Adverse Event (AD1)

Web Version: 1.0; 4.01; 05-28-19

Adverse event onset date *(AEDATE)*:
Event number *(AESEQNO)*:

This adverse event has been closed by the Medical Reviewer and may no longer be updated.

1. Adverse event name:*(A1DESCPT)*

2. Date site became aware of the event:*(A1AWARDT)* *(mm/dd/yyyy)*

3. Severity of event:*(A1SEVRTY)*
   - 1-Grade 1 - Mild
   - 2-Grade 2 - Moderate
   - 3-Grade 3 - Severe

4. Is there a reasonable possibility that the injectable study medication caused the event?*(A1RINJ)* ☐ 0-No ☐ 1-Yes
   If "Yes", action taken with the injectable study medication:*(A1AINJ)*
   - 0-None
   - 1-Temporarily stopped injection
   - 2-Permanently stopped injection

5. Is there a reasonable possibility that the oral study medication caused the event?*(A1RORMED)* ☐ 0-No ☐ 1-Yes
   If "Yes", action taken with the oral study medication:*(A1AORMED)*
   - 0-None
   - 1-Dose reduced
   - 2-Temporarily stopped medication
   - 3-Permanently stopped medication

6. If not caused by the injectable study medication and oral study medication, alternative etiology:*(A1ALTESD)*
   - 0-None apparent
   - 1-Study disease
   - 2-Concomitant medication
   - 3-Other pre-existing disease or condition
   - 4-Accident, trauma, or external factors
   - *Additional Options Listed Below

   If "Other", specify:*(A1AEPSP)*

7. Outcome of event:*(A1OUTCM)*
   - 1-Ongoing
   - 2-Resolved without sequelae
   - 3-Resolved with sequelae
   - 4-Resolved by convention
   - 5-Death

8. Date of resolution or medically stable:*(A1RESDT)* *(mm/dd/yyyy)*

Except for "None of the following", all selections in the question below will designate this as a Serious Adverse Event (SAE). The Serious Adverse Event Summary (AD2) form should be completed for all Serious Adverse Events reported.

9. Was this event associated with:*(A1ASSOC)*
   - 0-None of the following
   - 1-Death
   - 2-Life-threatening event
   - 7-Seizure
   - 3-Inpatient admission to hospital or prolongation of existing hospitalization
   - *Additional Options Listed Below

   a. If "Death", date of death:*(A1DTHDT)* *(mm/dd/yyyy)*

   b. If "Inpatient admission to hospital or prolongation of exisiting hospitalization":
   Date of hospital admission:*(A1HOSPAD)* *(mm/dd/yyyy)*
   Date of hospital discharge:*(A1HOSPDC)* *(mm/dd/yyyy)*

Comments:*(AD1COMM)*

Additional Selection Options for AD1

Event number *(AESEQNO)* (key field):
01-1st Adverse Event of the day
02-2nd Adverse Event of the day
03-3rd Adverse Event of the day
04-4th Adverse Event of the day
05-5th Adverse Event of the day
06-6th Adverse Event of the day
07-7th Adverse Event of the day
08-8th Adverse Event of the day
09-9th Adverse Event of the day
10-10th Adverse Event of the day

If not caused by the injectable study medication and oral study medication, alternative etiology:
5-Concurrent illness/condition (not pre-existing)
6-Study procedures
99-Other

Was this event associated with:
4-Persistent or significant incapacity
5-Congenital anomaly or birth defect
6-Important medical event that required intervention to prevent any of the above

NIDA Clinical Trials Network

Serious Adverse Event Summary (AD2)

Web Version: 1.0; 2.00; 10-03-17

Adverse event onset date *(AEDATE)*:
Event number *(AESEQNO)*:

This adverse event has been closed by the Medical Reviewer and may no longer be updated.

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1. Initial narrative description of serious adverse event:*(A2SUMM)*

2. Relevant past medical history:*(A2SAEMHX)* ☐ 0-No ☐ 1-Yes ☐ 97-Unknown

Allergies, pregnancy, smoking and alcohol use, hypertension, diabetes, epilepsy, depression, etc.
(A2MEDHX)

3. Medications at the time of the event:*(A2SAEMED)* ☐ 0-No ☐ 1-Yes ☐ 97-Unknown

Medication (Generic Name)	**Indication**
(A2_01DNM)	*(A2_01DIN)*
(A2_02DNM)	*(A2_02DIN)*
(A2_03DNM)	*(A2_03DIN)*
(A2_04DNM)	*(A2_04DIN)*
(A2_05DNM)	*(A2_05DIN)*
(A2_06DNM)	*(A2_06DIN)*
(A2_07DNM)	*(A2_07DIN)*
(A2_08DNM)	*(A2_08DIN)*
(A2_09DNM)	*(A2_09DIN)*
(A2_10DNM)	*(A2_10DIN)*

4. Treatments for the event:*(A2SAETRT)* ☐ 0-No ☐ 1-Yes ☐ 97-Unknown

Treatment	**Indication**	**Date Treated** *(mm/dd/yyyy)*
(A2_1TNME)	*(A2_1TIND)*	*(A2_1LTDT)*
(A2_2TNME)	*(A2_2TIND)*	*(A2_2LTDT)*
(A2_3TNME)	*(A2_3TIND)*	*(A2_3LTDT)*
(A2_4TNME)	*(A2_4TIND)*	*(A2_4LTDT)*
(A2_5TNME)	*(A2_5TIND)*	*(A2_5LTDT)*

5. Labs/tests performed in conjunction with this event:*(A2SAELAB)* ☐ 0-No ☐ 1-Yes ☐ 97-Unknown

Lab/Test	**Findings**	**Date of Test** *(mm/dd/yyyy)*
(A2_1LBNM)	*(A2_1LBIN)*	*(A2_1LBDT)*
(A2_2LBNM)	*(A2_2LBIN)*	*(A2_2LBDT)*
(A2_3LBNM)	*(A2_3LBIN)*	*(A2_3LBDT)*
(A2_4LBNM)	*(A2_4LBIN)*	*(A2_4LBDT)*
(A2_5LBNM)	*(A2_5LBIN)*	*(A2_5LBDT)*

6. Follow-up:*(A2FOLLUP)*

Include labs/test results as they become available, clinical changes, consultant diagnosis, etc.

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7. Additional information requested by the Medical Monitor:*(A2ADDINF)*

Have all Medical Monitor requests been addressed?*(A2RQADDR)* ☐ 1-Yes

Additional Selection Options for AD2

Event number *(AESEQNO)* (key field):
01-1st Adverse Event of the day
02-2nd Adverse Event of the day
03-3rd Adverse Event of the day
04-4th Adverse Event of the day
05-5th Adverse Event of the day
06-6th Adverse Event of the day
07-7th Adverse Event of the day
08-8th Adverse Event of the day
09-9th Adverse Event of the day
10-10th Adverse Event of the day

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Serious Adverse Event Medical Reviewer (AD3)

Web Version: 1.0; 3.01; 05-28-19

Adverse event onset date *(AEDATE)*:
Event number *(AESEQNO)*:

1. Was this determined to be a serious adverse event?*(A3SAE)*	☐ 0-No ☐ 1-Yes
2. Is there a reasonable possibility that the injectable study medication caused the event?*(A3RINJ)*	☐ 0-No ☐ 1-Yes
3. Is there a reasonable possibility that the oral study medication caused the event?*(A3RORMED)*	☐ 0-No ☐ 1-Yes
4. Was this event expected?*(A3EXPECT)*	☐ 0-No ☐ 1-Yes
5. Is this a standard expedited/reportable event? *(i.e., is it serious, unexpected and related to therapy)(A3EXPFDA)*	☐ 0-No ☐ 1-Yes
If "No", is this an expedited/reportable event for other reasons?*(A3EXPOTH)*	☐ 0-No ☐ 1-Yes
6. Does the protocol need to be modified based on this event?*(A3MPROT)*	☐ 0-No ☐ 1-Yes
7. Does the consent form need to be modified based on this event?*(A3MCNST)*	☐ 0-No ☐ 1-Yes
8. Is the review complete?*(A3REVDNE)*	☐ 0-No ☐ 1-Yes
If "No", what additional information is required:*(A3ADDINF)*	

Assessed by:*(A3ASRID)* (initials)

Reviewed by:*(A3REVID)* (initials)

Comments:*(A3COMM)*

Additional Selection Options for AD3

Event number *(AESEQNO)* (key field):
01-1st Adverse Event of the day
02-2nd Adverse Event of the day
03-3rd Adverse Event of the day
04-4th Adverse Event of the day
05-5th Adverse Event of the day
06-6th Adverse Event of the day
07-7th Adverse Event of the day
08-8th Adverse Event of the day
09-9th Adverse Event of the day
10-10th Adverse Event of the day

Concise Health Risk Tracking (CHRT) - Participant Rated Module (CHP)

Web Version: 1.0; 5.00; 02-23-18

Segment *(PROTSEG)*: B
Visit number *(VISNO)*:

Date of assessment:*(CHPASMDT)* _____ *(mm/dd/yyyy)*

Please rate the extent to which each of the following statements describes how you have been feeling or acting in the past week.
For example, if you feel the statement very accurately describes how you have been feeling in the past week, you would give a rating of "Strongly Agree." If you feel the statement is not at all how you have been feeling in the past week, you would give a rating of "Strongly Disagree."

		Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
1. I feel as if things are never going to get better.	*(CHNVRBTR)*	☐	☐	☐	☐	☐
2. I have no future.	*(CHNOFUTR)*	☐	☐	☐	☐	☐
3. It seems as if I can do nothing right.	*(CHNORGHT)*	☐	☐	☐	☐	☐
4. Everything I do turns out wrong.	*(CHWRONG)*	☐	☐	☐	☐	☐
5. There is no one I can depend on.	*(CHDPNDON)*	☐	☐	☐	☐	☐
6. The people I care the most for are gone.	*(CHPPLGNE)*	☐	☐	☐	☐	☐
7. I wish my suffering could just all be over.	*(CHSUFOVR)*	☐	☐	☐	☐	☐
8. I feel that there is no reason to live.	*(CHRSLIVE)*	☐	☐	☐	☐	☐
9. I wish I could just go to sleep and not wake up.	*(CHSLPNTW)*	☐	☐	☐	☐	☐
10. I find myself saying or doing things without thinking.	*(CHNOTHNK)*	☐	☐	☐	☐	☐
11. I often make decisions quickly or "on impulse."	*(CHIMPULS)*	☐	☐	☐	☐	☐
12. I often feel irritable or easily angered.	*(CHIRRITE)*	☐	☐	☐	☐	☐
13. I often overreact with anger or rage over minor things.	*(CHOVRRCT)*	☐	☐	☐	☐	☐
14. I have been having thoughts of killing myself.	*(CHKILLMS)*	☐	☐	☐	☐	☐
15. I have thoughts about how I might kill myself.	*(CHHOWKIL)*	☐	☐	☐	☐	☐
16. I have a plan to kill myself.	*(CHPLNKIL)*	☐	☐	☐	☐	☐

Comments:*(CHPCOMM)*

Demographics (DEM)

Web Version: 1.0; 5.00; 09-25-19

1. Date of birth:*(DEBRTHDT)* _____ *(mm/dd/yyyy)*

2. Sex:*(DESEX)* ☐ 1-Male ☐ 2-Female ☐ 97-Don't know ☐ 98-Refused to answer

3. Does the participant consider him or herself to be Hispanic/Latino?*(DEHISPNC)* ☐ 0-No ☐ 1-Yes ☐ 97-Don't know ☐ 98-Refused to answer

   If "Yes", indicate the group that represents his or her Hispanic origin or ancestry:*(DEHISPSP)*

   1-Puerto Rican
   2-Dominican (Republic)
   3-Mexican/Mexican American
   5-Chicano
   6-Cuban/Cuban American
   *Additional Options Listed Below

4. What race does the participant consider him or herself to represent? (Check all that apply)

   American Indian or Alaska Native:*(DEAMEIND)* ☐ 1-

   Asian:*(DEASIAN)* ☐ 1-

   - Asian Indian:*(DEASAIND)* ☐ 1-
   - Chinese:*(DECHINA)* ☐ 1-
   - Filipino:*(DEFILIPN)* ☐ 1-
   - Japanese:*(DEJAPAN)* ☐ 1-
   - Korean:*(DEKOREA)* ☐ 1-
   - Vietnamese:*(DEVIETNM)* ☐ 1-
   - Specify other Asian:*(DEASIAOT)* _____

   Black or African American:*(DEBLACK)* ☐ 1-

   Native Hawaiian or Pacific Islander:*(DEHAWAII)* ☐ 1-

   - Native Hawaiian:*(DENATHAW)* ☐ 1-
   - Guamanian or Chamorro:*(DEGUAM)* ☐ 1-
   - Samoan:*(DESAMOAN)* ☐ 1-
   - Specify other Pacific Islander:*(DEPACISO)* _____

