

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":

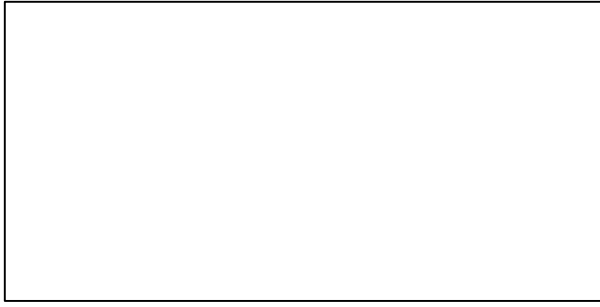
Date of hospital admission: (A1HOSPAD)

 (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) <input type="text"/>	(A2_01DIN) <input type="text"/>
(A2_02DNM) <input type="text"/>	(A2_02DIN) <input type="text"/>
(A2_03DNM) <input type="text"/>	(A2_03DIN) <input type="text"/>
(A2_04DNM) <input type="text"/>	(A2_04DIN) <input type="text"/>
(A2_05DNM) <input type="text"/>	(A2_05DIN) <input type="text"/>
(A2_06DNM) <input type="text"/>	(A2_06DIN) <input type="text"/>
(A2_07DNM) <input type="text"/>	(A2_07DIN) <input type="text"/>
(A2_08DNM) <input type="text"/>	(A2_08DIN) <input type="text"/>
(A2_09DNM) <input type="text"/>	(A2_09DIN) <input type="text"/>
(A2_10DNM) <input type="text"/>	(A2_10DIN) <input type="text"/>

4. Treatments for the event: (A2SAETR7) No Yes Unknown

Treatment	Indication	Date Treated (mm/dd/yyyy)
(A2_1TNME) <input type="text"/>	(A2_1TIND) <input type="text"/>	(A2_1LTD7) <input type="text"/>

(A2_2TNME)	(A2_2TIND)	(A2_2LTDI)
(A2_3TNME)	(A2_3TIND)	(A2_3LTDI)
(A2_4TNME)	(A2_4TIND)	(A2_4LTDI)
(A2_5TNME)	(A2_5TIND)	(A2_5LTDI)

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)

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 (*AESQNUM*) (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; 3.00; 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)

 (initials)

Reviewed by:(A3REVID)

 (initials)

Comments:(A3COMM)

Additional Selection Options for AD3

Event number (*AESQNUM*) (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

Alcohol and Substance Use History (ASU)

Web Version: 1.0; 2.00; 11-26-13

Segment (PROTSEG):

Visit number (VISNO):

Date of assessment:(ASUASMDT)

(mm/dd/yyyy)

Alcohol Use History

1. In your entire life, have you had at least 1 drink of any kind of alcohol, not counting small tastes or sips?(AUALCLFT) No Yes

If "Yes", about how old were you when you first started drinking, not counting small tastes or sips of alcohol?(AUALCAGE) (xx)

Substance Use History

Substance	Have you EVER used any of these medicines or drugs?	If "Yes", specify:	How old were you when you FIRST used? (age in years)
2. Sedatives: (e.g., sleeping pills, barbiturates, Seconal, Quaaludes, or Chloral Hydrate)	(AUSEDLFT) <input type="checkbox"/> No <input type="checkbox"/> Yes	(AUSEDLSP) _____ _____	(AUSEDAGE) <input type="text"/> (xx) years
3. Tranquilizers: or anti-anxiety drugs: (e.g., Valium, Librium, muscle relaxants, or Xanax)	(AUTNQLFT) <input type="checkbox"/> No <input type="checkbox"/> Yes	(AUTNQLSP) _____ _____	(AUTRQAGE) <input type="text"/> (xx) years
4. Painkillers: (e.g., Codeine, Darvon, Percodan, Oxycontin, Dilaudid, or Demerol)	(AUPNKLFT) <input type="checkbox"/> No <input type="checkbox"/> Yes	(AUPNKLSP) _____ _____	(AUPNKAGE) <input type="text"/> (xx) years
5. Stimulants: (e.g., Preludin, Benzedrine, Methedrine, Ritalin, uppers, or speed)	(AUSTMLFT) <input type="checkbox"/> No <input type="checkbox"/> Yes	(AUSTMLSP) _____ _____	(AUSTMAGE) <input type="text"/> (xx) years
6. Marijuana, hash, THC, grass, or cannabis:	(AUTHCLFT) <input type="checkbox"/> No <input type="checkbox"/> Yes	(AUTHCLSP) _____ _____	(AUTHCAGE) <input type="text"/> (xx) years
7. Cocaine or crack:	(AUCOCLFT) <input type="checkbox"/> No <input type="checkbox"/> Yes	(AUCOCLSP) _____ _____	(AUCOCAGE) <input type="text"/> (xx) years
8. Hallucinogens: (e.g., Ecstasy, MDMA, LSD, Mescaline, psilocybin, PCP, angel dust, or peyote)	(AUHALLFT) <input type="checkbox"/> No <input type="checkbox"/> Yes	(AUHALLSP) _____ _____	(AUHALAGE) <input type="text"/> (xx) years
9. Inhalants or solvents: (e.g., amyl nitrite, nitrous oxide, glue, toluene, or gasoline)	(AUINHLFT) <input type="checkbox"/> No <input type="checkbox"/> Yes	(AUINHLSP) _____ _____	(AUINHAGE) <input type="text"/> (xx) years
10. Heroin:	(AUHERLFT) <input type="checkbox"/> No <input type="checkbox"/> Yes	(AUHERLSP) _____ _____	(AUHERAGE) <input type="text"/> (xx) years
11. Any OTHER medicines, drugs, or substances: (e.g., methadone, Elavil, steroids, Thorazine, or Haldol)	(AUOTHLFT) <input type="checkbox"/> No <input type="checkbox"/> Yes	(AUOTHLSP) _____ _____	(AUOTHAGE) <input type="text"/> (xx) years

Comments:(ASUCOMM)

