NIDA Clinical Trials Network

Adverse Events (AD1)

Web Version: 1.0; 3.01; 10-01-14

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

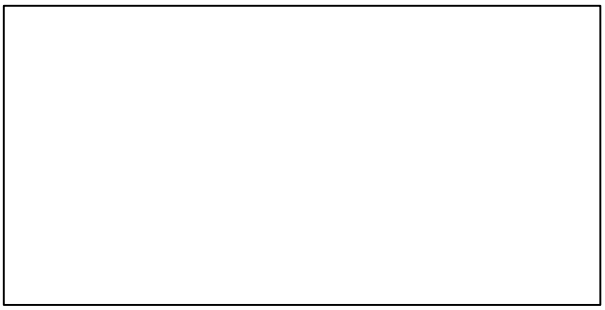
This adverse event has been closed by the Medical Reviewer and may no longer be updated.

1. Adverse event name:*(A1DESCPT)*
2. Date site became aware of the event:*(A1AWARDT)* *(mm/dd/yyyy)*
3. Severity of event:*(A1SEVRTY)*
4. Is there a reasonable possibility that the extended-release naltrexone caused the event?*(A1RDRUG1)* ☐ No ☐ Yes
   If "Yes", action taken with extended-release naltrexone:*(A1ADRUG1)*
5. Is there a reasonable possibility that bupropion (Wellbutrin XL) caused the event?*(A1RDRUG2)* ☐ No ☐ Yes
   If "Yes", action taken with bupropion (Wellbutrin XL):*(A1ADRUG2)*
6. If "Unrelated" to the study drug(s), alternative etiology:*(A1ALTESD)*
   If "Other," specify:*(A1AEPSP)*
7. Outcome of event:*(A1OUTCM)*
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)*
   a. If "Death", date of death:*(A1DTHDT)* *(mm/dd/yyyy)*
   b. If "Inpatient admission to hospital or prolongation of 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 *(AESEQNUM)* (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 "Unrelated" to the study drug(s), alternative etiology:
5-Concurrent illness/condition (not pre-existing)
6-Study procedures
7-Naloxone challenge
99-Other

Was this event associated with:
5-Congenital anomaly or birth defect
6-Important medical event that required intervention to prevent any of the above
7-Seizure
8-Hospitalization for a medical event

NIDA Clinical Trials Network

Serious Adverse Event Summary (AD2)

Web Version: 1.0; 1.00; 10-16-14

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

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

1. Initial narrative description of serious adverse event:

(A2SUMM)

2. Relevant past medical history: *(A2SAEMHX)* ☐ No ☐ Yes ☐ Unknown
Allergies, pregnancy, smoking and alcohol use, hypertension, diabetes, epilepsy, depression, etc.

(A2MEDHX)

3. Medications at the time of the event: *(A2SAEMED)* ☐ No ☐ Yes ☐ 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)* ☐ No ☐ Yes ☐ 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)* ☐ No ☐ Yes ☐ 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:

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

(A2FOLLUP)

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7. Additional information requested by the Medical Monitor:

(A2ADDINF)

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

Additional Selection Options for AD2

Event number *(AESEQNUM)* (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

NIDA Clinical Trials Network

Serious Adverse Event Medical Reviewer (AD3)

Web Version: 1.0; 3.00; 08-19-14

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

1. Was this determined to be a serious adverse event?*(A3SAE)*	☐ No ☐ Yes
2. Was this event considered associated with extended-release naltrexone? *(A3RXRNTX)*	☐ No ☐ Yes
3. Was this event considered associated with bupropion?*(A3RELDRG)*	☐ No ☐ Yes
4. Was this event expected?*(A3EXPECT)*	☐ No ☐ Yes
5. Is this a standard expedited/reportable event? *(i.e., is it serious, unexpected and related to therapy)(A3EXPFDA)*	☐ No ☐ Yes
If "No", is this an expedited/reportable event for other reasons?*(A3EXPOTH)*	☐ No ☐ Yes
6. Does the protocol need to be modified based on this event?*(A3MPROT)*	☐ No ☐ Yes
7. Does the consent form need to be modified based on this event?*(A3MCNST)*	☐ No ☐ Yes
8. Is the review complete?*(A3REVDNE)*	☐ No ☐ Yes
If "No", what additional information is required:*(A3ADDINF)*	

Assessed by:*(A3ASRID)* ☐ (intials)

Reviewed by:*(A3REVID)* ☐ (intials)

Comments:*(A3COMM)*

Additional Selection Options for AD3

Event number *(AESEQNUM)* (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

NIDA Clinical Trials Network

Bupropion Blood Levels (BBL)

Web Version: 1.0; 1.00; 10-10-13

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

1. Was a blood sample collected for the purpose of a bupropion pharmacokinetic analysis?*(BBBLDCLT)* ☐ No ☐ Yes
   If "No", why?*(BBNBLDSP)*
2. Collection date:*(BBCLTDT)* *(mm/dd/yyyy)*
3. Collection time (24-hour format):*(BBCLTTM)* *(hh:mm)*
4. Accession Number:*(BBPKACC)*

5. Date of last bupropion dose:*(BBBUPDT)* *(mm/dd/yyyy)*
   Time of last bupropion dose (24 - hour format):*(BBBUPTM)* *(hh:mm)*

6. Date of last XR-NTX dose:*(BBVVTLDT)* *(mm/dd/yyyy)*
   Time of last XR-NTX dose (24 - hour format):*(BBVVTLTM)* *(hh:mm)*

7. Was PK Primary Sample (3.6mL Green Cap) shipped for analysis?*(BBPK1SHP)* ☐ No ☐ Yes
   If "No", reason:*(BBPK1NSP)*
   If "Yes", date shipped:*(BBPK1SDT)* *(mm/dd/yyyy)*

8. Was PK Secondary Sample (3.6mL Red Cap) shipped for analysis? *(BBPK2SHP)* ☐ Yes
   If "Yes", reason:*(BBPK2NSP)*
   If "Yes", date shipped:*(BBPK2SDT)* *(mm/dd/yyyy)*

Comments:*(BBLCOMM)*

NIDA Clinical Trials Network

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

Web Version: 1.0; 1.02; 04-09-14

Segment *(PROTSEG)*:
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 two weeks.
For example, if you feel the statement very accurately describes how you have been feeling in the past two weeks, 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 two weeks, 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.	*(CHDEPEND)*	☐	☐	☐	☐	☐
6. The people I care the most for are gone.	*(CHPPLGNE)*	☐	☐	☐	☐	☐
7. I wish my suffering could just all be over.	*(CHSUFFER)*	☐	☐	☐	☐	☐
8. I feel that there is no reason to live.	*(CHRSLIVE)*	☐	☐	☐	☐	☐
9. I wish I could just go to sleep and not wake up.	*(CHSLEEP)*	☐	☐	☐	☐	☐
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)*

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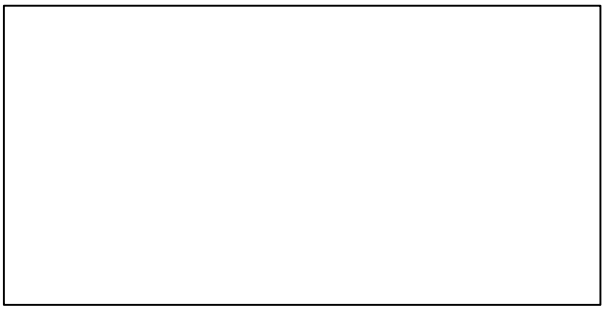
Bupropion Dose Log and Video Confirmation of Dosing (D54)

Web Version: 1.0; 3.00; 02-05-14

Segment *(PROTSEG)*:
Study week *(WKNM54)*:

Study Day	Study Day Date	Dose Dispensed 150mg(# of pills)	Date Dose Dispensed (mm/dd/yyyy)	Reported Dose Taken 150mg(# of pills)	Location Dose Taken	Valid Video Submitted	Video Confirmation of Dose Taken 150mg (# of pills)	Comments
	(D54DTD1)	*(D54D15D1)*	*(D54DSDT1)*	*(D54T15D1)*	*(D54LOCD1)*	*(D54VIDD1)*	*(D54V15D1)*	*(D54COMD1)*
	(D54DTD2)	*(D54D15D2)*	*(D54DSDT2)*	*(D54T15D2)*	*(D54LOCD2)*	*(D54VIDD2)*	*(D54V15D2)*	*(D54COMD2)*
	(D54DTD3)	*(D54D15D3)*	*(D54DSDT3)*	*(D54T15D3)*	*(D54LOCD3)*	*(D54VIDD3)*	*(D54V15D3)*	*(D54COMD3)*
	(D54DTD4)	*(D54D15D4)*	*(D54DSDT4)*	*(D54T15D4)*	*(D54LOCD4)*	*(D54VIDD4)*	*(D54V15D4)*	*(D54COMD4)*
	(D54DTD5)	*(D54D15D5)*	*(D54DSDT5)*	*(D54T15D5)*	*(D54LOCD5)*	*(D54VIDD5)*	*(D54V15D5)*	*(D54COMD5)*
	(D54DTD6)	*(D54D15D6)*	*(D54DSDT6)*	*(D54T15D6)*	*(D54LOCD6)*	*(D54VIDD6)*	*(D54V15D6)*	*(D54COMD6)*
	(D54DTD7)	*(D54D15D7)*	*(D54DSDT7)*	*(D54T15D7)*	*(D54LOCD7)*	*(D54VIDD7)*	*(D54V15D7)*	*(D54COMD7)*

Comments:*(D54COMM)*



Additional Selection Options for D54

Study week *(WKNM54)* (key field):
1-1
2-2
3-3
4-4
5-5
6-6
7-7
8-8
9-9

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Demographics (DEM)

Web Version: 1.0; 2.02; 07-11-14

1. Date of birth:*(DEBRTHDT)* _____ *(mm/dd/yyyy)*
2. Age:*(DEAGE)* _____ *(xx)*

3. Gender:*(DEGENDER)* ☐ Male ☐ Female ☐ Don't know ☐ Refused

4. Does the participant consider him or herself to be Hispanic/Latino?*(DEHISPNC)* ☐ No ☐ Yes ☐ Don't know ☐ Refused

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

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

White:	*(DEWHITE)* ☐		
Black/ African American:	*(DEBLACK)* ☐		
Indian (American):	*(DEAMEIND)* ☐		
Alaska native:	*(DEALASKA)* ☐		
Native Hawaiian:	*(DEHAWAII)* ☐		
Guamanian:	*(DEGUAM)* ☐		
Samoan:	*(DESAMOAN)* ☐		
Other Pacific Islander:	*(DEPACISL)* ☐	Specify:*(DEPACISO)*	
Asian Indian:	*(DEASAIND)* ☐		
Chinese:	*(DECHINA)* ☐		
Filipino:	*(DEFILIPN)* ☐		
Japanese:	*(DEJAPAN)* ☐		
Korean:	*(DEKOREA)* ☐		
Vietnamese:	*(DEVIETNM)* ☐		
Other Asian:	*(DEASIAN)* ☐	Specify:*(DEASIAOT)*	
Some other race:	*(DERACEOT)* ☐	Specify:*(DERACESP)*	

-OR- ---

Don't know:*(DERACEDK)* ☐

Refused: *(DERACERF)* ☐

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

7. 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)*

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

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

Comments:*(DEMCOMM)*

Additional Selection Options for DEM

If "Yes", indicate the group that represents his or her Hispanic origin or ancestry:
6-Cuban
7-Cuban American
8-Central or South American
9-Other Latin American
99-Other Hispanic
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 married, widowed, divorced, separated, never married, or living with a partner?
06-Living with partner
98-Refused
99-Don't know

NIDA Clinical Trials Network

End of Medication (EOM)

Web Version: 1.0; 3.02; 05-12-14

Segment *(PROTSEG)*:

1. Was a decision made by the investigator or participant to discontinue study medication early? *(EOEARLY)* ☐ No ☐ Yes

   If "Yes", primary reason for not completing study medication:*(EOSTOP54)*

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

   If "No", did the participant take the final dose of medication? ☐ No ☐ Yes
   (Day 60 for participants on the full dose or Day 58 for participants on a reduced dose.)
   (EOLASTDS)

   If "No", why?*(EOLDSRSN)*

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

2. Date of last reported bupropion dose:*(EODRUGDT)* *(mm/dd/yyyy)*

Comments:*(EOMCOMM)*

Additional Selection Options for EOM

If "Yes", primary reason for not completing study medication:
6-Clinical deterioration: Worsening of pre-existing psychiatric or medical condition
7-Clinical deterioration: Worsening of substance use disorder
8-Clinical deterioration: Overdose
9-Failed to return to clinic and window closed for second naltrexone injection
10-Participant declined to receive second naltrexone injection
11-Participant feels study treatment no longer necessary, cured
12-Participant feels study treatment no longer necessary, not working
13-Participant interested in seeking alternate treatment
14-Participant became incarcerated
15-Participant moved from area
16-Participant withdrew consent
17-Participant deceased
18-Participant unable to attend clinic visits (no childcare, transportation, schedule conflict)
19-Pressure or advice from others
99-Other

0054B (ENR)

Web Version: 1.0; 1.00; 12-16-13

Date of assessment:*(R3ASMDT)* _____ *(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.*(R3PTAGE)*	☐ No	☐ Yes	☐ Unknown	
2. Participant is able to speak English sufficiently to understand the study procedures and provide written informed consent to participate in the study. *(R3ENGLSH)*	☐ No	☐ Yes	☐ Unknown	
3. Participant demonstrates understanding of study procedures by correctly answering all questions on the consent competency tool.*(R3COMPT)*	☐ No	☐ Yes	☐ Unknown	
4. Participant is interested in reducing or stopping methamphetamine use.*(R3METSTP)*	☐ No	☐ Yes	☐ Unknown	
5. Participant meets DSM-5 criteria for severe methamphetamine use disorder. *(R3METDSM)*	☐ No	☐ Yes	☐ Unknown	
6. Participant self-reported methamphetamine use on 20 or more days in the 30 day period prior to consent via the Timeline Follow-back (TLFB).*(R3MET20D)*	☐ No	☐ Yes	☐ Unknown	
7. Participant submitted at least three urine samples positive for methamphetamine out of a possible four tests to occur within a 14-day period during which clinic visits occurred, with at least two days between visits.*(R3METUDS)*	☐ No	☐ Yes	☐ Unknown	
8. Participant meets subjective and objective measures of being opioid-free prior to enrollment and medication induction per study medical clinician's determination (including passing a naloxone challenge).*(R3OPFREE)*	☐ No	☐ Yes	☐ Unknown	
9. Participant is female of childbearing potential, and agrees to use acceptable birth control methods during participation in the study.*(R3BCUSE)*	☐ No	☐ Yes	☐ Unknown	☐ Not applicable
10. Participant agrees to use study cell phone to record videos of take-home dosing for transfer to study team.*(R3VIDEO)*	☐ No	☐ Yes	☐ 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. *(R3PSYCH)*	☐ No	☐ Yes	☐ Unknown
2. Participant has Stage II hypertension as determined by study medical clinician (e.g., greater than or equal to 160/100 in 2 out of 3 readings during screening). *(R3HYPTEN)*	☐ No	☐ Yes	☐ Unknown
3. Participant has suicidal or homicidal ideation that requires immediate attention. *(R3SUICDE)*	☐ No	☐ Yes	☐ Unknown
4. Participant has a known allergy or sensitivity to bupropion, naloxone, naltrexone, PLG (polyactide-co-glycolide), carboxymethylcellulose, or any other component of the XR-NTX diluent.*(R3ALERGY)*	☐ No	☐ Yes	☐ Unknown
5. Participant has a history of seizure, head trauma with neurological sequelae (i.e., loss of consciousness that required hospitalization), current anorexia nervosa or bulimia; in addition, any other conditions that increase seizure risk in the opinion of the study medical clinician will also be exclusionary.*(R3SEIZUR)*	☐ No	☐ Yes	☐ Unknown
6. Participant has evidence of second or third degree heart block, atrial fibrillation, atrial flutter, prolongation of the QTc; in addition, any other finding on the screening ECG that, in the opinion of the medical clinician, would preclude safe participation in the study will also be exclusionary.*(R3BLOCK)*	☐ No	☐ Yes	☐ Unknown
7. Participant has any liver function test (LFT) value > 5 times the upper limit of normal as per laboratory criteria.*(R3LIVER)*	☐ No	☐ Yes	☐ Unknown
8. Participant has platelet count <100k.*(R3PLATE)*	☐ No	☐ Yes	☐ Unknown
9. Participant has body habitus that precludes gluteal intramuscular injection of XR-NTX in accord with the administration equipment (needle) and procedures. *(R3HABTUS)*	☐ No	☐ Yes	☐ Unknown
10. Participant has been in a prior study of pharmacological or behavioral treatment for methamphetamine use disorder within 6 months of study consent. *(R3STUDY)*	☐ No	☐ Yes	☐ Unknown
11. Participant has taken an investigational drug in another study within 30 days of study consent.*(R3INDDRU)*	☐ No	☐ Yes	☐ Unknown
12. Participant is currently enrolled in behavioral or pharmacological addiction treatment services at the CTP.*(R3CTP)*	☐ No	☐ Yes	☐ Unknown

