

NIDA Clinical Trials Network

Adverse Events (AD1)

Web Version: 1.0; 5.00; 07-26-12

Adverse Event Onset Date (AEDATE):

Select Sequence Number (AESEQNUM):

The following AEs do not require reporting in the data system: Grade 1 (mild) Unrelated Events.

1. Adverse event name:(A1DESCR1)

2. Date site became aware of the event:(A1AWARDT)

3. Severity of event:(A1SEVR2)

4. Is there a reasonable possibility that the extended release Naltrexone caused the event?(A1RVIVTL)

Action taken with extended release Naltrexone:(A1ACVIVT)

5. Is there a reasonable possibility that Buprenorphine/Placebo caused the event?(A1RSUBXN)

Action taken with Buprenorphine/Placebo:(A1ACSUBX)

6. If "Unrelated" to either of the study drugs, alternative etiology:(A1ALTESD)

If "Other," specify:(A1AEPSP)

(mm/dd/yyyy) [Click here to view calendar](#)

1-Grade 1 - Mild
2-Grade 2 - Moderate
3-Grade 3 - Severe

0-No
1-Yes

0-None
1-Decreased drug
2-Increased drug
3-Temporarily stopped drug
4-Permanently stopped drug
*Additional Options Listed Below

0-No
1-Yes

0-None
1-Decreased drug
2-Increased drug
3-Temporarily stopped drug
4-Permanently stopped drug
*Additional Options Listed Below

0-None apparent
6-Naloxone Challenge
7-Oral Naltrexone
8-Study intervention / counseling
2-Concomitant medication
*Additional Options Listed Below

7. Outcome of event:(A1OUTCM)

1-Ongoing
2-Resolved without sequelae
3-Resolved with sequelae
4-Resolved by convention
5-Death

8. Date of resolution or medically stable:(A1RESDT)

(mm/dd/yyyy)

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

9. Was this event associated with:(A1ASSOC2)

0-None of the following
1-Hospitalization for a medical event
2-Death
3-Life-threatening event
4-Inpatient admission to hospital
*Additional Options Listed Below

If "Death", date of death:(A1DTHDTE)

(mm/dd/yyyy)

10. If "Inpatient admission to hospital" or "Prolongation of hospitalization":

Date of hospital admission:(A1HOSPAD)

(mm/dd/yyyy)

Date of hospital discharge:(A1HOSPDCE)

(mm/dd/yyyy)

Comments:(A1COMM)

Medical Clinician's Signature

I have reviewed all the data recorded on all CRF pages associated with this Adverse Event, as well as any associated documentation, and certify that they are accurate and complete to the best of my knowledge.

Principal Investigator or Medical Clinician designee:(A1PISIGN)

Date:(A1PISGDT)

(mm/dd/yyyy)

MedDRA:

The following fields are auto-populated by the DSC2 based on MedDRA coding of the Adverse Event name.

Preferred Term:(MEDRAPT)

Not Coded

System Organ Class:(MEDRASOC)

Additional Selection Options for AD1

Select Sequence 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
-

Action taken with extended release Naltrexone:

- 5-Participant terminated from study

If "Unrelated" to either of the study drugs, alternative etiology:

- 3-Other pre-existing disease or condition
- 4-Accident, trauma, or external factors
- 5-Concurrent illness / condition (not pre-existing)
- 9-Other

Was this event associated with:

- 5-Prolongation of hospitalization
- 6-Persistent or significant incapacity
- 7-Congenital anomaly or birth defect
- 8-Important medical event that required intervention to prevent any of the above

Serious Adverse Event Summary (AD2)

Adverse Event Onset Date (AEDATE):
Select Sequence Number (AESEQNUM):

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

5. Labs/Tests Performed in Conjunction with this Event: (A2SAELAB) ☐ No ☐ Yes ☐ Unknown

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

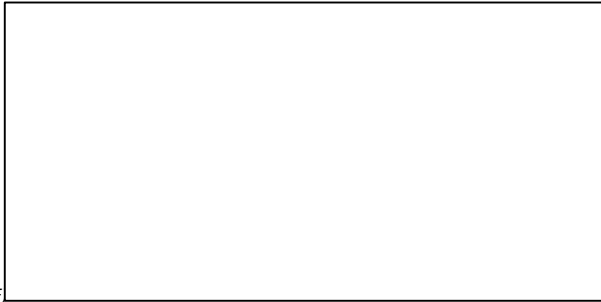
6. Follow-Up:

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

Select Sequence Number (*ASEQNUM*) (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; 03-09-12

Adverse Event Onset Date (AEDATE):

Select Sequence Number (AESEQNUM):

1. Was this determined to be a serious adverse event? (A3DETER)
2. Was this event considered associated with extended release Naltrexone? (A3XRNTX)
3. Was this event considered associated with Buprenorphine/PLB? (A3BUPPLB)
4. Was this event expected? (A3EXPECT)
5. Is this a standard expedited/reportable event? (i.e., is it serious, unexpected and related to therapy) (A3EXPFDA)
6. Is this an expedited/reportable event for other reasons? (A3EXPOTH)
7. Does the protocol need to be modified based on this event? (A3EXPDSM)
8. Does the consent form need to be modified based on this event? (A3CONSEN)
9. Is the review complete? (A3REVDNE)

- | | |
|-----------------------------|------------------------------|
| <input type="checkbox"/> No | <input type="checkbox"/> Yes |
| <input type="checkbox"/> No | <input type="checkbox"/> Yes |
| <input type="checkbox"/> No | <input type="checkbox"/> Yes |
| <input type="checkbox"/> No | <input type="checkbox"/> Yes |
| <input type="checkbox"/> No | <input type="checkbox"/> Yes |
| <input type="checkbox"/> No | <input type="checkbox"/> Yes |
| <input type="checkbox"/> No | <input type="checkbox"/> Yes |
| <input type="checkbox"/> No | <input type="checkbox"/> Yes |
| <input type="checkbox"/> No | <input type="checkbox"/> Yes |

If "No", what additional information is required: (A3ADDINF)

Assessed by: (A2ASRID)

Reviewed by: (A3REVID)

Comments: (A3COMM)

- | | |
|------------------------------------------|--------------------------------------------|
| <input type="checkbox"/> Robert Lindblad | <input type="checkbox"/> Radhika Kondapaka |
| <input type="checkbox"/> Robert Lindblad | |

Additional Selection Options for AD3

Select Sequence Number (*ASEQNUM*) (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

AE/Concomitant Medications Assessment Form (AEC)

Web Version: 1.0; 1.02; 06-18-12

Segment (*PROTSEG*):

Visit Number (*VISNO*):

Date of assessment: (*AEASMDT*)

(mm/dd/yyyy) [Click here for calendar](#)

1. Was an adverse event assessment completed at this visit? (*AEAEASSD*)

☐ No ☐ Yes

a. Were any new reportable AEs reported since the last assessment? (*AENEWAE*)

☐ No ☐ Yes

b. Were any changes in reportable AEs reported since the last assessment? (*AECHNGAE*)

☐ No ☐ Yes

2. Was a concomitant medication assessment completed at this visit? (*AECMASSD*)

☐ No ☐ Yes

a. Were any new concomitant medications reported since the last assessment? (*AENEWCNM*)

☐ No ☐ Yes

b. Were any changes in concomitant medications reported since the last assessment? (*AECHNGCM*)

☐ No ☐ Yes

Comments: (*AEMCOMM*)

NIDA Clinical Trials Network

CTN-ASI Lite v. 1: Drug/Alcohol Use (ASD)

Web Version: 1.0; 5.00; 06-18-12

Segment (PROTSEG):

Visit Number (VISNO):

CTN-ASI Lite v. 1 Follow-Up: Drug/Alcohol Use

Route of Administration:

1 = Oral 2 = Nasal 3 = Smoking 4 = Non-IV injection 5 = IV injection

Note the **usual or most recent route**. For more than one route, choose the most severe.

The routes are listed from least severe to most severe. If Past 30 Days is zero, route should be "Not applicable".