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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) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. I have no future.	(CHNOFUTR) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. It seems as if I can do nothing right.	(CHNORGHT) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Everything I do turns out wrong.	(CHWRONG) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. There is no one I can depend on.	(CHDEPEND) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. The people I care the most for are gone.	(CHPPLGNE) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. I wish my suffering could just all be over.	(CHSUFFER) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. I feel that there is no reason to live.	(CHRSLIVE) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. I wish I could just go to sleep and not wake up.	(CHSLEEP) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. I find myself saying or doing things without thinking.	(CHNO THINK) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. I often make decisions quickly or "on impulse."	(CHIMPULS) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. I often feel irritable or easily angered.	(CHIRRITE) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. I often overreact with anger or rage over minor things.	(CHOVRRCT) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. I have been having thoughts of killing myself.	(CHKILLMS) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. I have thoughts about how I might kill myself.	(CHHOWKIL) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. I have a plan to kill myself.	(CHPLNKIL) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments:(CHPCOMM)

NIDA Clinical Trials Network

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)

Samoa: (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)

Refuse: (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

Electrocardiogram (ECG) Results (ECG)

Web Version: 1.0; 3.00; 01-22-14

Segment (PROTSEG):

Visit number (VISNO):

Date of assessment: (ECGASMDT)

(mm/dd/yyyy)

12-Lead Electrocardiogram (ECG)

1. Normal sinus rhythm? (ECSINRTM)

No 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)

(xxx) (EC2PRAXS) (xxx) (EC3PRAXS) (xxx)

7. Results Relating to Eligibility Criteria (automatically excludes)

	Not Present	Present
a. QTc Prolongation (QTc interval => 460)	(ECQTCPLG) <input type="checkbox"/>	<input type="checkbox"/>
b. Atrial Fibrillation	(ECATFIB) <input type="checkbox"/>	<input type="checkbox"/>
c. Atrial Flutter	(ECATFLR) <input type="checkbox"/>	<input type="checkbox"/>
d. 2nd Degree A-V Block	(EC2AVBLK) <input type="checkbox"/>	<input type="checkbox"/>
e. 3rd Degree A-V Block	(EC3AVBLK) <input type="checkbox"/>	<input type="checkbox"/>

8. Additional ECG findings (refer to ECG for details): (ECSUMOTH)

Normal Abnormal

If normal, skip the "Additional ECG findings" grid [questions f-ff].

Additional ECG Findings (include borderline):

	Not Present	Present		Not Present	Present
f. Increased QRS Voltage	(ECQRSINC) <input type="checkbox"/>	<input type="checkbox"/>	u. Supraventricular Premature Beat	(ECSVPB) <input type="checkbox"/>	<input type="checkbox"/>
g. Left Atrial Hypertrophy	(ECLAHYPY) <input type="checkbox"/>	<input type="checkbox"/>	v. Ventricular Premature Beat	(ECVPB) <input type="checkbox"/>	<input type="checkbox"/>
h. Right Atrial Hypertrophy	(ECRAHYPY) <input type="checkbox"/>	<input type="checkbox"/>	w. Supraventricular Tachycardia	(ECSPVTTY) <input type="checkbox"/>	<input type="checkbox"/>
i. Left Ventricular Hypertrophy	(ECLVHYPY) <input type="checkbox"/>	<input type="checkbox"/>	x. Ventricular Tachycardia	(ECVTTY) <input type="checkbox"/>	<input type="checkbox"/>
j. Right Ventricular Hypertrophy	(ECRVHYP) <input type="checkbox"/>	<input type="checkbox"/>	y. Other Rhythm Abnormalities	(ECOTHRA) <input type="checkbox"/>	<input type="checkbox"/>
k. Acute Infarction	(ECACTINF) <input type="checkbox"/>	<input type="checkbox"/>	z. Implanted Pacemaker	(ECPACEMK) <input type="checkbox"/>	<input type="checkbox"/>
l. Subacute Infarction	(ECSATINF) <input type="checkbox"/>	<input type="checkbox"/>	aa. 1st Degree A-V Block	(EC1AVBLK) <input type="checkbox"/>	<input type="checkbox"/>
m. Old Infarction	(ECINFOLD) <input type="checkbox"/>	<input type="checkbox"/>	bb. LBB Block	(ECLBBBLK) <input type="checkbox"/>	<input type="checkbox"/>
n. Myocardial Ischemia	(ECMYISCH) <input type="checkbox"/>	<input type="checkbox"/>	cc. RBB Block	(ECRBBBLK) <input type="checkbox"/>	<input type="checkbox"/>
o. Digitalis Effect	(ECDGTEFT) <input type="checkbox"/>	<input type="checkbox"/>	dd. Pre-excitation syndrome	(ECPES) <input type="checkbox"/>	<input type="checkbox"/>
p. Symmetrical T-Wave Inversions	(ECSTWI) <input type="checkbox"/>	<input type="checkbox"/>	ee. Other Intraventricular Conduction Delay	(ECOTHVB) <input type="checkbox"/>	<input type="checkbox"/>
q. Poor R-Wave Progression	(ECPRWPG) <input type="checkbox"/>	<input type="checkbox"/>	ff. Other abnormal result: (ECOTHSP)	(ECOTH) <input type="checkbox"/>	<input type="checkbox"/>

r. Other nonspecific ST/T	(<i>ECOTHSTT</i>) <input type="checkbox"/>	<input type="checkbox"/>	
s. Sinus Tachycardia	(<i>ECSTACHY</i>) <input type="checkbox"/>	<input type="checkbox"/>	
t. Sinus Bradycardia	(<i>ECSBRADY</i>) <input type="checkbox"/>	<input type="checkbox"/>	

9. Does the participant have evidence of second or third degree heart block, atrial fibrillation, atrial flutter, or prolongation of the QT c? (*ECGELIG1*) No Yes

10. Does the participant have any other finding on the screening ECG that, in the opinion of the study medical clinician, would preclude safe participation in the study? (*ECGELIG2*) No Yes

Comments: (*ECGCOMM*)

NIDA Clinical Trials Network

0054A (ENR)

Web Version: 1.0; 1.00; 08-30-13

Date informed consent signed:(S3CNSTDT)

(mm/dd/yyyy)

Pre-screen ID (from Pre-screen Interview):(S3SCRNID)

(xxxx)

Comments:(S3COMM)

NIDA Clinical Trials Network

Self-Report of HIV Testing (HIV)

Web Version: 1.0; 1.03; 04-15-14

Segment (PROTSEG):

Visit number (VISNO):

Date of assessment:(HIVASMDT)

 (mm/dd/yyyy)

An HIV test checks whether someone has the virus that causes AIDS.