   White:*(DEWHITE)* ☐ 1-

   Some other race:*(DERACEOT)* ☐ 1- Specify:*(DERACESP)* _____

   -or-

   Don't know:*(DERACEDK)* ☐ 1-

   Refused:*(DERACERF)* ☐ 1-

5. What is the highest grade or level of school the participant has completed or the highest degree they have received? *(DEEDUCTN)*

   00-Never attended / kindergarten only
   01-1st grade
   02-2nd grade
   03-3rd grade
   04-4th grade
   *Additional Options Listed Below

6. We would like to know about what the participant does -- is he/she working now, looking for work, retired, keeping house, a student, or what?*(DEJOB)*

   01-Working now
   02-Only temporarily laid off, sick leave, or maternity leave
   03-Looking for work, unemployed
   04-Retired
   05-Disabled, permanently or temporarily
   *Additional Options Listed Below

   If "Other", specify:*(DEJOBSP)* _____

7. Is the participant currently married, widowed, divorced, separated, never married, or living with a partner?*(DEMARTL)*

   01-Married
   02-Widowed
   03-Divorced
   04-Separated
   05-Never married
   *Additional Options Listed Below

   Comments:*(DEMCOMM)* _____

Additional Selection Options for DEM

If "Yes", indicate the group that represents his or her Hispanic origin or ancestry:
8-Central or South American
9-Other Latin American
99-Other Hispanic or Latino
98-Refused
97-Don't know

What is the highest grade or level of school the participant has completed or the highest degree they have received?
05-5th grade
06-6th grade
07-7th grade
08-8th grade
09-9th grade
10-10th grade
11-11th grade
12-12th grade, no diploma
13-High school graduate
14-GED or equivalent
15-Some college, no degree
16-Associate's degree: occupational, technical, or vocational program
17-Associate's degree: academic program
18-Bachelor's degree (e.g., BA, AB, BS, BBA)
19-Master's degree (e.g., MA, MS, MEng, MEd, MBA)
20-Professional school degree (e.g., MD, DDS, DVM, JD)
21-Doctoral degree (e.g., PhD, EdD)
98-Refused
97-Don't know

We would like to know about what the participant does -- is he/she working now, looking for work, retired, keeping house, a student, or what?
06-Keeping house
07-Student
99-Other

Is the participant currently married, widowed, divorced, separated, never married, or living with a partner?
06-Living with partner
98-Refused
97-Don't know

Electrocardiogram (ECG) Results (ECG)

Web Version: 1.0; 1.02; 05-28-19

Segment *(PROTSEG)*: B
Visit number *(VISNO)*:

Date of assessment:*(ECGASMDT)* _____ *(mm/dd/yyyy)*

12-Lead Electrocardiogram (ECG)

1. Normal sinus rhythm?*(ECSINRTM)* ☐ 0-No ☐ 1-Yes
2. Ventricular rate:*(ECVENTRT)* _____ *(xxx)* bpm
3. QTc interval:*(ECQTC)* _____ *(xxx)* ms
4. PR interval:*(ECPR)* _____ *(xxx)* ms
5. QRS duration:*(ECQRS)* _____ *(xxx)* ms
6. PRT axis:*(EC1PRAXS)* _____ *(xxxx)* *(EC2PRAXS)* _____ *(xxxx)* *(EC3PRAXS)* _____ *(xxxx)*

	Not Present	Present
7. 2nd Degree A-V Block	*(EC2AVBLK)* ☐	☐
8. 3rd Degree A-V Block	*(EC3AVBLK)* ☐	☐
9. Atrial Fibrillation	*(ECATFIB)* ☐	☐
10. Atrial Flutter	*(ECATFLR)* ☐	☐
11. QTc Prolongation (QTc interval ≥ 500)	*(ECQTCPLG)* ☐	☐

Additional ECG Findings

12. Were additional ECG findings normal or abnormal (include borderline)?*(ECSUMOTH)* ☐ 0-Normal ☐ 1-Abnormal

	Not Present	Present		Not Present	Present
a. Increased QRS Voltage	*(ECQRSINC)* ☐	☐	p. Supraventricular Premature Beat	*(ECSVPB)* ☐	☐
b. Left Atrial Hypertrophy	*(ECLAHYPY)* ☐	☐	q. Ventricular Premature Beat	*(ECVPB)* ☐	☐
c. Right Atrial Hypertrophy	*(ECRAHYPY)* ☐	☐	r. Supraventricular Tachycardia	*(ECSPVTTY)* ☐	☐
d. Left Ventricular Hypertrophy	*(ECLVHYPY)* ☐	☐	s. Ventricular Tachycardia	*(ECVTTY)* ☐	☐
e. Right Ventricular Hypertrophy	*(ECRVHYP)* ☐	☐	t. Other Rhythm Abnormalities	*(ECOTHRA)* ☐	☐
f. Acute Infarction	*(ECACTINF)* ☐	☐	u. Implanted Pacemaker	*(ECPACEMK)* ☐	☐
g. Subacute Infarction	*(ECSATINF)* ☐	☐	v. 1st Degree A-V Block	*(EC1AVBLK)* ☐	☐
h. Old Infarction	*(ECINFOLD)* ☐	☐	w. LBB Block	*(ECLBBBLK)* ☐	☐
i. Myocardial Ischemia	*(ECMYISCH)* ☐	☐	x. RBB Block	*(ECRBBBLK)* ☐	☐
j. Digitalis Effect	*(ECDGTEFT)* ☐	☐	y. Pre-Excitation Syndrome	*(ECPES)* ☐	☐
k. Symmetrical T-Wave Inversions	*(ECSTWI)* ☐	☐	z. Other Intraventricular Conduction Delay	*(ECOTHIVB)* ☐	☐
l. Poor R-Wave Progression	*(ECPRWPG)* ☐	☐	aa. Other Abnormal Result:*(ECOTHSP)* _____	*(ECOTH)* ☐	☐
m. Other Nonspecific ST/T	*(ECOTHSTT)* ☐	☐			
n. Sinus Tachycardia	*(ECSTACHY)* ☐	☐			
o. Sinus Bradycardia	*(ECSBRADY)* ☐	☐			

Comments:*(ECGCOMM)*

End of Medication (EOM)

Web Version: 1.0; 3.00; 01-14-19

Segment *(PROTSEG):* B

1. Was a decision made by the investigator or participant to discontinue the **oral** study medication prior to day 85?*(EOOEARLY)*
   ☐ 0-No ☐ 1-Yes
   a. If "Yes", primary reason for not continuing with oral study medication:*(EOOSTOP)*
   1-Participant failed to return to site and unable to contact
   10-Participant feels treatment no longer necessary, cured
   11-Participant feels treatment no longer necessary, not working
   16-Participant interested in seeking alternate treatment
   19-Contraindicated concomitant medication
   *Additional Options Listed Below
   If "Other", specify:*(EOOSTPSP)*
   b. Date of last reported oral study medication dose taken:*(EOORALDT)* *(mm/dd/yyyy)*

2. Was a decision made by the investigator or participant to discontinue the **injectable** study medication prior to day 85? *(EOIEARLY)*
   ☐ 0-No ☐ 1-Yes
   If "Yes", primary reason for not continuing with injectable study medication:*(EOISTOP)*
   1-Participant failed to return to site and unable to contact
   10-Participant feels treatment no longer necessary, cured
   11-Participant feels treatment no longer necessary, not working
   16-Participant interested in seeking alternate treatment
   19-Contraindicated concomitant medication
   *Additional Options Listed Below
   If "Other", specify:*(EOISTPSP)*

Comments:*(EOMCOMM)*

Additional Selection Options for EOM

If "Yes", primary reason for not continuing with oral study medication:
20-Clinical deterioration: New onset of psychiatric or medical condition
21-Clinical deterioration: Worsening of pre-existing psychiatric or medical condition
22-Clinical deterioration: Worsening of substance use disorder
23-Clinical deterioration: Overdose
7-Participant became pregnant
8-Participant withdrew consent/assent
9-Participant reports intolerable symptoms or side effects
99-Other

0068B (ENR)

Web Version: 1.0; 1.04; 05-22-18

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

Inclusion Criteria

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

1. Participant is 18 to 65 years of age:*(R4PTAGE)* ☐ 0-No ☐ 1-Yes ☐ 97-Unknown
2. Participant is interested in reducing or stopping methamphetamine use:*(R4METSTP)* ☐ 0-No ☐ 1-Yes ☐ 97-Unknown
3. Participant is able to speak English sufficiently to understand the study procedures and provide written informed consent to participate in the study:*(R4ENGLSH)* ☐ 0-No ☐ 1-Yes ☐ 97-Unknown
4. Participant meets DSM-5 criteria for moderate or severe methamphetamine use disorder (4 or more criteria):*(R4METDSM)* ☐ 0-No ☐ 1-Yes ☐ 97-Unknown
5. Participant self-reported methamphetamine use on 18 or more days in the 30 day period prior to consent using the Timeline Followback (TLFB):*(R4METDAY)* ☐ 0-No ☐ 1-Yes ☐ 97-Unknown
6. Participant provided at least 2 urine samples positive for methamphetamine out of a possible 3 tests within a 10 day period during which clinic visits occurred with at least 2 days between visits:*(R4METUDS)* ☐ 0-No ☐ 1-Yes ☐ 97-Unknown
7. Participant is female and agrees to use acceptable birth control methods and have periodic urine pregnancy testing done during participation in the study unless documentation of hysterectomy provided:*(R4BCUSE)* ☐ 0-No ☐ 1-Yes ☐ 97-Unknown ☐ 96-Not applicable
8. Participant meets subjective and objective measures of being opioid-free prior to naltrexone induction per study medical clinician's determination:*(R4OPFREE)* ☐ 0-No ☐ 1-Yes ☐ 97-Unknown
9. Participant is willing to comply with all study procedures and medication instructions:*(R4COMPLY)* ☐ 0-No ☐ 1-Yes ☐ 97-Unknown
10. Participant agrees to use a smartphone app (downloaded for free to own device or on a study provided smartphone device) to take daily videos of medication dosing:*(R4VIDEO)* ☐ 0-No ☐ 1-Yes ☐ 97-Unknown

Exclusion Criteria

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

1. Participant has an acute medical or psychiatric disorder that would, in the judgment of the study medical clinician, make participation difficult or unsafe:*(R4PSYCH)* ☐ 0-No ☐ 1-Yes ☐ 97-Unknown
2. Participant has suicidal or homicidal ideation that requires immediate attention:*(R4SUICDE)* ☐ 0-No ☐ 1-Yes ☐ 97-Unknown
3. Participant has a history of epilepsy, seizure disorder, or head trauma with neurological sequelae (e.g., loss of consciousness that required hospitalization); current anorexia nervosa or bulimia; or any other conditions that increase seizure risk in the opinion of the study medical clinician:*(R4SEIZUR)* ☐ 0-No ☐ 1-Yes ☐ 97-Unknown
4. Participant has evidence of second or third degree heart block, atrial fibrillation, atrial flutter, prolongation of the QTc, or any other finding on the screening ECG that, in the opinion of the study medical clinician, would preclude safe participation in the study: *(R4BLOCK)* ☐ 0-No ☐ 1-Yes ☐ 97-Unknown
5. Participant has Stage 2 hypertension as determined by study medical clinician (e.g., greater than or equal to 160/100 in 2 out of 3 readings during screening):*(R4HYPTEN)* ☐ 0-No ☐ 1-Yes ☐ 97-Unknown
6. Participant has any elevated bilirubin test value per laboratory criteria OR any liver function test (LFT) value > 5 times the upper limit of normal as per laboratory criteria:*(R4LIVER)* ☐ 0-No ☐ 1-Yes ☐ 97-Unknown
7. Participant has platelet count <100x10^3/µL:*(R4PLATE)* ☐ 0-No ☐ 1-Yes ☐ 97-Unknown
8. Participant has a body habitus that precludes gluteal intramuscular injection of XR-NTX in accordance with the administration equipment (needle) and procedures:*(R4HABTUS)* ☐ 0-No ☐ 1-Yes ☐ 97-Unknown
9. Participant has a known allergy or sensitivity to bupropion, naloxone, naltrexone, PLG (polyactide-co-glycolide), carboxymethylcellulose, or any other component of the XR-NTX diluents:*(R4ALERGY)* ☐ 0-No ☐ 1-Yes ☐ 97-Unknown
10. Participant has been in a prior study of pharmacological or behavioral treatment for methamphetamine use disorder within 6 months of study consent:*(R4STUDY)* ☐ 0-No ☐ 1-Yes ☐ 97-Unknown
11. Participant has taken an investigational drug in another study within 30 days of study consent:*(R4INDDRU)* ☐ 0-No ☐ 1-Yes ☐ 97-Unknown
12. Participant has been prescribed and taken naltrexone or bupropion within 30 days of consent:*(R4PRESCR)* ☐ 0-No ☐ 1-Yes ☐ 97-Unknown
13. Participant is currently enrolled in formal behavioral or pharmacological addiction treatment services:*(R4ADDCTX)* ☐ 0-No ☐ 1-Yes ☐ 97-Unknown
14. Participant is receiving ongoing treatment with tricyclic antidepressants, xanthines (i.e., theophylline and aminophylline), systemic corticosteroids, nelfinavir, efavirenz, chlorpromazine, MAOIs, central nervous system stimulants (e.g., Adderall, Ritalin, etc.), or any medication that, in the judgment of the study medical clinician, could interact adversely with study medications:*(R4TREAT)* ☐ 0-No ☐ 1-Yes ☐ 97-Unknown
15. Participant has a current pattern of alcohol, benzodiazepine, or other sedative hypnotic use which would preclude safe participation in the study as determined by the study medical clinician:*(R4SEDATE)* ☐ 0-No ☐ 1-Yes ☐ 97-Unknown
16. Participant requires treatment with opioid-containing medications (e.g., opioid analgesics) during the study period:*(R4OPMED)* ☐ 0-No ☐ 1-Yes ☐ 97-Unknown
17. Participant has a surgery planned or scheduled during the study period:*(R4SURGRY)* ☐ 0-No ☐ 1-Yes ☐ 97-Unknown
18. Participant is currently in jail, prison or any inpatient overnight facility as required by court of law or has pending legal action or other situation (e.g., unstable living arrangements) that could prevent participation in the study or in any study activities: *(R4PRISON)* ☐ 0-No ☐ 1-Yes ☐ 97-Unknown
19. Participant is female and currently pregnant, breastfeeding, or planning on conception:*(R4PREGNT)* ☐ 0-No ☐ 1-Yes ☐ 97-Unknown ☐ 96-Not applicable

