0097Z (ENR)

Version: 1.01; 12-06-21

Date of assessment:*(STARTDT)* *(mm/dd/yyyy)*

Time of assessment:*(E97ASMTM)* *(hh:mm)* *(24-hour format)*

Date of admission:*(E97ADMDT)* *(mm/dd/yyyy)*

Time of admission:*(E97ADMTM)* *(hh:mm)* *(24-hour format)*

Inclusion Criteria

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

1. Is the participant 18 years of age or older?*(E97PTAGE)* ☐ 00-No ☐ 01-Yes ☐ 97-Not assessed
2. Does the participant meet current DSM-5 criteria for opioid use disorder?*(E97DSM5)* ☐ 00-No ☐ 01-Yes ☐ 97-Not assessed
3. Is the participant seeking treatment for opioid use disorder, willing to accept treatment with XR-NTX and, in the judgement of the treating physician, a good candidate for naltrexone-based treatment?*(E97STOUD)* ☐ 00-No ☐ 01-Yes ☐ 97-Not assessed
4. Is the participant willing and able to provide written informed consent?*(E97CNSNT)* ☐ 00-No ☐ 01-Yes ☐ 97-Not assessed
5. Is the participant able to speak English sufficiently to understand the study procedures and provide written informed consent to participate in the study?*(E97ENGLS)* ☐ 00-No ☐ 01-Yes ☐ 97-Not assessed
6. If the participant is of childbearing potential, is the participant willing to practice an effective method of birth control for the duration of participation in the study? *(E97BCUSE)* ☐ 00-No ☐ 01-Yes ☐ 97-Unknown ☐ 96-Not applicable

Exclusion Criteria

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

7. Does the participant have a serious medical, psychiatric or substance use disorder that, in the opinion of the study physician, would make a detoxification and naltrexone initiation, or maintenance treatment with XR-NTX, hazardous (relative contra-indications)? Examples include:*(E97PSYCH)* ☐ 00-No ☐ 01-Yes ☐ 97-Not assessed
   a. Disabling or terminal medical illness (e.g., uncompensated heart failure, severe acute hepatitis, cirrhosis or end-stage liver disease) as assessed by medical history and/or review of systems.
   b. Severe, untreated or inadequately treated mental disorder (e.g., active psychosis, uncontrolled manic-depressive illness) as assessed by history and/or clinical interview.
   c. Current severe alcohol, benzodiazepine, or other depressant or sedative hypnotic use likely to require a complicated medical detoxification (routine alcohol and sedative detoxifications may be included).
   d. Suicidal or homicidal ideation that requires immediate attention.
8. Does the participant have a known allergy or sensitivity to buprenorphine, naloxone, naltrexone, polylactide-co-glycolide, carboxymethylcellulose, or other components of the Vivitrol® diluent?*(E97ALRGY)* ☐ 00-No ☐ 01-Yes ☐ 97-Not assessed
9. Is the participant on maintenance treatment with methadone?*(E97MTDDP)* ☐ 00-No ☐ 01-Yes ☐ 97-Not assessed
10. Is the participant on maintenance treatment with buprenorphine unless the patient is determined to have a poor treatment response (in the form of buprenorphine non-adherence with or without the use of illicit opioids), warranting change to XR-NTX treatment.*(E97BUPDP)* ☐ 00-No ☐ 01-Yes ☐ 97-Not assessed
11. Is the participant experiencing the presence of pain of sufficient severity as to require ongoing pain management with opioids?*(E97OPIDP)* ☐ 00-No ☐ 01-Yes ☐ 97-Not assessed
12. Is the participant experiencing circumstances (legal, personal, occupational) that would threaten the feasibility of XR-NTX treatment or make another treatment (e.g. buprenorphine or methadone) a better choice?*(E97CRCMS)* ☐ 00-No ☐ 01-Yes ☐ 97-Not assessed
13. Is the participant currently in jail, prison or other overnight facility as required by court of law or have pending legal action that could prevent participation in study activities? *(E97PRISN)* ☐ 00-No ☐ 01-Yes ☐ 97-Not assessed
14. If the participant is female, is the participant currently pregnant or breastfeeding, or planning on conception?*(E97PREG)* ☐ 00-No ☐ 01-Yes ☐ 97-Unknown ☐ 96-Not applicable
15. Does the participant have a body habitus that, in the judgment of the study physician, precludes safe intramuscular injection of XR-NTX (e.g., BMI>40, excess fat tissue over the buttocks, emaciation)?*(E97BHEXC)* ☐ 00-No ☐ 01-Yes ☐ 97-Not assessed
16. Was the participant admitted to the inpatient detoxification or residential rehabilitation unit more than 3 days prior to consent?*(E973DAYS)* ☐ 00-No ☐ 01-Yes ☐ 97-Not assessed
17. Was the participant admitted to the inpatient detoxification or residential rehabilitation unit more than 4 calendar days prior to the enrollment assessment date?*(E973DAYS)* ☐ 00-No ☐ 01-Yes ☐ 97-Not assessed