Substance	A Past 30 (Days)	D Route of Administration	Comments
D1 Alcohol (any use at all):	(ADALA30D) <input type="text"/> (xx)	-	(ADALACOM) <input type="text"/>
D2 Alcohol (to intoxication):	(ADALI30D) <input type="text"/> (xx)	-	(ADALICOM) <input type="text"/>
D3 Heroin	(ADHER30D) <input type="text"/> (xx)	<div> 1-(1) Oral 2-(2) Nasal 3-(3) Smoking 4-(4) Non IV injection 5-(5) IV injection 96-(96) Not applicable 97-(97) Not answered </div>	(ADHERCOM) <input type="text"/>
		(ADHERRTE)	
D4 Methadone/LAAM (prescribed):	(ADM DP30D) <input type="text"/> (xx)	<div> 1-(1) Oral 2-(2) Nasal 3-(3) Smoking 4-(4) Non IV injection 5-(5) IV injection 96-(96) Not applicable 97-(97) Not answered </div>	(ADM DPCOM) <input type="text"/>
		(ADM DP RTE)	
D4a Methadone/LAAM (illicit):	(ADMLI30D) <input type="text"/> (xx)	<div> 1-(1) Oral 2-(2) Nasal 3-(3) Smoking 4-(4) Non IV injection 5-(5) IV injection 96-(96) Not applicable 97-(97) Not answered </div>	(ADMLICOM) <input type="text"/>
		(ADMLIRTE)	

D5 Other Opiates/Analgesics:	(ADOPI30D) (xx)	<div>1-(1) Oral 2-(2) Nasal 3-(3) Smoking 4-(4) Non IV injection 5-(5) IV injection 96-(96) Not applicable 97-(97) Not answered</div>	(ADOPICOM)
		(ADOPIRTE)	
D6 Barbiturates:	(ADBAR30D) (xx)	<div>1-(1) Oral 2-(2) Nasal 3-(3) Smoking 4-(4) Non IV injection 5-(5) IV injection 96-(96) Not applicable 97-(97) Not answered</div>	(ADBARCOM)
		(ADBARRTE)	
D7 Other Sedatives/ Hypnotics/Tranquilizers:	(ADSHT30D) (xx)	<div>1-(1) Oral 2-(2) Nasal 3-(3) Smoking 4-(4) Non IV injection 5-(5) IV injection 96-(96) Not applicable 97-(97) Not answered</div>	(ADSHTCOM)
		(ADSHTRTE)	
D8 Cocaine:	(ADCOC30D) (xx)	<div>1-(1) Oral 2-(2) Nasal 3-(3) Smoking 4-(4) Non IV injection 5-(5) IV injection 96-(96) Not applicable 97-(97) Not answered</div>	(ADCOCOM)
		(ADCOCRTE)	
D9 Amphetamines:	(ADAMP30D) (xx)	<div>1-(1) Oral 2-(2) Nasal 3-(3) Smoking 4-(4) Non IV injection 5-(5) IV injection 96-(96) Not applicable 97-(97) Not answered</div>	(ADAMPOM)
		(ADAMP RTE)	
D9a Methamphetamine:	(ADMET30D) (xx)	<div>1-(1) Oral 2-(2) Nasal 3-(3) Smoking 4-(4) Non IV injection 5-(5) IV injection 96-(96) Not applicable 97-(97) Not answered</div>	(ADMETCOM)
		(ADMETRTE)	

D10 Cannabis:

(ADTHC30D) (xx)

1-(1) Oral
2-(2) Nasal
3-(3) Smoking
4-(4) Non IV injection
5-(5) IV injection
96-(96) Not applicable
97-(97) Not answered

(ADTHCRTE)

(ADTHCCOM)

D11 Hallucinogens:

(ADHAL30D) (xx)

1-(1) Oral
2-(2) Nasal
3-(3) Smoking
4-(4) Non IV injection
5-(5) IV injection
96-(96) Not applicable
97-(97) Not answered

(ADHALRTE)

(ADHALCOM)

D12 Inhalants:

(ADINH30D) (xx)

1-(1) Oral
2-(2) Nasal
3-(3) Smoking
4-(4) Non IV injection
5-(5) IV injection
96-(96) Not applicable
97-(97) Not answered

(ADINHRTE)

(ADINHCOM)

D13 More than 1 substance per day
(including alcohol, excluding nicotine):

(ADGT130D) (xx)

-

(ADGT1COM)

D14 Currently, which substance is the major problem?

- Interviewer should determine the major drug or drugs of abuse (excluding Nicotine use). Code the number next to the drug in 01-12 (code prescribed or illicit methadone as 04). 00 = no problem, 15 = alcohol and one or more drugs; 16 = more than one drug but no alcohol. Ask participant when not clear.