Eligibility for Randomization

1. Is the participant eligible for the study?*(R4ELGSTY)* ☐ 0-No ☐ 1-Yes
2. Will the participant be enrolled?*(R4ELGRDM)* ☐ 0-No ☐ 1-Yes

If "No", specify:*(R4NORSP)*

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:*(R4JGOTSP)* _____

Comments:*(R4COMM)* _____

Genetics (GEN)

Web Version: 1.0; 1.00; 02-23-17

Segment *(PROTSEG)*: B
Visit number *(VISNO)*:

1. Was a blood sample collected?*(GESMPL)* ☐ 0-No ☐ 1-Yes
   a. Date blood sample collected:*(GETAKNDT)* _____ *(mm/dd/yyyy)*
   b. RUCDR subject code:*(GESITEID)* _____ - *(GEPARTID)* _____
   c. Alternate ID:*(GEALTID)* _____
   d. Date blood sample shipped:*(GESHIPDT)* _____ *(mm/dd/yyyy)*

2. Reason blood sample was not collected:*(GENORSN)*
   1-Phlebotomist unable to draw sample
   2-Phlebotomist not available to draw sample
   3-Withdrew consent

3. Was genetic sample consent withdrawn?*(GECNSWTH)* ☐ 0-No ☐ 1-Yes
   If "Yes", date withdrawn:*(GECWTHDT)* _____ *(mm/dd/yyyy)*

Comments:*(GENCOMM)*

Injection Administration 1 (IN1)

Web Version: 1.0; 2.01; 04-19-18

Segment *(PROTSEG)*: B
Injection number *(INJNUM)*:

1. Has the participant arrived in clinic for their visit?*(I1PARTIC)*
   The participant must be physically present in clinic in order for an injection kit to be ordered.
   ☐ 1-Yes
2. Will an injection kit be ordered?*(I1KITORD)*
   ☐ 0-No ☐ 1-Yes
   Note that the participant must have arrived for a visit within this injection window in order for a kit to be ordered.
   a. If "Yes", date ordered:*(I1KITODT)*
   _____ *(mm/dd/yyyy)*
   b. If "No", select the reason why:*(I1ADMRSN)*

```
1-Participant declined to receive injection
2-Participant pregnant
3-Participant use of medication(s) could adversely interact with injection
4-Unsafe for participant to receive injection due to failed naloxone challenge(s)
5-Participant missed injection window
*Additional Options Listed Below
```

   If "Other", specify:*(I1ADMSP)*
   _____
3. Injection kit number assigned:*(I1NUMAGN)*
   _____
4. Location of previous injection:*(I1PREV)*
   ☐ 1-Right buttock ☐ 2-Left buttock
   Comments:*(IN1COMM)*
   _____

Additional Selection Options for IN1

Injection number *(INJNUM)* (key field):
1-1
2-2
3-3
4-4
5-5
6-6
7-7
8-8

If "No", select the reason why:
6-Participant refused injection for other reason
7-Physician cancelled injection for other reason
99-Other

Injection Administration 2 (IN2)

Web Version: 1.0; 1.03; 04-19-18

Segment *(PROTSEG)*: B
Injection number *(INJNUM)*:

1. Was an injection administered?*(I2ADMYN)* — 0-No 1-Yes
   If "No", select the reason why:*(I2NADMRN)*
   1-Participant declined to receive injection
   2-Participant pregnant
   3-Participant use of medication(s) could adversely interact with injection
   4-Unsafe for participant to receive injection due to failed naloxone challenge(s)
   5-Participant missed injection window
   *Additional Options Listed Below
   If "Other", specify:*(I2NADMSP)*
2. Date injection administered:*(I2INJDT)* *(mm/dd/yyyy)*
3. Injection kit number used:*(I2NUMUSE)*
4. Previous injection location:*(I2PRVLOC)* — 1-Right buttock 2-Left buttock
5. Injection location:*(I2INJLOC)* — 1-Right buttock 2-Left buttock
6. Time injection given: *(24-hour format)(I2INJTM)* *(hh:mm)*
7. Did you experience difficulty with injection administration?*(I2DIFFCT)* — 0-No 1-Yes
   If "Yes", was it due to clogging?*(I2DIFRSN)* — 0-No 1-Yes
   If "No", describe:*(I2RSNNO)*

Comments:*(IN2COMM)*

Additional Selection Options for IN2

Injection number *(INJNUM)* (key field):
1-1
2-2
3-3
4-4
5-5
6-6
7-7
8-8

If "No", select the reason why:
6-Participant refused injection for other reason
7-Physician cancelled injection for other reason
99-Other

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Injection Site Abnormality (INA)

Web Version: 1.0; 2.00; 09-13-17

Segment *(PROTSEG)*: B

If abnormality results in a Serious Adverse Event (SAE), complete the Adverse Event forms as well.

Abnormal Event *(If "Other", specify in comments)*	Event Start Date	Severity	Treatment *(If "Yes", specify in comments)*	Event Resolution Date	Comments
1. *(INTYP1)* 1-Pain; 2-Tenderness; 3-Induration; 4-Swelling; 5-Erythema (redness); *Additional Options Listed Below	*(INSDT1)*	*(INSVR1)* 1-Mild; 2-Moderate; 3-Severe	*(INTRT1)* 0-No 1-Yes	*(INRDT1)*	*(INCOM1)*
2. *(INTYP2)* 1-Pain; 2-Tenderness; 3-Induration; 4-Swelling; 5-Erythema (redness); *Additional Options Listed Below	*(INSDT2)*	*(INSVR2)* 1-Mild; 2-Moderate; 3-Severe	*(INTRT2)* 0-No 1-Yes	*(INRDT2)*	*(INCOM2)*
3. *(INTYP3)* 1-Pain; 2-Tenderness; 3-Induration; 4-Swelling; 5-Erythema (redness); *Additional Options Listed Below	*(INSDT3)*	*(INSVR3)* 1-Mild; 2-Moderate; 3-Severe	*(INTRT3)* 0-No 1-Yes	*(INRDT3)*	*(INCOM3)*
4. *(INTYP4)* 1-Pain; 2-Tenderness; 3-Induration; 4-Swelling; 5-Erythema (redness); *Additional Options Listed Below	*(INSDT4)*	*(INSVR4)* 1-Mild; 2-Moderate; 3-Severe	*(INTRT4)* 0-No 1-Yes	*(INRDT4)*	*(INCOM4)*
5. *(INTYP5)* 1-Pain; 2-Tenderness; 3-Induration; 4-Swelling; 5-Erythema (redness); *Additional Options Listed Below	*(INSDT5)*	*(INSVR5)* 1-Mild; 2-Moderate; 3-Severe	*(INTRT5)* 0-No 1-Yes	*(INRDT5)*	*(INCOM5)*
6. *(INTYP6)* 1-Pain; 2-Tenderness; 3-Induration; 4-Swelling; 5-Erythema (redness); *Additional Options Listed Below	*(INSDT6)*	*(INSVR6)* 1-Mild; 2-Moderate; 3-Severe	*(INTRT6)* 0-No 1-Yes	*(INRDT6)*	*(INCOM6)*
7. *(INTYP7)* 1-Pain; 2-Tenderness; 3-Induration; 4-Swelling; 5-Erythema (redness); *Additional Options Listed Below	*(INSDT7)*	*(INSVR7)* 1-Mild; 2-Moderate; 3-Severe	*(INTRT7)* 0-No 1-Yes	*(INRDT7)*	*(INCOM7)*
8. *(INTYP8)* 1-Pain; 2-Tenderness; 3-Induration; 4-Swelling; 5-Erythema (redness); *Additional Options Listed Below	*(INSDT8)*	*(INSVR8)* 1-Mild; 2-Moderate; 3-Severe	*(INTRT8)* 0-No 1-Yes	*(INRDT8)*	*(INCOM8)*
9. *(INTYP9)* 1-Pain; 2-Tenderness; 3-Induration; 4-Swelling; 5-Erythema (redness); *Additional Options Listed Below	*(INSDT9)*	*(INSVR9)* 1-Mild; 2-Moderate; 3-Severe	*(INTRT9)* 0-No 1-Yes	*(INRDT9)*	*(INCOM9)*
10. *(INTYP_10)* 1-Pain; 2-Tenderness; 3-Induration; 4-Swelling; 5-Erythema (redness); *Additional Options Listed Below	*(INSDT_10)*	*(INSVR_10)* 1-Mild; 2-Moderate; 3-Severe	*(INTRT_10)* 0-No 1-Yes	*(INRDT_10)*	*(INCOM_10)*
11. *(INTYP_11)* 1-Pain; 2-Tenderness; 3-Induration; 4-Swelling; 5-Erythema (redness); *Additional Options Listed Below	*(INSDT_11)*	*(INSVR_11)* 1-Mild; 2-Moderate; 3-Severe	*(INTRT_11)* 0-No 1-Yes	*(INRDT_11)*	*(INCOM_11)*
12. *(INTYP_12)* 1-Pain; 2-Tenderness; 3-Induration; 4-Swelling; 5-Erythema (redness); *Additional Options Listed Below	*(INSDT_12)*	*(INSVR_12)* 1-Mild; 2-Moderate; 3-Severe	*(INTRT_12)* 0-No 1-Yes	*(INRDT_12)*	*(INCOM_12)*
13. *(INTYP_13)*	*(INSDT_13)*	*(INSVR_13)*	*(INTRT_13)* 0-No 1-Yes	*(INRDT_13)*	*(INCOM_13)*

1-Pain 2-Tenderness 3-Induration 4-Swelling 5-Erythema (redness) *Additional Options Listed Below		1-Mild 2-Moderate 3-Severe			
14. *(INTYP_14)* 1-Pain 2-Tenderness 3-Induration 4-Swelling 5-Erythema (redness) *Additional Options Listed Below	*(INSDT_14)*	*(INSVR_14)* 1-Mild 2-Moderate 3-Severe	*(INTRT_14)* 0-No 1-Yes	*(INRDT_14)*	*(INCOM_14)*
15. *(INTYP_15)* 1-Pain 2-Tenderness 3-Induration 4-Swelling 5-Erythema (redness) *Additional Options Listed Below	*(INSDT_15)*	*(INSVR_15)* 1-Mild 2-Moderate 3-Severe	*(INTRT_15)* 0-No 1-Yes	*(INRDT_15)*	*(INCOM_15)*
16. *(INTYP_16)* 1-Pain 2-Tenderness 3-Induration 4-Swelling 5-Erythema (redness) *Additional Options Listed Below	*(INSDT_16)*	*(INSVR_16)* 1-Mild 2-Moderate 3-Severe	*(INTRT_16)* 0-No 1-Yes	*(INRDT_16)*	*(INCOM_16)*
17. *(INTYP_17)* 1-Pain 2-Tenderness 3-Induration 4-Swelling 5-Erythema (redness) *Additional Options Listed Below	*(INSDT_17)*	*(INSVR_17)* 1-Mild 2-Moderate 3-Severe	*(INTRT_17)* 0-No 1-Yes	*(INRDT_17)*	*(INCOM_17)*
18. *(INTYP_18)* 1-Pain 2-Tenderness 3-Induration 4-Swelling 5-Erythema (redness) *Additional Options Listed Below	*(INSDT_18)*	*(INSVR_18)* 1-Mild 2-Moderate 3-Severe	*(INTRT_18)* 0-No 1-Yes	*(INRDT_18)*	*(INCOM_18)*
19. *(INTYP_19)* 1-Pain 2-Tenderness 3-Induration 4-Swelling 5-Erythema (redness) *Additional Options Listed Below	*(INSDT_19)*	*(INSVR_19)* 1-Mild 2-Moderate 3-Severe	*(INTRT_19)* 0-No 1-Yes	*(INRDT_19)*	*(INCOM_19)*
20. *(INTYP_20)* 1-Pain 2-Tenderness 3-Induration 4-Swelling 5-Erythema (redness) *Additional Options Listed Below	*(INSDT_20)*	*(INSVR_20)* 1-Mild 2-Moderate 3-Severe	*(INTRT_20)* 0-No 1-Yes	*(INRDT_20)*	*(INCOM_20)*

Comments:*(INACOMM)*

Additional Selection Options for INA

Event 1 type
6-Bruising
7-Pruritus
8-Nodule
9-Hematoma
10-Abscess
11-Sterile abscess
12-Necrosis
13-Cellulitis
14-Warmth
99-Other

Injection Site Examination (INX)

Web Version: 1.0; 2.02; 04-24-18

Segment *(PROTSEG)*: B
Injection number *(INJNUM)*:

Date of examination:*(INXEXMDT)* _____ *(mm/dd/yyyy)*

1. Location of injection:*(IXINJLOC)* ☐ 1-Right buttock ☐ 2-Left buttock
2. Is this injection site normal?*(INJNORM)* ☐ 0-Normal ☐ 1-Abnormal

If the injection site is "abnormal", complete the Injection Site Abnormality log.
If abnormality results in a Serious Adverse Event (SAE), complete the Adverse Event forms as well.

