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: 05-20-24

PART-2

Title of Study: NIDA CTN Protocol 0109: Randomized, Placebo-Controlled Trial of Extended-Release Naltrexone and Monthly Extended-Release Buprenorphine for Cocaine Use Disorder (CURB-2)

Consent and Authorization to be part of a Research Study
to be conducted at
University of Texas Southwestern Medical Center

Who is conducting the study?
Sidharth Wakhlu, MD, Department of Psychiatry, University of Texas Southwestern Medical Center, is the Principal Investigator (PI) responsible for conducting this study. The PI can be contacted by email (sidarth.wakhlu@utsouthwestern.edu) or phone (214.645.6905).

This information sheet will describe any information that you are required to know and is specific to the University of Texas Southwestern Medical Center (UTSW). 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.

Your doctor is a research investigator in this study. He is interested in both your medical care, welfare, and the conduct of this research study. At any time, you may discuss your care with another doctor who is not part of this research study. You do not have to take part in any research study offered by your doctor.

Compensation

You will be compensated for your participation in this study. This compensation is for your time and to help with costs involved with your participation Additionally, assistance with transportation may be provided at the discretion of the study team.

You will be issued a UT Southwestern Greenphire ClinCard, which can be used as a credit or debit card. Compensation will be credited to the card at the **completion / end** of each study visit. Your name, address, date of birth, and social security number will be shared with a third-party solely for the purposes of compensation processing. Your social security number is needed to process your payments. Study payments are considered taxable income and are reportable to the IRS. Should you decide not to provide your social security number, or your social security number does not match the name on file with the IRS, your study participation payment will be decreased in accordance with the current IRS tax rate. All information will be stored in a secure fashion.

Your Greenphire ClinCard will be credited at the end of each study visit. 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.

Please note that if you are on record as owing money to the State of Texas, 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 $600 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 at no cost to you during this study.

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 your study doctor. 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. We have no plans to give you money if you are injured. The investigator can provide you with more information.

Neither the University of Texas Southwestern Medical Center or affiliates 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

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 (PHI) is information about a person's health that includes information that would make it possible to figure out who it belongs to. 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.

How will your PHI be shared?

Because this is a research study, we will be unable to keep your PHI completely confidential. We may share your health information with people and groups involved in overseeing this research study including:

- The Sponsor (Dr. Trivedi) and the Funding Agency (National Institute on Drug Abuse, 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.
- 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.

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.

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
- 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.

What if I change my mind and do not want my information used or disclosed?
The permission to use or disclose your protected health information for this study does not have an expiration date. If you no longer want to share your protected health information, you may cancel your permission at any time by writing to the researchers at your research site.

Sidarth Wakhlu, MD
University of Texas Southwestern Medical Center
Center for Depression Research and Clinical Care
1440 Empire Central Drive,
Level 3 Mood Disorders,
Dallas, Texas, 75247

If you cancel your permission after you have started in the study, the researchers will stop collecting your health information. Although they will stop collecting new information about you, they will need to use the information they have already collected to evaluate the study results. If you start the study and then cancel your permission, you will not be able to continue to participate in the study or receive any medications as part of the study. This is because the researchers would not be able to collect the information needed to evaluate the study medications.

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 previous 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 UT Southwestern Medical Center for review or testing.

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. 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 Texas Department of State Health Services.

Do you have to allow the use of your health information?
You do not have to allow (authorize) the researchers and other groups to see and share your health information. If you choose not to let the researchers and other groups use your health information, there will be no penalties, but you will not be allowed to participate in the study.

After you enroll in this study, you may ask the researchers to stop using your health information at any time. However, you need to say this in writing and send your letter to Sidharth Wakhlu, MD. If you tell the researchers to stop using your health information, your participation in the study will end and the study staff will stop collecting new health information from you and about you for this study. However, the study staff will continue to use the health information collected up to the time they receive your letter asking them to stop.

Can you ask to see the PHI that is collected about you for this study?
The federal rules say that you can see the health information that we collect about you and use in this study. Contact the researchers if you have a need to review your PHI collected for this study.

Because of the type of research, you can only access your PHI when the study is done. At that time, you have the right to see and copy the medical information we collect about you during the study, for as long as that information is kept by the researchers and other groups involved.

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:

Primary contact:
Sidarth Wakhlu, MD at Sidarth.Wakhlu@UTSouthwestern.edu or 214.645.6905

Secondary contact:
If primary is not available, contact
McKenna Dougherty at McKenna.Dougherty@UTSouthwestern.edu or 469.602.2362
Isabella Huddleston at Isabella.Huddleston@UTSouthwestern.edu or 817.262.9157

Additionally, you may also contact the Department of Psychiatry after-hours or during holidays at 214.648.5555.

The University of Texas Southwestern Medical Center Human Research Protection Program (HRPP) oversees investigational treatment on patients. HRPP and Institutional Review Board (IRB) representatives will answer any questions about your rights as a treatment patient, and take any concerns, comments, or complaints you may wish to offer. You can contact the HRPP by calling the office at 214.648.3060.

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 participate 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

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 take part 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_____

Statement of Consent

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 form 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

Title of Study: NIDA CTN Protocol 0109: Randomized, Placebo-Controlled Trial of Extended-Release Naltrexone and Monthly Extended-Release Buprenorphine for Cocaine Use Disorder (CURB-2)

Consent to be part of a Research Study
To be conducted at
University of California, Los Angeles
910 Vine Street Clinic

Who is conducting the study? Jesse Clark MD, MSc, Associate Professor-in-Residence at UCLA is the Principal Investigator conducting the study at the Vine Street Clinic. The PI's email address is uclavsc@mednet.ucla.edu. and phone number is 323-461-3106.

This information sheet will describe any information that you are required to know and is specific to the Vine Street Clinic. 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.

California Experimental Subject's Bill of Rights

California requires that every research participant be provided with a copy of the California Experimental Subject's Bill of Rights. The California Experimental Subject's Bill of Rights is included as part of the consent documents.

Confidentiality Statement

Your records may be inspected by the Research Advisory Panel of California.

Compensation

To compensate you for your time and travel, you will be paid in cash. 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. If a visit is not completed entirely, the visit compensation may be prorated for the screening visit only.

