

NIDA Clinical Trials Network

A251B (ENR)

Web Version: 1.0; 1.04; 04-04-17

Date of assessment (R8ASMDT)

 (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? (R8PTAGE) No Yes
- 2. Participant meets DSM-5 criteria for opioid-use disorder (heroin and/or prescription opioids)? (R8OPIDEP) No Yes Unknown
 than as specifically prescribed within thirty days prior to consent? (R8OPIUSE) No Yes Unknown
 opioid dependence? (R8SEEKTX) No Yes Unknown
- 5. Participant is able to provide written informed consent? (R8INFORM) No Yes Unknown
- 6. Participant is able to speak English sufficiently to understand the study procedures? (R8ENGLISH) 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 Site PI, would make study participation hazardous to the participant, compromise study findings or prevent the participant from completing the study? (R8PSYCH) No Yes Unknown
 deatation that requires immediate attention? (R8SUICDE) No Yes Unknown
- 3. Participant is on maintenance of methadone at doses of 30mg or greater at the time of signing consent? (R8TDMNT) No Yes Unknown
- 4. Participant has presence of pain of sufficient severity as to require ongoing pain management with opioids? (R8PAIN) No Yes Unknown
- 5. Participant is currently in jail, prison or any inpatient overnight facility as required by court of law or has a pending legal action which may prevent the individual from completing the study. (R8LEGAL) No Yes Unknown
- 6. Participant is female of child bearing potential and currently pregnant, breastfeeding, or planning on conception? (R8PREGNT) No Yes Not assessed Not applicable
- 7. Participant has participated in parent trial CTN-0051? (R8PARENT) No Yes Unknown

Eligibility for Enrollment

- 1. Participant discharged to the community from: (R8DSCHRG) Detox unit Residential facility Not discharged
 - a. Date of discharge from detox unit: (R8DDCDT) (mm/dd/yyyy)
 - b. If "residential facility", date of discharge from residential facility: (R8FCDCDT) (mm/dd/yyyy)
- 2. Is the participant eligible for the study? (R8ELGSTY) No Yes
- 3. Have all inclusion/exclusion criteria been reviewed by the Site Principal or Sub Investigator? (R8PHYREV) No Yes
 If "Yes", review date: (R8PHRVDT) (mm/dd/yyyy)

Comments: (R8COMM)

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)

- 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)

Seg Z - CTN-0051A2 Annotated CRFs Segment Z

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