NIDA Clinical Trials Network

Demographics (DEM)

Web Version: 1.0; 2.02; 07-11-14

1. Date of birth:*(DEBRTHDT)* _____ *(mm/dd/yyyy)*
2. Age:*(DEAGE)* _____ *(xx)*

3. Gender:*(DEGENDER)* ☐ Male ☐ Female ☐ Don't know ☐ Refused

4. Does the participant consider him or herself to be Hispanic/Latino?*(DEHISPNC)* ☐ No ☐ Yes ☐ Don't know ☐ Refused

   If "Yes", indicate the group that represents his or her Hispanic origin or ancestry:*(DEHISPSP)*

5. What race does the participant consider him or herself to represent:
   (Check all that apply)

White:	*(DEWHITE)* ☐		
Black/ African American:	*(DEBLACK)* ☐		
Indian (American):	*(DEAMEIND)* ☐		
Alaska native:	*(DEALASKA)* ☐		
Native Hawaiian:	*(DEHAWAII)* ☐		
Guamanian:	*(DEGUAM)* ☐		
Samoan:	*(DESAMOAN)* ☐		
Other Pacific Islander:	*(DEPACISL)* ☐	Specify:*(DEPACISO)*	
Asian Indian:	*(DEASAIND)* ☐		
Chinese:	*(DECHINA)* ☐		
Filipino:	*(DEFILIPN)* ☐		
Japanese:	*(DEJAPAN)* ☐		
Korean:	*(DEKOREA)* ☐		
Vietnamese:	*(DEVIETNM)* ☐		
Other Asian:	*(DEASIAN)* ☐	Specify:*(DEASIAOT)*	
Some other race:	*(DERACEOT)* ☐	Specify:*(DERACESP)*	

-OR- ---

Don't know:*(DERACEDK)* ☐

Refused: *(DERACERF)* ☐

6. What is the highest grade or level of school the participant has completed or the highest degree they have received?*(DEEDUCTN)*

7. We would like to know about what the participant does -- is he/she working now, looking for work, retired, keeping house, a student, or what?*(DEJOB)*

If "Other", specify:*(DEJOBSP)*

8. Is the participant married, widowed, divorced, separated, never married, or living with a partner?*(DEMARTL)*

Comments:*(DEMCOMM)*

Additional Selection Options for DEM

If "Yes", indicate the group that represents his or her Hispanic origin or ancestry:
6-Cuban
7-Cuban American
8-Central or South American
9-Other Latin American
99-Other Hispanic
98-Refused
97-Don't know

What is the highest grade or level of school the participant has completed or the highest degree they have received?
05-5th grade
06-6th grade
07-7th grade
08-8th grade
09-9th grade
10-10th grade
11-11th grade
12-12th grade, no diploma
13-High school graduate
14-GED or equivalent
15-Some college, no degree
16-Associate's degree: occupational, technical, or vocational program
17-Associate's degree: academic program
18-Bachelor's degree (e.g., BA, AB, BS, BBA)
19-Master's degree (e.g., MA, MS, MEng, MEd, MBA)
20-Professional school degree (e.g., MD, DDS, DVM, JD)
21-Doctoral degree (e.g., PhD, EdD)
98-Refused
97-Don't know

We would like to know about what the participant does -- is he/she working now, looking for work, retired, keeping house, a student, or what?
06-Keeping house
07-Student
99-Other

Is the participant married, widowed, divorced, separated, never married, or living with a partner?
06-Living with partner
98-Refused
99-Don't know

NIDA Clinical Trials Network

0054Z (ENR)

Web Version: 1.0; ; 12-16-13

Date of assessment:*(R3ASMDT)* _____ *(mm/dd/yyyy)*

Inclusion Criteria

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

1. Participant is 18 to 65 years of age.*(R3PTAGE)*	☐ No	☐ Yes	☐ Unknown	
2. Participant is able to speak English sufficiently to understand the study procedures and provide written informed consent to participate in the study. *(R3ENGLSH)*	☐ No	☐ Yes	☐ Unknown	
3. Participant demonstrates understanding of study procedures by correctly answering all questions on the consent competency tool.*(R3COMPT)*	☐ No	☐ Yes	☐ Unknown	
4. Participant is interested in reducing or stopping methamphetamine use.*(R3METSTP)*	☐ No	☐ Yes	☐ Unknown	
5. Participant meets DSM-5 criteria for severe methamphetamine use disorder. *(R3METDSM)*	☐ No	☐ Yes	☐ Unknown	
6. Participant self-reported methamphetamine use on 20 or more days in the 30 day period prior to consent via the Timeline Follow-back (TLFB).*(R3MET20D)*	☐ No	☐ Yes	☐ Unknown	
7. Participant submitted at least three urine samples positive for methamphetamine out of a possible four tests to occur within a 14-day period during which clinic visits occurred, with at least two days between visits.*(R3METUDS)*	☐ No	☐ Yes	☐ Unknown	
8. Participant meets subjective and objective measures of being opioid-free prior to enrollment and medication induction per study medical clinician's determination (including passing a naloxone challenge).*(R3OPFREE)*	☐ No	☐ Yes	☐ Unknown	
9. Participant is female of childbearing potential, and agrees to use acceptable birth control methods during participation in the study.*(R3BCUSE)*	☐ No	☐ Yes	☐ Unknown	☐ Not applicable
10. Participant agrees to use study cell phone to record videos of take-home dosing for transfer to study team.*(R3VIDEO)*	☐ No	☐ Yes	☐ Unknown	