An IRS Form 1099 will be sent to you if your total payments are $600 or more in a calendar year, unless it's a reimbursement.

Costs – Will taking part in this study cost anything?

The study will pay for the cost of supplying and administering the study drug, and all required study items and services as described in this consent form.

What if a research-related injury occurs?

It is important that you promptly tell the researchers if you believe that you have been injured because of taking part in this study. You can tell the researcher in person or call him/her at the number(s) listed above.

If you are injured as a result of being in this study, UCLA will provide necessary medical treatment.

The costs of the treatment may be covered by the University of California or billed to you or your insurer just like other medical costs, depending on a number of factors. The University does not normally provide any other form of compensation for injury. For more information about this, you may call the UCLA Office of the Human Research Protection Program at 310-206-2040 or email mirb@research.ucla.edu.

Additional information about your local site:

You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

Information and/or specimens collected from you for this study will become the property of the University of California or a third party designated by the University. The information/specimens may be used in this research or other research, and shared with other organizations. Under state law you will not share in any commercial value or other compensation from products developed using the information/specimens.

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.

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. 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 Study Sponsor and people who work with the Study Sponsor 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. 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 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.

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 UT Southwestern Medical Center for review or testing

Privacy and Confidentiality
California regulations require laboratories to report new cases of HIV to the county public health department. HIV test result reporting includes CD4+ count (or T-cell count), viral load, and viral genotype for positive results. The reports include details like: your name, social security number, and other identifying information. Information about these new infections is used to track these diseases statewide and nationwide. Other than this required reporting, your results will be treated confidentially by the study staff. Personally identifying information will not be reported to other departments or agencies. For a full list of reportable conditions, go to the following link:

https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/ReportableDiseases.pdf

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: the Vine Street Clinic at 323-461-3106.

Primary contact:
Jesse Clark MD, MSc can be reached at 323-461-3106.

If primary is not available, contact the pager service at UCLA at (310) 825-6301 and ask that Dr. Clark be paged.

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 participate 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 Signature Section

Signatures - Permission for specific study procedures

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

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, sign this section. You will be given a copy Part 1 and Part 2 of this form and the California Experimental Subject's Bill of Rights 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.
  You have read (or have been read) the California Experimental Subject's Bill of Rights, 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.

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

University of California, San Francisco, and San Francisco Department of Public Health
Consent to Participate in a Research Study
To be conducted at
Center on Substance Use and Health (CSUH)

Who is conducting the study? Phillip Coffin, MD, the Director of Substance Use Research at the Center on Substance Use and Health is the Principal Investigator (PI) conducting the study at the San Francisco Department of Public Health. The PI's email address is phillip.coffin@sfdph.org and phone number is 628-217-6282.

This information sheet will describe any information that you are required to know and is specific to the San Francisco Department of Public Health. 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.

Site-specific Procedures and Risks

All in-person study procedures will be done at the Center on Substance Use and Health at 25 Van Ness Ave., San Francisco.

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. The amount you will be paid for each study activity can be found in a table in Part 1 of the consent form. You will be paid at the end of each study visit. In addition to payment for completing individual study tasks, you may receive an attendance bonus for completing ALL study activities in a given block of time. These bonuses are also detailed in the table below. You will not be paid for study tasks you do not complete, including if you are unable to complete the study.

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

Because your total payments may exceed $600 in a calendar year, it requires reporting for tax purposes, for which you will need to complete a W-9 form that includes your social security number. An IRS Form 1099 will be sent to you if your total payments are $600 or more in a calendar year, unless it's a reimbursement.

Costs – Will taking part in this study cost anything?

The sponsor has agreed to pay for all items associated with this research study; you or your insurer will not be billed. The sponsor will provide the study drugs (XR-NTX and XR-BUP or placebo) and administration at no cost to you.

What if a research-related injury occurs?

It is important that you tell your study doctor, Phillip Coffin, if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call him/her at 628-217-6282.

If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs,or covered by the University of California or the study sponsor, depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Institutional Review Board at 415- 476-1814.

Additional information about your local site:

What if I become incarcerated during the study?
Under California law, if you become incarcerated while participating in this study, you will not be able to continue your participation in the study.

Privacy and Confidentiality
A UCSF medical record will be created because of your participation in this study. Your consent form and some of your research test results will be included in this record. Therefore, your other UCSF doctors may become aware of your participation. Hospital regulations require that all health care providers treat information in medical records confidentially.

California regulations require laboratories to report new cases of HIV to the county public health department. HIV test result reporting includes CD4+ count (or T-cell count), viral load, and viral genotype for positive results. All COVID-19 test results (positive, negative or inconclusive) must be reported. The reports include details like: your name, social security number, and other identifying information. Information about these new infections is used to track these diseases statewide and nationwide. Other than this required reporting, your results will be treated confidentially by the study staff. Personally identifying information will not be reported to other departments or agencies. For a full list of reportable conditions, go to the following link:

https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/ReportableDiseases.pdf

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:

Primary contact:
Phillip Coffin, MD, MIA can be reached at 628-217-6282

If primary is not available, contact:
John Walker, NP can be reached at 628-217-6227

A request to revoke consent must be sent to Phillip Coffin, MD at mailing address 25 Van Ness Ave, Ste. 500, San Francisco, CA 94102.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please contact the office of the UCSF Institutional Review Board by phone: 415-476-1814; by email: IRB@ucsf.edu; or by mail: Human Research Protection Program, Box 1288, 490 Illinois Street, Floor 6, San Francisco, CA 94143.

This form and the Experimental Subjects Bill of Rights is yours to keep.

You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

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 participate 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.