Comments:*(INXCOMM)*

Additional Selection Options for INX

Injection number *(INJNUM)* (key field):
1-1
2-2
3-3
4-4
5-5
6-6
7-7
8-8

Clinical Laboratory Tests (LAB)

Web Version: 1.0; 9.00; 03-12-19

Segment *(PROTSEG)*: B
Visit number *(VISNO)*:

Date of lab collection:*(LABCOLDT)* _____ *(mm/dd/yyyy)*

CBC	Result
1. WBC:	*(LAWBC)* _____ *(xx.x)* x10^3/µL
2. WBC:	*(LAWBC)* _____ *(xx.x)* x10^3/µL
3. RBC:	*(LARBC)* _____ *(xx.xx)* x10^6/µL
4. RBC:	*(LARBC)* _____ *(xx.xx)* x10^6/µL
5. Hemoglobin:	*(LAHEMGLB)* _____ *(xx.x)* g/dL
6. Hemoglobin:	*(LAHEMGLB)* _____ *(xx.x)* g/dL
7. Hematocrit:	*(LAHEMATO)* _____ *(xx.x)* %
8. Hematocrit:	*(LAHEMATO)* _____ *(xx.x)* %
9. Platelets:	*(LAPLATES)* _____ *(xxxx.x)* x10^3/µL
Comprehensive Metabolic Panel	**Result**
10. Blood Urea Nitrogen (BUN):	*(LABUN)* _____ *(xxx.x)* mg/dL
11. Blood Urea Nitrogen (BUN):	*(LABUN)* _____ *(xxx.x)* mg/dL
12. Creatinine:	*(LACREATE)* _____ *(xx.xx)* mg/dL
13. Creatinine:	*(LACREATE)* _____ *(xx.xx)* mg/dL
14. Total Protein:	*(LAPROTEN)* _____ *(xx.x)* g/dL
15. Albumin:	*(LAALBUMN)* _____ *(x.x)* g/dL
16. Albumin:	*(LAALBUMN)* _____ *(x.x)* g/dL
17. Globulin:	*(LAGLOBIN)* _____ *(x.x)* g/dL
18. Globulin:	*(LAGLOBIN)* _____ *(x.x)* g/dL
19. Aspartate Aminotransferase (AST/SGOT):	*(LAAST)* _____ *(xxxx.x)* U/L
20. Alanine Aminotransferase (ALT/SGPT):	*(LAALT)* _____ *(xxxx.x)* U/L
21. Alkaline Phosphatase (ALP):	*(LAALP)* _____ *(xxxx.x)* U/L
22. Total Bilirubin:	*(LABILRBT)* _____ *(xx.x)* mg/dL

23. CBC assessment:*(LACBCNRM)*
1-Normal
2-Abnormal, not clinically significant
3-Abnormal, clinically significant

If "Abnormal, clinically significant", specify:*(LACBCSP)* _____

24. Comprehensive metabolic panel assessment:*(LACMPNRM)*
1-Normal
2-Abnormal, not clinically significant
3-Abnormal, clinically significant

If "Abnormal, clinically significant", specify:*(LACMPSP)* _____

25. Urinalysis assessment:*(LAURINRM)*
1-Normal
2-Abnormal, not clinically significant
3-Abnormal, clinically significant

If "Abnormal, clinically significant", specify:*(LAURINSP)* _____

Comments:*(LABCOMM)* _____

Oral Study Medication Blood Levels (MBL)

Web Version: 1.0; 1.01; 05-15-17

Segment *(PROTSEG)*: B
Visit number *(VISNO)*:

1. Was a blood sample collected for the purpose of oral study medication analysis?*(MBBLDCLT)* ☐ 0-No ☐ 1-Yes
   If "No", specify the reason:*(MBNBLDSP)*
2. Date of collection:*(MBCLTDT)* *(mm/dd/yyyy)*
3. Time of collection *(24-hour format)*:*(MBCLTTM)* *(hh:mm)*
4. Accession number:*(MBACCNUM)*

5. Was the primary (Green Cap) sample successfully stored?*(MB1STORE)* ☐ 0-No ☐ 1-Yes
   Cryobox ID number of primary sample:*(MBCRYPRI)* *(xx)*
   Tube identification number of primary sample:*(MBTUBPRI)*
   If "No", what was the reason?*(MB1NOSTR)*

   01-Sample lost
   02-Sample damaged or destroyed
   03-Centrifuge malfunction
   04-Insufficient volume
   99-Other

   If "Other", specify:*(MB1NSTSP)*

6. Was the secondary (Red Cap) sample successfully stored?*(MB2STORE)* ☐ 0-No ☐ 1-Yes
   Cryobox ID number of secondary sample:*(MBCRYSEC)* *(xx)*
   Tube identification number of secondary sample:*(MBTUBSEC)*
   If "No", what was the reason?*(MB2NOSTR)*

   01-Sample lost
   02-Sample damaged or destroyed
   03-Centrifuge malfunction
   04-Insufficient volume
   99-Other

   If "Other", specify:*(MB2NSTSP)*

Comments:*(MBLCOMM)*

Missed Visit (MVF)

Web Version: 1.0; 1.01; 07-10-17

Segment *(PROTSEG)*: B
Visit number *(VISNO)*:

Reason for missed visit:*(MVREASON)*

1-Participant failed to return to site and unable to contact
2-Participant unable to attend visit (e.g., no childcare, transportation, schedule conflict)
3-Participant on vacation
4-Participant illness
5-Participant in hospital, in-patient, or residential treatment
*Additional Options Listed Below

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

Comments:*(MVFCOMM)*

Additional Selection Options for MVF

Reason for missed visit:
6-Participant moved from area
7-Participant incarcerated
8-Site closed
9-Participant withdrew consent
10-Participant deceased
99-Other

Naloxone Challenge (NXC)

Web Version: 1.0; 3.00; 09-21-18

Segment *(PROTSEG)*: B
Visit number *(VISNO)*:
Challenge number *(NXC_CHNO)*:

Date of naloxone administration:*(NXCDOSDT)* *(mm/dd/yyyy)*

First Dose

1. Time of administration *(24-hour format)*:*(NXDOSTM1)* *(hh:mm)*
2. Total dose:*(NXDOS1)* *(x.xx)* mg
3. Route of administration:*(NXROUTE1)*
   - 1-I.V. (Intravenous)
   - 2-I.M. (Intramuscular injection)
   - 3-S.C. (Subcutaneous injection)

Second Dose (if applicable)

If a second dose was administered within 30 seconds of the first dose, the total quantity should be entered above as a first dose.

4. Time of administration *(24-hour format)*:*(NXDOSTM2)* *(hh:mm)*
5. Total dose:*(NXDOS2)* *(x.xx)* mg
6. Route of administration:*(NXROUTE2)*
   - 1-I.V. (Intravenous)
   - 2-I.M. (Intramuscular injection)
   - 3-S.C. (Subcutaneous injection)

Third Dose (if applicable)

If a third dose was administered within 30 seconds of the second dose, the total quantity should be entered above as a second dose.

7. Time of administration *(24-hour format)*:*(NXDOSTM3)* *(hh:mm)*
8. Total dose:*(NXDOS3)* *(x.xx)* mg
9. Route of administration:*(NXROUTE3)*
   - 1-I.V. (Intravenous)
   - 2-I.M. (Intramuscular injection)
   - 3-S.C. (Subcutaneous injection)

Results

Precipitated withdrawal:*(NXWTHDRW)* ☐ 0-No ☐ 1-Yes

Comments:*(NXCCOMM)*

Additional Selection Options for NXC

Challenge number *(NXC_CHNO)* (key field):
01-1
02-2
03-3
04-4
05-5
06-6
07-7
08-8
09-9
10-10
11-11
12-12
13-13
14-14
15-15

Oral Study Medication Dosing Log (ODL)

Web Version: 1.0; 2.00; 06-08-18

Segment *(PROTSEG)*: B
Visit number *(VISNO)*:

1. Blister card number dispensed:*(ODNUMDIS)*
2. Date blister card dispensed:*(ODDISPDT)* *(mm/dd/yyyy)*
3. Week start date:*(ODWEEKDT)* *(mm/dd/yyyy)*
4. Was the blister card returned?*(ODCRDRTN)* 0-No 1-Yes
5. Were all 21 tablets ordered and taken this week? 0-No 1-Yes

If "No", select the well for each tablet the participant DID take.(ODALLTAB)

Date	Number of Tablets Ordered	^3Tablets Taken		
		Well 1	**Well 2**	**Well 3**
(ODDATE1) *(mm/dd/yyyy)*	*(ODORDER1)* 0-Not ordered, 1-1 tablet, 2-2 tablets, 3-3 tablets	*(ODD1W1)*	*(ODD1W2)*	*(ODD1W3)*
(ODDATE2) *(mm/dd/yyyy)*	*(ODORDER2)* 0-Not ordered, 1-1 tablet, 2-2 tablets, 3-3 tablets	*(ODD2W1)*	*(ODD2W2)*	*(ODD2W3)*
(ODDATE3) *(mm/dd/yyyy)*	*(ODORDER3)* 0-Not ordered, 1-1 tablet, 2-2 tablets, 3-3 tablets	*(ODD3W1)*	*(ODD3W2)*	*(ODD3W3)*
(ODDATE4) *(mm/dd/yyyy)*	*(ODORDER4)* 0-Not ordered, 1-1 tablet, 2-2 tablets, 3-3 tablets	*(ODD4W1)*	*(ODD4W2)*	*(ODD4W3)*
(ODDATE5) *(mm/dd/yyyy)*	*(ODORDER5)* 0-Not ordered, 1-1 tablet, 2-2 tablets, 3-3 tablets	*(ODD5W1)*	*(ODD5W2)*	*(ODD5W3)*
(ODDATE6) *(mm/dd/yyyy)*	*(ODORDER6)* 0-Not ordered, 1-1 tablet, 2-2 tablets, 3-3 tablets	*(ODD6W1)*	*(ODD6W2)*	*(ODD6W3)*
(ODDATE7) *(mm/dd/yyyy)*	*(ODORDER7)* 0-Not ordered, 1-1 tablet, 2-2 tablets, 3-3 tablets	*(ODD7W1)*	*(ODD7W2)*	*(ODD7W3)*

Comments:*(ODLCOMM)*

Oral Study Med Dispensation 1 (OM1)

Web Version: 1.0; 2.00; 08-25-17

Segment *(PROTSEG)*: B
Visit number *(VISNO)*:

1. Has the participant arrived in clinic for their visit?*(O1PARTIC)* ☐ 0-No ☐ 1-Yes
2. Has the participant arrived in clinic for their visit?*(O1PARTIC)* ☐ 1-Yes

The participant must be physically present in clinic in order for a blister card to be ordered.

