

# NIDA Clinical Trials Network

0075Z (ENR)

Web Version: 1.0; 1.03; 05-11-18

Date of assessment:(*STARTDT*)

(mm/dd/yyyy)

Date of last stabilization visit:(*R8STVSDT*)

(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:(*R8PTAGE*)  0-No  1-Yes
2. Participant uses adequate birth control methods:(*R8BCUSE*)  0-No  1-Yes  97-Unknown  96-Not applicable
3. Participant meets DSM-5 criteria for past-year opioid use disorder:(*R8PYOUD*)  0-No  1-Yes  97-Unknown
4. Participant has completed buprenorphine induction for opioid use disorder:(*R8BIOUD*)  0-No  1-Yes  97-Unknown
5. Participant has expressed the intention to receive maintenance (>=6 months) buprenorphine treatment:(*R8BUPMNT*)  0-No  1-Yes  97-Unknown
6. Participant is willing to receive pharmacist administered buprenorphine maintenance treatment:(*R8PHRBUP*)  0-No  1-Yes  97-Unknown
7. Participant is willing and able to provide written informed consent and HIPAA authorization:(*R8ICHIPA*)  0-No  1-Yes  97-Unknown
8. Participant is able to read and communicate in English:(*R8COMENG*)  0-No  1-Yes  97-Unknown
9. Participant is able to comply with buprenorphine treatment policies:(*R8BUPPOL*)  0-No  1-Yes  97-Unknown

## Exclusion Criteria

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

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, compromise study findings, or prevent the participant from completing the study:(*R8MPSDIS*)  0-No  1-Yes  97-Unknown  
Examples Include:
  - A disabling or terminal medical illness (e.g., heart failure, cirrhosis or end-stage liver disease, acute hepatitis or moderate to severe renal impairment) as assessed by medical history, review of systems, physical exam, and/or laboratory assessments.
  - A current severe, untreated or inadequately treated mental health disorder (e.g., active psychosis, uncontrolled manic-depressive illness) as assessed by mental health history and/or clinical interview.
  - A current severe benzodiazepine or other substance use requiring medical detoxification.
  - Suicidal or homicidal ideations requiring immediate action.
2. Participant has a known allergy or hypersensitivity to buprenorphine, naloxone, or other components of the buprenorphine/naloxone formulation:(*R8BUPALG*)  0-No  1-Yes  97-Unknown
3. Participant has aspartate aminotransferase (AST) or alanine aminotransferase (ALT) liver enzymes greater than 5 times the upper limit of normal on screening phlebotomy performed within 60 days prior to the date of the last stabilization visit:(*R8ASTALT*)  0-No  1-Yes  97-Unknown
4. Participant has chronic pain requiring ongoing pain  0-No  1-Yes  97-Unknown

management with opioid analgesics:(R8PAIN)

5. Participant is currently in jail, prison or any overnight facility as required by court of law or pending legal action that could prevent participation in study activities (i.e., unable to complete 6 months of pharmacy-based OUD management): (R8LGLOTH)

0-No  1-Yes  97-Unknown

6. Participant is pregnant or breastfeeding at the time of screening:(R8PREGBF)

0-No  1-Yes  97-Unknown  96-Not applicable

## Eligibility for Study Enrollment

1. Is the participant eligible for the study?(R8ELGSTY)

0-No  1-Yes

2. Will the participant be enrolled?(R8ELGRND)

0-No  1-Yes

If "No", specify:(R8NORAND)

2-Declined study participation  
3-Death  
4-Judgement of site/research staff  
5-Failed to return to clinic prior to enrollment  
99-Other

If "Judgement of site/research staff" or "Other", specify:  
(R8NORDSP)

Comments:(R8COMM)