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 form and the California Experimental Subject's Bill of Rights 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.
- You have read (or have been read) the California Experimental Subject's Bill of Rights, 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

Experimental Research Subject's Bill of Rights

California law, under Health & Safety Code 24172, requires that any person asked to take part as a subject in research involving a medical experiment, or any person asked to consent to such participation on behalf of another, is entitled to receive the following list of rights written in a language in which the person is fluent. This includes the right to:

1. Be informed of the nature and purpose of the experiment.
2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.
3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.
4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.
5. Be given a disclosure of any appropriate alternative procedures, drugs, or devices that might be advantageous to the subject, and their relative risks and benefits.
6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.
7. Be given the opportunity to ask any questions concerning the experiment or the procedures involved.
8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.
9. Be given a copy of the signed and dated written consent form.
10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

Consent and Authorization to be part of a Research Study
To be conducted at
Mountain Manor Treatment Center

Who is conducting the study? Marc Fishman, M.D., the Medical Director at Mountain Manor Treatment Center - Baltimore (MMTC) / Maryland Treatment Centers is the Principal Investigator conducting the study at MMTC. The PI's email address is mfishman@marylandtreatment.org and phone number is 410-233-1400.

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

The site Principal Investigator for this study (Dr. Fishman) has been a paid consultant for Alkermes, the manufacturer of extended-release naltrexone, one of the medications used in the study. This financial interest has been reviewed in keeping with Maryland Treatment Centers' policies. It has been approved with certain conditions, which are intended to guard against bias and to protect participants.

If you have any questions about this financial interest, please talk to Dr. Kevin Wenzel at (410) 233-1400. This person is a member of the study team, but does not have a financial interest related to the study. You may also call the Compliance Officer for Mountain Manor / Maryland Treatment Centers, Jennifer Watson at (410) 233-1400, ext 270.

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Site-specific Procedures and Risks

Not applicable.

Compensation

You will be compensated for your participation in this study. To be compensated, you will need to complete Form 1099. Name, Address, social security number (SSN), and signature are all required for this form. In accordance with the business practices of Mountain Manor Treatment Center's business office, if you do not want to provide your SSN, then you can still participate in the study; however, you will not be able to get compensated.

This compensation is for your time and to help with travel, and other costs involved with you participating. You will be issued a gift card that contains funds to compensate you for your time. Compensation will be credited to the card at the **COMPLETION/END** of each study visit. Your name, address, date of birth and social security number will be shared with a third-party solely for the purposes of compensation processing. All information will be stored in a secure fashion.

Your card will be credited at the end of each study visit. 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.

An IRS Form 1099 will be sent to you if your total payments are $600 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 free of charge during this study.

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 your study doctor. 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. We have no plans to give you money if you are injured. The investigator can provide you with more information.

Neither the University of Texas Southwestern Medical Center, affiliates, or Mountain Manor Treatment Center / Maryland Treatment Centers 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:

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 whose 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.

How will your PHI be shared?

Because this is a research study, we will be unable to keep your PHI completely confidential. We may share

your health information with people and groups involved in overseeing this research study including:

- The Sponsor (Dr. Trivedi at University of Texas) 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.
- All 12 sites participating in the CURB-2 study nationwide.
- 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.

- Maryland state or local health department for reporting of certain infections and labs which require PHI identifiers to process biological specimens.

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.
Furthermore, we will be using electronic means of communicating with you (for example, email, text, and possibly video conferencing platforms such as Zoom). While such communications are convenient in today's modern world, these methods may be less secure than traditional methods of communication (for example, in person and landline phone contacts).

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.

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.

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.

What if I change my mind and do not want my information used or disclosed?
The permission to use or disclose your protected health information for this study does not have an expiration date. If you no longer want to share your protected health information, you may cancel your permission at any time by writing to the researchers at your research site. Please refer to the **Local Context Information Sheet**.

If you cancel your permission after you have started in the study, the researchers will stop collecting your health information. Although they will stop collecting new information about you, they will need to use the information they have already collected to evaluate the study results. If you start the study and then cancel your permission, you will not be able to continue to participate in the study or receive any medications as part of the study. This is because the researchers would not be able to collect the information needed to evaluate the study medications.

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 previous 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, with the exceptions where PHI must be shared that are listed above in the section entitled, “How will your PHI be shared.” 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 UT Southwestern Medical Center.

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. 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 Maryland Department of Health. Also, PHI will be released to Maryland state or local health department for reporting of certain infections and labs which require PHI identifiers to process biological specimens.

Do you have to allow the use of your health information?
You do not have to allow (authorize) the researchers and other groups to see and share your health information. If you choose not to let the researchers and other groups use your health information, there will be no penalties, but you will not be allowed to participate in the study.

After you enroll in this study, you may ask the researchers to stop using your health information at any time. However, you need to say this in writing and send your letter to the following address: ATTN: Dr. Aline Rabalais, Mountain Manor Treatment Center, 3800 Frederick Avenue, Baltimore, MD, 21229. If you tell the researchers to stop using your health information, your participation in the study will end and the study staff will stop collecting new health information from you and about you for this study. However, the study staff will continue to use the health information collected up to the time they receive your letter asking them to stop.

Can you ask to see the PHI that is collected about you for this study?
The federal rules say that you can see the health information that we collect about you and use in this study. Contact the researchers if you have a need to review your PHI collected for this study.

Because of the type of research, you can only access your PHI when the study is done. At that time, you have the right to see and copy the medical information we collect about you during the study, for as long as that information is kept by the researchers and other groups involved.

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: CURB-2 Research Coordinator (RC) and/or CURB-2 Research Assistants (RAs) who can be reached at (443) 265-9980

Primary contact:
Aline Rabalais, PhD. (RC) can be reached at (443) 265-9980.

If primary is not available, contact
Kevin Wenzel, Ph.D. can be reached at 410-233-1400.

If you decide to revoke your authorization for study participation please mail it to the following address:

ATTN: Kevin Wenzel, PhD.
Mountain Manor Treatment Center
3800 Frederick Ave.
Baltimore, MD 21229

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 participate 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_____

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 form 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

Title of Study: NIDA CTN Protocol 0109: Randomized, Placebo-Controlled Trial of Extended-Release Naltrexone and Monthly Extended-Release Buprenorphine for Cocaine Use Disorder (CURB-2)
COG Protocol # & type of consent; Amendment #; Consent Revision Date; CIRB Expiration Date

Consent and Authorization to be part of the Research Study

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

To be conducted at

University of Alabama at Birmingham
IRB-300010032

Who is conducting the study? Dr. Peter Hendricks, a Professor of Public Health, at the University of Alabama at Birmingham (UAB) is the Principal Investigator conducting the study at UAB. The PI's email address is phendricks@uab.edu and phone number is 205-202-1387.