3. Will an oral study medication blister card be ordered?*(O1CRDORD)* ☐ 0-No ☐ 1-Yes

If "No", select the reason why:*(O1DISRSN)*

1-Participant declined to receive blister card
2-Participant pregnant
3-Participant use of medication(s) that could adversely interact with study medication
99-Other

If "Other", specify:*(O1DISSP)*

4. Blister card number assigned:*(O1NUMAGN)*

Comments:*(OM1COMM)*

Oral Study Med Dispensation 2 (OM2)

Web Version: 1.0; 1.00; 06-26-17

Segment *(PROTSEG)*: B
Visit number *(VISNO)*:

1. Was a blister card dispensed?*(O2DISPEN)*
   ☐ 0-No ☐ 1-Yes

   If "No", select the reason why:*(O2NDISRN)*
   1-Participant declined to receive blister card
   2-Participant pregnant
   3-Participant use of medication(s) that could adversely interact with study medication
   99-Other

   If "Other", specify:*(O2NDISSP)*

2. Date blister card dispensed:*(O2DISDT)* *(mm/dd/yyyy)*

3. Blister card number dispensed:*(O2NUMDIS)*

   Comments:*(OM2COMM)*

Pregnancy and Birth Control Assessment (PBC)

Web Version: 1.0; 3.02; 10-10-18

Segment *(PROTSEG)*: B
Visit number *(VISNO)*:

Complete this form only for females.

Date of assessment:*(PBCASMDT)* _____ *(mm/dd/yyyy)*

1. Is the participant of childbearing potential?*(PBCHILD)* ☐ 0-No ☐ 1-Yes
2. Is the participant continuing to use an effective method of birth control?*(PBUSEBC)* ☐ 0-No ☐ 1-Yes
3. Date of the first day of the participant's last period:*(PBPRDDT)* _____ *(mm/dd/yyyy)*
4. Was a pregnancy test performed?*(PBPRGTST)* ☐ 0-No ☐ 1-Yes
   a. Date of pregnancy test:*(PBPTSTDT)* _____ *(mm/dd/yyyy)*
   b. Result of pregnancy test:*(PBRESULT)* ☐ 0-Negative ☐ 1-Positive

Positive results must be reported on the Confirmed Pregnancy and Outcome form.

Comments:*(PBCCOMM)*

Prior and Concomitant Medications (PCM)

Web Version: 1.0; 1.00; 02-22-19

Segment *(PROTSEG)*: B
Medication name *(PCMEDNME)*:
Medication start date *(PCSTRTDT)*:

1. Indication for use:*(PCINDICT)*

A99-GASTROINTESTINAL
01A---Acid related
02A---Antiemetics
03A---Constipation
04A---Antidiarrheal
*Additional Options Listed Below

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

2. Was this medication used to treat an adverse event?*(PCMEDAE)*

☐ 0-No ☐ 1-Yes

3. Is medication ongoing?*(PCONGOIN)*

☐ 0-No ☐ 1-Yes ☐ 2-Yes (continuing at protocol completion or study termination)

If "No", specify date medication was discontinued or changed:*(PCTERMDT)* *(mm/dd/yyyy)*

Comments:*(PCMCOMM)*

Additional Selection Options for PCM

Indication for use:
05A---Diabetes
06A---Vitamins
07A---Mineral
99A---Other gastrointestinal
B99-BLOOD AND BLOOD FORMING ORGANS
01B---Aspirin/coumadin/heparin
02B---Antianemic
03B---Blood products/IV fluids
99B---Other blood and blood forming organs
C99-CARDIOVASCULAR SYSTEM
01C---Antihypertensives
02C---Diuretics
03C---Beta blocking
04C---Calcium Channel
05C---Lipid modifying agents
99C---Other cardiovascular system
D99-ALL SKIN CREAMS
01D---All skin creams
G99-CONTRACEPTIVES/ED/SEX HORMONES
01G---Contraceptives/ED/Sex hormones
H99-STEROIDS/THYROID HORMONES
01H---Steroids/Thyroid hormones
J99-ANTIBACTERIAL/ANTIVIRAL/ANTIFUNGAL/TB/VACCINES
01J---Antibacterial/Antiviral/Antifungal/TB/Vaccines
M99-MUSCULOSKELETAL SYSTEM
01M---Antiinflammatory and antirheumatic
02M---Muscle relaxants
03M---Antigout
99M---Other musculoskeletal system
N99-NERVOUS SYSTEM
01N---Analgesics including antipyretics
02N---Antiepileptics
03N---Anxiety/Depression/Sleep
99N---Other nervous system
R99-RESPIRATORY SYSTEM
01R---Nasal
02R---Throat
03R---Obstructive airway
04R---Cough and cold
05R---Antihistamines
99R---Other respiratory system
S99-EYE AND EAR DROPS
01S---Eye and ear drops
Z01-VARIOUS
01V---Allergens
02V---All other therapeutic products
03V---Diagnostic agents
04V---General nutrients
05V---All other non-therapeutic products
06V---Contrast media
07V---Diagnostic radiopharmaceuticals
08V---Therapeutic radiopharmaceuticals
99-OTHER

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Protocol Deviation (PDV)

Web Version: 1.0; 2.06; 03-12-19

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

1. Is this deviation related to one or more participants?*(PDPPTREL)* ☐ 0-No ☐ 1-Yes

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)* 9999999999999-DUMMYPARTICIPANTID

Participant ID 2:*(PDPPT02)* 9999999999999-DUMMYPARTICIPANTID

Participant ID 3:*(PDPPT03)* 9999999999999-DUMMYPARTICIPANTID

Participant ID 4:*(PDPPT04)* 9999999999999-DUMMYPARTICIPANTID

Participant ID 5:*(PDPPT05)* 9999999999999-DUMMYPARTICIPANTID

Participant ID 6:*(PDPPT06)* 9999999999999-DUMMYPARTICIPANTID

Participant ID 7:*(PDPPT07)* 9999999999999-DUMMYPARTICIPANTID

Participant ID 8:*(PDPPT08)* 9999999999999-DUMMYPARTICIPANTID

Participant ID 9:*(PDPPT09)* 9999999999999-DUMMYPARTICIPANTID

Participant ID 10:*(PDPPT10)* 9999999999999-DUMMYPARTICIPANTID

Participant ID 11:*(PDPPT11)* 9999999999999-DUMMYPARTICIPANTID

Participant ID 12:*(PDPPT12)* 9999999999999-DUMMYPARTICIPANTID

Participant ID 13:*(PDPPT13)* 9999999999999-DUMMYPARTICIPANTID

Participant ID 14:*(PDPPT14)* 9999999999999-DUMMYPARTICIPANTID

Participant ID 15:*(PDPPT15)* 9999999999999-DUMMYPARTICIPANTID

Participant ID 16:*(PDPPT16)* 9999999999999-DUMMYPARTICIPANTID

Participant ID 17:*(PDPPT17)* 9999999999999-DUMMYPARTICIPANTID

Participant ID 18:*(PDPPT18)* 9999999999999-DUMMYPARTICIPANTID

Participant ID 19:*(PDPPT19)* 9999999999999-DUMMYPARTICIPANTID

Participant ID 20:*(PDPPT20)* 9999999999999-DUMMYPARTICIPANTID

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

3. Deviation type:*(PDTYPE)*

010-INFORMED CONSENT/ASSENT PROCEDURES
01A--- No consent/assent obtained
01B--- Invalid/incomplete informed consent/assent form
01C--- Unauthorized assessments and/or procedures conducted prior to obtaining informed consent/assent
01D--- Non IRB approved/outdated/obsolete informed consent/assent documents used
*Additional Options Listed Below

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

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

5. Brief description of the actual or expected corrective action for this event:*(PDACTION)*

6. Brief description of the plan to prevent recurrence:*(PDPREVRE)*

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

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

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

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:
01E--- Informed consent/assent process not properly conducted and/or documented
01Z--- Other informed consent/assent procedures issues (specify)
020-INCLUSION/EXCLUSION CRITERIA
02A--- Ineligible participant randomized/inclusion/exclusion criteria not met
02B--- Ineligible participant enrolled/inclusion/exclusion criteria not met
02Z--- Other inclusion/exclusion criteria issues (specify)
040-LABORATORY ASSESSMENTS
04A--- Biologic specimen not collected/processed as per protocol
04Z--- Other laboratory assessments issues (specify)
050-STUDY PROCEDURES/ASSESSMENTS
05A--- Protocol required visit/assessment not scheduled or conducted
05B--- Study assessments not completed/followed as per protocol
05C--- Inappropriate unblinding
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 dispensed to ineligible participant
08B--- Medication dispensed to incorrect participant
08C--- Medication dosing errors (protocol specified dose not dispensed)
08D--- Participant use of protocol prohibited medication
08Z--- Other study medication management issues (specify)
090-STUDY BEHAVIORAL INTERVENTION
09A--- Study behavioral intervention was not provided/performed as per protocol
09Z--- Other study behavioral intervention issues (specify)
100-STUDY DEVICES
10A--- Study devices dispensed to ineligible participant
10Z--- Other study devices issues (specify)
110-SAFETY EVENT
11A--- Safety event not reported
11B--- Safety event reported out of protocol specified reporting timeframe
11C--- Safety event not elicited, observed and/or documented as per protocol
11D--- Safety event assessment not conducted per protocol
11Z--- Other safety event issues (specify)
990-OTHER SIGNIFICANT DEVIATIONS
99A--- Destruction of study materials without prior authorization from sponsor
99B--- Breach of Confidentiality
99Z--- Other significant deviations issues (specify)

Physical Examination (PEX)

Web Version: 1.0; 1.02; 08-07-18

Segment *(PROTSEG)*: B
Visit number *(VISNO)*:

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

			Comments
1. General appearance:	*(PEGENAPP)*	*(PEGASP)*	
2. Skin, hair, and nails:	*(PESKHRNA)*	*(PESHNSP)*	
3. Head and neck:	*(PEHDNK)*	*(PEHDNKSP)*	
4. Ears, eyes, nose, and throat:	*(PEEENT)*	*(PEENTSP)*	
5. Cardiovascular:	*(PECARD)*	*(PECARDSP)*	
6. Respiratory:	*(PERESP)*	*(PERESPSP)*	
7. Gastrointestinal:	*(PEGAST)*	*(PEGASTSP)*	
8. Extremities:	*(PEEXTR)*	*(PEEXTRSP)*	
9. Lymph nodes:	*(PELYMP)*	*(PELYMPSP)*	
10. Musculoskeletal:	*(PEMUSC)*	*(PEMUSCSP)*	
11. Neurological:	*(PENEUR)*	*(PENEURSP)*	
12. Other: *(specify in comments)*	*(PEOTHER)*	*(PEOTHESP)*	

1-Normal
2-Abnormal, not clinically significant
3-Abnormal, clinically significant
97-Not assessed

Comments:*(PEXCOMM)*

NIDA Clinical Trials Network

Patient Health Questionnaire (PHQ-9) (PHQ)

Web Version: 1.0; 5.00; 03-15-19

Segment *(PROTSEG)*: B
Visit number *(VISNO)*:

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

Please answer the following to the best of your ability.

Over the last week, how often have you been bothered by any of the following problems?	Not At All	Several Days	More Than Half The Days	Nearly Every Day
1. Little interest or pleasure in doing things:	*(PHINTPLE)*			
2. Feeling down, depressed, or hopeless:	*(PHDEPRES)*			
3. Trouble falling or staying asleep, or sleeping too much:	*(PH2SLEEP)*			
4. Feeling tired or having little energy:	*(PH2TIRED)*			
5. Poor appetite or overeating:	*(PHAPPEAT)*			
6. Feeling bad about yourself - or that you are a failure or have let yourself or your family down:	*(PHFAILUR)*			
7. Trouble concentrating on things, such as reading the newspaper or watching television:	*(PH2CONC)*			
8. Moving or speaking so slowly that other people could have noticed. Or the opposite - being so fidgety or restless that you have been moving around a lot more than usual:	*(PHMOVSPK)*			
9. Thoughts that you would be better off dead, or of hurting yourself in some way:	*(PHDEADHU)*			

10. If you checked off *any* problems, how *difficult* have those problems made it for you to do your work, take care of things at home, or get along with other people?*(PHDIFFCL)*

- 0-Not difficult at all
- 1-Somewhat difficult
- 2-Very difficult
- 3-Extremely difficult

Comments:*(PHQCOMM)*

Confirmed Pregnancy and Outcome (PRG)

Web Version: 1.0; 1.01; 04-26-19

Pregnancy number *(PGSEQNUM)*:

Information About Pregnancy

1. Date on which study staff became aware of pregnancy:*(PRGAWRDT)* _____ *(mm/dd/yyyy)*
2. How was the pregnancy confirmed? *(select all that apply)*
   a. Urine pregnancy test result:*(PRURICNF)* ☐ 0-No ☐ 1-Yes
   b. Serum pregnancy test result:*(PRSERCNF)* ☐ 0-No ☐ 1-Yes
   c. Ultrasound result:*(PRULTCNF)* ☐ 0-No ☐ 1-Yes
   d. Other:*(PROTHCNF)* ☐ 0-No ☐ 1-Yes
      If "Other", specify:*(PROTCNSP)* _____
3. Date on which the pregnancy was confirmed:*(PRCNFMDT)* _____ *(mm/dd/yyyy)*
4. Action taken with study medication:*(PRACTIND)*
   - 0-None
   - 1-Dose reduced
   - 2-Temporarily stopped medication
   - 3-Permanently stopped medication
5. Approximate due date:*(PRAPXDDT)* _____ *(mm/dd/yyyy)* *(PRDDTUNK)***OR** ☐ 97-Unknown
6. Outcome of pregnancy:*(PROUTCME)*
   - 1-Vaginal delivery
   - 2-Cesarean delivery
   - 3-Miscarriage
   - 4-Termination
   - 99-Other
   - *Additional Options Listed Below

   If "Other", specify:*(PROTCMSP)* _____
7. Date of pregnancy outcome:*(PROTCMDT)* _____ *(mm/dd/yyyy)*
8. Number of live births:*(PRNMLIVB)*
   - 0-0
   - 1-1
   - 2-2
   - 3-3
   - 4-4
   - *Additional Options Listed Below

   If "0" live births, indicate reason:*(PRRSOBSP)*

Comments:*(PRGCOMM)*

Additional Selection Options for PRG

Pregnancy number *(PGSEQNUM)* (key field):
1-1
2-2
3-3
4-4

Outcome of pregnancy:
97-Unknown

Number of live births:
99-Other
97-Unknown

NIDA Clinical Trials Network

Protocol Satisfaction Survey (PXS)

Web Version: 1.0; 1.01; 05-23-17

Segment *(PROTSEG)*: B

Date of assessment:*(PXSASMDT)* _____ *(mm/dd/yyyy)*

Section 1: Study Participation

Please answer the following questions about your satisfaction with study participation.