Exclusion Criteria

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

1. Participant has an acute medical or psychiatric disorder that would, in the judgment of the study medical clinician, make participation difficult or unsafe. *(R3PSYCH)*	☐ No	☐ Yes	☐ Unknown
2. Participant has Stage II hypertension as determined by study medical clinician (e.g., greater than or equal to 160/100 in 2 out of 3 readings during screening). *(R3HYPTEN)*	☐ No	☐ Yes	☐ Unknown
3. Participant has suicidal or homicidal ideation that requires immediate attention. *(R3SUICDE)*	☐ No	☐ Yes	☐ Unknown
4. Participant has a known allergy or sensitivity to bupropion, naloxone, naltrexone, PLG (polyactide-co-glycolide), carboxymethylcellulose, or any other component of the XR-NTX diluent.*(R3ALERGY)*	☐ No	☐ Yes	☐ Unknown
5. Participant has a history of seizure, head trauma with neurological sequelae (i.e., loss of consciousness that required hospitalization), current anorexia nervosa or bulimia; in addition, any other conditions that increase seizure risk in the opinion of the study medical clinician will also be exclusionary.*(R3SEIZUR)*	☐ No	☐ Yes	☐ Unknown
6. Participant 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 safe participation in the study will also be exclusionary.*(R3BLOCK)*	☐ No	☐ Yes	☐ Unknown
7. Participant has any liver function test (LFT) value > 5 times the upper limit of normal as per laboratory criteria.*(R3LIVER)*	☐ No	☐ Yes	☐ Unknown
8. Participant has platelet count <100k.*(R3PLATE)*	☐ No	☐ Yes	☐ Unknown
9. Participant has body habitus that precludes gluteal intramuscular injection of XR-NTX in accord with the administration equipment (needle) and procedures. *(R3HABTUS)*	☐ No	☐ Yes	☐ Unknown
10. Participant has been in a prior study of pharmacological or behavioral treatment for methamphetamine use disorder within 6 months of study consent. *(R3STUDY)*	☐ No	☐ Yes	☐ Unknown
11. Participant has taken an investigational drug in another study within 30 days of study consent.*(R3INDDRU)*	☐ No	☐ Yes	☐ Unknown
12. Participant is currently enrolled in behavioral or pharmacological addiction treatment services at the CTP.*(R3CTP)*	☐ No	☐ Yes	☐ Unknown

13. Participant is receiving ongoing treatment with tricyclic antidepressants, duloxetine, venlafaxine, xanthines (i.e., theophilline and aminophylline), systemic corticosteroids, nelfinavir, efavirenz, chlorpromazine, MAOIs, central nervous system stimulants (i.e., Adderall, Ritalin, etc), or any medication that, in the judgment of the study medical clinician, could interact adversely with study drugs.*(R3TREAT)* ☐ No ☐ Yes ☐ Unknown
14. Participant has been prescribed and taken naltrexone or bupropion within 30 days of consent.*(R3PRESCR)* ☐ No ☐ Yes ☐ Unknown
15. Participant has pending legal action or other situation (e.g., unstable living arrangements) that could prevent participation in the study or in study activities. *(R3LEGAL)* ☐ No ☐ Yes ☐ Unknown
16. Participant has a surgery planned or scheduled during the study period. *(R3SURGRY)* ☐ No ☐ Yes ☐ Unknown
17. Participant requires treatment with opioid-containing medications (e.g., opioid analgesics) during the study period.*(R3OPMED)* ☐ No ☐ Yes ☐ Unknown
18. Participant has a current pattern of alcohol, benzodiazepine, or other sedative hypnotic use which would preclude safe participation in the study as determined by the study medical clinician.*(R3SEDATE)* ☐ No ☐ Yes ☐ Unknown
19. Participant is currently pregnant or breastfeeding.*(R3PREGNT)* ☐ No ☐ Yes ☐ Unknown ☐ Not applicable

Eligibility for Enrollment

1. Is the participant eligible for the study?*(R3ELGSTY)* ☐ No ☐ Yes

2. Will the participant be enrolled?*(R3ELGRDM)* ☐ No ☐ Yes

If "No", specify:*(R3NORSP)*

If "Other" or "Judgment of CTP/research staff", specify:*(R3JGOTSP)*

Comments:*(R3COMM)*