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

Site-specific Procedures and Risks

As part of this study, you will be tested for chlamydia trachomatis, gonorrhea, and hepatitis A, B, and C. If the results show that you are positive for any of these infections, the study staff will tell you the results. If you test positive your results will be reported to the county or state health department as required by law. You will also be referred to your primary care doctor or the state health department for treatment.

If you agree to the optional HIV testing, you will be given your test results and will be given information on where you can receive counseling if your test results are positive. You will also be referred to your primary care doctor or the state health department. Positive test results will be reported to the county or state health department as required by law.

Information obtained during the course of the study which, in the opinion of the investigator(s), suggests that you may be at significant risk of harm to yourself or others will be reportable to a third party in the interest of protecting the rights and welfare of those at potential risk.

You will be randomly assigned to a study group by chance, which may prove to be less effective or to have more side effects than the other study group.

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 issued a Greenphire ClinCard, which can be used as a credit or debit card. Compensation will be credited to the card at the **COMPLETION / END** of each study visit. Your name, address, date of birth and social security number will be shared with a third-party solely for the purposes of compensation processing. All information will be stored in a secure fashion.

Your Greenphire ClinCard will be credited at the end of each study visit. 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.

An IRS Form 1099 will be sent to you if your total payments are $600 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.

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 your study doctor. 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. We have no plans to give you money if you are injured. The investigator can provide you with more information.

Neither the University of Texas Southwestern Medical Center, affiliates, or the University of Alabama at Birmingham have a program to pay you if you are hurt or have other bad results from being in the study. If you are hurt, treatment will be provided, but this treatment will not be provided free of charge. 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:

Information obtained about you for this study will be kept confidential to the extent allowed by law. However, research information that identifies you may be shared with people or organizations for quality assurance or data analysis, or with those responsible for ensuring compliance with laws and regulations related to research. They include:

- the UAB Institutional Review Board (IRB). An IRB is a group that reviews the study to protect the rights and welfare of research participants.
- Madhukar Trivedi, MD -University of Texas Southwestern Medical Center
- the Food and Drug Administration (FDA)
- the Office for Human Research Protections (OHRP)

The information from the research may be published for scientific purposes; however, your identity will not be given out.

The medical record includes either a paper medical record or electronic medical record (EMR). An EMR is an electronic version of a paper medical record of your care within this health system. The only information that will be included in your EMR is: 1) the fact that you are participating in a clinical trial; 2) the name and contact

information of the investigator in charge of the clinical trial, and 3) that as a study participant, you will be randomized to receive either the combination of injectable naltrexone and long-acting injectable buprenorphine or placebo injections.

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.

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.

Information relating to this study, including your name, medical record number, date of birth and social security number, may be shared with the billing offices of UAB and UAB Health System affiliated entities so costs for clinical services can be appropriately paid for by the study account

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.

What if I change my mind and do not want my information used or disclosed?
The permission to use or disclose your protected health information for this study does not have an expiration date. If you no longer want to share your protected health information, you may cancel your permission at any time by writing to Dr. Peter Hendricks at: Department of Psychiatry and Neurobiology Beacon Towers, 530 Beacon Parkway, Suite 702 Birmingham, Alabama 35209.

If you cancel your permission after you have started in the study, the researchers will stop collecting your health information. Although they will stop collecting new information about you, they will need to use the information they have already collected to evaluate the study results. If you start the study and then cancel your permission, you will not be able to continue to participate in the study or receive any medications as part of the study. This is because the researchers would not be able to collect the information needed to evaluate the study medications.

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 previous 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 UT Southwestern Medical Center for review or testing.

Do you have to allow the use of your health information?
You do not have to allow (authorize) the researchers and other groups to see and share your health information. If you choose not to let the researchers and other groups use your health information, there will be no penalties, but you will not be allowed to participate in the study.

After you enroll in this study, you may ask the researchers to stop using your health information at any time. However, you need to say this in writing and send your letter to Dr. Peter Hendricks. If you tell the researchers to stop using your health information, your participation in the study will end and the study staff will stop collecting new health information from you and about you for this study. However, the study staff will continue to use the health information collected up to the time they receive your letter asking them to stop.

Can you ask to see the PHI that is collected about you for this study?
The federal rules say that you can see the health information that we collect about you and use in this study. Contact the researchers if you have a need to review your PHI collected for this study.

Because of the type of research, you can only access your PHI when the study is done. At that time, you have the right to see and copy the medical information we collect about you during the study, for as long as that information is kept by the researchers and other groups involved.

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: Dr. Peter Hendricks: 205-202-1387 or phendricks@uab.edu

Primary contact:
Dr. Peter Hendricks, PhD., can be reached at 205-202-1387
If primary is not available, contact
Dr. Karen Cropsey, Psy.D., can be reached at 205-514-2025

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the IRB (OIRB) at (205) 934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday. You may also call this number in the event the research staff cannot be reached or you wish to talk to someone else

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 participate 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 form 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

University of Alabama at Birmingham
AUTHORIZATION FOR USE/DISCLOSURE OF PROTECTED HEALTH INFORMATION (PHI) FOR RESEARCH

Participant Name: _____ **UAB IRB Protocol Number: IRB-300010032**

Principal Investigator: Peter Hendricks

Research Protocol: UTSW IRB - Randomized, Placebo-Controlled Trial of Extended-Release Naltrexone and Monthly Extended-Release Buprenorphine for Cocaine Use Disorder (CURB-2)

Sponsor: *National Institute on Drug Abuse*

What is the purpose of this form? You are being asked to sign this form so that UAB may use and release your protected health information for research. Participation in research is voluntary. If you choose to participate in the research, you must sign this form so that your protected health information may be used for the research.

Why do the researchers want my protected health information? The researchers want to use your protected health information as part of the research protocol listed above and as described to you in the informed consent.