1. Have you ever been tested for HIV?(HIHIVTST)

2. When did you have your most recent HIV test?(HITESTMO)

 (xx) month (HITESTYR)/ (xxxx) year

3. What was the result of your most recent HIV test?(HIRESULT)

4. Which of these best describes the most important reason you have not been tested for HIV in the past 12 months?(HINORESNI)

Comments:(HIVCOMM)

Additional Selection Options for HIV

What was the result of your most recent HIV test?

97-Don't know

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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 <i>Earliest Date</i> (mm/dd/yyyy)
<u>Biological Assessments</u>		
1. QuickTox Drug Screens	(INUDSEA) <input style="width: 50px;" type="text"/> (xxx) Full Box(es)	(INUDSEX) <input style="width: 50px;" type="text"/>
2. Urine Adulterant Test Strips	(INADLTEA) <input style="width: 50px;" type="text"/> (xxx) Full Bottle(s)	(INADLTEx) <input style="width: 50px;" type="text"/>
3. Urine Cups with Temp Strips	(INTEMPEA) <input style="width: 50px;" type="text"/> (xxx) Each	N/A
4. Pregnancy Tests	(INPREGEA) <input style="width: 50px;" type="text"/> (xxx) Each	(INPREGEX) <input style="width: 50px;" type="text"/>
5. OPI 300 Single Test Strip	(INOPI300) <input style="width: 50px;" type="text"/> (xxx) Each	(INOPI3DT) <input style="width: 50px;" type="text"/>
<u>Lab Supplies</u>		
1. Screening and Follow-up Lab Kit Coolers	(INFRZSHP) <input style="width: 50px;" type="text"/> (xxx) Each	N/A
2. Butterfly Needles	(INBFLYEA) <input style="width: 50px;" type="text"/> (xxx) Each	N/A
3. Vacutainers	(INNHLEA) <input style="width: 50px;" type="text"/> (xxx) Each	N/A
4. Screening and Follow-up Lab Kits	(INSCFUKT) <input style="width: 50px;" type="text"/> (xx) Each	(INSCFUDT) <input style="width: 50px;" type="text"/>
5. UDS Lab Kits	(INUDSKT) <input style="width: 50px;" type="text"/> (xxx) Each	N/A
6. PK Lab Kits	(INPKKT) <input style="width: 50px;" type="text"/> (xxx) Each	(INPKDT) <input style="width: 50px;" type="text"/>
<u>Medication</u>		
1. Naltrexone (Vivitrol) IM Injection Kit	(INVIVTEA) <input style="width: 50px;" type="text"/> (xx) Each	(INVIVTEX) <input style="width: 50px;" type="text"/>
2. Wellbutrin XL, bupropion 150 mg Tablets (Bulk 90 Tabs/Bottle)	(INBU15EA) <input style="width: 50px;" type="text"/> (xx.x) Bottle(s)	(INBU15DT) <input style="width: 50px;" type="text"/>
3. Wellbutrin XL, bupropion 150 mg Tablets (Bulk 30 Tabs/Bottle)	(INBU30EA) <input style="width: 50px;" type="text"/> (xx.x) Bottle(s)	(INBU30DT) <input style="width: 50px;" type="text"/>
4. Take Home Amber Prescription Vials	(INPRVIAL) <input style="width: 50px;" type="text"/> (xx) Vials	N/A
5. Take Home Prescription Vial Labels	(INPRLABL) <input style="width: 50px;" type="text"/> (xx) Labels	N/A

Comments:(INVCOMM)

NIDA Clinical Trials Network

Clinical Laboratory Tests (LAB)

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



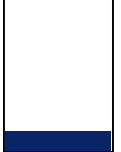








Segment (PROTSEG):

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	(LAL YMPHO) [] (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 %	(LAL YMPPT) [] (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	(LAGRA VTY) <input data-bbox="943 793 1062 823" type="text"/> (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	<input type="text"/> (LAUCRYSL)
37. Urine microscopic - Casts	<input type="text"/> (LAUCASTS)
38. Urine microscopic - Epithelial cells	<input type="text"/> (LAUEPI)
39. Glucose	(LAGLU) <input type="text"/> (xxxx) mg/dL
40. Blood urea nitrogen (BUN)	(LABUN) <input type="text"/> (xxx.x) mg/dL
41. Creatinine	(LACREATE) <input type="text"/> (xx.xx) mg/dL
42. BUN/Creatinine ratio	(LABUNCRT) <input type="text"/> (xx) Ratio
43. Sodium (NA)	(LANA) <input type="text"/> (xxx) mmol/L
44. Potassium (K)	(LAK) <input type="text"/> (x.x) mmol/L
45. Chloride	(LACL) <input type="text"/> (xxx) mmol/L
46. CO2	(LACO2) <input type="text"/> (xx) mmol/L
47. AGAP	(LAAGAP) <input type="text"/> (xx) mmol/L
48. Calcium results	(LACA) <input type="text"/> (xx.x) mg/dL
49. Total protein	(LAPROTEIN) <input type="text"/> (x.x) g/dL
50. Albumin	(LAALBUMN) <input type="text"/> (x.x) g/dL
51. Globulin	(LAGLOBIN) <input type="text"/> (x.x) g/dL
52. Aspartate Amino transferase (AST/SGOT)	(LAAST) <input type="text"/> (xxxx.x) U/L
53. Alanine Aminotransferase (ALT/SGPT)	(LAALT) <input type="text"/> (xxxx.x) U/L
54. Alkaline Phosphatase (ALP)	(LAALP) <input type="text"/> (xxxx.x) U/L
55. Total Bilirubin	(LABILRBT) <input type="text"/> (xx.x) mg/dL