13. Participant is receiving ongoing treatment with tricyclic antidepressants, duloxetine, venlafaxine, xanthines (i.e., theophilline and aminophylline), systemic corticosteroids, nelfinavir, efavirenz, chlorpromazine, MAOIs, central nervous system stimulants (i.e., Adderall, Ritalin, etc), or any medication that, in the judgment of the study medical clinician, could interact adversely with study drugs.*(R3TREAT)* ☐ No ☐ Yes ☐ Unknown
14. Participant has been prescribed and taken naltrexone or bupropion within 30 days of consent.*(R3PRESCR)* ☐ No ☐ Yes ☐ Unknown
15. Participant has pending legal action or other situation (e.g., unstable living arrangements) that could prevent participation in the study or in study activities. *(R3LEGAL)* ☐ No ☐ Yes ☐ Unknown
16. Participant has a surgery planned or scheduled during the study period. *(R3SURGRY)* ☐ No ☐ Yes ☐ Unknown
17. Participant requires treatment with opioid-containing medications (e.g., opioid analgesics) during the study period.*(R3OPMED)* ☐ No ☐ Yes ☐ Unknown
18. 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.*(R3SEDATE)* ☐ No ☐ Yes ☐ Unknown
19. Participant is currently pregnant or breastfeeding.*(R3PREGNT)* ☐ No ☐ Yes ☐ Unknown ☐ Not applicable

Eligibility for Enrollment

1. Is the participant eligible for the study?*(R3ELGSTY)* ☐ No ☐ Yes

2. Will the participant be enrolled?*(R3ELGRDM)* ☐ No ☐ Yes

If "No", specify:*(R3NORSP)*

If "Other" or "Judgment of CTP/research staff", specify:*(R3JGOTSP)*

Comments:*(R3COMM)*

NIDA Clinical Trials Network

Injection Site Abnormality (INA)

Web Version: 1.0; 1.00; 10-04-13

Segment *(PROTSEG)*:

Note: If abnormality results in a SAE, complete SAE CRFs.

Abnormal Event If "Other", specify in comments	**Event Start Date** (mm/dd/yyyy)	**Severity**	**Treatment**	**Event Resolution Date** (mm/dd/yyyy)	
1. *(INETYP1)*	*(INESDT1)*	*(INESVR1)* ☐ Mild ☐ Moderate ☐ Severe	*(INETRT1)*	*(INERDT1)*	*(INECOM1)*
2. *(INETYP2)*	*(INESDT2)*	*(INESVR2)* ☐ Mild ☐ Moderate ☐ Severe	*(INETRT2)*	*(INERDT2)*	*(INECOM2)*
3. *(INETYP3)*	*(INESDT3)*	*(INESVR3)* ☐ Mild ☐ Moderate ☐ Severe	*(INETRT3)*	*(INERDT3)*	*(INECOM3)*
4. *(INETYP4)*	*(INESDT4)*	*(INESVR4)* ☐ Mild ☐ Moderate ☐ Severe	*(INETRT4)*	*(INERDT4)*	*(INECOM4)*
5. *(INETYP5)*	*(INESDT5)*	*(INESVR5)* ☐ Mild ☐ Moderate ☐ Severe	*(INETRT5)*	*(INERDT5)*	*(INECOM5)*
6. *(INETYP6)*	*(INESDT6)*	*(INESVR6)* ☐ Mild ☐ Moderate ☐ Severe	*(INETRT6)*	*(INERDT6)*	*(INECOM6)*
7. *(INETYP7)*	*(INESDT7)*	*(INESVR7)* ☐ Mild ☐ Moderate	*(INETRT7)*	*(INERDT7)*	*(INECOM7)*

1-Pain 2-Tenderness 3-Induration 4-Swelling 5-Erythema (redness) *Additional Options Listed Below		☐ Severe			
8. *(INETYP8)*	*(INESDT8)*	*(INESVR8)* ☐ Mild ☐ Moderate ☐ Severe	*(INETRT8)*	*(INERDT8)*	*(INECOM8)*
9. *(INETYP9)*	*(INESDT9)*	*(INESVR9)* ☐ Mild ☐ Moderate ☐ Severe	*(INETRT9)*	*(INERDT9)*	*(INECOM9)*
10. *(INETYP10)*	*(INESDT10)*	*(INESVR10)* ☐ Mild ☐ Moderate ☐ Severe	*(INETRT10)*	*(INERDT10)*	*(INECOM10)*
11. *(INETYP11)*	*(INESDT11)*	*(INESV11)* ☐ Mild ☐ Moderate ☐ Severe	*(INETRT11)*	*(INERDT11)*	*(INECOM11)*
12. *(INETYP12)*	*(INESDT12)*	*(INESV12)* ☐ Mild ☐ Moderate ☐ Severe	*(INETRT12)*	*(INERDT12)*	*(INECOM12)*

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
99-Other

NIDA Clinical Trials Network

XR-NTX Administration (INJ)

Web Version: 1.0; 2.00; 12-30-13

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

Date of injection:*(INJINJDT)* *(mm/dd/yyyy)*

1. Location of previous injection:*(INPREV)* ☐ Right buttock ☐ Left buttock
2. Injection location:*(ININJLOC)* ☐ Right buttock ☐ Left buttock

3. Time injection given (24 - hour format):*(ININJTM)* *(hh:mm)*

4. Did you experience difficulty with XR-NTX administration?*(INDIFFCT)* ☐ No ☐ Yes
   If "Yes", describe:*(INDIFRES)*

5. Administered by:*(INADMN)*
   If "Other", specify:*(INADMNSP)*

Comments:*(INJCOMM)*

Additional Selection Options for INJ

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

Administered by:
6-Licensed Vocational Nurse (LVN)
7-Certified Medical Assistant (CMA)
9-Other

NIDA Clinical Trials Network

Inventory - Medication and Supplies (INV)

Web Version: 1.0; 7.02; 01-13-15

Date of inventory *(INVTRYDT)*:

A new form must be submitted by the last business day of each week.