Eligibility for Enrollment

18. Is the participant eligible for enrollment into the study?*(E97ELGST)* ☐ 0-No ☐ 1-Yes
19. If the participant is eligible, will they be enrolled in the study?*(E97ELENR)* ☐ 0-No ☐ 1-Yes

a. If "No", specify: *(E97NORSP)*

- 00-No longer interested in participating in the study
- 02-Judgment of site/research staff
- 05-Time commitment
- 07-Left prior to completion
- 92-COVID-19: Illness
- 93-COVID-19: Public health measures
- 94-COVID-19: Other
- 99-Other

1. If "Other", specify: *(E97OTHSP)*

Comments: *(E97COMM)*

Protocol Deviation (PDV)

Version: 2.02; 02-24-22

Date of deviation *(PDDATE)*:
Protocol deviation number *(PDSEQNO)*:

1. Is this deviation related to one or more participants?*(PDPPTREL)* ☐ 0-No ☐ 1-Yes
   a. If "Yes", how many participants?*(PDPRELNO)*

01-1
02-2
03-3
04-4
05-5
*Additional Options Listed Below

Select related participants:

Participant ID 1:*(PDPPT01)*	999999999999999-DUMMYPARTICIPANTID
Participant ID 2:*(PDPPT02)*	999999999999999-DUMMYPARTICIPANTID
Participant ID 3:*(PDPPT03)*	999999999999999-DUMMYPARTICIPANTID
Participant ID 4:*(PDPPT04)*	999999999999999-DUMMYPARTICIPANTID
Participant ID 5:*(PDPPT05)*	999999999999999-DUMMYPARTICIPANTID
Participant ID 6:*(PDPPT06)*	999999999999999-DUMMYPARTICIPANTID
Participant ID 7:*(PDPPT07)*	999999999999999-DUMMYPARTICIPANTID
Participant ID 8:*(PDPPT08)*	999999999999999-DUMMYPARTICIPANTID
Participant ID 9:*(PDPPT09)*	999999999999999-DUMMYPARTICIPANTID
Participant ID 10:*(PDPPT10)*	999999999999999-DUMMYPARTICIPANTID
Participant ID 11:*(PDPPT11)*	999999999999999-DUMMYPARTICIPANTID
Participant ID 12:*(PDPPT12)*	999999999999999-DUMMYPARTICIPANTID
Participant ID 13:*(PDPPT13)*	999999999999999-DUMMYPARTICIPANTID
Participant ID 14:*(PDPPT14)*	999999999999999-DUMMYPARTICIPANTID
Participant ID 15:*(PDPPT15)*	999999999999999-DUMMYPARTICIPANTID
Participant ID 16:*(PDPPT16)*	999999999999999-DUMMYPARTICIPANTID
Participant ID 17:*(PDPPT17)*	999999999999999-DUMMYPARTICIPANTID
Participant ID 18:*(PDPPT18)*	999999999999999-DUMMYPARTICIPANTID
Participant ID 19:*(PDPPT19)*	999999999999999-DUMMYPARTICIPANTID