What protected health information do the researchers want to use? All medical information, including but not limited to information and/or records of any diagnosis or treatment of disease or condition, which may include sexually transmitted diseases (e.g., HIV, etc.) or communicable diseases, drug/alcohol dependency, etc.; all personal identifiers, including but not limited to your name, social security number, medical record number, date of birth, dates of service, etc.; any past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of whatever kind, including but not limited to drug/alcohol treatment, psychiatric/psychological treatment; financial/billing information, including but not limited to copies of your medical bills, and any other information related to or collected for use in the research protocol, regardless of whether the information was collected for research or non-research (e.g., treatment) purposes.

Who will disclose, use and/or receive my protected health information? All Individuals/entities listed in the informed consent documents, including but not limited to, the physicians, nurses and staff and others performing services related to the research (whether at UAB or elsewhere); other operating units of UAB, HSF, UAB Highlands, Children's of Alabama, Eye Foundation Hospital, and the Jefferson County Department of Health, as necessary for their operations; the IRB and its staff; the sponsor of the research and its employees and agents, including any CRO; and any outside regulatory agencies, such as the Food and Drug Administration, providing oversight or performing other legal and/or regulatory functions for which access to participant information is required.

How will my protected health information be protected once it is given to others? Your protected health information that is given to the study sponsor will remain private to the extent possible, even though the study sponsor is not required to follow the federal privacy laws. However, once your information is given to other organizations that are not required to follow federal privacy laws, we cannot assure that the information will remain protected.

How long will this Authorization last? Your authorization for the uses and disclosures described in this Authorization does not have an expiration date.

Can I cancel this Authorization? You may cancel this Authorization at any time by notifying the Principal Investigator, in writing, referencing the research protocol and IRB Protocol Number. If you cancel this Authorization, the study doctor and staff will not use any new health information for research. However, researchers may continue to use the protected health information that was provided before you cancelled your authorization.

Can I see my protected health information? You have a right to request to see your protected health information. However, to ensure the scientific integrity of the research, you will not be able to review the research information until after the research protocol has been completed.

Signature of participant: Date:

or participant's legally authorized representative: Date:

Printed Name of participant's representative:

Relationship to the participant: _____

Title of Study: NIDA CTN Protocol 0109: Randomized, Placebo-Controlled Trial of Extended-Release Naltrexone and Monthly Extended-Release Buprenorphine for Cocaine Use Disorder (CURB-2)

Consent and Authorization to be part of a Research Study
To be conducted at
Cove Behavioral Health

Who is conducting the study? Dr. Muvva, a Medical Doctor at Cove Behavioral Health is the Principal Investigator conducting the study at the Florida Alliance Node, Cove Behavioral Health. The PI's email address is venkatm@covebh.org and phone number is 813-384-4154

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

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. A reloadable debit card called the CT Payer Card will be provided to you at the **COMPLETION/END** of each study visit.

Your compensation will be provided to you at the end of each study visit. 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.

Please note that if you are on record as owing money to the State of Florida, 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 $600 or more in a calendar year, unless it's a reimbursement. Your name, address, date of birth and social security number will be needed for form 1099. All information will be stored in a secure fashion.

Please note that should your Social Security or Taxpayer Identification Number not be provided for IRS Form 1099, you will not be compensated for study visits.

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?

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 your study doctor. 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. We have no plans to give you money if you are injured. The investigator can provide you with more information.

Neither the University of Texas Southwestern Medical Center, affiliates, or Cove Behavioral Health 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:

Allegations of Abuse, Neglect or Exploitation – As required by law, after supervisory review, allegations of abuse, neglect or exploitation against vulnerable populations will be reported via the State of Florida Abuse Hotline (1-800-96ABUSE).

Mandated Health Department Reporting—As required by law, if you test positive for an HIV Infection, Hepatitis A, Hepatitis B, Hepatitis C, Chlamydia, and/or Gonorrhea, Cove must report this result to the Florida Department of Health.

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 whose 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.

How will your PHI be shared?
Because this is a research study, we will be unable to keep your PHI completely confidential. We may share your health information with people and groups involved in overseeing this research study including:

- 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, including University of Miami.
- 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.
- 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.

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.

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What if I change my mind and do not want my information used or disclosed?
The permission to use or disclose your protected health information for this study does not have an expiration date. If you no longer want to share your protected health information, you may cancel your permission at any time by writing to the researchers at your research site. Please refer to the **Local Context Information Sheet**.

If you cancel your permission after you have started in the study, the researchers will stop collecting your health information. Although they will stop collecting new information about you, they will need to use the information they have already collected to evaluate the study results. If you start the study and then cancel your permission, you will not be able to continue to participate in the study or receive any medications as part

of the study. This is because the researchers would not be able to collect the information needed to evaluate the study medications.

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 previous section. 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?
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The federal rules say that you can see the health information that we collect about you and use in this study. Contact the researchers if you have a need to review your PHI collected for this study.

Because of the type of research, you can only access your PHI when the study is done. At that time, you have the right to see and copy the medical information we collect about you during the study, for as long as that information is kept by the researchers and other groups involved.

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: Dr. Muvva

Primary contact:
Dr. Muvva can be reached at 813-384-4154 or venkatm@covebh.org

If primary is not available, contact
Stephanie Samayoa can be reached at 813-894-3609 or stephanies@covebh.org

To request to revoke authorization please send to
Dr. Muvva
4422 E Columbus Dr, Tampa, FL 33605

Local HRPP Office:

Janet Ramos
Program Manager/ HRP
813-277-4563
Janetr@covebh.org

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 participate 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 form 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 Sections

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

Consent and Authorization to be part of a Research Study
To be conducted at
Hennepin Healthcare: Berman Center for Outcomes and Clinical Research

Who is conducting the study? Dr. Gavin Bart, MD, PhD, the Director for the Division of Addiction Medicine at Hennepin Healthcare is the Principal Investigator conducting the study at the Berman Center for Outcomes and Clinical Research at Hennepin Healthcare. The PI's phone number is 612-873-9095.

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

Site-specific Procedures and Risks

If you agree to participate in the EEG component of the study, the potential risks include mild discomfort such as headache or skin irritation from wearing an EEG cap. This is completely optional. You may still participate in the study even if you choose not to participate in the EEG portion of the study.