	Current Inventory Level	**Expiration Date** *Earliest Date* (mm/dd/yyyy)
Biological Assessments		
1. QuickTox Drug Screens	*(INUDSEA)* *(xxx)* Full Box(es)	*(INUDSEX)*
2. Urine Adulterant Test Strips	*(INADLTEA)* *(xxx)* Full Bottle(s)	*(INADLTEX)*
3. Urine Cups with Temp Strips	*(INTEMPEA)* *(xxx)* Each	N/A
4. Pregnancy Tests	*(INPREGEA)* *(xxx)* Each	*(INPREGEX)*
5. OPI 300 Single Test Strip	*(INOPI300)* *(xxx)* Each	*(INOPI3DT)*
Lab Supplies		
1. Screening and Follow-up Lab Kit Coolers	*(INFRZSHP)* *(xxx)* Each	N/A
2. Butterfly Needles	*(INBFLYEA)* *(xxx)* Each	N/A
3. Vacutainers	*(INNHLDEA)* *(xxx)* Each	N/A
4. Screening and Follow-up Lab Kits	*(INSCFUKT)* *(xx)* Each	*(INSCFUDT)*
5. UDS Lab Kits	*(INUDSKT)* *(xxx)* Each	N/A
6. PK Lab Kits	*(INPKKT)* *(xxx)* Each	*(INPKDT)*
Medication		
1. Naltrexone (Vivitrol) IM Injection Kit	*(INVIVTEA)* *(xx)* Each	*(INVIVTEX)*
2. Wellbutrin XL, bupropion 150 mg Tablets (Bulk 90 Tabs/Bottle)	*(INBU15EA)* *(xx.x)* Bottle(s)	*(INBU15DT)*
3. Wellbutrin XL, bupropion 150 mg Tablets (Bulk 30 Tabs/Bottle)	*(INBU30EA)* *(xx.x)* Bottle(s)	*(INBU30DT)*
4. Take Home Amber Prescription Vials	*(INPRVIAL)* *(xx)* Vials	N/A
5. Take Home Prescription Vial Labels	*(INPRLABL)* *(xx)* Labels	N/A

Comments:*(INVCOMM)*

NIDA Clinical Trials Network

Injection Site Examination (INX)

Web Version: 1.0; 1.01; 10-30-13

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

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

Location of previous injection:*(INJPREV)* ☐ Right buttock ☐ Left buttock

1. Location of injection:*(INJLOC)* ☐ Right buttock ☐ Left buttock
2. Is this injection site normal?*(INJOK)* ☐ No ☐ Yes

If the injection site is "abnormal", complete the Injection Site Abnormality Log.
Note: If this event is an SAE, you must complete the AE forms.

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

NIDA Clinical Trials Network

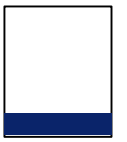
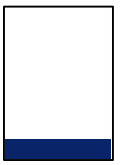
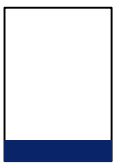
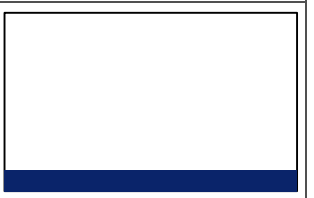
Clinical Laboratory Tests (LAB)

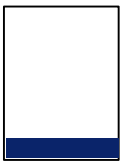
Web Version: 1.0; 6.02; 02-17-15

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

Lab collection date:*(LABDATE)* _____ *(mm/dd/yyyy)*

	Test	Result
CBC	1. WBC	*(LAWBC)* _____ *(xx.x)* x10^3/µL
	2. RBC	*(LARBC)* _____ *(xx.xx)* x10^6/µL
	3. Haemoglobin	*(LAHEMGLB)* _____ *(xx.x)* g/dL
	4. Haematocrit	*(LAHEMATO)* _____ *(xx.x)* %
	5. MCV	*(LAMCV)* _____ *(xxx.x)* fL
	6. MCH	*(LAMCH)* _____ *(xx.x)* pg
	7. MCHC	*(LAMCHC)* _____ *(xx.x)* g/dL
	8. RDW	*(LARDW)* _____ *(xx.x)* %
	9. Platelets	*(LAPLATES)* _____ *(xxxx.x)* dL
	10. MPV	*(LAMPV)* _____ *(xx.x)* fL
	11. Neutrophils, Absolute	*(LANEUTRO)* _____ *(xx.x)* x10^3/µL
	12. Lymphocytes, Absolute	*(LALYMPHO)* _____ *(xx.x)* x10^3/µL
	13. Monocytes, Absolute	*(LAMONOCY)* _____ *(xx.x)* x10^3/µL
	14. Eosinophils, Absolute	*(LAEOSINO)* _____ *(xx.x)* x10^3/µL
	15. Basophils, Absolute	*(LABASOPH)* _____ *(xx.x)* x10^3/µL
	16. Neutrophils %	*(LANEUTPT)* _____ *(xxx.x)* %
	17. Lymphocytes %	*(LALYMPPT)* _____ *(xxx.x)* %
	18. Monocytes %	*(LAMONOPT)* _____ *(xxx.x)* %
	19. Eosinophils %	*(LAEOSIPT)* _____ *(xxx.x)* %
	20. Basophils %	*(LABASOPT)* _____ *(xxx.x)* %
Urinalysis	21. pH	*(LAPH)* _____ *(x.x)*
	22. Protein	*(LAUPROT)* 
	23. Glucose	*(LAUGLU)* 

24. Ketones	*(LAKETONE)* 
25. Bilirubin	*(LAUBILIR)* 
26. Blood	*(LABLOOD)* 
27. Nitrite	*(LANITRTE)* 
28. Urobilinogen	*(LAUBILNG)* 
29. Specific gravity	*(LAGRAVTY)* *(x.xxxx)*
30. Leukocyte esterase	*(LALEUKES)* 
31. Color	*(LACOLOR)* 
32. Clarity	*(LACLARTY)* 
33. Urine microscopic - Bacteria	*(LAUBACT)* 
34. Urine microscopic - WBC	*(LAUWBC)* 
35. Urine microscopic - RBC	*(LAURBC)* 

		36. Urine microscopic - Crystals	*(LAUCRYSL)* 
		37. Urine microscopic - Casts	*(LAUCASTS)* 
		38. Urine microscopic - Epithelial cells	*(LAUEPI)* 
Comprehensive Metabolic Panel		39. Glucose	*(LAGLU)* _____ *(xxxx)* mg/dL
		40. Blood urea nitrogen (BUN)	*(LABUN)* _____ *(xxx.x)* mg/dL
		41. Creatinine	*(LACREATE)* _____ *(xx.xx)* mg/dL
		42. BUN/Creatinine ratio	*(LABUNCRT)* _____ *(xx)* Ratio
		43. Sodium (NA)	*(LANA)* _____ *(xxx)* mmol/L
		44. Potassium (K)	*(LAK)* _____ *(x.x)* mmol/L
		45. Chloride	*(LACL)* _____ *(xxx)* mmol/L
		46. CO2	*(LACO2)* _____ *(xx)* mmol/L
		47. AGAP	*(LAAGAP)* _____ *(xx)* mmol/L
		48. Calcium results	*(LACA)* _____ *(xx.x)* mg/dL
		49. Total protein	*(LAPROTEN)* _____ *(x.x)* g/dL
		50. Albumin	*(LAALBUMN)* _____ *(x.x)* g/dL
		51. Globulin	*(LAGLOBIN)* _____ *(x.x)* g/dL
		52. Aspartate Aminotransferase (AST/SGOT)	*(LAAST)* _____ *(xxxx.x)* U/L
		53. Alanine Aminotransferase (ALT/SGPT)	*(LAALT)* _____ *(xxxx.x)* U/L
		54. Alkaline Phosphatase (ALP)	*(LAALP)* _____ *(xxxx.x)* U/L
		55. Total Bilirubin	*(LABILRBT)* _____ *(xx.x)* mg/dL

Comments:*(LABCOMM)*

Additional Selection Options for LAB

Urinalysis color
5-Amber
6-Red
7-Orange
8-Green
99-Other

Urinalysis clarity
6-Turbid

Urine micro bacteria
5-3+
6-Moderate
7-Many

Urine micro WBC
5-20-40/HPF
6-Full field

Urine micro RBC
5-2-7/HPF
6-10-20/HPF
7-20-40/HPF
8-Full field

NIDA Clinical Trials Network

Missed Visit Form (MVF)

Web Version: 1.0; 1.00; 12-06-13

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

Reason for missed visit:*(MVREASON)*

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

Comments:*(MVFCOMM)*

Additional Selection Options for MVF

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

NIDA Clinical Trials Network

Naloxone Challenge (NXC)

Web Version: 1.0; 2.00; 01-03-14

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

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

First Dose

1. Time of administration:*(NXDOSTM1)* *(hh:mm)* (24-hour clock)
2. Total dose:*(NXDOSE1)* *(x.xx)* mg
3. Route of administration:*(NXROUTE1)*

Second Dose (if applicable)

Note: If a second dose was administered within 5 minutes, the total quantity should be entered above as a single first dose.