Participant ID 20:*(PDPPT20)*

999999999999999-DUMMYPARTICIPANTID

2. Date deviation identified:*(PDVDATE)* *(mm/dd/yyyy)*

3. Deviation type:*(PDTYPE)*

010-INFORMED CONSENT/ASSENT PROCEDURES
01A--- No consent/assent obtained
01B--- Unauthorized assessments and/or procedures conducted prior to obtaining informed consent/assent
01C--- Non IRB approved/outdated/obsolete informed consent/assent documents used
01Y--- Other major informed consent/assent procedures issues (specify)
*Additional Options Listed Below

a. If "Other", specify:*(PDTYPSP)*

4. Reason for Protocol Deviation: *(select all that apply)*

a. Research staff error:*(PDRSSTFF)* ☐ 0-No ☐ 1-Yes
b. Hospital error:*(PDRSHSP)* ☐ 0-No ☐ 1-Yes
c. Laboratory error:*(PDRSLAB)* ☐ 0-No ☐ 1-Yes
d. Pharmacy error:*(PDRSPHRM)* ☐ 0-No ☐ 1-Yes
e. Equipment/supply failure:*(PDRSEQSP)* ☐ 0-No ☐ 1-Yes
f. Issue with Advantage eClinical (e.g., system down, system glitch):*(PDRSEDC)* ☐ 0-No ☐ 1-Yes
g. Participant unable to comply:*(PDRSPTNC)* ☐ 0-No ☐ 1-Yes
h. Participant refusal:*(PDRSPTRF)* ☐ 0-No ☐ 1-Yes
i. Investigator/study decision:*(PDRSINDC)* ☐ 0-No ☐ 1-Yes
j. Other:*(PDRSOTHR)* ☐ 0-No ☐ 1-Yes
1. If "Other", specify:*(PDRSOTSP)*

5. Is this deviation related to COVID-19?*(PDCVD19)* ☐ 0-No ☐ 1-Yes

6. Brief description of what occurred:*(PDDESCPT)*

7. Was/will there be corrective action for this event?*(PDCORRNY)* ☐ 0-No ☐ 1-Yes

a. If "No", describe why corrective action was not or will not be taken:*(PDNOCRSP)*

b. If "Yes", which of the following corrective actions were/will be taken: *(select all that apply)*

1. Participant consent/reconsent was/will be obtained:*(PDCACNST)* ☐ 0-No ☐ 1-Yes
2. Research staff corrected/will correct error(s) and/or completed/will complete document(s):*(PDCASTCR)* ☐ 0-No ☐ 1-Yes
3. Participant corrected/will correct error(s) and/or completed/will complete document(s):*(PDCAPTCR)* ☐ 0-No ☐ 1-Yes
4. Document(s) was/will be moved to correct file location(s):*(PDCADCMV)* ☐ 0-No ☐ 1-Yes
5. Participant was/will be withdrawn from study:*(PDCAPTWD)* ☐ 0-No ☐ 1-Yes
6. Study drug administration was/will be halted:*(PDCADGSP)* ☐ 0-No ☐ 1-Yes
7. Study assessment was/will be performed or repeated:*(PDCAASAD)* ☐ 0-No ☐ 1-Yes
8. Other:*(PDCAOTHR)* ☐ 0-No ☐ 1-Yes
1. If "Other", specify:*(PDCAOTSP)*

c. As needed or requested, provide additional details about the corrective action plan:*(PDCAPSP)*

