NIDA Clinical Trials Network

Demographics (DEM)

Web Version: 1.0; 1.00; 06-03-11

1. Date of birth:*(DEBRTHDT)* _____ *(mm/dd/yyyy)*

2. Sex:*(DEGENDER)* ☐ Male ☐ Female ☐ Participant chooses not to answer

3. Ethnicity:*(DEETHNIC)* ☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Participant chooses not to answer

4. Race:

American Indian or Alaska Native*(DEAMEIND)*	☐ No ☐ Yes
Asian*(DEASIAN)*	☐ No ☐ Yes
Black or African American*(DEBLACK)*	☐ No ☐ Yes
Native Hawaiian or Pacific Islander*(DEHAWAII)*	☐ No ☐ Yes
White*(DEWHITE)*	☐ No ☐ Yes
Other*(DEOTHER)*	☐ No ☐ Yes
If "Yes", specify:*(DEOTHRSP)*	_____

OR

Unknown*(DEUNKNOW)*	☐ Yes
Participant chooses not to provide their race*(DENORACE)*	☐ Yes

Comments:*(DEMCOMM)* _____

NIDA Clinical Trials Network

0048Z (ENR)

Web Version: 1.0; 1.00; 06-08-12

Date of assessment *(R4ASMTDT)* _____ *(mm/dd/yyyy)* Click here for calendar

Inclusion Criteria

In order to meet eligibility ALL Inclusion answers must be "Yes".

1. Is between the ages of 18 and 65? *(R4PTAGE)* — ☐ No ☐ Yes ☐ Unknown
2. Is in good general health? *(R4HEALTH)* — ☐ No ☐ Yes ☐ Unknown
3. Meets DSM-IV criteria for cocaine dependence? *(R4COPDEP)* — ☐ No ☐ Yes ☐ Unknown
4. Has either past-year opioid abuse or dependence (DSM-IV) or past-year opioid use and a history of opioid dependence during the lifetime (DSM-IV Addendum)? *(R4PYOPUS)* — ☐ No ☐ Yes ☐ Unknown
5. Is interested in receiving treatment for cocaine dependence? *(R4SKTRT)* — ☐ No ☐ Yes ☐ Unknown
6. Provided a negative urine drug screen for opioids immediately prior to naloxone challenge? *(R4NEGUDS)* — ☐ No ☐ Yes ☐ Unknown
7. Meets objective or subjective definition of being "opioid detoxified" as per study medical clinician's determination? *(R4DETOX)* — ☐ No ☐ Yes ☐ Unknown
8. Is able to tolerate induction onto oral naltrexone and XR-NTX? *(R4TOLNAL)* — ☐ No ☐ Yes ☐ Unknown
9. If female of childbearing potential, is willing to practice an effective method of birthcontrol for the duration of participation in the study? *(R4BCUSE)* — ☐ No ☐ Yes ☐ Unknown ☐ N/A
10. Is able to speak English sufficiently to understand the study procedures and provide written informed consent to participate in the study? *(R4OKCSNT)* — ☐ No ☐ Yes ☐ Unknown

Exclusion Criteria

In order to meet eligibility ALL Exclusion answers must be "No".

1. Shows evidence of an acute psychiatric disorder as assessed by the study medical clinician that would make participation difficult or unsafe? *(R4PSYCH)* — ☐ No ☐ Yes ☐ Unknown
2. Exhibits suicidal or homicidal ideation that requires immediate attention? *(R4SUICDE)* — ☐ No ☐ Yes ☐ Unknown
3. Has a known allergy or sensitivity to buprenorphine, naloxone, naltrexone, PLG (polyactide-co-glycolide), carboxymethylcellulose or any other component of the XR-NTX diluent? *(R4ALGY)* — ☐ No ☐ Yes ☐ Unknown
4. Has a serious medical illness that, in the opinion of the medical clinician, would make participation medically hazardous? *(R4MEDILN)* — ☐ No ☐ Yes ☐ Unknown
5. Has evidence of second or third degree heart block, atrial fibrillation, atrial flutter, prolongation of the QTc; (in addition any other finding on the screening ECG that, in the opinion of the medical clinician, would preclude the participant from participating safely in the study will also be exclusionary)? *(R4HEART)* — ☐ No ☐ Yes ☐ Unknown
6. Has any LFT values > 5 times the upper limit of normal as per laboratory criteria? *(R4LFTVAL)* — ☐ No ☐ Yes ☐ Unknown
7. Has INR >1.5 or platelet count <100k? *(R4INR)* — ☐ No ☐ Yes ☐ Unknown
8. Has a body habitus that precludes gluteal intramuscular injection of naltrexone with provided needle? *(R4NOIMIJ)* — ☐ No ☐ Yes ☐ Unknown
9. Has taken an investigational drug study within 30 days of study consent? *(R4PTOTHS)* — ☐ No ☐ Yes ☐ Unknown
10. Is receiving ongoing treatment with tricyclic antidepressants, chlorpromazine, modafinil, disulfuram, or any medication that, in the judgment of the study medical clinician, could interact adversely with study drugs? *(R4MEDAE)* — ☐ No ☐ Yes ☐ Unknown
11. Has participated in a methadone maintenance program within 15 days of study consent? *(R4MTHMPG)* — ☐ No ☐ Yes ☐ Unknown
12. Has participated in a buprenorphine maintenance treatment within 30 days of study consent? *(R4BUPMTN)* — ☐ No ☐ Yes ☐ Unknown
13. Has pending legal action or other reasons that might prevent the individual from remaining in the area for the duration of the study? *(R4NOMOVE)* — ☐ No ☐ Yes ☐ Unknown
14. Has a surgery planned or scheduled during the study period? *(R4SURGRY)* — ☐ No ☐ Yes ☐ Unknown
15. Requires therapy with opioid-containing medicines (e.g., opioid analgesics) during the study period? *(R4NDMEDS)* — ☐ No ☐ Yes ☐ Unknown
16. Has a current pattern of alcohol, benzodiazepine, or sedative-hypnotic use, as determined by the study medical clinician which would preclude safe participation in the study? *(R4DEPRUS)* — ☐ No ☐ Yes ☐ Unknown
17. If female, is currently pregnant or breastfeeding? *(R4PREGNT)* — ☐ No ☐ Yes ☐ Unknown ☐ N/A

Eligibility for Randomization

1. Is the participant eligible for the study? *(R4ELGSTY)* — ☐ No ☐ Yes
2. Is the participant eligible for randomization? *(R4ELGRDM)* — ☐ No ☐ Yes

If "No", specify: *(R4NORSP)*

- 2-Declined study participation
- 3-Death
- 4-Judgement of CTP/research staff
- 5-Failed to return to clinic prior to randomization
- 9-Other

If "Judgment of research staff", specify: *(R4JGTSP)* _____

If "Other", specify: *(R4OTHRSP)* _____

Opioid Use

- Ever injected an opioid? *(R4OPINJ)* — ☐ No ☐ Yes ☐ Unknown
- Greater than or equal to 2 years of regular opioid use? *(R42YRUSE)* — ☐ No ☐ Yes ☐ Unknown
- Opioid use on 20 or more days in the month preceding screening? *(R45XWKUS)* — ☐ No ☐ Yes ☐ Unknown

3. **Opioid use level:** *(R4OPUSLV)* — ☐ Low ☐ High ☐ Unknown

Comments: *(R4COMM)*