4. Time of administration:*(NXDOSTM2)* *(hh:mm)* (24-hour clock)
5. Total dose:*(NXDOSE2)* *(x.xx)* mg
6. Route of administration:*(NXROUTE2)*

Comments:*(NXCCOMM)*

Additional Selection Options for NXC

Challenge number *(NXC_CHNO)* (key field):
1-1
2-2
3-3
4-4
5-5
6-6
7-7

NIDA Clinical Trials Network

Pregnancy and Birth Control Assessment (PBC)

Web Version: 1.0; 3.02; 12-09-14

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

Complete this form only for females.

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

1. Is participant continuing to use an effective method of birth control?*(PBUSEBC)* ☐ No ☐ Yes
2. Was a pregnancy test performed?*(PBPRGTST)* ☐ No ☐ Yes
   a. Date of pregnancy test:*(PBPTSTDT)* _____ *(mm/dd/yyyy)*
   b. Result of pregnancy test:*(PBRESULT)* ☐ Negative ☐ 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; 10-04-13

Medication name *(PCMEDNME)*:
Medication start date *(PCSTRTDT)*:

1. Indication for use:*(PCINDICT)*

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

2. Was this medication used to treat an adverse event?*(PCMEDAE)* ☐ No ☐ Yes

3. Is medication ongoing?*(PCONGOIN)* ☐ No ☐ Yes ☐ 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
99B-BLOOD AND BLOOD FORMING ORGANS
01B---Aspirin/coumadin/heparin
02B---Antianemic
03B---Blood products/IV fluids
99C-CARDIOVASCULAR SYSTEM
01C---Antihypertensives
02C---Diuretics
03C---Beta blocking
04C---Calcium Channel
05C---Lipid modifying agents
01D-ALL SKIN CREAMS
01G-CONTRACEPTIVES/ED/SEX HORMONES
01H-STEROIDS/THYROID HORMONES
01J-ANTIBACTERIAL/ANTIVIRAL/ANTIFUNGAL/TB/VACCINES
99M-MUSCULOSKELETAL SYSTEM
01M---Antiinflammatory and antirheumatic
02M---Muscle relaxants
03M---Antigout
99N-NERVOUS SYSTEM
01N---Analgesics including antipyretics
02N---Antiepileptics
03N---Anxiety/Depression/Sleep
99R-RESPIRATORY SYSTEM
01R---Nasal
02R---Throat
03R---Obstructive airway
04R---Cough and cold
05R---Antihistamines
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

NIDA Clinical Trials Network

Protocol Deviation Review (PDR)

Web Version: 1.0; 2.00; 03-24-14

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

Completed by Protocol Specialist:

1. What section of the protocol does this deviation refer to?*(PDSECTN)*

2. Does the report of this deviation require site staff retraining?*(PDTRAIN)* ☐ No ☐ Yes
   If "Yes", specify plan for retraining:*(PDPLATRA)*

3. Deviation was discussed with Lead Investigative Team on:*(PDDISCDT)* *(mm/dd/yyyy)*

4. Deviation is categorized as:*(PDCATGRY)* ☐ Major ☐ Minor

5. Deviation assessment by Protocol Specialist complete:*(PDPSCMP)* ☐ No ☐ Yes
   Protocol Specialist reviewer:*(PDPSRVID)* (initials)

Completed by Protocol Monitor:

6. Corrective action for this deviation was completed and documented on-site as described:*(PDACTDOC)* ☐ No ☐ Yes
   If "No", specify reason:*(PDSITESP)*

7. Deviation was reported to the IRB as required:*(PDIRBRPT)* ☐ No ☐ Yes

If "No", specify reason:*(PDIRBSP)*

8. Preventive action plan related to this event was completed and documented on-site as described:*(PDPREVNT)*
   ☐ No ☐ Yes
9. Review by Protocol Monitor is complete:*(PDPMCMP)*
   ☐ No ☐ Yes

   Protocol Monitor reviewer:*(PDPMRVID)* (initials)

Comments:*(PVCOMM)*

Additional Selection Options for PDR

Protocol deviation number *(PDSEQNUM)* (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

NIDA Clinical Trials Network

Protocol Deviation (PDV)

Web Version: 1.0; 1.00; 03-21-14

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

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

2. Deviation type:*(PDTYPE)*

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

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

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

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

6. Is this deviation reportable to your IRB?*(PDIRBREP)* ☐ No ☐ Yes

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

Deviation type:
01E--- Informed consent process not properly conducted and/or documented
01Z--- Other (specify)
Z02-INCLUSION/EXCLUSION CRITERIA
02A--- Ineligible participant randomized/inclusion/exclusion criteria not met
02Z--- Other (specify)
Z04-LABORATORY ASSESSMENTS
04A--- Biologic specimen not collected/processed as per protocol
04Z--- Other (specify)
Z05-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 (specify)
Z06-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 (specify)
Z07-RANDOMIZATION PROCEDURES
07A--- Stratification error
07Z--- Other (specify)
Z08-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 (specify)
Z09-STUDY BEHAVIORAL INTERVENTION
09A--- Study behavioral intervention was not provided/performed as per protocol
09Z--- Other (specify)
Z99-OTHER SIGNIFICANT DEVIATIONS
99A--- Destruction of study materials without prior authorization from sponsor
99B--- Breach of Confidentiality
99Z--- Other (specify)

NIDA Clinical Trials Network

Physical Examination (PEX)

Web Version: 1.0; 2.00; 11-19-13

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

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

Comments

General appearance: *(PEGENAPP)*

(PEGASP)

Skin, hair, and nails: *(PESKHRNA)*

(PESHNSP)

Head and neck:

(PEHDNKSP)

(PEHDNK)

Ears, eyes, nose, and throat:

(PEEENT)

(PEENTSP)

Cardiovascular:

(PECARD)

(PECARDSP)

Respiratory:

(PERESP)

(PERESPSP)

Gastrointestinal:

(PEGAST)

(PEGASTSP)

Extremities:

(PEEXTR)

(PEEXTRSP)

Lymph nodes:

(PELYMP)

(PELYMPSP)

Musculoskeletal:

(PEMUSC)

(PEMUSCSP)

Neurological: *(PENEUR)*

(PENEURSP)

Injection site assessment: *(PEINJS)*

(PEINJSSP)

Other (specify in comments): *(PEOTHER)*

(PEOTHESP)

Comments:*(PEXCOMM)*

NIDA Clinical Trials Network

Pregnancy Outcome 1 (PO1)

Web Version: 1.0; 1.00; 07-26-13

Pregnancy number *(PGSEQNUM)*:

Newborn Information

1. Gender:*(PO1GENDR)* ☐ Male ☐ Female ☐ Unknown
2. Gestational age at delivery:*(PO1GESWK)* _____ *(xx)* Weeks *(PO1GESDY)* _____ *(x)* Days *(PO1GESUN)***OR** ☐ Unknown
3. Weight at delivery:*(PO1WTLBS)* _____ *(xx)* Lbs *(PO1WTOZ)* _____ *(xx)* Oz *(PO1WTUNK)***OR** ☐ Unknown
4. Apgar score at 1 minute:*(PO1APG1M)* _____ *(xx)* *(PO11APUK)***OR** ☐ Unknown
5. Apgar score at 5 minutes:*(PO1APG5M)* _____ *(xx)* *(PO15APUK)***OR** ☐ Unknown
6. Normal infant?*(PO1NORML)* ☐ No ☐ Yes

   If "No", is there a congenital anomaly?*(PO1CONAN)* ☐ No ☐ Yes ☐ Unknown

   If "Yes", specify abnormality and contributing factors:*(PO1ABNSP)*

Comments:*(PO1COMM)*

Additional Selection Options for PO1

Pregnancy number *(PGSEQNUM)* (key field):
01-1st Pregnancy
02-2nd Pregnancy
03-3rd Pregnancy
04-4th Pregnancy

NIDA Clinical Trials Network

Pregnancy Outcome 2 (PO2)

Web Version: 1.0; 1.00; 07-26-13

Pregnancy number *(PGSEQNUM)*:

Newborn Information

1. Gender:*(PO2GENDR)* ☐ Male ☐ Female ☐ Unknown
2. Gestational age at delivery:*(PO2GESWK)* *(xx)* Weeks *(PO2GESDY)* *(x)* Days *(PO2GESUN)***OR** ☐ Unknown
3. Weight at delivery:*(PO2WTLBS)* *(xx)* Lbs *(PO2WTOZ)* *(xx)* Oz *(PO2WTUNK)***OR** ☐ Unknown
4. Apgar score at 1 minute:*(PO2APG1M)* *(xx)* *(PO21APUK)***OR** ☐ Unknown
5. Apgar score at 5 minutes:*(PO2APG5M)* *(xx)* *(PO25APUK)***OR** ☐ Unknown
6. Normal infant?*(PO2NORML)* ☐ No ☐ Yes

   If "No", is there a congenital anomaly?*(PO2CONAN)* ☐ No ☐ Yes ☐ Unknown

   If "Yes", specify abnormality and contributing factors:*(PO2ABNSP)*

Comments:*(PO2COMM)*

Additional Selection Options for PO2

Pregnancy number *(PGSEQNUM)* (key field):
01-1st Pregnancy
02-2nd Pregnancy
03-3rd Pregnancy
04-4th Pregnancy

NIDA Clinical Trials Network

Pregnancy Outcome 3 (PO3)

Web Version: 1.0; 1.00; 07-26-13

Pregnancy number *(PGSEQNUM)*:

Newborn Information

1. Gender:*(PO3GENDR)* ☐ Male ☐ Female ☐ Unknown
2. Gestational age at delivery:*(PO3GESWK)* _____ *(xx)* Weeks *(PO3GESDY)* _____ *(x)* Days *(PO3GESUN)***OR** ☐ Unknown
3. Weight at delivery:*(PO3WTLBS)* _____ *(xx)* Lbs *(PO3WTOZ)* _____ *(xx)* Oz *(PO3WTUNK)***OR** ☐ Unknown
4. Apgar score at 1 minute:*(PO3APG1M)* _____ *(xx)* *(PO31APUK)***OR** ☐ Unknown
5. Apgar score at 5 minutes:*(PO3APG5M)* _____ *(xx)* *(PO35APUK)***OR** ☐ Unknown
6. Normal infant?*(PO3NORML)* ☐ No ☐ Yes

   If "No", is there a congenital anomaly?*(PO3CONAN)* ☐ No ☐ Yes ☐ Unknown

   If "Yes", specify abnormality and contributing factors:*(PO3ABNSP)*

Comments:*(PO3COMM)*

Additional Selection Options for PO3

Pregnancy number *(PGSEQNUM)* (key field):
01-1st Pregnancy
02-2nd Pregnancy
03-3rd Pregnancy
04-4th Pregnancy

NIDA Clinical Trials Network

Pregnancy Outcome 4 (PO4)

Web Version: 1.0; 1.00; 08-06-13

Pregnancy number *(PGSEQNUM)*:

Newborn Information

1. Gender:*(PO4GENDR)* ☐ Male ☐ Female ☐ Unknown
2. Gestational age at delivery:*(PO4GESWK)* _____ *(xx)* Weeks *(PO4GESDY)* _____ *(x)* Days *(PO4GESUN)***OR** ☐ Unknown
3. Weight at delivery:*(PO4WTLBS)* _____ *(xx)* Lbs *(PO4WTOZ)* _____ *(xx)* Oz *(PO4WTUNK)***OR** ☐ Unknown
4. Apgar score at 1 minute:*(PO4APG1M)* _____ *(xx)* *(PO41APUK)***OR** ☐ Unknown
5. Apgar score at 5 minutes:*(PO4APG5M)* _____ *(xx)* *(PO45APUK)***OR** ☐ Unknown
6. Normal infant?*(PO4NORML)* ☐ No ☐ Yes

   If "No", is there a congenital anomaly?*(PO4CONAN)* ☐ No ☐ Yes ☐ Unknown

   If "Yes", specify abnormality and contributing factors:*(PO4ABNSP)*

Comments:*(PO4COMM)*

Additional Selection Options for PO4

Pregnancy number *(PGSEQNUM)* (key field):
01-1st Pregnancy
02-2nd Pregnancy
03-3rd Pregnancy
04-4th Pregnancy

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Confirmed Pregnancy and Outcome (PRG)

Web Version: 1.0; 1.00; 07-26-13

Pregnancy number *(PGSEQNUM)*:

Information About Pregnancy

1. Date on which study staff became aware of pregnancy:*(PRAWARDT)* *(mm/dd/yyyy)*
2. How was the pregnancy confirmed? *(select all that apply)*
   a. Urine pregnancy test result:*(PRURICNF)* ☐ No ☐ Yes
   b. Serum pregnancy test result:*(PRSERCNF)* ☐ No ☐ Yes
   c. Ultrasound result:*(PRULTCNF)* ☐ No ☐ Yes
   d. Other:*(PROTHCNF)* ☐ No ☐ Yes
   If "Other", specify:*(PROTCNSP)*
3. Date on which the pregnancy was confirmed:*(PRCNFMDT)* *(mm/dd/yyyy)*
4. Action taken with study drug:*(PRACTIND)*
5. Approximate due date:*(PRAPXDDT)* *(mm/dd/yyyy)* *(PRDDTUNK)***OR** ☐ Unknown
6. Outcome of pregnancy:*(PROUTCME)*
   If "Other", specify:*(PROTCMSP)*
7. Date of pregnancy outcome:*(PROTCMDT)* *(mm/dd/yyyy)*
8. Number of live births:*(PRNMLIVB)*
   If "0" live births, indicate reason:*(PRRSOBSP)*

Comments:*(PRGCOMM)*

Additional Selection Options for PRG

Pregnancy number *(PGSEQNUM)* (key field):
01-1st Pregnancy
02-2nd Pregnancy
03-3rd Pregnancy
04-4th Pregnancy

Outcome of pregnancy:
97-Unknown

Number of live births:
99-Other
97-Unknown

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Protocol Satisfaction Survey (PXS)

Web Version: 1.0; 1.01; 05-07-14

Segment *(PROTSEG)*:

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 medications (oral and injected) you received in reducing or stopping your methamphetamine use?*(PXMEDEFT)*

2. Which part of the treatment was most helpful in reducing or stopping your methamphetamine?*(PXHELPTR)*

3. Did being in the study help you in ways other than my methamphetamine use?*(PXHELP)* ☐ No ☐ Yes

If "Yes", check all that apply:

Medically:*(PXHELPMD)*	☐ No ☐ Yes
Psychologically:*(PXHELPPS)*	☐ No ☐ Yes
Relationships:*(PXHELPRL)*	☐ No ☐ Yes
Employment:*(PXHELPEM)*	☐ No ☐ Yes
Legally:*(PXHELPLE)*	☐ No ☐ Yes
Financially:*(PXHELPFI)*	☐ No ☐ Yes
Referrals to other services:*(PXHELPRE)*	☐ No ☐ Yes
Other:*(PXHELPOT)*	☐ No ☐ Yes

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

4. How satisfied were you with the overall experience in the study?*(PXSATFY)*

5. If you had to do it all over again, would you still choose to participate in this study?*(PXPARTAG)*

6. What is the primary reason you would choose to participate again? *(PXPRTAGY)*

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

7. What is the primary reason you would choose NOT to participate again? *(PXPRTAGN)*

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

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 (cash and/or gift cards) was sufficient.	*(PXCASH)* ☐	☐	☐	☐	☐
2. The cellphone 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 injected medication caused undesirable side effects.	*(PXINJSD)* ☐	☐	☐	☐	☐
7. The oral 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)* ☐	☐	☐	☐	☐
14. It was helpful to receive my study medication on a weekly basis and not have to come to the clinic for each dose.	*(PXMEDWE)* ☐	☐	☐	☐	☐