8. Brief description of the plan to prevent recurrence: *(select all that apply)*

a. Complete local retraining:*(PDPLPTRN)* ☐ 0-No ☐ 1-Yes
1. If "Complete local retraining", specify:*(PDPLPSP)*
b. Revise local SOP(s):*(PDPLPRV)* ☐ 0-No ☐ 1-Yes
c. Recalibrate/fix or replace faulty equipment/supplies:*(PDPLPEQ)* ☐ 0-No ☐ 1-Yes
d. Remove and/or replace incorrect/outdated document(s) from file(s)*(PDPLPDOC)* ☐ 0-No ☐ 1-Yes
e. No site action needed:*(PDPLPNAN)* ☐ 0-No ☐ 1-Yes
f. Other:*(PDPLPOTH)* ☐ 0-No ☐ 1-Yes
1. If "Other", specify:*(PDPLPOSP)*

9. Is this deviation reportable to your IRB?*(PDIRBREP)* ☐ 0-No ☐ 1-Yes

a. If "Yes", will the IRB be notified at the time of continuing review?*(PDIRBCON)* ☐ 0-No ☐ 1-Yes

b. If "Yes", date of planned submission:*(PDIRBPDT)* *(mm/dd/yyyy)*

c. If "No", date of actual submission:*(PDIRBADT)* *(mm/dd/yyyy)*

Comments:*(PDVCOMM)*

Additional Selection Options for PDV

Protocol deviation number *(PDSEQNO)* (key field):

01-1st Protocol Deviation of the day
02-2nd Protocol Deviation of the day
03-3rd Protocol Deviation of the day
04-4th Protocol Deviation of the day
05-5th Protocol Deviation of the day
06-6th Protocol Deviation of the day
07-7th Protocol Deviation of the day
08-8th Protocol Deviation of the day
09-9th Protocol Deviation of the day
10-10th Protocol Deviation of the day

If "Yes", how many participants?

06-6
07-7
08-8
09-9
10-10
11-11
12-12
13-13
14-14
15-15
16-16
17-17
18-18
19-19
20-20

Deviation type:

010--- INFORMED CONSENT/ASSENT PROCEDURES
01A--- No consent/assent obtained
01B--- Unauthorized assessments and/or procedures conducted prior to obtaining informed consent/assent
01C--- Non IRB approved/outdated/obsolete informed consent/assent documents used
01Y--- Other major informed consent/assent procedures issues (specify)
020-INCLUSION/EXCLUSIONCRITERIA
02A--- Ineligible participant enrolled/inclusion/exclusion criteria not met or eligibility not fully assessed prior to enrollment
02Z--- Other inclusion/exclusion criteria issues (specify)
040-LABORATORY ASSESSMENTS
04Y--- Other laboratory assessment issues - Minor (specify)
04Z--- Other laboratory assessments issues - Major (specify)
050-STUDY PROCEDURES/ASSESSMENTS
05A--- Study assessment/procedures not followed in accordance with study protocol
05Z--- Other study procedures/assessments issues (specify)
060-ADVERSE EVENT
06A--- AE not reported
06B--- SAE not reported
06C--- AE/SAE reported out of protocol specified reporting timeframe
06D--- AE/SAE not elicited, observed and/or documented as per protocol
06E--- Safety assessment (e.g., labs, ECG, clinical referral to care) not conducted per protocol
06Z--- Other adverse events issues (specify)
070-RANDOMIZATION PROCEDURES
07A--- Stratification error
07Z--- Other randomization procedures issues (specify)
080-STUDY MEDICATION MANAGEMENT
08A--- Medication not dispensed/administered in accordance with the study protocol
08B--- Participant use of protocol prohibited medication
08Z--- Other study medication management issues (specify)
990-OTHER SIGNIFICANT DEVIATIONS
99A--- Destruction of study materials without prior authorization from sponsor
99B--- Breach of Confidentiality
99Y--- Other significant deviations issues - Minor (specify)
99Z--- Other significant deviations issues - Major (specify)