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)*

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0052Z (ENR)

Web Version: 1.0; 1.00; 07-27-12

Date of assessment:*(R7ASMDT)* _____ *(mm/dd/yyyy)* Click here for calendar

Inclusion Criteria

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

1. Is the individual 18 years of age or older? (See 5209 - Demographics, Q1)*(R7PTAGE)* ☐ No ☐ Yes ☐ Not assessed
2. Is the individual able to understand the study, and having understood, provided written informed consent in English? (See SIGNED Informed Consent Form)*(R7ENGLSH)* ☐ No ☐ Yes ☐ Not assessed
3. Is the individual currently (within the last 12 months) cocaine dependent (See MindLinc CIDI Diagnostic Report), self-reporting having used crack cocaine a minimum of four times in the 28 days prior to inpatient/residential admission (See 5233 - TLFB Screening/Baseline), and reporting that their typical pattern of use is at least once a week (See 5206 - CRAC, Q2)?*(R7COCDEP)* ☐ No ☐ Yes ☐ Not assessed
4. Does the individual have a willingness to comply with all study procedures and medication instructions? (Based on the judgment of the study investigator and inherent in the SIGNED Informed Consent Form)*(R7COMPLY)* ☐ No ☐ Yes ☐ Not assessed
5. Is the individual enrolled in an inpatient/residential program at a participating CTP, scheduled to be in inpatient/residential treatment for 12-19 days when randomized, and planning to enroll in local outpatient treatment through the end of the active treatment phase (i.e., study week 15)? (See 5230 - Substance Abuse Treatment Status)*(R7RSDNTL)* ☐ No ☐ Yes ☐ Not assessed
6. If female, and of child bearing potential, does the individual agree to use an acceptable form of birth control? (See 5222 - Pregnancy, and Birth Control Assessment, Q2)*(R7BCUSE)* ☐ No ☐ Yes ☐ Not assessed ☐ Not applicable (male)

Exclusion Criteria

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

7. Is the individual currently (within the last 12 months) opioid dependent according to the DSM-IV-TR diagnostic criteria? (See MindLinc CIDI Diagnostic Report) *(R7OPDDEP)* ☐ No ☐ Yes ☐ Not assessed
8. Does the individual have a medical or psychiatric condition that, in the judgment of the study medical clinician, would make study participation unsafe or which would make treatment compliance difficult? (See 5204 - Blood Chemistry, 5214 - Medical History)*(R7MEDCDN)* ☐ No ☐ Yes ☐ Not assessed
   a. If "Yes", does the individual have AIDS according to the current CDC criteria for AIDS? (See 5214 - Medical History, Q19)*(R7AIDS)* ☐ No ☐ Yes ☐ Not assessed
   b. If "Yes", does the individual have liver function tests greater than 3x the upper limit of normal? (See 5204 - Blood Chemistry, Q3-5)*(R7LIVER3)* ☐ No ☐ Yes ☐ Not assessed
   c. If "Yes", is the individual's serum creatinine greater than 2 mg/dL? (See 5204 - Blood Chemistry, Q2)*(R7CRTNE)* ☐ No ☐ Yes ☐ Not assessed
   d. If "Yes", other?*(R7MEDOTH)* ☐ No ☐ Yes ☐ Unknown If "Other", specify:*(R7MDOTSP)* _____
9. Does the individual have a psychiatric disorder requiring continued treatment with a psychotropic medication? (See 5223 - Prior and Concomitant Medication and 5214 - Medical History)*(R7PSYCH)* ☐ No ☐ Yes ☐ Not assessed
10. Does the individual have a known or suspected hypersensitivity to Buspirone? (See 5214 - Medical History, Q20)*(R7SENBUP)* ☐ No ☐ Yes ☐ Not assessed
11. Is the individual pregnant or breastfeeding? (See 5222 - Pregnancy, and Birth Control Assessment, Q3b and Q1)*(R7PREGNT)* ☐ No ☐ Yes ☐ Not assessed ☐ Not applicable (male)
12. Has the individual used any of the following medications within 14 days of randomization: monoamine oxidase (MAO) inhibitors such as phenelzine (Nardil), selegiline (Eldepryl), isocarboxazid (Marplan), or tranylcypromine (Parnate)? (See 5223 - Prior and Concomitant Medications)*(R7MED14D)* ☐ No ☐ Yes ☐ Not assessed
13. Is the individual taking any medications, which in the judgment of the study medical clinician, may produce interactions with buspirone that are sufficiently dangerous so as to exclude the patient from participating in the study? (See 5223 - Prior and Concomitant Medications)*(R7MEDINT)* ☐ No ☐ Yes ☐ Not assessed
14. Is the individual anyone who would not be expected to complete the study protocol? (Based on 5210 - Drop-Out Risk Assessment and the judgment of the study investigator)*(R7CMPLTE)* ☐ No ☐ Yes ☐ Not assessed
15. Is the individual a significant suicidal/homicidal risk? (Based on the judgment of the study investigator and 5224 - PRISM)*(R7SUICDE)* ☐ No ☐ Yes ☐ Not assessed

Eligibility

16. Is the individual eligible for the study as defined by the inclusion/exclusion criteria?*(R7ELGSTY)* ☐ No ☐ Yes

    How many days did the participant report using cocaine in the 28 days prior to residential admission? (See 5233 - Timeline Follow-Back - Screening/Baseline, Q1-28)*(R7COCFRQ)* ☐ Less than 10 days ☐ 10 days of use or more

Randomization

17. If Participant is eligible, will they be randomized?*(R7ELGRDM)* ☐ No ☐ Yes

    If "No", specify:*(R7NORSP)*

    1-No longer interested in participating in the study
    2-Left prior to randomization and failed to return
    99-Other

    If "Other", specify:*(R7OTHRSP)*

    Comments:*(R7COMM)*