Comprehensive Metabolic Panel

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

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 the participant breastfeeding?(PBBSTFED)

No Yes

2. Does the participant agree to use an acceptable method of birth control?
(PBUSEBC)

No Yes

If "Yes", select all that apply:

a. Oral contraceptives:(PBORALCN)

No Yes

b. Contraceptive patch:(PBPATCH)

No Yes

c. Barrier (diaphragm or condom):(PBBARRIR)

No Yes

d. Levonorgestrel implant:(PBLEVIMP)

No Yes

e. Medroxyprogesterone acetate injection:(PBMEDINJ)

No Yes

f. Hormonal vaginal contraceptive ring:(PBRING)

No Yes

g. Surgical sterilization:(PBSURGSZ)

No Yes

h. Intrauterine contraceptive device (IUD):(PBINTDEV)

No Yes

i. Participant is post menopausal:(PBMENOPA)

No Yes

j. Other:(PBBCOTH)

No Yes

If "Other", specify:(PBBCOSP)

3. 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

Comments:(PBCCOMM)

NIDA Clinical Trials Network

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-STERIODS/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:(PDCA TGRY)

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: *(PDPREVENT)*

No Yes

9. Review by Protocol Monitor is complete: *(PDPMCMP)*

No Yes

Protocol Monitor review er: *(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/d/yyyy)

2. Deviation type: (PDTYPE)

If "Other", specify: (PDYSP)

3. Brief description of what occurred: (PDESCPT)

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:(PDIRBPD)

(mm/d/yyyy)

If "No", date of actual submission:(PDIRBADT)

(mm/d/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 time frame
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:

(PEHDNK)

(PEHDNKSP)

Ears, eyes, nose, and throat

(PEEENT)

(PEENTSP)

Cardiovascular:

(PECARD)

(PECARDSP)

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

Respiratory:

(PERESP)

(PERESPSP)

Gastrointestinal:

(PEGAST)

(PEGASTSP)

Extremities:

(PEEXTR)

(PEEXTRSP)

Lymph nodes:

(PELYMP)

(PELYMPSP)

Musculoskeletal:

(PEMUSC)

(PEMUSCSP)

Neurological:

(PENEUR)

(PENEURSP)

Planned injection site
assessment:

(PEINJS)

(PEINJSSP)

Other (specify in comments):

(PEOTHER)

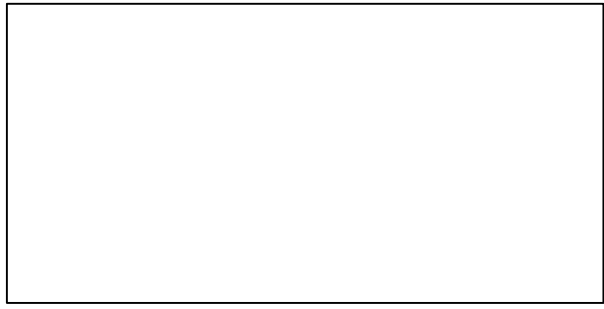
(PEOTHESP)

1. Does participant have a body habitus that precludes gluteal intramuscular injection of XR-NTX in accord with the administration equipment (needle) and procedures?*(PEB54HBT)*

No Yes

Comments:*(PEBDHBS P)*

Comments:(PEXCOMM)



NIDA Clinical Trials Network

Pre-screening Interview (PSF)

Web Version: 1.0; 1.02; 03-10-14

Pre-Screen ID (PRESCNID):

(YYPSFCH)

Date of assessment: (PSFASMDT)

 (mm/dd/yyyy)

1. Do you give verbal consent to answer pre-screening questions? (PSVECNST)

 No Yes

If "Yes", date of verbal consent: (PSCNSTDT)

 (mm/dd/yyyy)

2. How did you hear about this research?

If multiple sources, select the one that was most instrumental in the decision to come to the study. (PSFINDOT)

If "Other", specify: (PSFINDSP)

3. How old are you? (PSAGE)

 (xx) years old

4. Are you male or female? (PSSEX)

 Male Female

5. If female, are you pregnant or currently breastfeeding? (PSPREG)

 No Yes

6. What substances are you using?

a. Alcohol: (PSALCHL)

 No Yes

b. Cocaine: (PSCOCANE)

 No Yes

c. Opioids: (PSOPIATE)

 No Yes

d. Methamphetamine: (PSMETHAM)

 No Yes

e. Amphetamine/other stimulants: (PSAMPHET)

 No Yes

f. Marijuana: (PSMARJNA)

 No Yes

g. Benzodiazepines: (PSBENZO)

 No Yes

h. Other substances: (PSUSEOT)

 No Yes Specify: (PSUSESP)

7. What substance do you consider the biggest problem for you right now?

If more than one substance reported, ask potential candidate to indicate the substance that is most problematic. (PSPRMSUB)

If "Other", specify: (PSPRMSP)

8. Are you able to refrain from opioid use for at least 7 days before being given study medications? (PSNOOPTD)

 No Yes

9. Are you currently enrolled in addiction treatment services? (PSADDTRT)

 No Yes

If "Yes", where are you receiving these services? (PSTRTSRV)

10. Have you taken naltrexone or bupropion (Wellbutrin) within the last 30 days? (PSTKN30D)

 No Yes

If "Yes", was this prescribed to you? (PSRX30D)

 No Yes

11. Are you interested in reducing or stopping your methamphetamine use? (PSRTMET)

 No Yes

12. Have you used methamphetamine in the past 30 days? (PSMET30D)

 No Yes

a. If "Yes", how many days of use? (PSMETDAY)

 (xx)

b. If "Yes", when did you last use methamphetamine? (PSMETDT)

