room or dial 911.

You should let any health care provider who treats you know that you are in a research study. If you do seek

medical treatment, please take a copy of this document with you because it may help the doctors where you seek treatment to treat you. It will also provide the doctors where you seek treatment with information they may need if they want to contact the research doctors.

You or your health insurance plan will be billed. No money has been set aside to pay the costs of this treatment. Health insurance plans may or may not cover costs of research-related injury or illness. You should check with your insurance company before deciding to participate in this research study. Costs not covered by insurance could be substantial.

UIC has not set aside any money to pay you or to pay for your treatment if you get ill or injured from being in the study. There are no plans for the University to provide other forms of compensation (such as lost wages or pain and suffering) to you for research related illnesses or injuries. The only exception to this policy is if it is proven that your injury or illness is directly caused by the negligence of an UIC employee.
By signing this form, you are not giving up any legal rights to seek compensation of injury.

Additional information for the local research site:

Research policies require that private information about you be protected, and this is especially true for your health information. However, the law sometimes allows or requires others to see your information. The information given below describes how your privacy and the confidentiality of your research records will be protected in this study. Medical information collected during this study and the results of any test or procedure that may affect your medical care may be included in your medical record. The information included in your medical record will be available to health care providers and authorized persons including your insurance company.

What is Protected Health Information (PHI)?

Protected Health Information is information about a person's health that includes information that would make it possible to figure out who's it is. According to the law, you have the right to decide who can see your protected health information. If you choose to take part in this study, you will be giving your permission to researchers to see and use your health information for this study. In carrying out this study, the health information we will see and use about you will include: your medical history, blood work, information we get from your medical record, information contained in your underlying medical records related to your medical history and prior treatments, information that is created or collected during your participation in the study including medical and treatment history, information you give us during your participation in the study such as during interviews or from questionnaires, results of blood tests; demographic information like your age, marital status, the type of work you do and the years of education you have completed.

We will get this information by asking you or by looking at your medical records as relevant.

Will health information about you be created, used or shared with others during this study?

State and federal laws, including the Health Insurance Portability and Accountability Act (HIPAA), require researchers to protect your health information. This section of this form describes how researchers, with your authorization (permission), may use and release (disclose or share) your protected health information in this research study. By signing this form you are authorizing Dr. Niranjan Karnik, MD, PhD and their research team to create, get, use, store, and share protected health information that identifies you for the purposes of this research.

The health information includes all information created and/or collected during the research as described within this consent form and/or any health information in your medical record. If you receive medical care from other institutions and you have agreed to share your medical record information through EPIC Care Everywhere (as

described further in the UI Health Notice of Privacy Practices), the information from the other institution(s) may be used in the research. The specific information includes:

- Personal identifiers (your name, address, phone number, date of birth, social security number, medical record number), dates of service, and demographic information (e.g., race, ethnicity, financial information, education information, insurance information, marital status, type of work, etc.)
- Results of physical examinations
- Medical history
- blood tests, x-rays and other diagnostic and medical procedures including ECG, EEG, lab tests, and genetic samples
- certain health information indicating or relating to a particular condition as well diaries, calendars, questionnaires, and computerized assessments
- Records about study medication or drugs
- Records about study devices
- Billing information
- HIV/Hepatitis testing results
- Substance Use Disorder information including all substance use
- Mental Health information
- Genetic Testing information
- Genetic Counseling information
- Sexual Assault/Abuse
- Domestic Abuse of an Adult with a Disability
- Child Abuse and Neglect
- Sexually Transmitted Illnesses
- Pregnancy
- Birth Control

Some of the information collected in this research study will be stored in the electronic medical record and may then be visible to healthcare providers and staff who are not associated with this research study, both at UIC and at other hospitals or healthcare institutions.

During the conduct of the research, the researchers may use or share your health information:

- With each other and with other researchers involved with the study.
- The members of the local study team.
- With local laboratories and pharmacies in order to process and analyze samples and dispense study-related medications.
- With law enforcement or other agencies, when required by law.
    - As required by law, if you test positive for an HIV Infection, Hepatitis B, Hepatitis C, Chlamydia, and/or Gonorrhea, our staff must report this result to the Chicago Department of Public Health and the Illinois Department of Public Health.
- With the sponsor/funding agency of the research, National Institute on Drug Abuse (NIDA) / University of Texas Southwestern Medical Center and its agents or contractors, as required to conduct the research and/or confirm the results of the research.
- With non-UIC collaborators of the research study:
    - 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.