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 issued a Hennepin Healthcare Research Institute Greenphire ClinCard, which can be used as a credit or debit card. Compensation will be credited to the card at the **COMPLETION/END** of each study visit. Your name, address, date of birth and social security number will be shared with a third-party solely for the purposes of compensation processing. All information will be stored in a secure fashion.

Your Greenphire ClinCard will be credited at the end of each study visit. 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.

An IRS Form 1099 will be sent to you if your total payments are $600 or more in a calendar year, unless it's a reimbursement.

Bus passes, parking passes, taxis or other transportation arrangements may be available. Please notify your research coordinator if you are in need.

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?

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 your study doctor. 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. We have no plans to give you money if you are injured. The investigator can provide you with more information.

Neither the University of Texas Southwestern Medical Center, affiliates, or Hennepin Healthcare Research Institute, the Berman Center for Clinical Outcomes, or Hennepin Healthcare System, Inc. 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:

If we learn about communicable, infectious, or other diseases required to be reported under Minnesota’s Reportable Disease Rule, we may be required or permitted by law or policy to report this information.

If we learn about excessive use of alcohol or use of controlled substances for non-medical reasons during pregnancy, we may be required or permitted by Minnesota law or Hennepin Healthcare policy to report this information to the Hennepin County Child Protection Agency.

If we learn about current, ongoing, or past (within the past three years) child abuse or neglect or current or ongoing vulnerable adult abuse or neglect, we may be required or permitted by Minnesota law or Hennepin Healthcare Policy to report this information.

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 whose 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.

How will your PHI be shared?

Because this is a research study, we will be unable to keep your PHI completely confidential. We may share your health information with people and groups involved in overseeing this research study including:

- 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, Hennepin Healthcare Research Institute, and Hennepin Healthcare System, Inc.
- 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.

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.

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. As required by Minnesota state law, if you test positive for HIV, Hepatitis B, Hepatitis C, Chlamydia, and/or Gonorrhea, we must report this result to the Minnesota Department of Health.

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.

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.

What if I change my mind and do not want my information used or disclosed?
The permission to use or disclose your protected health information for this study does not have an expiration date. If you no longer want to share your protected health information, you may cancel your permission at any time by writing to the researchers at your research site. Please refer below to the **Local Context Information Sheet**.

If you cancel your permission after you have started in the study, the researchers will stop collecting your health information. Although they will stop collecting new information about you, they will need to use the information they have already collected to evaluate the study results. If you start the study and then cancel your permission, you will not be able to continue to participate in the study or receive any medications as part of the study. This is because the researchers would not be able to collect the information needed to evaluate the study medications.

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 previous 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 UT Southwestern Medical Center for review or testing.

Do you have to allow the use of your health information?
You do not have to allow (authorize) the researchers and other groups to see and share your health information. If you choose not to let the researchers and other groups use your health information, there will be no penalties, but you will not be allowed to participate in the study.

After you enroll in this study, you may ask the researchers to stop using your health information at any time. However, you need to say this in writing and send your letter to:

Berman Center for Clinical Outcomes
Attn: CURB-2 Study Team
701 Park Avenue, Suite PPC4.440
Minneapolis, MN 55415
Email: CURB-2@BermanCenter.org

If you tell the researchers to stop using your health information, your participation in the study will end and the study staff will stop collecting new health information from you and about you for this study. However, the study staff will continue to use the health information collected up to the time they receive your letter asking them to stop.

Can you ask to see the PHI that is collected about you for this study?

The federal rules say that you can see the health information that we collect about you and use in this study. Contact the researchers if you have a need to review your PHI collected for this study.

Because of the type of research, you can only access your PHI when the study is done. At that time, you have the right to see and copy the medical information we collect about you during the study, for as long as that information is kept by the researchers and other groups involved.

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:

Berman Center for Clinical Outcomes
Attn: CURB-2 Study Team 701 Park Avenue, Suite PPC4.440
Minneapolis, MN 55415
Email: CURB-2@BermanCenter.org

In the event of a medical emergency the PI can be reached by pager at 612-979-1614. To use the pager, you need to have a touch tone (push button) telephone. Dial the pager number as you would any phone number. When you hear 3 short high-pitched beeps, dial in the number where you want the doctor to call you back. Push the # button, hang up and wait for the doctor to return your call.

To revoke an authorization please send a written request to:
Berman Center for Clinical Outcomes
Attn: CURB-2 Study Team
701 Park Avenue, Suite PPC4.440
Minneapolis, MN 55415
Email: CURB-2@BermanCenter.org

If you have any problems, concerns, or questions about the study or your rights as a participant in this research study, want to obtain information, or want to offer input to someone other than the study Principal Investigator, please contact the Hennepin Healthcare Human Research Protection Office (HRPO) at HRPO@hhrinstitute.org or (612) 873-6881.

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 participate 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_____

Do you agree to be contacted through social media platforms? *(Please initial either yes or no.)*

Yes Initials_____

No Initials_____

Do you agree to be contacted through text message? *(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 form 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

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

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

Title of Study: NIDA CTN Protocol 0109: Randomized, Placebo-Controlled Trial of Extended-Release Naltrexone and Monthly Extended-Release Buprenorphine for Cocaine Use Disorder (CURB-2)

Consent and Authorization to be part of a Research Study
To be conducted at
University of Arkansas for Medical Sciences (UAMS)

Who is conducting the study? Dr. Alison Oliveto, PhD, a professor at the University of Arkansas for Medical Sciences (UAMS) is the Principal Investigator conducting the study at the UAMS Center for Addiction Research. The PI's email address is OlivetoAlison@uams.edu and phone number is (501) 526-8441.

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

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 issued a UAMS Greenphire ClinCard, which can be used as a credit or debit card. Compensation will be credited to the card at the **COMPLETION/END** of each study visit. Your name, address, date of birth and social security number will be shared with a third-party solely for the purposes of compensation processing. All information will be stored in a secure fashion.

Your Greenphire ClinCard will be credited at the end of each study visit. 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.

An IRS Form 1099 will be sent to you if your total payments are $600 or more in a calendar year, unless it's a reimbursement.