 (mm/dd/yyyy)

13. Do you have any medical or mental health conditions that require ongoing monitoring, care, or medication? (PSPSYCH) No Yes

If "Yes", specify: (PSPSYHSP)

14. Are you taking medication(s) for any ongoing medical or mental health problem? (PSMEDS) No Yes

If "Yes", list medications, and indication: (PSMEDSP)

15. Have you been mandated to attend treatment? (PSMANDTE) No Yes

16. Do you have a personal cellphone? (PSCCELL) No Yes

If "Yes", is it a smartphone? (PSSMART) No Yes

17. Are you aware of the use of cellphones for health-related purposes? (PSCELUSE) No Yes

18. Are you comfortable using a cellphone? (PSCELCOM) No Yes

19. Are you willing and able to attend the clinic two times a week during the 8 week treatment period? (e.g., no transportation problems, legal problems, or plans to move out of the area) (PSCLN2X) No Yes

20. Are you interested in participating in a study where you will receive two injections of long-acting naltrexone (a medication that stops you from feeling many of the effects of opioids), as well as daily oral medication (bupropion)? (PSXRNTX) No Yes

21. Is this person eligible to continue with in-person screening? (PSELIG) No Yes

22. Are you interested in scheduling an appointment? (PSSCHED) No Yes
If "Yes", complete the prescreen contact form and set appointment date and time.

a. If "Yes", in-person screening appointment date: (PSAPTDT) (mm/dd/yyyy)

b. If "No", are any of the following reasons why?

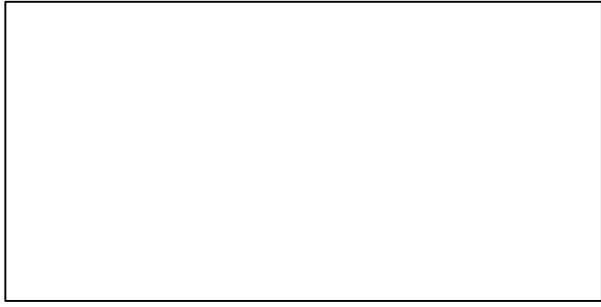
1. Declined to schedule: (PSDEC SCH) No Yes

2. Not interested in study: (PSNOSTUD) No Yes

3. Doesn't want the study medication: (PSNOMED) No Yes

4. Other: (PSSCHOTH) No Yes Specify: (PSSCHSP)

Comments:(*PSFCOMM*)



Additional Selection Options for PSF

How did you hear about this research?

If multiple sources, select the one that was most instrumental in the decision to come to the study.

6-TV

7-Radio

8-Referral from another agency or medical/mental health provider

9-Craigslist

10-Clinicaltrials.gov

99-Other

What substance do you consider the biggest problem for you right now?

If more than one substance reported, ask potential candidate to indicate the substance that is most problematic.

6-Marijuana

7-Benzodiazepines

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

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)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7	<input type="checkbox"/> 8	<input type="checkbox"/> 9	<input type="checkbox"/> 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)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7	<input type="checkbox"/> 8	<input type="checkbox"/> 9	<input type="checkbox"/> 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)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7	<input type="checkbox"/> 8	<input type="checkbox"/> 9	<input type="checkbox"/> 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)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7	<input type="checkbox"/> 8	<input type="checkbox"/> 9	<input type="checkbox"/> 10

Remarks:

(TECOMRM)

Comments:(TEACOMM)

NIDA Clinical Trials Network

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)

[]

NIDA Clinical Trials Network

Urine Drug Screen (UDS)

Web Version: 1.0; 4.00; 03-06-14

Segment (PROTSEG):

Visit number (VISNO):

1. Was a urine drug screen performed? (UDTEST1)

If "No", reason: (UDNORSN)

No Yes

If "Other", specify: (UDNOSP1)

1st Urine Drug Screen

2. Date 1st urine specimen collected: (UDCOLDT)

3. Was the 1st urine temperature within range? (90 - 100 °F) (UDTEMP1)

4. Was the 1st urine specimen determined to be adulterated? (UDADULT1)

5. 1st Urine Drug Screen Result(s):

(mm/dd/yyyy)

No Yes

No Yes

Drug Name (Abbreviation)	Negative	Positive	Invalid
Benzodiazepines (BZO):	(UDBZO1) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Amphetamine (AMP):	(UDAMP1) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Marijuana (THC):	(UDTHC1) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Methamphetamine (MET):	(UDMET1) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Opiates (2000 ng) (OPI):	(UDOPI1) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cocaine (COC):	(UDCOC1) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ecstasy (MDMA):	(UDMDA1) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Oxycodone (OXY):	(UDOXY1) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Methadone (MTD):	(UDMTD1) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Barbiturate (BAR):	(UDBAR1) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Opiates (300ng) (OPI): (UDOP1300)

Negative Positive Invalid

2nd Urine Drug Screen

6. If the 1st urine specimen was determined to be adulterated, was a second specimen collected? (UDTES2)

If "No", reason: (UDNORSN2)

No Yes

If "Other", specify: (UDNOSP2)

7. Was the 2nd urine temperature within range? (90 - 100 °F) (UDTEMP2)

8. Was the 2nd urine specimen determined to be adulterated? (UDADULT2)

9. 2nd Urine Drug Screen Result(s):

No Yes

No Yes

Drug Name (Abbreviation)	Negative	Positive	Invalid
Benzodiazepines (BZO):	(UDBZO2) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Amphetamine (AMP):	(UDAMP2) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Marijuana (THC):	(UDTHC2) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Methamphetamine (MET):	(UDMET2) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Opiates (2000 ng) (OPI):	(UDOP12) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cocaine (COC):	(UDCOC2) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ecstasy (MDMA):	(UDMDA2) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Oxycodone (OXY):	(UDOXY2) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Methadone (MTD):	(UDMTD2) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Barbiturate (BAR):	(UDBAR2) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Opiates (300ng) (OPI); (UDOP2300)

Negative Positive Invalid

Comments: (UDSCOMM)

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)

Body Mass Index

1. Standing height:(VIHG TIN)

(xx.x) inches (VIHGTCM) (xxx) cm

2. Measured weight:(VIWTLBS)

(xxx.x) lbs (VIWTKGS) (xxx.x) kgs

3. BMI:(VIBMI)

Vital Signs

4. Temperature:(VITEMPF)

(xxx.x) °F or (VITEMPC) (xx.x) °C

5. Respirations (1 min):(VIRESPS)

(xx)

6. Heart rate:(VIPULSE)

(xxx) BPM

7. Blood pressure:(VIBPSYS1)

/ (VIBPDIS1) Systolic/Diastolic (mmHg)

If blood pressure is repeated during screening for clinically indicated reasons, report the results below.

