

0051Z (ENR)

Web Version: 1.0; :09-10-15

Date of assessment *(R1ASMDT)*

(mm/dd/yyyy)

**Inclusion Criteria**

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

1. Participant is 18 years of age or older? *(R1PTAGE)*
2. Participant meets DSM-5 criteria for opioid-use disorder (heroin and/or prescription opioids)? *(R1OPIDEP)*
3. Participant has used opioids other than as specifically prescribed within thirty days prior to consent? *(R1OPIUSE)*
4. Participant is seeking treatment for opioid dependence and willing to accept "agonist-based" or "antagonist-based" therapy? *(R1SEKTX)*
- If "No", specify: *(R1THRSPSP)*

☐ No ☐ Yes ☐ Unknown  
☐ No ☐ Yes ☐ Unknown  
☐ No ☐ Yes ☐ Unknown  
☐ No ☐ Yes ☐ Unknown

0-Participant did not want medication  
1-Participant did not want buprenorphine  
2-Participant did not want naltrexone  
3-Participant preferred another treatment

5. Participant is female of childbearing potential, and agrees to use acceptable birth control methods during participation in the study? *(R1BCUSE)*
6. Participant is in good-enough health, as determined by the study physician on the basis of medical history, review of systems, physical exam and laboratory assessments, to permit treatment with XR-NTX or BUP-NX? *(R1HEALTH)*
7. Participant is able to provide written informed consent? *(R1INFORM)*
8. Participant is able to speak English sufficiently to understand the study procedures and provide written informed consent to participate in the study? *(R1ENGLISH)*

☐ No ☐ Yes ☐ Not assessed ☐ Not applicable  
☐ No ☐ Yes ☐ Unknown  
☐ No ☐ Yes ☐ Unknown  
☐ No ☐ Yes ☐ Unknown

**Exclusion Criteria**

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

1. Participant has a serious medical, psychiatric or substance use disorder that, in the opinion of the study physician, would make study participation hazardous to the participant, or compromise study findings or would prevent the participant from completing the study?  
Examples include:  
(a) Disabling or terminal medical illness (e.g., uncompensated heart failure, cirrhosis or end-stage liver disease) as assessed by medical history, review of systems, physical exam and/or laboratory assessments  
(b) Severe, untreated or inadequately treated mental disorder (e.g., active psychosis, uncontrolled manic-depressive illness) as assessed by history and/or clinical interview  
(c) Current severe alcohol, benzodiazepine, or other depressant or sedative hypnotic use likely to require a complicated medical detoxification (routine alcohol and sedative detoxifications may be included) *(R1PSYCH)*
2. Participant has LFTs greater than 5 times upper limit of normal? *(R1LFTS)*
3. Participant has suicidal or homicidal ideation that requires immediate attention? *(R1SUICDE)*
4. Participant has a known allergy or sensitivity to buprenorphine, naltrexone, poly lactide-co-glycolide, carboxymethylcellulose, or other components of the Vivitrol® diluent? *(R1ALLERGY)*
5. Participant is on maintenance of methadone at doses of 30mg or greater at the time of signing consent? *(R1TDMNT)*
6. Participant has presence of pain of sufficient severity as to require ongoing pain management with opioids? *(R1PAIN)*
7. Participant has pending legal action or other reasons that might prevent an individual from completing the study? *(R1LEGAL)*
8. Participant is female of child bearing potential and currently pregnant, breastfeeding, or planning on conception? *(R1PREGNT)*
9. Participant has a body habitus that, in the judgment of the study physician, precludes safe intramuscular injection of XR-NTX (e.g., BMI>40, excess fat tissue over the buttocks, emaciation)? *(R1HABTUS)*

☐ No ☐ Yes ☐ Unknown  
☐ No ☐ Yes ☐ Unknown  
☐ No ☐ Yes ☐ Unknown  
☐ No ☐ Yes ☐ Unknown  
☐ No ☐ Yes ☐ Unknown  
☐ No ☐ Yes ☐ Unknown  
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☐ No ☐ Yes ☐ Unknown

☐ No ☐ Yes ☐ Unknown  
☐ No ☐ Yes ☐ Unknown  
☐ No ☐ Yes ☐ Unknown  
☐ No ☐ Yes ☐ Not assessed ☐ Not applicable  
☐ No ☐ Yes ☐ Unknown

**Eligibility for Randomization**

1. Did the participant complete the screening visit? *(R1MPSCR)*
- If "No", specify: *(R1NCMPSP)*

☐ No ☐ Yes

0-Participant dropped out of CTP  
1-Participant did not meet eligibility criteria  
2-Participant did not want research  
99-Other

If "Other", specify: *(R1NCMOTH)*

2. Is the participant eligible for the study? *(R1ELGS TY)*
- a. In the 7 day period prior to detox admission, on average how many bags (or equivalent) of IV heroin per day did the participant report using? *(R1HERBAG)*
- b. Last (licit or illicit) opioid use prior to randomization entered on the Detoxification Utilization Summary form? *(R1LSTOPP)*
3. Will the participant be randomized? *(R1ELGRDM)*

☐ No ☐ Yes  
☐ < 6 bags ☐ >= 6 bags  
☐ No ☐ Yes  
☐ No ☐ Yes

If "No", specify: (R1NORSP)

If "Other", specify: (R1OTHRSP)

4. Have all eligibility criteria been reviewed by the study physician? (R1PHYREV)

If "Yes", review date: (R1PHRVDT)

Comments: (R1COMM)

0-Participant dropped out of CTP  
1-Participant did not meet eligibility criteria  
2-Participant did not want research  
99-Other

☐ No ☐ Yes

(mm/dd/yyyy)

## NIDA Clinical Trials Network

### Demographics (DEM)

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

1. Date of birth:(DEBRTHTD)

(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)

1-Puerto Rican  
2-Dominican (Republic)  
3-Mexican/Mexicano  
4-Mexican American  
5-Chicano  
\*Additional Options Listed Below

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)*

00-Never attended / kindergarten only

01-1st grade

02-2nd grade

03-3rd grade

04-4th grade

\*Additional Options Listed Below

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)*

01-Working now

02-Only temporarily laid off, sick leave, or maternity leave

03-Looking for work, unemployed

04-Retired

05-Disabled, permanently or temporarily

\*Additional Options Listed Below

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

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

01-Married

02-Widowed

03-Divorced

04-Separated

05-Never married

\*Additional Options Listed Below

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