1. How helpful were the study medications (oral and injected) you received in reducing or stopping your methamphetamine use? *(PXMEDEFT)*
   - 4-Very helpful
   - 3-Helpful
   - 2-Neutral
   - 1-Slightly helpful
   - 0-Not helpful

2. Which part of the treatment was most helpful in reducing or stopping your methamphetamine use?*(PXHELPTR)*
   - 1-Oral study medication
   - 2-Injectable study medication
   - 3-Both oral and injectable study medications
   - 4-None of the above were helpful

3. Which treatment group do you think you were assigned to throughout the study?*(PXTRTGRP)*
   - 1-Active medications group (injectable Vivitrol and oral bupropion)
   - 2-Placebo medications group (injectable placebo and oral placebo)
   - 3-Active medications group first, then switched to placebo medications group
   - 4-Placebo medications group first, then switched to active medications group
   - 5-Unsure

4. How confident are you about the accuracy of your answer to the previous question?*(PXTRTACC)*
   - 1-Really not confident
   - 2-Not confident
   - 3-Somewhat confident
   - 4-Confident
   - 5-Really confident

5. Did being in the study help you in ways other than with your methamphetamine use?*(PXHELP)* ☐ 0-No ☐ 1-Yes

   If "Yes", check all that apply:

   Medically:*(PXHELPMD)* ☐ 0-No ☐ 1-Yes

   Psychologically:*(PXHELPPS)* ☐ 0-No ☐ 1-Yes

   Relationships:*(PXHELPRL)* ☐ 0-No ☐ 1-Yes

   Employment:*(PXHELPEM)* ☐ 0-No ☐ 1-Yes

   Legally:*(PXHELPLE)* ☐ 0-No ☐ 1-Yes

   Financially:*(PXHELPFI)* ☐ 0-No ☐ 1-Yes

   Referrals to other services:*(PXHELPRE)* ☐ 0-No ☐ 1-Yes

   Other:*(PXHELPOT)* ☐ 0-No ☐ 1-Yes

   If "Other", specify:*(PXHELPSP)* _____

6. How often did you attend support groups (like AA or NA) during the study?*(PXATTEND)*
   - 0-None
   - 1-Less than once a month
   - 2-Once a month
   - 3-A few times a month
   - 4-Once a week
   - *Additional Options Listed Below

7. How satisfied were you with the overall experience in the study?*(PXSATFY)*
   - 5-Very satisfied
   - 4-Satisfied
   - 3-Neither satisfied nor dissatisfied
   - 2-Dissatisfied
   - 1-Very dissatisfied

8. If you had to do it all over again, would you still choose to participate in this study?*(PXPARTAG)*
   - 4-Definitely participate
   - 3-Probably participate
   - 2-Probably not participate
   - 1-Definitely not participate

9. What is the primary reason you would choose to participate again?*(PXYPRSN)*
   - 1-I liked the compensation/money
   - 2-I liked using the smartphone app
   - 3-I liked how the injectable study medication made me feel
   - 4-I liked how the oral study medication made me feel
   - 5-I didn't have to pay for study medications
   - *Additional Options Listed Below

   If "Other", specify:*(PXYPRNSP)* _____

10. What is the primary reason you would choose NOT to participate again?*(PXNPRSN)*
    - 1-There was not enough compensation/money
    - 2-The injectable study medication caused undesirable side effects
    - 3-The oral study medication caused undesirable side effects
    - 4-The study/treatment didn't help me
    - 5-There were too many visits per week
    - *Additional Options Listed Below

    If "Other", specify:*(PXNPRNSP)* _____

Section 2: Study Procedures

Please provide your responses indicating whether you agree or disagree with each statement.

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
1. The compensation/money was sufficient.	*(PXCOMP)* ☐	☐	☐	☐	☐
2. The study app was easy to use.	*(PXEZCELL)* ☐	☐	☐	☐	☐
3. I was able to get into the study quickly.	*(PXSTUDY)* ☐	☐	☐	☐	☐

4. There were too many procedures.	*(PXPROC)* ☐	☐	☐	☐	☐	
5. The visits lasted too long.	*(PXVISLNG)* ☐	☐	☐	☐	☐	
6. The injectable study medication caused undesirable side effects.	*(PXINJSD)* ☐	☐	☐	☐	☐	
7. The oral study medication caused undesirable side effects.	*(PXORASD)* ☐	☐	☐	☐	☐	
8. Coming to the clinic 2 times per week worked for me.	*(PXTWICE)* ☐	☐	☐	☐	☐	
9. The staff treated me well.	*(PXSTAFF)* ☐	☐	☐	☐	☐	
10. The clinic was in a good location.	*(PXLOCATE)* ☐	☐	☐	☐	☐	
11. The clinic hours and days were convenient.	*(PXHOURS)* ☐	☐	☐	☐	☐	
12. I would have liked to have counseling provided.	*(PXCOUNS)* ☐	☐	☐	☐	☐	
13. I would have been interested in receiving the medications used in the study for a longer period of time.	*(PXMEDLO)* ☐	☐	☐	☐	☐	

Section 3: Smartphone Procedures

In this section, we would like your opinion on the smartphone procedures used in this trial. Please provide your responses indicating how much you agree or disagree with each statement.

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	Not Applicable
1. I received enough training so that I could use the study app.	*(PXTRAIN)* ☐	☐	☐	☐	☐	
2. I am better able to use a smartphone now than I was at the beginning of the study.	*(PXUSECEL)* ☐	☐	☐	☐	☐	
3. The reminders to take the dosing video were helpful.	*(PXREMIN)* ☐	☐	☐	☐	☐	
4. It was easy to take the dosing videos.	*(PXRECORD)* ☐	☐	☐	☐	☐	
5. Taking the dosing videos helped me to take oral study medication as directed.	*(PXDIRECT)* ☐	☐	☐	☐	☐	
6. I liked the fact that study staff could monitor my oral study medication dosing.	*(PXMONIT)* ☐	☐	☐	☐	☐	
7. The compensation I received for the videos was important.	*(PXVIDCMP)* ☐	☐	☐	☐	☐	
8. I was confident that my privacy was protected when using the study app.	*(PXPRIVAC)* ☐	☐	☐	☐	☐	
9. If applicable, there was sufficient technical support when I ran into problems using the study app.	*(PXTECSUP)* ☐	☐	☐	☐	☐	☐
10. If applicable, having both a study smartphone and personal phone was cumbersome.	*(PXTWOPHO)* ☐	☐	☐	☐	☐	☐

11. Please provide any additional comments about the use of smartphones in this study. For example, how did the study smartphone app affect your daily life, how you planned your day, and/or how you communicated with study staff:*(PXCOMCEL)*

12. Please provide any additional comments about participation in this study in general:*(PXCOMPAR)*

Comments:*(PXSCOMM)*

Additional Selection Options for PXS

How often did you attend support groups (like AA or NA) during the study?
5-More than once a week

What is the primary reason you would choose to participate again?
6-The study/treatment helped me
7-I was able to get into the study quickly
8-There aren't many other treatment options available to me
9-My participation may help others
10-My participation may help contribute to science
11-I liked coming to the clinic two times per week
12-The staff treated me well
13-The clinic was in a desirable location and was easy to access
14-The clinic hours and days were convenient
99-Other

What is the primary reason you would choose NOT to participate again?
6-There were too many procedures/visits lasted too long
7-Lack of counseling/non-medication treatment
8-I didn't like having to use the smartphone app
9-I didn't like having to use a computer for assessments
10-I would rather enroll in a usual treatment program
11-The staff didn't treat me well
12-The clinic was in an undesirable location and was difficult to access
13-The clinic had inconvenient hours and days
99-Other

NIDA Clinical Trials Network

Quality of Life (QLP)

Web Version: 1.0; 3.00; 02-23-18

Segment *(PROTSEG)*: B
Visit number *(VISNO)*:

Date of assessment:*(QLPASMDT)* _____ *(mm/dd/yyyy)*

1. Would you say that in general your health is:*(QLHEALTH)*

1-Excellent
2-Very good
3-Good
4-Fair
5-Poor
97-Don't know/Not sure
98-Refused

2. Now thinking about your physical health, which includes physical illness and injury, for how many days during the past 30 days was your physical health not good?*(QLPHYNGD)* _____ *(xx)* days

3. Now thinking about your mental health, which includes stress, depression, and problems with emotions, for how many days during the past 30 days was your mental health not good?*(QLMTLNG)* _____ *(xx)* days

4. During the past 30 days, for about how many days did poor physical or mental health keep you from doing your usual activities, such as self-care, work, or recreation?*(QLACT)* _____ *(xx)* days

Comments:*(QLPCOMM)*

NIDA Clinical Trials Network

Protocol Satisfaction Survey: Staff (RXS)

Web Version: 1.0; 1.00; 01-26-17

Segment *(PROTSEG)*: B

Date of assessment:*(RXSASMDT)* _____ *(mm/dd/yyyy)*

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
1. This participant was very tech-savvy at the beginning of the study.	*(RXTECHBG)* ☐	☐	☐	☐	☐
2. This participant was very tech-savvy at the end of the study.	*(RXTECHED)* ☐	☐	☐	☐	☐
3. This participant was able to learn the study app procedures in the standard 3 training sessions.	*(RXCELLPR)* ☐	☐	☐	☐	☐
4. The study app procedures were burdensome for study staff.	*(RXBURDEN)* ☐	☐	☐	☐	☐
5. The study app procedures were unnecessary/not useful.	*(RXUNNESS)* ☐	☐	☐	☐	☐
6. This participant needed additional assistance after training to troubleshoot a problem with the study app or to take a dosing video.	*(RXASSIST)* ☐	☐	☐	☐	☐
7. Using the study app helped to improve medication adherence for this participant.	*(RXMEDADH)* ☐	☐	☐	☐	☐
8. Using the study app helped to improve attendance at study visits for this participant.	*(RXATTEND)* ☐	☐	☐	☐	☐
9. Using the study app helped to foster a strong relationship with this participant.	*(RXRELATE)* ☐	☐	☐	☐	☐
10. Using the study app helped to collect accurate study data on this participant.	*(RXACCURA)* ☐	☐	☐	☐	☐
11. This participant seemed to like using the study app.	*(RXLIKE)* ☐	☐	☐	☐	☐
12. This participant seemed to be overwhelmed by the study app.	*(RXOVERWH)* ☐	☐	☐	☐	☐
13. The study app was useful in documenting this participant's adherence with study dosing.	*(RXDOCUM)* ☐	☐	☐	☐	☐
14. The study app helped study staff stay in touch with the participant.	*(RXINTUCH)* ☐	☐	☐	☐	☐

15. On which device did this participant use the study app?*(RXDEVUSE)*

1-On personal device
2-On study device
3-First on personal device, then on study device
4-First on study device, then on personal device

a. If this participant changed devices during the study, who primarily initiated the change?*(RXDEVCHG)*

0-Participant
1-Study staff

b. If this participant changed from a personal to study device during the study, what was the primary reason for the change? *(RXSTYRSN)*

0-Lost/stolen personal device
1-Unreliable personal service
2-Did not want study app on personal device anymore
3-Did not think $10 per month was enough for data used due to study app
4-Change in personal device or service that no longer supports study app
*Additional Options Listed Below

If "Other", specify:*(RXDEV1SP)* _____

c. If this participant changed from a study to personal device during the study, what was the primary reason for the change? *(RXPERRSN)*

0-Lost/stolen study device
1-Disliked having an additional device
2-Had logistical problems (e.g., keeping device charged, leaving device at home)
3-Had technical problems operating study device
4-Obtained new personal device
*Additional Options Listed Below

If "Other", specify:*(RXDEV2SP)* _____

d. Did this participant return the study device?*(RXRTRNN)* ☐ 0-No ☐ 1-Yes

16. Which treatment group does the study team think the participant was assigned to throughout the study?*(RXTRTGRP)*

1-Active medications group (injectable Vivitrol and oral bupropion)
2-Placebo medications group (injectable placebo and oral placebo)
3-Active medications group first, then switched to placebo medications group
4-Placebo medications group first, then switched to active medications group
5-Unsure

17. How confident is the team about the accuracy of their answer to the previous question?*(RXTRTACC)*

1-Really not confident
2-Not confident
3-Somewhat confident
4-Confident
5-Really confident

Comments:*(RXSCOMM)* _____

Additional Selection Options for RXS

If this participant changed from a personal to study device during the study, what was the primary reason for the change?
99-Other

If this participant changed from a study to personal device during the study, what was the primary reason for the change?
99-Other

Sexual Risk Behaviors (SRB)

Web Version: 1.0; 1.00; 05-04-17

Segment *(PROTSEG)*: B
Visit number *(VISNO)*:

Date of assessment:*(SRBASMDT)* _____ *(mm/dd/yyyy)*

The next questions are about having sex. When we refer to sex it includes vaginal, oral and anal sex with anyone. (Vaginal sex is when a man puts his penis into a woman's vagina. Oral sex is when one person puts his or her mouth onto the other person's penis or vagina. Anal sex is when a man puts his penis into another person's anus or butt.)

