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)* _____

NIDA Clinical Trials Network

0049Z (ENR)

Web Version: 1.0; ; 09-16-13

Date of assessment:*(R6ASMDT)* _____ *(mm/dd/yyyy)* Click here for calendar

Inclusion Criteria

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

1. Participant is at least 18 years old:*(R6PTAGE)* ☐ No ☐ Yes ☐ Unknown
2. Participant signed HIPAA and/or ROI to abstract hospital records to verify CD4 and VL eligibility criteria: *(R6HIPAA)* ☐ No ☐ Yes ☐ Unknown
3. Participant reports living in the vicinity and is able to return for follow-up visits:*(R6LIVRET)* ☐ No ☐ Yes ☐ Unknown
4. Participant is able to communicate in English:*(R6ENGLSH)* ☐ No ☐ Yes ☐ Unknown
5. Participant was admitted to a hospital and was HIV-infected at the time of recruitment:*(R6ADMIT)* ☐ No ☐ Yes ☐ Unknown
6. Participant has a Karnofsky performance scale index score of greater than or equal to 60:*(R6KARNOF)* ☐ No ☐ Yes ☐ Unknown
7. Participant reports any opioid and/or stimulant and/or heavy alcohol use within the past year:*(R6DRGUSE)* ☐ No ☐ Yes ☐ Unknown
8. Participant has an indication of any opioid and/or stimulant and/or heavy alcohol use within the past 12 months:*(R6DRGUSE)* ☐ No ☐ Yes ☐ Unknown
   a. If female, the AUDIT-C score is greater than or equal to 3 or if male, the AUDIT-C score is greater than or equal to 4:*(R6AUC)* ☐ No ☐ Yes ☐ Unknown
   b. In the past year, participant has used one of the following for non-medical reasons: Ecstasy, Heroin, Methamphetamine, Powdered Cocaine, Rock Cocaine, or Recreational use of prescription drugs or pain killers to get high:*(R6SUB)* ☐ No ☐ Yes ☐ Unknown
   c. The hospital system medical record for this participant has evidence of opioid or stimulant use in the past 12 months:*(R6SUBHR)* ☐ No ☐ Yes ☐ Unknown
   d. The hospital system medical record for this participant has evidence of heavy alcohol use in the past 12 months:*(R6AUCHR)* ☐ No ☐ Yes ☐ Unknown
9. Participant has a detectable (>200 copies/mL) viral load or unknown level in the past 6 months: *(R6VRLOAD)* ☐ No ☐ Yes ☐ Unknown
   a. If "Yes" or "No", specify viral load:*(R6LOADVL)* _____ *(xxxxxxxx)* copies/mL **-or-** *(R6VRUNK)* ☐ Unknown
   b. Date viral load obtained:*(R6LOADDT)* _____ *(mm/dd/yyyy)*
10. Participant has a baseline CD4 count <350 cells/uL in the past 6 months:*(R6BSECD4)* ☐ No ☐ Yes ☐ Unknown
    a. If "Yes" or "No", specify CD4 count:*(R6CD4VAL)* _____ *(xxxxx)* cells/uL
    b. Date CD4 count obtained:*(R6CD4DT)* _____ *(mm/dd/yyyy)*
11. Participant meets one or more of the following:*(R6VLCD4)* ☐ No ☐ Yes
    a. Participant has an AIDS-defining illness during the current hospital admission:*(R6AIDS)* ☐ No ☐ Yes ☐ Unknown
    b. Within the past 6 months, participant's most recent CD4 count performed is less than 350 cells/uL and viral load is greater than 200 copies/mL:*(R6VLCD6)* ☐ No ☐ Yes ☐ Unknown
    c. Within the past 12 months, participant's most recent CD4 count performed is less than or equal to 500 cells/uL and viral load is greater than 200 copies/mL or unknown **AND** the Site PI's discretion indicates that the participant is likely to currently have a viral load greater than 200 copies/mL, is not currently successfully/correctly taking ART, and needs to be on ART:*(R6VLCD12)* ☐ No ☐ Yes ☐ Unknown

If the above criteria are "Yes," the patient is eligible to enroll in the study (proceed with main consent and locator information form).

12. Participant provided informed consent for baseline assessments: *(R6INFORM)* ☐ No ☐ Yes
    a. Date informed consent signed for baseline assessment: *(R6CNSTDT)* *(mm/dd/yyyy)* Click here for calendar
    b. If "No", specify: *(R6CNSNO)*
    1-Ineligible due to screening criteria
    2-Participant's decision/changed mind
    3-Judgment of study personnel
    4-Failed to return to complete ICF
    99-Other
    If "Judgment of study personnel", specify: *(R6CNSJUD)*
    If "Other", specify: *(R6CNSOSP)*
    c. Provided consent for audio recording: *(R6INFAUD)* ☐ No ☐ Yes
    d. Provided consent to be contacted for optional future studies: *(R6INFFUT)* ☐ No ☐ Yes
13. Participant provides sufficient locator information: *(R6LCATOR)* ☐ No ☐ Yes ☐ Unknown
14. A baseline blood draw has been completed for this participant: *(R6BLOOD)* ☐ No ☐ Yes ☐ Unknown
15. Participant has completed the baseline CAPI assessments: *(R6CAPI)* ☐ No ☐ Yes

Exclusion Criteria

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

1. Participant has a significant cognitive or developmental impairment to the extent that they are unable to provide informed consent: *(R6SIGCOG)* ☐ No ☐ Yes ☐ Unknown
2. Participant is terminated via site PI decision with agreement from study LI: *(R6TERM)* ☐ No ☐ Yes ☐ Unknown
   If "Yes", specify: *(R6TERMSP)*

Eligibility for Randomization

1. Is the participant eligible for the study? *(R6PTELIG)* ☐ No ☐ Yes
2. Is the participant eligible for randomization? *(R6PTRAND)* ☐ No ☐ Yes
   a. If "No", specify: *(R6NORASP)*
   1-Failed to return to clinic
   2-Declined study participation
   3-Death
   4-Judgment of CTP/research staff
   5-Other
   b. If "Judgment of CTP/research staff", specify: *(R6JUDGSP)*
   c. If "Other", specify: *(R6OTHRSP)*

Comments:*(R6COMM)*