8. Date of second blood pressure:(VIBP2DT)

(mm/dd/yyyy)

Second blood pressure:(VIBPSYS2)

/ (VIBPDIS2) Systolic/Diastolic (mmHg)

9. Date of third blood pressure:(VIBP3DT)

(mm/dd/yyyy)

Third blood pressure:(VIBSYS3)

/ (VIBDIS3) 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 (TFWKSTDY):

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

methadone:							
9. Heroin:	(TLHERR1)	(TLHERR2)	(TLHERR3)	(TLHERR4)	(TLHERR5)	(TLHERR6)	(TLHERR7)
10. Hallucinogens, including MDMA/ecstasy:	(TLM DAR1)	(TLM DAR2)	(TLM DAR3)	(TLM DAR4)	(TLM DAR5)	(TLM DAR6)	(TLM DAR7)
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) <input type="text"/>	(TLOTSP12) <input type="text"/>	(TLOTSP13) <input type="text"/>	(TLOTSP14) <input type="text"/>	(TLOTSP15) <input type="text"/>	(TLOTSP16) <input type="text"/>	(TLOTSP17) <input type="text"/>
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) <input type="text"/>	(TLOTSP22) <input type="text"/>	(TLOTSP23) <input type="text"/>	(TLOTSP24) <input type="text"/>	(TLOTSP25) <input type="text"/>	(TLOTSP26) <input type="text"/>	(TLOTSP27) <input type="text"/>

Comments:(T54COMM)

Additional Selection Options for T54

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

NIDA Clinical Trials Network

Medical and Psychiatric History (MHX)

Web Version: 1.0; 4.01;09-17-14

Segment (PROTSEG):

Visit number (VISNO):

Date of assessment:(MHXASMDT)

_____ (mm/dd/yyyy)

Medical History			
Condition	History of the Condition:	If "Yes", specify:	Condition Present Currently:
1. Eye disorders:	(MHEYEH) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MHEYESP) _____	(MHEYEC) <input type="checkbox"/> No <input type="checkbox"/> Yes
2. Ear disorders:	(MHEARH) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MHEARSP) _____	(MHEARC) <input type="checkbox"/> No <input type="checkbox"/> Yes
3. Respiratory and throat disorders:	(MHRESPH) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MHRESPSP) _____	(MHRESPC) <input type="checkbox"/> No <input type="checkbox"/> Yes
4. Cardiovascular disorders:	(MHCARDH) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MHCARDSP) _____	(MHCARDC) <input type="checkbox"/> No <input type="checkbox"/> Yes
5. Liver and gallbladder disorders:	(MHLIVRH) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MHLIVRSP) _____	(MHLIVRC) <input type="checkbox"/> No <input type="checkbox"/> Yes
6. Other gastrointestinal disorders:	(MHGIH) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MHGISP) _____	(MHGIC) <input type="checkbox"/> No <input type="checkbox"/> Yes
7. Skin disorders:	(MHSKINH) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MHSKINSP) _____	(MHSKINC) <input type="checkbox"/> No <input type="checkbox"/> Yes
8. Musculoskeletal disorders:	(MHMUSCH) <input type="checkbox"/> <input type="checkbox"/> No <input type="checkbox"/> Yes	(MHMUSCSP) _____	(MHMUSCC) <input type="checkbox"/> <input type="checkbox"/> No <input type="checkbox"/> Yes
9. Metabolic disorders:	(MHMETAH) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MHMETASP) _____	(MHMETAC) <input type="checkbox"/> No <input type="checkbox"/> Yes
10. Endocrine disorders:	(MHENDO) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MHENDOSP) _____	(MHENDOC) <input type="checkbox"/> No <input type="checkbox"/> Yes
11. Renal and urinary tract disorders:	(MHRENLH) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MHRENLSP) _____	(MHRENLC) <input type="checkbox"/> No <input type="checkbox"/> Yes
12. Reproductive system and breast disorders:	(MHREPOH) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MHREPOSP) _____	(MHREPOC) <input type="checkbox"/> No <input type="checkbox"/> Yes
13. Epilepsy or seizure disorder:	(MHELPYH) <input type="checkbox"/>	(MHELPYSP) _____	(MHELPYC) <input type="checkbox"/>

	No <input type="checkbox"/> Yes		No <input type="checkbox"/> Yes
14. Clinically significant neurological damage:	(MHNEURH) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MHNEURSP) _____	(MHNEURC) <input type="checkbox"/> No <input type="checkbox"/> Yes
15. Other nervous system disorders:	(MHNERVH) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MHNERVSP) _____	(MHNERVC) <input type="checkbox"/> No <input type="checkbox"/> Yes