1. When was the **last** time, if ever, that you **had any kind of vaginal, oral, or anal sex** with another person?*(SRLSTSEX)*

6-Within the past 2 days
5-3 to 7 days ago
4-1 to 4 weeks ago
3-1 to 3 months ago
2-4 to 12 months ago
*Additional Options Listed Below

We want to ask you some questions about your sexual partners.
During the past 30 days:

2. How many sex partners did you have who were male?*(SR3SXMAL)* _____ *(xx)*

How many of your male partners were:

a. HIV positive?*(SRMHIVPS)* _____ *(xx)*
b. HIV negative?*(SRMHIVNG)* _____ *(xx)*
c. You did not know their status?*(SRMHIVUK)* _____ *(xx)*

3. How many sex partners did you have who were female?*(SR3SXFEM)* _____ *(xx)*

How many of your female partners were:

a. HIV positive?*(SRFHIVPS)* _____ *(xx)*
b. HIV negative?*(SRFHIVNG)* _____ *(xx)*
c. You did not know their status?*(SRFHIVUK)* _____ *(xx)*

4. With how many of your sexual partners have you been high (on alcohol or drugs) when having sex in the past 30 days? *(SR3ALSEX)* _____ *(xx)*
5. **During the past 30 days**, when you had sex with your male and/or female partners:
   a. How many times did you have vaginal or anal sex with HIV negative partners?*(SRSHIVNG)* _____ *(xx)* times
      Of these, how many times was a condom worn from start to finish?*(SR3CONDN)* _____ *(xx)* times
   b. How many times did you have vaginal or anal sex with HIV positive or unknown partners?*(SRSHIVPU)* _____ *(xx)* times
      Of these, how many times was a condom worn from start to finish?*(SR3CONDP)* _____ *(xx)* times
6. During the past 30 days, how many times did you have sex while you were **high on methamphetamine**?*(SR3MTSEX)* _____ *(xx)* times
7. During the past 30 days, how many times did you have sex while you were **high on alcohol or drugs other than methamphetamine**?*(SR3OTSEX)* _____ *(xx)* times
8. During the past 30 days, how many times did you **trade sex** for drugs, gifts, or money?*(SRTRADE)* _____ *(xx)* times
9. During the past 30 days, how many times did you use drugs, gifts, or money to purchase or get sex?*(SRPURCHS)* _____ *(xx)* times

Comments:*(SRBCOMM)*

Additional Selection Options for SRB

When was the last time, if ever, that you had any kind of vaginal, oral, or anal sex with another person?
1-More than 12 months ago
0-Never

Study Completion (STC)

Web Version: 1.0; 8.00; 03-15-19

Segment *(PROTSEG)*: B

1. Did the participant stop attending visits prior to study completion (week 16)?*(STSTPVIS)* ☐ 0-No ☐ 1-Yes

   If "Yes", select the primary reason for study discontinuation:*(STSTPRSN)*

   1-Participant failed to return to clinic and unable to contact
   2-Participant stopped participation due to practical problems (e.g., no childcare or transportation)
   3-Participant moved from area
   4-Participant incarcerated
   5-Participant terminated due to AE/SAE
   *Additional Options Listed Below

   If "Participant terminated for other clinical reasons" or "Participant terminated for other reason", specify:*(STSTPSP)*

2. Date of last data collection or date of withdrawn consent:*(STCOMPDT)* *(mm/dd/yyyy)*

   Comments:*(STCCOMM)*

Investigator's Signature

With this act of signing, I confirm that all data collected for this participant was under my guidance and the data submitted to Advantage eClinical are complete and accurate to the best of my knowledge.

Principal Investigator:*(STPISIGN)*

Date:*(STPISGDT)* *(mm/dd/yyyy)*

Additional Selection Options for STC

If "Yes", select the primary reason for study discontinuation:
6-Participant terminated for other clinical reasons
7-Participant had a significant psychiatric risk (e.g., suicidal, homicidal, psychotic)
8-Participant withdrew consent/assent
9-Participant deceased
16-Participant terminated due to protocol deviation
20-Participant became pregnant
21-Participant reports intolerable symptoms or side effects
22-Participant reports use of medication that could adversely interact with study medication
23-Clinical deterioration: New onset of psychiatric or medical condition
24-Clinical deterioration: Worsening of pre-existing psychiatric or medical condition
25-Clinical deterioration: Worsening of substance use disorder
26-Clinical deterioration: Overdose
99-Participant terminated for other reason

NIDA Clinical Trials Network

Timeline Followback (T68)

Web Version: 1.0; 1.00; 06-02-17

TFB week start date *(TFWKSTDT)*:

Day	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Date	*(TLDATE1)*	*(TLDATE2)*	*(TLDATE3)*	*(TLDATE4)*	*(TLDATE5)*	*(TLDATE6)*	*(TLDATE7)*
1. Have any cigarettes or e-cigarettes, alcohol, marijuana or any other drugs been used during this assessment period?	*(TLSUBAL1)* 0-No 1-Yes	*(TLSUBAL2)* 0-No 1-Yes	*(TLSUBAL3)* 0-No 1-Yes	*(TLSUBAL4)* 0-No 1-Yes	*(TLSUBAL5)* 0-No 1-Yes	*(TLSUBAL6)* 0-No 1-Yes	*(TLSUBAL7)* 0-No 1-Yes
2. Number of cigarettes (xx):	*(TLNMCIG1)*	*(TLNMCIG2)*	*(TLNMCIG3)*	*(TLNMCIG4)*	*(TLNMCIG5)*	*(TLNMCIG6)*	*(TLNMCIG7)*
3. E-cigarettes:	*(TLECIG1)* 0-No 1-Yes	*(TLECIG2)* 0-No 1-Yes	*(TLECIG3)* 0-No 1-Yes	*(TLECIG4)* 0-No 1-Yes	*(TLECIG5)* 0-No 1-Yes	*(TLECIG6)* 0-No 1-Yes	*(TLECIG7)* 0-No 1-Yes
4. Number of standard alcoholic drinks (xx):	*(TLALCHL1)*	*(TLALCHL2)*	*(TLALCHL3)*	*(TLALCHL4)*	*(TLALCHL5)*	*(TLALCHL6)*	*(TLALCHL7)*
5. Cannabinoids/ Marijuana:	*(TLTHCR1)*	*(TLTHCR2)*	*(TLTHCR3)*	*(TLTHCR4)*	*(TLTHCR5)*	*(TLTHCR6)*	*(TLTHCR7)*
6. Cocaine:	*(TLCOCR1)*	*(TLCOCR2)*	*(TLCOCR3)*	*(TLCOCR4)*	*(TLCOCR5)*	*(TLCOCR6)*	*(TLCOCR7)*
7. Crack:	*(TLCRAKR1)*	*(TLCRAKR2)*	*(TLCRAKR3)*	*(TLCRAKR4)*	*(TLCRAKR5)*	*(TLCRAKR6)*	*(TLCRAKR7)*
8. Methamphetamine:	*(TLMETR1)*	*(TLMETR2)*	*(TLMETR3)*	*(TLMETR4)*	*(TLMETR5)*	*(TLMETR6)*	*(TLMETR7)*
9. Amphetamine-type stimulants, excluding Methamphetamine:	*(TLAMPR1)*	*(TLAMPR2)*	*(TLAMPR3)*	*(TLAMPR4)*	*(TLAMPR5)*	*(TLAMPR6)*	*(TLAMPR7)*
10. Opioid analgesics, including methadone:	*(TLMTDR1)*	*(TLMTDR2)*	*(TLMTDR3)*	*(TLMTDR4)*	*(TLMTDR5)*	*(TLMTDR6)*	*(TLMTDR7)*
11. Heroin:	*(TLHERR1)*	*(TLHERR2)*	*(TLHERR3)*	*(TLHERR4)*	*(TLHERR5)*	*(TLHERR6)*	*(TLHERR7)*
12. Hallucinogens, including MDMA/ecstasy:	*(TLMDAR1)*	*(TLMDAR2)*	*(TLMDAR3)*	*(TLMDAR4)*	*(TLMDAR5)*	*(TLMDAR6)*	*(TLMDAR7)*
13. Sedatives and hypnotics, excluding Benzodiazepines:	*(TLBARR1)*	*(TLBARR2)*	*(TLBARR3)*	*(TLBARR4)*	*(TLBARR5)*	*(TLBARR6)*	*(TLBARR7)*

0-00-No use
1-01-Oral
2-02-Nasal
3-03-Smoking
4-04-Non-IV Injection
*Additional Options Listed Below

14. Benzodiazepines:	*(TLBZOR1)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLBZOR2)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLBZOR3)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLBZOR4)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLBZOR5)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLBZOR6)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLBZOR7)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below
15. Inhalants:	*(TLINHR1)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLINHR2)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLINHR3)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLINHR4)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLINHR5)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLINHR6)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLINHR7)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below
Other Drugs							
16. Other drug 1 use:	*(TLOT1R1)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLOT1R2)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLOT1R3)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLOT1R4)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLOT1R5)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLOT1R6)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLOT1R7)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below
Specify other drug 1:	*(TLOTSP11)*	*(TLOTSP12)*	*(TLOTSP13)*	*(TLOTSP14)*	*(TLOTSP15)*	*(TLOTSP16)*	*(TLOTSP17)*
17. Other drug 2 use:	*(TLOT2R1)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLOT2R2)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLOT2R3)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLOT2R4)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLOT2R5)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLOT2R6)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLOT2R7)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below
Specify other drug 2:	*(TLOTSP21)*	*(TLOTSP22)*	*(TLOTSP23)*	*(TLOTSP24)*	*(TLOTSP25)*	*(TLOTSP26)*	*(TLOTSP27)*

Comments: *(TFBCOMM)*

Additional Selection Options for T68

D1 cannabinoids
5-05-IV Injection
99-99-Other

TLFB Assessment Period (TAP)

Web Version: 1.0; 4.01; 02-07-19

Segment *(PROTSEG)*: B
Visit number *(VISNO)*:

Date of assessment:*(TAPASMDT)* _____ *(mm/dd/yyyy)*

1. Assessment period:*(TATFSTDT)*
(TATFENDT)

From: _____ *(mm/dd/yyyy)*
To: _____ *(mm/dd/yyyy)*

2. Have any cigarettes or e-cigarettes, alcohol, marijuana or any other drugs been used during this assessment period? *(TASUBALC)*

☐ 0-No ☐ 1-Yes

Comments:*(TAPCOMM)*

Treatment Effectiveness Assessment (TEA)

Web Version: 1.0; 1.00; 02-23-17

Segment *(PROTSEG)*: B
Visit number *(VISNO)*:

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

These questions ask you to express the extent to which things have improved because of your involvement in this study. The questions ask about four areas: substance use, health, lifestyle, and community. For each area, think about how things have become better and select the results on the scale below: the more you have improved, the higher the number - from 1 (not better at all) and 10 (very much better). In each area type in the one or two changes most important to you in the Remarks section. Feel free to add details, to explain remarks, and to make comments.

1. **Substance use:** How much better are you with drug and alcohol use? Consider the frequency and amount of use, money spent on drugs, amount of drug craving, time spent being loaded, being sick, in trouble and in other drug-using activities, etc.

None or not much					Better				Much better
(TESUBUSE) ☐ 01-1	☐ 02-2	☐ 03-3	☐ 04-4	☐ 05-5	☐ 06-6	☐ 07-7	☐ 08-8	☐ 09-9	☐ 10-10

Remarks: *(TSSUBRM)*

2. **Health:** Has your health improved? In what way and how much? Think about your physical and mental health: Are you eating and sleeping properly, exercising, taking care of health problems or dental problems, feeling better about yourself, etc?

