INFORMED CONSENT FORM

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

NCT number: NCT05262270

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PART-2

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. You may receive up to $1,035 in cash for completing all study activities. The amount you will be paid for each study activity can be found in the table below. 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.

Visit/Assessment	Amount	# of Payments	Total
Screening and Baseline Assessments	$60	2	$120
Randomization/Medication Induction visits	$30	2	$60
Injection Administrations	$15	5	$75
Response Bias Probabilistic Reward Tasks	Avg $5	3	Avg $15
Iowa Gambling Task Incentive	$5	1	$5
Clinic Visits (8-week Medication Phase)	$20	16	$320
End-of-Treatment Visit Bonus (Week 8 visit 2)	$60	1	$60
Attendance Bonus (attending all expected visits in each 2-week block, Weeks 1-4)	$30	2	$60

Visit/Assessment	Amount	# of Payments	Total
Attendance Bonus (attending all expected visits in each 2-week block, Weeks 5-8)	$50	2	$100
Follow-up & Safety Visits (Weeks 9-12)	$30	4	$120
Total Compensation without EEG			**$935**
Total Compensation with EEG			**$1035**

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?

Study participants will be provided with study medication and study related procedures at no cost to them or their insurance. 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 drug/device 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. 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 at 628-217-6282. You may also need to tell your regular doctors.

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.

Neither the University of Texas Southwestern Medical Center, affiliates, or the University of California, San Francisco, or the San Francisco Department of Public 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:

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. You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about 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 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.
- The Research Advisory Panel of California (RAP-C)

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.

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

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.

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.

Your specimens may be used for commercial use. If this happens, you will not share in any profits.

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:
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.

Comprehension Quiz Questionnaire

CTN-0109: CURB-2
COMPREHENSION QUESTIONS

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

Research Consent & Authorization Signature Section

Signatures - Permission for specific study procedures

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

Do you agree to participate in the HIV (Human Immunodeficiency Virus) testing? *(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 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

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.