Section 3: Cellphone Procedures

In this section, we would like your opinion on the cellphone 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
1. I received enough training so that I could use the cellphone.	*(PXTRAIN)* ☐	☐	☐	☐	☐
2. It was easy to record the dosing video.	*(PXRECORD)* ☐	☐	☐	☐	☐
3. It was easy to send the dosing video.	*(PXSEND)* ☐	☐	☐	☐	☐
4. I am better able to use a smart phone now than I was at the beginning of the study.	*(PXUSECEL)* ☐	☐	☐	☐	☐
5. I used the study cellphone for personal calls.	*(PXPERCEL)* ☐	☐	☐	☐	☐
6. The reminders to record and send the dosing video were helpful.	*(PXREMIN)* ☐	☐	☐	☐	☐
7. The cellphone reminders helped me to remember to take study drug as directed.	*(PXDIRECT)* ☐	☐	☐	☐	☐
8. Having to take videos of my dosing helped me to take my study drug.	*(PXVIDEO)* ☐	☐	☐	☐	☐
9. There was sufficient technical support when I ran into problems using the cellphone.	*(PXTECSUP)* ☐	☐	☐	☐	☐
10. I liked the fact that study staff could monitor my medication dosing and I didn't have to come to the clinic.	*(PXMONIT)* ☐	☐	☐	☐	☐
11. The compensation I received for sending the videos was important.	*(PXVIDCMP)* ☐	☐	☐	☐	☐
12. I was confident that my privacy was protected when using the cellphone and sending the dosing video.	*(PXPRIVAC)* ☐	☐	☐	☐	☐

13. If applicable, having both a study cellphone and personal cellphone was cumbersome.	*(PXTWOPHO)* ☐	☐	☐	☐	☐

Please provide any additional comments about the use of cellphones in this study.
For example, how did the study cellphone affect your daily life, how you planned your day,
how you communicated with study staff, friends or family: *(PXCOMCEL)*

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

Comments:*(PXSCOMM)*

Additional Selection Options for PXS

What is the primary reason you would choose to participate again?
6-I was able to get into the study quickly
7-There aren't many other treatment options available to me
8-My participation may help others
9-My participation may help contribute to science
10-I liked coming to the clinic two times per week
11-The staff treated me well
12-The clinic was in a desirable location and was easy to access
12-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 visits per week
7-There were too many procedures/visits lasted too long
8-Lack of counseling
9-I didn't like having to use the cellphone
10-I didn't like having to use a computer for assessments
11-I would rather enroll in a usual treatment program
12-The staff didn't treat me well
13-The clinic was in an undesirable location and was difficult to access
14-The clinic had inconvenient hours and days
99-Other

NIDA Clinical Trials Network

Quality of Life - PhenX (QLP)

Web Version: 1.0; 1.02; 01-03-14

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

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

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

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?*(QLHLTNGD)* _____ *(xx)* Number of 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)* Number of 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)* Number of days

Comments:*(QLPCOMM)*

NIDA Clinical Trials Network

Protocol Satisfaction Survey: Staff (RXS)

Web Version: 1.0; 1.00; 10-15-13

Segment *(PROTSEG)*:

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. The participant was able to learn the cellphone procedures in 1-2 training sessions.	*(RXCELLPR)* ☐	☐	☐	☐	☐
4. The study cellphone procedures were burdensome for study staff.	*(RXBURDEN)* ☐	☐	☐	☐	☐
5. The study cellphone procedures were unnecessary/not useful.	*(RXUNNESS)* ☐	☐	☐	☐	☐
6. The participant needed additional assistance after training to troubleshoot a problem with the cellphone or to record/send a dosing video.	*(RXASSIST)* ☐	☐	☐	☐	☐
7. Using cellphone technology helped to improve medication adherence for this participant.	*(RXMEDADH)* ☐	☐	☐	☐	☐
8. Using cellphone technology helped to improve attendance at study visits for this participant.	*(RXATTEND)* ☐	☐	☐	☐	☐
9. Using cellphone technology helped to foster a strong relationship with this participant.	*(RXRELATE)* ☐	☐	☐	☐	☐
10. Using cellphone technology helped to collect accurate study data on this participant.	*(RXACCURA)* ☐	☐	☐	☐	☐
11. This participant seemed to like using the cellphone in this study.	*(RXLIKE)* ☐	☐	☐	☐	☐
12. The participant seemed to be overwhelmed by the cellphone components like the dosing videos or sending the videos.	*(RXOVERWH)* ☐	☐	☐	☐	☐
13. The study cellphone was useful in documenting the participant's compliance with study dosing.	*(RXDOCUM)* ☐	☐	☐	☐	☐
14. The study cellphone was useful in promoting/increasing the participant's compliance with study dosing.	*(RXINCRSE)* ☐	☐	☐	☐	☐

15. Did this participant report a lost or stolen study cellphone during the course of the study? *(RXLOST)* ☐ No ☐ Yes

    a. If "Yes", was a replacement phone provided? *(RXREPLAC)* ☐ No ☐ Yes

    b. Was GPS tracking used to locate the lost/stolen phone? *(RXGPS)* ☐ No ☐ Yes

16. Did this participant return the cellphone at the end of the study? *(RXRETURN)* ☐ No ☐ Yes

    If "Yes", did the participant receive compensation for the cellphone? *(RXCOMPEN)* ☐ No ☐ Yes

17. Did the participant send videos besides dosing videos? *(RXVIDEOS)* ☐ No ☐ Yes

Comments:*(RXCOMM)*

NIDA Clinical Trials Network

Study Termination (STT)

Web Version: 1.0; 2.03; 09-16-14

Segment *(PROTSEG)*:

1. Date of last attended study visit:*(STTRMDT)* _____ *(mm/dd/yyyy)*
2. Did the participant stop attending visits on or before the last visit of active treatment phase (visit 802)?*(STSTOP)* ☐ No ☐ Yes
   a. If "No", did the participant complete the week 9 visit?*(STT54WK)* ☐ No ☐ Yes
   b. If "Yes", select the primary reason for study termination:*(STTRMRES)*

If "Participant terminated for other reason", specify:*(STTRMOSP)*

Comments:*(STTCOMM)*

Investigator's Signature

I have reviewed all the data recorded on all CRF pages and certify that they are accurate and complete to the best of my knowledge.

Principal Investigator:*(STPISIGN)*

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

Additional Selection Options for STT

b. If "Yes", select the primary reason for study termination:
3-Participant moved from area
4-Participant incarcerated
18-CTP/ Site closed
8-Participant withdrew consent
9-Participant deceased
99-Participant terminated for other reason

NIDA Clinical Trials Network

TLFB Assessment Period (TAP)

Web Version: 1.0; 3.02; 07-11-14

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

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

1. Assessment period:*(TATFSTDT)*
   From: _____ *(mm/dd/yyyy)*
   (TATFENDT)
   To: _____ *(mm/dd/yyyy)*

2. Have any illicit substances or alcohol been taken during this assessment period?*(TASUBALC)*
   ☐ No ☐ Yes

Comments:*(TAPCOMM)*

NIDA Clinical Trials Network

Treatment Effect Assessment (TEA)

Web Version: 1.0; 1.01; 10-24-13

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

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

The TEA asks you to express what you think about how you are doing in four categories: substance use, health, lifestyle, and community. For each topic, think about what is going on in your life and how you are doing in those areas, then mark down the result on the scale. The better you are doing, the higher the number - just check the number that indicates how things are for you in each area, from 1 (poor) to 10 (great). You might want to jot down some remarks in each category to provide some details about why you checked a specific number on the scale, although this is not required.

1. **Substance Use:** How do you think you are doing with alcohol and drug use? Consider amount and frequency of drug use, money spent on drugs, amount of drug craving, time spent with drug-using acquaintances, etc.

Poor				Ok					Great
(TESUBUSE) ☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10

Remarks:

(TSSUBRM)

2. **Health:** How do you think you are doing in terms of your health? Think about your physical and mental health: Are you exercising? Sleeping and eating properly? Seen a doctor/dentist? Receiving treatment for a health problem?

Poor				Ok					Great
(TEHEALTH) ☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10

Remarks:

(TEHLTHRM)

3. **Lifestyle/Personal Responsibility:** Think about your living conditions, family situation, employment, relationships: How are you doing in your life regarding personal responsibilities? Are you paying your bills? Following through with your personal or professional commitments?