If you are a recipient of Social Security Income (SSI), Social Security Disability Income (SSDI) recipient, or other income-based assistance programs, the additional income from this study will increase your yearly income and possibly making you ineligible for these benefits. If you are currently receiving SSI, Medicaid or Medicare low-income subsidies, please ask your study coordinator for details. Please contact your Social Security Office or your financial advisor if you have any questions.

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).

The sponsor will not pay for visits, laboratory work, tests or procedures that are standard of care (your usual medical care) and not study related. You (and/or your insurance company) will still need to pay for your usual medical care. You will be responsible for any co-payments and/or deductibles as required by your insurance company for such routine medical care. If you have any questions, staff are available to help you contact your insurance company to answer any questions you may have about insurance coverage relating to this study.

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 your study doctor. 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. In the event you are hurt by being in this research, treatment will be available. This treatment may include: first aid, emergency treatment and/or follow-up care. This treatment may be billed to you or you insurance company in the normal manner. Normally, no other form of compensation is available. If you think you have been hurt by this research, let the study investigator know right away. The investigator can provide you with more information.

Neither the University of Texas Southwestern Medical Center, affiliates, nor UAMS 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:

Research policies require that private information about you be protected, and this is especially true for your health information. All research information is protected under a Certificate of Confidentiality, which allows researchers to withhold information from all individuals not part of the study except in certain limited situations (see consent form part 1 for details). We will code your information and study samples and keep the code linked to your personal identifiers in a locked file. Records containing your personal identifiers will be kept in a separate locked file. Only research staff members will have access to the code for your information. All research records will be kept totally separate from the UAMS medical record system. However, the law sometimes allows or requires others to see your information. The information given below describes in more detail how your privacy and the confidentiality of your research records will be protected in this study.

State law requires us to report to the Arkansas Department of Health cases of certain diseases that a sick person could give to someone else (such as HIV, Chlamydia, Gonorrhea, or Hepatitis B or C). If we learn you have one of these during the study, we will share your name and contact information with the Arkansas Health Department.

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 whose 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 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.

How will your PHI be shared?

Because this is a research study, we will be unable to keep your PHI completely confidential. We may share your health information with people and groups involved in overseeing this research study including:

- 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 University of Arkansas for Medical Sciences (UAMS) Institutional Review Board (IRB).
- 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.
- Quest Diagnostics
- 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.

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;
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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.

What happens to information collected about me?

The following information explains how the 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 from the end of the trial.

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.

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What if I change my mind and do not want my information used or disclosed?
The permission to use or disclose your protected health information for this study does not have an expiration date. If you no longer want to share your protected health information, you may cancel your permission at any time by writing to the researchers at your research site. Please refer to the **Local Context Information Sheet**.

If you cancel your permission after you have started in the study, the researchers will stop collecting your health information. Although they will stop collecting new information about you, they will need to use the information they have already collected to evaluate the study results. If you start the study and then cancel your permission, you will not be able to continue to participate in the study or receive any medications as part of the study. This is because the researchers would not be able to collect the information needed to evaluate the study medications.

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 previous 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 UT Southwestern Medical Center or UAMS for review or testing.

Do you have to allow the use of your health information?
You do not have to allow (authorize) the researchers and other groups to see and share your health information. If you choose not to let the researchers and other groups use your health information, there will be no penalties, but you will not be allowed to participate in the study.

After you enroll in this study, you may ask the researchers to stop using your health information at any time. However, you need to say this in writing and send your letter to Dr. Alison Oliveto, PhD. If you tell the researchers to stop using your health information, your participation in the study will end and the study staff will stop collecting new health information from you and about you for this study. However, the study staff will continue to use the health information collected up to the time they receive your letter asking them to stop.

Can you ask to see the PHI that is collected about you for this study?
The federal rules say that you can see the health information that we collect about you and use in this study. Contact the researchers if you have a need to review your PHI collected for this study. If any tests or procedures reveal any potential medical issues, a copy of the results will be provided to you for follow-up with your personal healthcare provider.

Because of the type of research, you can only access your PHI when the study is done. At that time, you have the right to see and copy the medical information we collect about you during the study, for as long as that information is kept by the researchers and other groups involved.

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:

Primary contact:
Dr. Alison Oliveto, PhD can be reached at (501) 526-8441.

If primary is not available, contact

Dr. Michael Mancino, MD can be reached at (501) 526-8442.

If you decide to take part in the study, you may withdraw from participation at any time without penalty or loss of benefits to which you would otherwise be entitled. If you do decide to withdraw your consent, we ask that you contact Dr. Alison Oliveto and let her know that you are withdrawing from the study. Her mailing address is 4301 W. Markham St., # 843, Little Rock, AR 72205.

You may also contact the UAMS Institutional Review Board (IRB) representative at 501-686-5667, if you:

- have questions about your rights as a study subject
- can't reach the study team
- need to speak to someone not directly involved with this study
- The IRB makes sure people in research studies are protected from harm by the study. For more information go to https://irb.uams.edu/about_us/

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 participate 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

[Use the below signature block templates modify as per local requirements. Please note that any requirements for signatures beyond those required by appropriate federal regulations must be accompanied by a written policy, state law, or other local requirement or the IRB may not approve.]

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_____

[End of Genetics sections to be removed for sites located in California]
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 form 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 information about you and/or your participation in this study may be disclosed without your written consent in certain limited situations, such as a medical or mental health emergency, communicable disease diagnosis, stated intent to harm self or others, and suspected child or elder abuse.
- 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

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

Who is conducting the study? Jon E. Grant, MD, JD, MPH, Professor of Psychiatry and Behavioral Neuroscience at the University of Chicago, is the Principal Investigator conducting the study at the University of Chicago. The PI's email address is jgrant4@bsd.uchicago.edu and phone number is 773-834-3125.

This information sheet will describe any information that you are required to know and is specific to the University of Chicago. 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
The study staff at the University of Chicago have no conflict of interests to report.

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. For the schedule of compensation for each **completed** assessment, please refer to Part 1 of the consent form.

You will be compensated in one of two ways for your participation in this study. The study staff will determine which method you receive:

Method #1:

At the end of each study visit, you will receive a plastic or electronic gift card. Gift cards are issued in pre-set amounts (e.g., $15, $20), so if your total compensation for a study visit does not fall into one of these pre-set amounts, you will be issued your remaining compensation in the form of cash.