None or not much					Better				Much better
(TEHEALTH) ☐ 01-1	☐ 02-2	☐ 03-3	☐ 04-4	☐ 05-5	☐ 06-6	☐ 07-7	☐ 08-8	☐ 09-9	☐ 10-10

Remarks: *(TEHLTHRM)*

3. **Lifestyle:** How much better are you in taking care of personal responsibilities? Think about your living conditions, family situation, employment, relationships: Are you paying your bills? Following through with your personal or professional commitments?

None or not much					Better				Much better
(TELIFEST) ☐ 01-1	☐ 02-2	☐ 03-3	☐ 04-4	☐ 05-5	☐ 06-6	☐ 07-7	☐ 08-8	☐ 09-9	☐ 10-10

Remarks: *(TELIFERM)*

4. **Community:** Are you a better member of the community? Think about things like obeying laws and meeting your responsibilities to society: Do your actions have positive or negative impacts on other people?

None or not much					Better				Much better
(TECOMMUN) ☐ 01-1	☐ 02-2	☐ 03-3	☐ 04-4	☐ 05-5	☐ 06-6	☐ 07-7	☐ 08-8	☐ 09-9	☐ 10-10

Remarks: *(TECOMRM)*

Comments:*(TEACOMM)*

Tobacco Use History (TUH)

Web Version: 1.0; 5.00; 02-23-18

Segment *(PROTSEG)*: B
Visit number *(VISNO)*:

Date of assessment:*(TUHASMDT)* _____ *(mm/dd/yyyy)*

1. Have you smoked at least 100 cigarettes in your entire life?*(TUSMK100)* ☐ 0-No ☐ 1-Yes ☐ 97-Don't know/refused
2. Do you now smoke cigarettes every day, some days, or not at all?*(TUSMFREQ)*
   1-Every day
   2-Some days
   3-Not at all
   97-Don't know/refused
3. Have you EVER smoked cigarettes EVERY DAY for at least 6 months?*(TUEVERY)* ☐ 0-No ☐ 1-Yes ☐ 97-Don't know/refused
4. How old were you when you first started smoking cigarettes FAIRLY REGULARLY?*(TUSTRTRG)* _____ *(xx)* years old *(TUSTRGDR)* ☐ 97-Don't know/refused
5. Did you quit smoking cigarettes within the past 30 days?*(TUQUIT30)* ☐ 0-No ☐ 1-Yes ☐ 97-Don't know/refused

Section A: Every-Day Smokers

6. On the average, about how many cigarettes do you now smoke each day?*(TUNUMDY)* _____ *(xx)* cigarettes per day *(TUNMDYDR)* ☐ 97-Don't know/refused
7. How old were you when you first started smoking cigarettes every day?*(TUSTRTAG)* _____ *(xx)* years old *(TUSTAGDR)* ☐ 97-Don't know/refused
8. How soon after you wake up do you smoke your first cigarette?*(TUEVRYTM)*
   0-Within 5 minutes
   1-6-30 minutes
   2-31-60 minutes
   3-After 60 minutes
   (TUEVTMDR) ☐ 97-Don't know/refused

Section B: Some-Day Smokers

9. On how many of the past 30 days did you smoke cigarettes?*(TU30DAYS)* _____ *(xx)* days *(TU30DDR)* ☐ 97-Don't know/refused
10. On the average, on those days, how many cigarettes did you usually smoke each day?*(TU30AVG)* _____ *(xx)* cigarettes per day *(TU30ADR)* ☐ 97-Don't know/refused
11. How soon after you wake up do you smoke your first cigarette?*(TUSOMETM)*
    0-Within 5 minutes
    1-6-30 minutes
    2-31-60 minutes
    3-After 60 minutes
    (TUSMTMDR) ☐ 97-Don't know/refused

Section C: Former Smokers

12. How old were you when you stopped smoking?*(TUSTPSMO)* _____ *(xx)* years old *(TUSPSMDR)* ☐ 97-Don't know/refused
13. When you last smoked every day, on average how many cigarettes did you smoke each day?*(TUNUMEDY)* _____ *(xx)* cigarettes per day *(TUNMEDDR)* ☐ 97-Don't know/refused
14. When you last smoked fairly regularly, on average how many cigarettes did you smoke each day?*(TUNUMRDY)* _____ *(xx)* cigarettes per day *(TUNMRDDR)* ☐ 97-Don't know/refused

Comments:*(TUHCOMM)*

Urine Drug Screen (UDS)

Web Version: 1.0; 8.00; 06-08-18

Segment *(PROTSEG)*: B
Visit number *(VISNO)*:

1. Was a urine drug screen performed?*(UDTEST1)* ☐ 0-No ☐ 1-Yes

   If "No", reason:*(UDNORSN1)*

   1-Participant reported being unable to provide sample
   2-Participant refused to provide sample
   3-Study staff error
   99-Other

   If "Other", specify:*(UDNOSP1)*

1st Urine Drug Screen

2. Date 1st urine specimen collected:*(UDCOLDT)* *(mm/dd/yyyy)*
3. Was the 1st urine specimen temperature within range? (90 - 100 °F)*(UDTEMP1)* ☐ 0-No ☐ 1-Yes
4. Was the 1st urine specimen determined to be adulterated?*(UDADULT1)* ☐ 0-No ☐ 1-Yes
5. 1st Urine Drug Screen Result(s):

Drug Name (Abbreviation)	Negative	Positive	Invalid	Not Required
Benzodiazepines (BZO):	*(UDBZO1)* ☐	☐	☐	
Amphetamine (AMP):	*(UDAMP1)* ☐	☐	☐	
Marijuana (THC):	*(UDTHC1)* ☐	☐	☐	
Methamphetamine (MET):	*(UDMET1)* ☐	☐	☐	
Opiates (2000 ng) (OPI):	*(UDOPI1)* ☐	☐	☐	
Cocaine (COC):	*(UDCOC1)* ☐	☐	☐	
Ecstasy (MDMA):	*(UDMDA1)* ☐	☐	☐	
Oxycodone (OXY):	*(UDOXY1)* ☐	☐	☐	
Methadone (MTD):	*(UDMTD1)* ☐	☐	☐	
Barbiturate (BAR):	*(UDBAR1)* ☐	☐	☐	
Opiates (300 ng) (OPI):	*(UDOPI31)* ☐	☐	☐	☐
Buprenorphine (10 ng) (BUP):	*(UDBUP1)* ☐	☐	☐	☐

2nd Urine Drug Screen

6. If the 1st urine specimen was determined to be adulterated, was a second specimen collected?*(UDTEST2)* ☐ 0-No ☐ 1-Yes
7. Date 2nd urine specimen collected:*(UDCOLDT2)* *(mm/dd/yyyy)*

   If "No", reason:*(UDNORSN2)*

   1-Participant reported being unable to provide sample
   2-Participant refused to provide sample
   3-Study staff error
   99-Other

   If "Other", specify:*(UDNOSP2)*

8. Was the 2nd urine specimen temperature within range? (90 - 100 °F)*(UDTEMP2)* ☐ 0-No ☐ 1-Yes
9. Was the 2nd urine specimen determined to be adulterated?*(UDADULT2)* ☐ 0-No ☐ 1-Yes
10. 2nd Urine Drug Screen Result(s):

Drug Name (Abbreviation)	Negative	Positive	Invalid	Not Required
Benzodiazepines (BZO):	*(UDBZO2)* ☐	☐	☐	
Amphetamine (AMP):	*(UDAMP2)* ☐	☐	☐	
Marijuana (THC):	*(UDTHC2)* ☐	☐	☐	
Methamphetamine (MET):	*(UDMET2)* ☐	☐	☐	
Opiates (2000 ng) (OPI):	*(UDOPI2)* ☐	☐	☐	
Cocaine (COC):	*(UDCOC2)* ☐	☐	☐	
Ecstasy (MDMA):	*(UDMDA2)* ☐	☐	☐	
Oxycodone (OXY):	*(UDOXY2)* ☐	☐	☐	
Methadone (MTD):	*(UDMTD2)* ☐	☐	☐	
Barbiturate (BAR):	*(UDBAR2)* ☐	☐	☐	
Opiates (300 ng) (OPI):	*(UDOPI32)* ☐	☐	☐	☐
Buprenorphine (10 ng) (BUP):	*(UDBUP2)* ☐	☐	☐	☐

Comments:*(UDSCOMM)*

Visual Analog Craving Scale (VAS)

Web Version: 1.0; 5.00; 02-23-18

Segment *(PROTSEG)*: B
Visit number *(VISNO)*:

Date of assessment:*(VASASMDT)* _____ *(mm/dd/yyyy)*

In the past week, how much have you craved **methamphetamine**?*(VACRMETH)* _____ *(xxx)*

Think about your craving for methamphetamine over the past week.
How intense was your worst craving?
Click on the circle on the line below and drag it to the spot that indicates the intensity of your worst craving from the past week.
0 means you did not crave meth at all.
100 means you had the most intense craving possible.
You can leave your circle anywhere on the line to show how intense your craving was.

Comments:*(VASCOMM)*

Vital Signs (VIT)

Web Version: 1.0; 4.00; 05-28-19

Segment *(PROTSEG)*: B
Visit number *(VISNO)*:

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

1. Standing height:*(VIHGTIN)* *(xx.x)* in *(VIHGTCM)* *(xxx.x)* cm
2. Measured weight:*(VIWTLBS)* *(xxx.x)* lbs *(VIWTKGS)* *(xxx.x)* kgs
3. BMI:*(VIBMI)*

4. Was a naloxone challenge administered?*(VINALOXN)* ☐ 0-No ☐ 1-Yes

	Temperature *(°F)*		Respiration *(breaths per minute)*		Heart Rate/Pulse *(beats per minute)*		Systolic BP *(mmHg)*		Diastolic BP *(mmHg)*	
a. Pre naloxone challenge:	*(VITMPFN1)*	*(xxx.x)*	*(VIRESPN1)*	*(xx)*	*(VIPULSN1)*	*(xxx)*	*(VIBPSYN1)*	*(xxx)*	*(VIBPDIN1)*	*(xxx)*
b. 10 minutes post naloxone challenge:	*(VITMPFN2)*	*(xxx.x)*	*(VIRESPN2)*	*(xx)*	*(VIPULSN2)*	*(xxx)*	*(VIBPSYN2)*	*(xxx)*	*(VIBPDIN2)*	*(xxx)*
c. 20 minutes post naloxone challenge:	*(VITMPFN3)*	*(xxx.x)*	*(VIRESPN3)*	*(xx)*	*(VIPULSN3)*	*(xxx)*	*(VIBPSYN3)*	*(xxx)*	*(VIBPDIN3)*	*(xxx)*
d. 30 minutes post naloxone challenge:	*(VITMPFN4)*	*(xxx.x)*	*(VIRESPN4)*	*(xx)*	*(VIPULSN4)*	*(xxx)*	*(VIBPSYN4)*	*(xxx)*	*(VIBPDIN4)*	*(xxx)*
e. Last vitals after 30 minutes post naloxone challenge:	*(VITMPFN5)*	*(xxx.x)*	*(VIRESPN5)*	*(xx)*	*(VIPULSN5)*	*(xxx)*	*(VIBPSYN5)*	*(xxx)*	*(VIBPDIN5)*	*(xxx)*

5. Was a gluteal injection of study medication administered?*(VIGLUINJ)* ☐ 0-No ☐ 1-Yes

	Temperature *(°F)*		Respiration *(breaths per minute)*		Heart Rate/Pulse *(beats per minute)*		Systolic BP *(mmHg)*		Diastolic BP *(mmHg)*	
a. Pre-medication administration:	*(VITMPFG1)*	*(xxx.x)*	*(VIRESPG1)*	*(xx)*	*(VIPULSG1)*	*(xxx)*	*(VIBPSYG1)*	*(xxx)*	*(VIBPDIG1)*	*(xxx)*
b. 15 minutes post-medication administration:	*(VITMPFG2)*	*(xxx.x)*	*(VIRESPG2)*	*(xx)*	*(VIPULSG2)*	*(xxx)*	*(VIBPSYG2)*	*(xxx)*	*(VIBPDIG2)*	*(xxx)*
c. Last vitals after 15 minutes post-medication administration:	*(VITMPFG3)*	*(xxx.x)*	*(VIRESPG3)*	*(xx)*	*(VIPULSG3)*	*(xxx)*	*(VIBPSYG3)*	*(xxx)*	*(VIBPDIG3)*	*(xxx)*

6. Temperature:*(VITMPF)* *(xxx.x)* °F
7. Respiration:*(VIRESP)* *(xx)* breaths per minute
8. Heart rate/pulse:*(VIPULS)* *(xxx)* beats per minute
9. Systolic/diastolic blood pressure:*(VIBPSY)* *(xxx)* / *(VIBPDI)* *(xxx)* mmHg

Comments:*(VITCOMM)*