

NIDA Clinical Trials Network

Demographics (DEM)

Web Version: 1.0; 6.00; 11-25-19

1. Date of birth:(DEBRTHDT)

Text input field with placeholder (mm/dd/yyyy)

2. Sex:(DESEX)

Radio buttons for Male, Female, Don't know, Refused to answer

3. Does the participant consider him or herself to be Hispanic/Latino?(DEHISPNC)

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

Radio buttons for No, Yes, Don't know, Refused to answer

Dropdown menu for Hispanic origin/ancestry: Puerto Rican, Dominican (Republic), Mexican/Mexican American, Chicano, Cuban/Cuban American, *Additional Options Listed Below

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

American Indian or Alaska Native:(DEAMEIND)

Checkbox

Asian:(DEASIAN)

Checkbox

Asian Indian:(DEASAIND)

Checkbox

Chinese:(DECHINA)

Checkbox

Filipino:(DEFILIPN)

Checkbox

Japanese:(DEJAPAN)

Checkbox

Korean:(DEKOREA)

Checkbox

Vietnamese:(DEVIETNM)

Checkbox

Specify other Asian:(DEASIAOT)

Text input field

Black or African American:(DEBLACK)

Checkbox

Native Hawaiian or Pacific Islander:(DEHAWAII)

Checkbox

Native Hawaiian:(DENATHAW)

Checkbox

Guamanian or Chamorro:(DEGUAM)

Checkbox

Samoa:(DESAMOAN)

Checkbox

Specify other Pacific Islander:(DEPACISO)

Text input field

White:(DEWHITE)

Checkbox

Some other race:(DERACEOT)

Checkbox

Specify:(DERACESP)

Text input field

-or-

Don't know:(DERACEDK)

Checkbox

Refused:(DERACERF)

Checkbox

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

Dropdown menu for education level: Never attended / kindergarten only, 1st grade, 2nd grade, 3rd grade, 4th grade, *Additional Options Listed Below

6. 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)

Dropdown menu for employment status: Working now, Only temporarily laid off, sick leave, or maternity leave, Looking for work, unemployed, Retired, Disabled, permanently or temporarily, *Additional Options Listed Below

If "Other", specify:(DEJOBSP)

Text input field

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

Dropdown menu for marital status: Married, Widowed, Divorced, Separated, Never married, *Additional Options Listed Below

Comments:(DEMCOMM)

Text area for comments

Additional Selection Options for DEM

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

Central or South American
Other Latin American
Other Hispanic or Latino
Refused
Don't know

What is the highest grade or level of school the participant has completed or the highest degree they have received?

5th grade
6th grade
7th grade
8th grade
9th grade
10th grade
11th grade
12th grade, no diploma
High school graduate
GED or equivalent
Some college, no degree
Associate's degree: occupational, technical, or vocational program
Associate's degree: academic program
Bachelor's degree (e.g., BA, AB, BS, BBA)
Master's degree (e.g., MA, MS, MEng, MEd, MBA)
Professional school degree (e.g., MD, DDS, DVM, JD)
Doctoral degree (e.g., PhD, EdD)
Refused
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?

Keeping house
Student
Other

Is the participant currently married, widowed, divorced, separated, never married, or living with a partner?

Living with partner
Refused
Don't know

0067Z (ENR)

Web Version: 1.0; 2.00; 04-20-18

Date participant is being randomized or screen failed:(STARTDT) (mm/dd/yyyy)

Inclusion Criteria

In order to meet eligibility ALL Inclusion answers must be "Yes" or "Not applicable".

1. Participant is 18 years of age or older:(R7PTAGE) No Yes
2. Participant is willing and able to provide written informed consent and HIPAA Authorization (if applicable) for medical record abstraction: (R7MRAB) No Yes Unknown
3. Participant meets DSM-5 criteria for moderate or severe opioid use disorder:(R7OPIDIS) No Yes Unknown
4. Participant is willing to be randomized to antagonist-based therapy or TAU:(R7OKRAND) No Yes Unknown
5. Participant has an HIV viral RNA count > 200 copies/ml: *HIV viral RNA may be drawn with screening blood draw or abstracted from medical records if drawn in the 90 days prior to the date of consent. (R7HIVRNA)* No Yes Unknown
6. Participant is willing to establish ongoing HIV care at the site if not already receiving ongoing care:(R7HIVCAR) No Yes Unknown
7. Participant is willing to take at least one evidence-based measure to avoid becoming pregnant:(R7BCUSE) No Yes Unknown Not applicable

Exclusion Criteria

In order to meet eligibility ALL Exclusion answers must be "No" or "Not applicable".

1. Participant has a severe medical, psychiatric or substance use disorder that, in the opinion of the study physician, would make study participation hazardous to the participant, compromise study findings, or prevent the participant from completing the study due to imminent risk of death: *Hospitalized patients who do not meet these conditions remain eligible for participation.(R7MEDRSK)* No Yes Unknown
2. Participant has aspartate aminotransferase (AST) or alanine aminotransferase (ALT) liver enzymes greater than 5 times upper limit of normal on screening phlebotomy: *Results from tests conducted within the past 30 days from date of consent may be abstracted from medical records.(R7ASTALT)* No Yes Unknown
3. Participant has INR > 1.5 or platelet count <100k: *Results from tests conducted within the past 30 days from date of consent may be abstracted from medical records.(R7INRPLT)* No Yes Unknown
4. Participant has known allergy or sensitivity to naloxone, naltrexone, polylactide-co-glycolide, carboxymethylcellulose, or other components of the Vivitrol® diluents:(R7SENSIT) No Yes Unknown
5. Participant anticipates undergoing surgery during study participation: (R7SURGRY) No Yes Unknown
6. Participant has chronic pain requiring ongoing pain management with opioid analgesics:(R7CHRONP) No Yes Unknown
7. Participant (at time of consent) is pregnant or breastfeeding or planning on conceiving in the coming months:(R7PRGBF) No Yes Unknown Not applicable
8. Participant has body habitus that, in the judgment of the study physician, precludes safe intramuscular injection of XR-NTX (e.g., excess fat tissue over the buttocks):(R7HABITU) No Yes Unknown

- 9. Participant has received methadone or buprenorphine maintenance therapy for treatment of opioid use disorder in the 4 weeks prior to consent:
(medically supervised withdrawal therapy is allowed)(R7BUPTRT) No Yes Unknown
- 10. Participant has received ongoing XR-NTX injections as maintenance therapy for opioid or alcohol use disorder in the 4 weeks prior to consent:
(does not exclude individuals leaving incarceration with a single injection and no specific follow up)(R7PRITRT) No Yes Unknown
- 11. Participant has taken an investigational drug in another study within 30 days of study consent:*(R7INVDRG)* No Yes Unknown
- 12. Participant is currently in jail, prison or any overnight facility as required by court of law or have pending legal action that could prevent participation in study activities:*(R7JAIL)* No Yes Unknown

Eligibility for Randomization

- 1. Is the participant eligible for the study?*(R7ELGSTY)* No Yes
- 2. Will the participant be randomized?*(R7ELGRND)* No Yes
- a. If "No", specify:*(R7NORAND)*

Participant refused
 Declined study participation
 Death
 Judgement of site/research staff
 Failed to return to clinic prior to randomization
 Other

If "Judgement of site/research staff" or "Other", specify:
(R7NORDSP)

b. If "Yes", date eligibility was confirmed by clinician:*(R7ELIGDT)*

 (mm/dd/yyyy)

Comments:*(R7COMM)*