Method #2:

You will be issued a University of Chicago Greenphire ClinCard, which can be used as a credit or debit card. Compensation will be credited to the card at the **COMPLETION/END** of each study visit.

To support this stipend process, Greenphire, Inc. will need to process certain personal information about you. This information will be collected from you by the study site and given to Greenphire, Inc. through the Greenphire portal. The personal information that you provide is stored in a secure, electronic database that has access limited to only those who need to know your information. Those parties include the study site, and Greenphire, Inc. and their service providers who host data or provide tax processing services. Greenphire, Inc. employs reasonable precautions to prevent your personal information from loss, misuse, unauthorized access, disclosure, alteration or destruction.

Greenphire, Inc. will collect and use your information for the following purpose(s):

ClinCard
You will be issued a Greenphire, Inc. ClinCard, which is a debit card that your stipends are loaded onto and can be used at your discretion. When a visit is completed, funds will be approved and loaded onto your card. Once approved to be released to your card, the funds will be available for use within 1 business day. In order

to assign a ClinCard to you and load funds onto the ClinCard, the study site will provide Greenphire, Inc. your Name, Address, and Date of Birth.

Taxation
The stipend(s) you receive to help with your incidental expenses is considered taxable income. If payment exceeds $600 in any one calendar year, an IRS Form 1099 will be sent to you.

The samples collected in this study may be used for commercial profit by the sponsor. There are no plans for you to share in the profit from this use.

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.

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?

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 your study doctor. See the section "Contact Information" for phone numbers and additional information. You may also need to tell your regular doctors.

If you suffer an unanticipated injury as a direct result of this research and require emergency medical treatment, the University of Chicago Medical Center will provide such treatment at the University of Chicago Medical Center at no cost to you. You must notify Dr. Jon E. Grant as promptly as possible after your injury in order to receive this care. An injury is "unanticipated" if it is not one of the known effects of a study drug, medical device or procedure, and is not the result of your disease or condition. The costs of any non-emergency care for such an injury will be billed to you or your insurance in the ordinary manner. If you think that you have suffered a research related injury, you must let Dr. Jon E. Grant know right away

Neither the University of Texas Southwestern Medical Center, affiliates, or the University of Chicago 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:

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)?
During this study, Dr. Jon E. Grant and his research team will collect protected health information (PHI) about you for the purposes of this research. The research team includes the individuals listed on this consent form and other personnel involved in this study at the University of Chicago.

Protected Health Information is information about a person's health that includes information that would make it possible to figure out whose 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 name, address, dates, contact information such as phone number and e-mail address, social security number for compensation, and demographic information like your age, marital status, the type of work you do and the years of education you have completed.
- Your medical history, including information we get from your medical record and 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, and information you give us during your participation in the study such as during interviews or from questionnaires.
- Results of examinations and laboratory tests, including blood tests and medical imaging

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

How will your PHI be shared?
Because this is a research study, we will be unable to keep your PHI completely confidential. We may share your health information with people and groups involved in overseeing this research study including:

- 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.

- 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.

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.

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.

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.

What if I change my mind and do not want my information used or disclosed?
The permission to use or disclose your protected health information for this study does not have an expiration date. If you no longer want to share your protected health information, you may cancel your permission at any time by writing to the researchers at your research site. Please refer to the **Local Context Information Sheet**.

If you cancel your permission after you have started in the study, the researchers will stop collecting your health information. Although they will stop collecting new information about you, they will need to use the information they have already collected to evaluate the study results. If you start the study and then cancel your permission, you will not be able to continue to participate in the study or receive any medications as part of the study. This is because the researchers would not be able to collect the information needed to evaluate the study medications.

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 previous 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 UT Southwestern Medical Center for review or testing.

Do you have to allow the use of your health information?
You do not have to allow (authorize) the researchers and other groups to see and share your health information. If you choose not to let the researchers and other groups use your health information, there will be no penalties, but you will not be allowed to participate in the study.

After you enroll in this study, you may ask the researchers to stop using your health information at any time. However, you need to say this in writing and send your letter to Dr. Jon E. Grant. If you tell the researchers to stop using your health information, your participation in the study will end and the study staff will stop collecting new health information from you and about you for this study. However, the study staff will continue to use the health information collected up to the time they receive your letter asking them to stop.

Can you ask to see the PHI that is collected about you for this study?
The federal rules say that you can see the health information that we collect about you and use in this study. Contact the researchers if you have a need to review your PHI collected for this study.

Because of the type of research, you can only access your PHI when the study is done. At that time, you have the right to see and copy the medical information we collect about you during the study, for as long as that information is kept by the researchers and other groups involved.

HIV Test Results
For this research study, you will be tested for HIV. HIV is the term used for the virus that produces HIV infection and may ultimately lead to AIDS. The results of this test will become part of your medical record. You have a right to know the results of this test. The study doctor must report a positive HIV test including your name, address and telephone number, date of birth, demographic information (age, sex, and race/ethnicity) and social security number to the Illinois Department of Public Health (IDPH). The IDPH keeps track of all persons in the state with positive HIV tests. The database that keeps track of this information is labeled with a unique identification number so that your name does not appear with your HIV status. This helps keep your name private. You will be informed about the results of HIV testing done for this study.

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: Dr. Jon E. Grant at 773-834-1325.

Primary contact:
Dr. Jon E. Grant, MD, JD, MPH can be reached at 773-834-1325 during normal work hours or at 312-998-9956 outside of normal work hours.

If primary is not available, contact
Dr. Dustin A. Ehsan, MD can be reached at 773-834-2349 during normal work hours and at 405-521-7565 outside of normal work hours.

If you wish to revoke your authorization for the research site to use your protected health information, please send a letter to:
Dr. Jon E. Grant
The University of Chicago
5841 S Maryland Ave, MC3077
Chicago, IL 60637

The contact information for the University of Chicago Human Research Protection Program is:

University of Chicago Biological Sciences Division Institutional Review Board
5841 South Maryland Ave I-625, MC7172
Chicago, IL 60637
Phone: 773-702-6505

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 participate 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 form 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

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