0097A (ENR)

Version: 2.01; 02-24-22

Date pre-screened:*(STARTDT)* _____ *(mm/dd/yyyy)*

Date of birth:*(P97DOBDT)* _____ *(mm/dd/yyyy)*

1. Is the candidate diagnosed with current and active OUD?*(P97CAOUD)* ☐ 0-No ☐ 1-Yes
2. Is the candidate eligible for XR-NTX?*(P97ELNTX)* ☐ 0-No ☐ 1-Yes

   If "No", specify:
   a. Patient is currently pregnant or breastfeeding, or planning conception:*(P97PREG)* ☐ 01-
   b. Patient has serious medical, psychiatric or substance use disorder that is a contraindication to XR-NTX in the opinion of the investigator:*(P97SMEDD)* ☐ 01-
   c. Patient has known allergy or sensitivity buprenorphine, naloxone, naltrexone, polylactide-coglycolide, carboxymethylcellulose, or other components of the Vivitrol diluent:*(P97ALRGY)* ☐ 01-
   d. Patient requires ongoing pain management with opioids:*(P97ONGPM)* ☐ 01-
   e. Patient has body habitus that, in the opinion of the investigator, precludes safe intramuscular injection of XR-NTX:*(P97BHEXC)* ☐ 01-
   f. Other:*(P97OTHNE)* ☐ 01-
      1. If "Other", specify:*(P97ONSP)* _____
3. Is the candidate attempting XR-NTX induction?*(P97NTXIN)* ☐ 0-No ☐ 1-Yes

   If "No", specify:
   a. Prefers buprenorphine maintenance:*(P97PBUPR)* ☐ 01-
   b. Prefers methadone maintenance:*(P97MTD)* ☐ 01-
   c. Prefers detoxification without MOUD afterwards:*(P97DMOUD)* ☐ 01-
   d. Previous side effects from XR-NTX:*(P97PRVSE)* ☐ 01-
   e. Previous attempt to XR-NTX failed to maintain abstinence:*(P97PRVAT)* ☐ 01-
   f. Does not like injections:*(P97DLINJ)* ☐ 01-
   g. There is a concern about finding a provider for vivitrol injections after the study:*(P97CCPRO)* ☐ 01-
   h. There is a concern about paying for the shots after the study:*(P97CCPAY)* ☐ 01-
   i. There is a concern about their insurance coverage for the inpatient induction:*(P97CCINS)* ☐ 01-
   j. Other:*(P97OTHIE)* ☐ 01-
      1. If "Other", specify:*(P97OISP)* _____
4. Does the candidate meet basic eligibility to move forward in the study?*(P97CNSNT)* ☐ 0-No ☐ 1-Yes

   If "No", specify:
   a. Patient refused study participation:*(P97RFCNS)* ☐ 01-
   b. Patient has received maintenance treatment with methadone since admission:*(P97MNTAD)* ☐ 01-
   c. Patient < 18 years of age:*(P97UND18)* ☐ 01-
   d. Patient displays suicidal or homicidal ideation that requires immediate attention:*(P97SUICD)* ☐ 01-
   e. Consent could not be obtained within 4 days of admission:*(P97CNST3)* ☐ 01-
   f. Not English-speaking patient:*(P97ENGLS)* ☐ 01-
   g. Patient has pending legal action that could prevent participation in study activities:*(P97PNDLA)* ☐ 01-
   h. Other:*(P97OTHDE)* ☐ 01-
      1. If "Other", specify:*(P97ODSP)* _____

Comments:*(P97COMM)* _____

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
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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)