Psychiatric History

Condition	History of the Condition:	If "Yes", specify:	Condition Present Currently:
16. Anxiety or panic disorder:	(MHANXH) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MHANXSP) _____	(MHANXC) <input type="checkbox"/> No <input type="checkbox"/> Yes
17. Attention Deficit Hyperactivity Disorder:	(MHADHDH) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MHADHDSP) _____	(MHADHDC) <input type="checkbox"/> No <input type="checkbox"/> Yes
18. Bipolar Disorder:	(MHBPLRH) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MHBPLRSP) _____	(MHBPLRC) <input type="checkbox"/> No <input type="checkbox"/> Yes
19. Major Depressive Disorder:	(MHMDDH) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MHMDDSP) _____	(MHMDDC) <input type="checkbox"/> No <input type="checkbox"/> Yes
20. Schizophrenia:	(MHSCHZH) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MHSCHZSP) _____	(MHSCHZC) <input type="checkbox"/> No <input type="checkbox"/> Yes
21. Suicidal ideation:	(MHSIDH) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MHSIDSP) _____	(MHSIDC) <input type="checkbox"/> No <input type="checkbox"/> Yes
22. Suicidal behavior:	(MHSBEHH) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MHSBEHSP) _____	(MHSBEHC) <input type="checkbox"/> No <input type="checkbox"/> Yes
23. Homicidal ideation:	(MHHIDH) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MHHIDSP) _____	(MHHIDC) <input type="checkbox"/> No <input type="checkbox"/> Yes
24. Homicidal behavior:	(MHHBEHH) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MHHBEHSP) _____	(MHHBEHC) <input type="checkbox"/> No <input type="checkbox"/> Yes
25. Violent behavior:	(MHVBEHH) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MHVBEHSP) _____	(MHVBEHC) <input type="checkbox"/> No <input type="checkbox"/> Yes
26. Psychotic episodes:	(MHPSYEH) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MHPSYESP) _____	(MHPSYEC) <input type="checkbox"/> No <input type="checkbox"/> Yes
27. Other psychiatric disorder:	(MHPSYOH) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MHPSYOSP) _____	(MHPSYOC) <input type="checkbox"/> No <input type="checkbox"/> Yes

Other Conditions not Listed Above	Specific Details:	Condition Present Currently:
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28. (MHOTHR1)	(MHOTHR1S)	(MHOTHR1C) <input type="checkbox"/> No <input type="checkbox"/> Yes
29. (MHOTHR2)	(MHOTHR2S)	(MHOTHR2C) <input type="checkbox"/> No <input type="checkbox"/> Yes
30. (MHOTHR3)	(MHOTHR3S)	(MHOTHR3C) <input type="checkbox"/> No <input type="checkbox"/> Yes

31. Does the participant have a history of surgical and/or medical procedures?(MHSURGRY) No Yes

If the participant has had major surgery, provide most important/significant surgical event data below, including date of surgery.

If the participant remembers only the year, then record "06" for the month and "15" for the day. If the participant remembers only the month and year, then record "15" for the day.

Type of Surgery and/or Medical Procedure	Surgery/Procedure Date : (mm/dd/yyyy)
32. (MHSRG1)	(MHSRG1DT)
33. (MHSRG2)	(MHSRG2DT)
34. (MHSRG3)	(MHSRG3DT)
35. (MHSRG4)	(MHSRG4DT)
36. (MHSRG5)	(MHSRG5DT)

Medical History - Specific Study Eligibility Criteria

37. Does the participant have a history of seizure, head trauma with neurological sequelae (i.e., loss of consciousness that required hospitalization), current anorexia nervosa or bulimia? (MHMEDCON) No Yes

38. Does the participant have a known allergy or sensitivity to bupropion, naloxone, naltrexone, PLG (polyactide-co-glycolide), carboxymethylcellulose or any other component of the XR-NTX diluent? *(MHDRGALG)* No Yes
39. In your opinion, does the participant have any other conditions that increase seizure risk? *(MHMEDCO2)* No Yes
40. Does the participant have a surgery planned or scheduled during the study period? *(MHSRGSCH)* No Yes
41. In your opinion, does the participant require treatment with opioid-containing medications (e.g., opioid analgesics) during the study period? *(MHOPIMED)* No Yes

Comments: *(MHXCOMM)*

NIDA Clinical Trials Network

DSM - 5 - Substance Use Disorders (DSM)

Web Version: 1.0; 2.00; 02-27-14

Segment (PROTSEG):

Visit number (VISNO):

Date of assessment: (DSMASMDT)

(mm/dd/yyyy)

	Opioids	Alcohol	Amphetamines	Methamphetamine	Cannabis	Cocaine	Sedatives
Have you used in the past 12 months:	<input type="checkbox"/> (DSOFI12M)	<input type="checkbox"/> (DSALC12M)	<input type="checkbox"/> (DSAMP12M)	<input type="checkbox"/> (DSMET12M)	<input type="checkbox"/> (DSTHC12M)	<input type="checkbox"/> (DSCOC12M)	<input type="checkbox"/> (DSSED12M)