Poor				Ok					Great
(TELIFEST) ☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10

Remarks:

(TELIFERM)

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

Poor				Ok					Great
(TECOMMUN) ☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10

Remarks:

(TECOMRM)

Comments:*(TEACOMM)*

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Tobacco Use History (TUH)

Web Version: 1.0; 1.02; 01-10-14

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

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

1. Have you smoked at least 100 cigarettes in your entire life?*(TUSMK100)* ☐ No ☐ Yes ☐ Don't Know/Refused
2. Do you now smoke cigarettes every day, some days, or not at all?*(TUSMFREQ)*
3. Have you EVER smoked cigarettes EVERY DAY for at least 6 months? *(TUEVERY)* ☐ No ☐ Yes ☐ Don't Know/Refused
4. How old were you when you first started smoking cigarettes FAIRLY REGULARLY?*(TUSTRTRG)* _____ *(xx)* Years old

Section A: Every-Day Smokers

5. On the average, about how many cigarettes do you now smoke each day?*(TUNUMDY)* _____ *(xx)* Cigarettes per day
6. How old were you when you first started smoking cigarettes every day?*(TUSTRTAG)* _____ *(xx)* Years old

Section B: Some-Day Smokers

7. On how many of the past 30 days did you smoke cigarettes?*(TU30DAYS)* _____ *(xx)* Days
8. On the average, on those [answer to Q7] days, how many cigarettes did you usually smoke each day?*(TU30AVG)* _____ *(xx)* Cigarettes per day

Section C: Former Smokers

9. When you last smoked every day, on average how many cigarettes did you smoke each day?*(TUNUMEDY)* _____ *(xx)* Cigarettes per day
10. When you last smoked fairly regularly, on average how many cigarettes did you smoke each day?*(TUNUMRDY)* _____ *(xx)* Cigarettes per day

Comments:*(TUHCOMM)*

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Urine Drug Screen Central Lab (UDC)

Web Version: 1.0; 1.01; 01-22-14

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

1. Was a urine sample collected at this visit?*(UDCENCOL)* ☐ No ☐ Yes
   a. If "No", why?*(UDCENNO)*

   If "Other", specify:*(UDSPNO)*
   b. If "Yes", date collected:*(UDCENDT)* *(mm/dd/yyyy)*
2. Was the urine temperature within range? (90 - 100 °F)*(UDTEMP)* ☐ No ☐ Yes
3. Was the urine specimen determined to be adulterated?*(UDADULT)* ☐ No ☐ Yes
4. Date shipped to central lab:*(UDCENSDT)* *(mm/dd/yyyy)*
5. Accession number (Barcode):*(UDCENACC)*

Comments:*(UDCCOMM)*

NIDA Clinical Trials Network

Visual Analog Scale (VAS)

Web Version: 1.0; 2.01; 07-08-14

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

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

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

Comments:*(VASCOMM)*

NIDA Clinical Trials Network

Vital Signs (VIS)

Web Version: 1.0; 3.02; 01-09-15

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

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

1. Measured weight:*(VIWTLBS)* _____ *(xxx.x)* lbs *(VIWTKGS)* _____ *(xxx.x)* kgs
2. Temperature:*(VITEMPF)* _____ *(xxx.x)* °F or *(VITEMPC)* _____ *(xx.x)* °C
3. Respirations (1 min):*(VIRESPS)* _____ *(xx)*
4. Heart rate:*(VIPULSE)* _____ *(xxx)* BPM
5. Blood pressure:*(VIBPSYS1)* _____ / *(VIBPDIS1)* _____ Systolic/Diastolic (mmHg)

Comments:*(VISCOMM)*

NIDA Clinical Trials Network

Timeline Followback (T54)

Web Version: 1.0; 1.00; 07-24-14

TFB week start date *(TFWKSTDT)*:

Day	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Date	*(TLDATE1)*	*(TLDATE2)*	*(TLDATE3)*	*(TLDATE4)*	*(TLDATE5)*	*(TLDATE6)*	*(TLDATE7)*
1. Have any illicit substances or alcohol been used on this day?	*(TLSUBAL1)* ☐ No ☐ Yes	*(TLSUBAL2)* ☐ No ☐ Yes	*(TLSUBAL3)* ☐ No ☐ Yes	*(TLSUBAL4)* ☐ No ☐ Yes	*(TLSUBAL5)* ☐ No ☐ Yes	*(TLSUBAL6)* ☐ No ☐ Yes	*(TLSUBAL7)* ☐ No ☐ Yes
2. Alcohol number of standard drinks (xx):	*(TLALCHL1)*	*(TLALCHL2)*	*(TLALCHL3)*	*(TLALCHL4)*	*(TLALCHL5)*	*(TLALCHL6)*	*(TLALCHL7)*
3. Cannabinoids/ Marijuana:	*(TLTHCR1)*	*(TLTHCR2)*	*(TLTHCR3)*	*(TLTHCR4)*	*(TLTHCR5)*	*(TLTHCR6)*	*(TLTHCR7)*
4. Cocaine:	*(TLCOCR1)*	*(TLCOCR2)*	*(TLCOCR3)*	*(TLCOCR4)*	*(TLCOCR5)*	*(TLCOCR6)*	*(TLCOCR7)*
5. Crack:	*(TLCRAKR1)*	*(TLCRAKR2)*	*(TLCRAKR3)*	*(TLCRAKR4)*	*(TLCRAKR5)*	*(TLCRAKR6)*	*(TLCRAKR7)*
6. Methamphetamine:	*(TLMETR1)*	*(TLMETR2)*	*(TLMETR3)*	*(TLMETR4)*	*(TLMETR5)*	*(TLMETR6)*	*(TLMETR7)*
7. Amphetamine-type stimulants, excluding Methamphetamine:	*(TLAMPR1)*	*(TLAMPR2)*	*(TLAMPR3)*	*(TLAMPR4)*	*(TLAMPR5)*	*(TLAMPR6)*	*(TLAMPR7)*
8. Opioid analgesics, induding	*(TLMTDR1)*	*(TLMTDR2)*	*(TLMTDR3)*	*(TLMTDR4)*	*(TLMTDR5)*	*(TLMTDR6)*	*(TLMTDR7)*

methadone:							
9. Heroin:	*(TLHERR1)*	*(TLHERR2)*	*(TLHERR3)*	*(TLHERR4)*	*(TLHERR5)*	*(TLHERR6)*	*(TLHERR7)*
10. Hallucinogens, including MDMA/ecstasy:	*(TLMDAR1)*	*(TLMDAR2)*	*(TLMDAR3)*	*(TLMDAR4)*	*(TLMDAR5)*	*(TLMDAR6)*	*(TLMDAR7)*
11. Sedatives and hypnotics, excluding Benzodiazepines:	*(TLBARR1)*	*(TLBARR2)*	*(TLBARR3)*	*(TLBARR4)*	*(TLBARR5)*	*(TLBARR6)*	*(TLBARR7)*
12. Benzodiazepines:	*(TLBZOR1)*	*(TLBZOR2)*	*(TLBZOR3)*	*(TLBZOR4)*	*(TLBZOR5)*	*(TLBZOR6)*	*(TLBZOR7)*
13. Inhalants:	*(TLINHR1)*	*(TLINHR2)*	*(TLINHR3)*	*(TLINHR4)*	*(TLINHR5)*	*(TLINHR6)*	*(TLINHR7)*
Other Drugs							
14. Other drug 1 use:	*(TLOT1R1)*	*(TLOT1R2)*	*(TLOT1R3)*	*(TLOT1R4)*	*(TLOT1R5)*	*(TLOT1R6)*	*(TLOT1R7)*
Specify other drug 1:	*(TLOTSP11)*	*(TLOTSP12)*	*(TLOTSP13)*	*(TLOTSP14)*	*(TLOTSP15)*	*(TLOTSP16)*	*(TLOTSP17)*
15. Other drug 2 use:	*(TLOT2R1)*	*(TLOT2R2)*	*(TLOT2R3)*	*(TLOT2R4)*	*(TLOT2R5)*	*(TLOT2R6)*	*(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:*(T54COMM)*

Additional Selection Options for T54

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