  - 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.
  - 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.
- Representatives of the university committee and office that reviews and approves research studies, the Institutional Review Board (IRB) and Office for the Protection of Research Subjects.
- Other representatives of the State and University responsible for ethical, regulatory, or financial oversight of research.
- United States Government Regulatory Agencies, including but not limited to the Office for Human Research Protections (OHRP) and Food and Drug Administration (FDA).

If you decide to participate in this study, you will be giving your permission for the groups named above, to collect, use and share your health information. If you choose not to let these groups collect, use, and share your health information as explained above, you will not be able to participate in the research study.

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.

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.

If all information that identifies you is removed from the research data, the remaining information is no longer subject to the limits of this Authorization or to the HIPAA privacy laws. Therefore, the de-identified information may be used and released by the researchers (as permitted by law) for other purposes, such as other research projects.

During your participation in this research, you will not have access to the research records or information that is not usually kept in your medical record. However, this information is available to your doctor in the case of an emergency. The researcher may provide you with access to the research records or information related to this research once the study is done.

What happens to information collected about me?
Some of the laboratory results and a copy of the informed consent will be stored in the electronic medical record of University of Illinois Health (UIH). The informed consent document and lab results will become a part of your medical record and may remain visible to providers and healthcare institutions who are not affiliated with this study. 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.

Can I get a copy of my medical records?
You have a right to see and make copies of your medical records. However, to ensure the reliability of the study, you agree that you will not be able to see or copy your records related to the study until the Sponsor and Funding Agency have completed all work related to the study. At that time, you may ask to see the study files related to your participation in the study, and you may ask the researchers to correct any study-related information about you that is wrong.

How long will your PHI be used?
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. You may cancel this authorization at any time according to the appropriate section on the following page. By signing this form, you agree to let us use and disclose your health information for purposes of the study until the end of the study. This permission to use your personal health information expires when the research ends, and all required study monitoring is over.

How will your PHI be protected?
To protect your privacy, the study staff will use code numbers instead of your name, to identify your health information. These code numbers will be used on any photocopies of your study records, and other study materials containing health information that are sent outside of the University of Illinois at Chicago (UIC) for review or testing.

The researchers agree to protect your health information and will only share this information as described within this research consent/authorization form.

When your health information is given to people outside of the research study, those agencies that receive your health information may not be required by federal privacy laws (such as the Privacy Rule) to protect it. They may also share your information with others without your permission, if permitted by laws that they have to follow.

What if I change my mind and do not want my information used or disclosed?
Your Authorization for release of health information for this research study does not have an expiration date, but can be canceled sooner if you decide to withdraw your permission.

You may change your mind and cancel this Authorization at any time. To cancel this Authorization, you must write to:

Dr. Niranjan S. Karnik, MD, PhD
1747 W. Roosevelt Rd.
WROB-247
Chicago, IL 60608

If you cancel this Authorization, you may no longer be allowed to take part in the research study. Even if you cancel this Authorization, the researchers may still use and disclose health information they have already obtained as necessary to maintain the integrity and reliability of the research and to report any adverse (bad) effects that may have happened to you.

Right to Refuse to Sign this Authorization
You do not have to sign this Consent/Authorization. However, because your health information is required for research participation, you cannot be in this research study if you do not sign this form. If you decide not to sign this Consent/Authorization form, it will only mean you cannot take part in this research. Not signing this

form will not affect your non-research related treatment, payment or enrollment in any health plans or your eligibility for other medical benefits.

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

For questions, concerns, or complaints about the study, please contact the Site Principal Investigator, Dr. Niranjan Karnik, MD, PhD at (312) 273-0185 or nkarnik@uic.edu and Site Study Coordinator, Veronica Bucci, BS at 312-355-4055 or vmbucci@uic.edu.

If you have a research related injury, you should immediately contact the Site Principal Investigator, Dr. Niranjan Karnik, MD, PhD at (312) 273-0185.

If you have questions about your rights as a study subject; including questions, concerns, complaints, or if you feel you have not been treated according to the description in this form; or to offer input you may call the UIC Office for the Protection of Research Subjects (OPRS) at 312-996-1711 or 1-866-789-6215 (toll-free) or e-mail OPRS at uicirb@uic.edu.

If you have questions or concerns regarding your privacy rights under HIPAA, you should contact the University of Illinois HIPAA Privacy Office at (844) 341-2201 or hipaa@uillinois.edu.

Participants will be contacted by study staff via participants' preferred method (phone/text/email).

To revoke authorization, please send a letter to:
Dr. Niranjan S. Karnik, MD, PhD
1747 W. Roosevelt Rd.
WROB-247
Chicago, IL 60608

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 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 subject was:

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

Printed Name of Witness	Signature of Witness	Date	Time AM PM