Answer the following for drugs used in the past 12 months

Criteria	Opioids	Alcohol	Amphetamines	Methamphetamine	Cannabis	Cocaine	Sedatives
1. Recurrent substance use resulting in a failure to fulfill major role obligations at work, school, or home (e.g., repeated absences or poor work performance related to substance use; substance-related absences, suspensions, or expulsions from school; neglect of children or household):	<input type="checkbox"/> (DSOPIOBL)	<input type="checkbox"/> (DSALCOBL)	<input type="checkbox"/> (DSAMPOBL)	<input type="checkbox"/> (DSMETOBL)	<input type="checkbox"/> (DSTHCOBL)	<input type="checkbox"/> (DSCOCOBL)	<input type="checkbox"/> (DSSEDOBL)
2. Recurrent substance use in situations in which it is physically hazardous (e.g., driving an automobile or operating a machine when impaired by substance use):	<input type="checkbox"/> (DSOPIHAZ)	<input type="checkbox"/> (DSALCHAZ)	<input type="checkbox"/> (DSAMPHAZ)	<input type="checkbox"/> (DSMETHAZ)	<input type="checkbox"/> (DSTHCHAZ)	<input type="checkbox"/> (DSCOCHAZ)	<input type="checkbox"/> (DSSEDHAZ)
3. Continued substance use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of the substance (e.g., arguments with spouse about consequences of intoxication, physical fights):	<input type="checkbox"/> (DSOPISOC)	<input type="checkbox"/> (DSALCSOC)	<input type="checkbox"/> (DSAMPSOC)	<input type="checkbox"/> (DSMETSOC)	<input type="checkbox"/> (DSTHCSOC)	<input type="checkbox"/> (DSCOCSOC)	<input type="checkbox"/> (DSSEDSOC)
4. Tolerance, as defined by either of the following: a. a need for markedly increased amounts of the substance to achieve intoxication or desired effect b. markedly diminished effect with continued use of the same amount of the substance (Note: Tolerance is not counted for those taking medications under medical supervision such as analgesics, antidepressants, anti-anxiety medications or beta-blockers.)	<input type="checkbox"/> (DSOPITOL)	<input type="checkbox"/> (DSALCTOL)	<input type="checkbox"/> (DSAMPTOL)	<input type="checkbox"/> (DSMETTOL)	<input type="checkbox"/> (DSTHCTOL)	<input type="checkbox"/> (DSCOCTOL)	<input type="checkbox"/> (DSSEDTOL)
5. Withdrawal, as manifested by either of the following: a. the characteristic withdrawal syndrome for the substance b. the same (or a closely related) substance is taken to relieve or avoid withdrawal symptoms (Note: Withdrawal is not counted for those taking medications under medical supervision such as analgesics, antidepressants, anti-anxiety medications or beta-blockers.)	<input type="checkbox"/> (DSOPIWIT)	<input type="checkbox"/> (DSALCWIT)	<input type="checkbox"/> (DSAMPWIT)	<input type="checkbox"/> (DSMETWIT)	<input type="checkbox"/> (DSTHCWIT)	<input type="checkbox"/> (DSCOCWIT)	<input type="checkbox"/> (DSSEDWIT)

Criteria	Opioids	Alcohol	Amphetamines	Methamphetamine	Cannabis	Cocaine	Sedatives
6. The substance is often taken in larger amounts or over a longer period than was intended:	<input type="checkbox"/> (DSOPIDOS)	<input type="checkbox"/> (DSALCDOS)	<input type="checkbox"/> (DSAMPDOS)	<input type="checkbox"/> (DSMETDOS)	<input type="checkbox"/> (DSTHCDOS)	<input type="checkbox"/> (DSCOCDOS)	<input type="checkbox"/> (DSSEDDOS)

7. There is a persistent desire or unsuccessful efforts to cut down or control substance use:

(DSOPICUT)	<input type="checkbox"/>	(DSALCCUT)	<input type="checkbox"/>	(DSAMP CUT)	<input type="checkbox"/>	(DSMETCUT)	<input type="checkbox"/>	(DSTHCCUT)	<input type="checkbox"/>	(DSCOCCUT)	<input type="checkbox"/>	(DSSEDCUT)	<input type="checkbox"/>
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8. A great deal of time is spent in activities necessary to obtain the substance, use the substance, or recover from its effects:

(DSOPTIM)	<input type="checkbox"/>	(DSALCTIM)	<input type="checkbox"/>	(DSAMP TIM)	<input type="checkbox"/>	(DSMETTIM)	<input type="checkbox"/>	(DSTHCTIM)	<input type="checkbox"/>	(DSCOCTIM)	<input type="checkbox"/>	(DSSEDTIM)	<input type="checkbox"/>
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9. Important social, occupational, or recreational activities are given up or reduced because of substance use:

(DSOPIACT)	<input type="checkbox"/>	(DSALCACT)	<input type="checkbox"/>	(DSAMPACT)	<input type="checkbox"/>	(DSMETACT)	<input type="checkbox"/>	(DSTHCACT)	<input type="checkbox"/>	(DSCOCACT)	<input type="checkbox"/>	(DSSEDACT)	<input type="checkbox"/>
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10. The substance use is continued despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance:

(DSOPICON)	<input type="checkbox"/>	(DSALCCON)	<input type="checkbox"/>	(DSAMP CON)	<input type="checkbox"/>	(DSMETCON)	<input type="checkbox"/>	(DSTHCCON)	<input type="checkbox"/>	(DSCOCCON)	<input type="checkbox"/>	(DSSEDCON)	<input type="checkbox"/>
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11. Craving or a strong desire or urge to use a specific substance:

(DSOPICRA)	<input type="checkbox"/>	(DSALCCRA)	<input type="checkbox"/>	(DSAMP CRA)	<input type="checkbox"/>	(DSMETCRA)	<input type="checkbox"/>	(DSTHCCRA)	<input type="checkbox"/>	(DSCOCCRA)	<input type="checkbox"/>	(DSSEDCRA)	<input type="checkbox"/>
------------	--------------------------	------------	--------------------------	-------------	--------------------------	------------	--------------------------	------------	--------------------------	------------	--------------------------	------------	--------------------------

	Opioids	Alcohol	Amphetamines	Methamphetamine	Cannabis	Cocaine	Sedatives
Meets criteria for Substance Use Disorder:	(DSOPISCO) <input type="checkbox"/> Severe <input type="checkbox"/> Moderate <input type="checkbox"/> Mild <input type="checkbox"/> None	(DSALCSCO) <input type="checkbox"/> Severe <input type="checkbox"/> Moderate <input type="checkbox"/> Mild <input type="checkbox"/> None	(DSAMPSCO) <input type="checkbox"/> Severe <input type="checkbox"/> Moderate <input type="checkbox"/> Mild <input type="checkbox"/> None	(DSMETSCO) <input type="checkbox"/> Severe <input type="checkbox"/> Moderate <input type="checkbox"/> Mild <input type="checkbox"/> None	(DSTHCSCO) <input type="checkbox"/> Severe <input type="checkbox"/> Moderate <input type="checkbox"/> Mild <input type="checkbox"/> None	(DSCOCSCO) <input type="checkbox"/> Severe <input type="checkbox"/> Moderate <input type="checkbox"/> Mild <input type="checkbox"/> None	(DSSEDCSCO) <input type="checkbox"/> Severe <input type="checkbox"/> Moderate <input type="checkbox"/> Mild <input type="checkbox"/> None

Comments: (DSMCOMM)