0-00 - No problem
1-01 - Alcohol (any use at all)
2-02 - Alcohol (to intoxication)
3-03 - Heroin
4-04 - Methadone/LA AM (prescribed or illicit)
5-05 - Other Opiates/Analgesics
6-06 - Barbiturates
7-07 - Other Sedatives/Hypnotics/Tranquilizers
8-08 - Cocaine
9-09 - Amphetamines
9a-09a - Methamphetamine
10-10 - Cannabis
11-11 - Hallucinogens
12-12 - Inhalants
15-15 - Alcohol & one or more drugs
16-16 - More than one drug, but no alcohol

(ADMAJDRG)

OR

(ADMJDGNA) ☐ (97) Not Answered

Comments: (ADMJDGCM)

D17 How many times since your last ASI have you had Alcohol DTs?

- Delirium Tremens (DT's): Occur 24-48 hours after last drink, or significant decrease in alcohol intake. Characterized by shaking, severe disorientation, fever, hallucinations; they usually require medical attention.

(ADALCDT) (xx)

OR

(ADALDTNA) ☐ (97) Not Answered

Comments: (ADALDTCM)

How many times since your last ASI have you been treated for:
Include detoxification, halfway houses, in/outpatient counseling and AA or NA (if 3+ meetings within one month period).

D19 Alcohol abuse:

(ADALCTRT) (xx)

OR

(ADATRTNA) ☐ (97) Not Answered

Comments: (ADATRTCM)

D20 Drug abuse:

(ADDRGTRT) (xx)

OR

(ADDTRTNA) ☐ (97) Not Answered

Comments: (ADDTRTCM)

How many of these were detox only:

D21 Alcohol:

- If D19 = 00, then question D21 is Not applicable.

(ADADETOX) (xx)

OR

(ADADTXNA) ☐ (96) Not applicable ☐ (97) Not answered

Comments: (ADADTXCM)

D22 Drugs:

- If D20 = 00, then question D22 is Not applicable.

(ADDDETOX) (xx)

OR

(ADDDTXNA) ☐ (96) Not applicable ☐ (97) Not answered

Comments: (ADDDTXCM)

How much money would you say you spent during the past 30 days on:

Max. = \$99999

D23 Alcohol:

- Only count actual money spent. What is the financial burden caused by alcohol?

(ADALCMNY) \$ (xxxxx)

OR

(ADAMNYNA) ☐ (97) Not Answered

Comments: (ADAMNYCM)

D24 Drugs:

- *Only count actual money spent. What is the financial burden caused by drugs?*

(ADDRGMNY) \$ (xxxxx)

OR

(ADDMNYNA) ☐ (97) Not Answered

Comments: (ADDMNYCM)

D25 How many days have you been treated in an outpatient setting for alcohol or drugs in the past 30 days?

- *Include AANA*

(ADOPTPAT) (xx) days

OR

(ADOPTNA) ☐ (97) Not Answered

Comments: (ADOPTCOM)

D26 How many days in the past 30 have you experienced alcohol problems?

- Include: Craving, withdrawal symptoms, disturbing effects of use, or wanting to stop and being unable to.

(ADAP30D) (xx) days

OR

(ADAP30NA) ☐ (97) Not Answered

Comments: (ADAP30CM)

For questions D28-D31, please ask participant to use the Participant Rating Scale. The participant is rating the need for additional substance abuse treatment.

D28 How troubled or bothered have you been in the past 30 days by these alcohol problems?

0-(0) Not at all
1-(1) Slightly
2-(2) Moderately
3-(3) Considerably
4-(4) Extremely

(ADAPB30D)

OR

(ADAB30NA) ☐ (97) Not Answered

Comments: (ADAB30CM)

D30 How important to you **now** is treatment for these alcohol problems?

- 0-(0) Not at all
1-(1) S lightly
2-(2) Moderately
3-(3) C onsiderably
4-(4) E xtremely

(ADAP30D)

OR

(ADA30NA) ☐ (97) Not Answered

Comments: (ADA30CM)

D27 How many days in the past 30 have you experienced drug problems?

- *Include: Craving, withdrawal symptoms, disturbing effects of use, or wanting to stop and being unable to.*

(ADDP30D) (xx) days

OR

(ADDP30NA) ☐ (97) Not Answered

Comments: (ADDP30CM)

D29 How troubled or bothered have you been in the past 30 days by these drug problems?

- 0-(0) Not at all
- 1-(1) Slightly
- 2-(2) Moderately
- 3-(3) Considerably
- 4-(4) Extremely

(ADDPB30D)

OR

(ADDB30NA) ☐ (97) Not Answered

Comments: (ADDB30CM)

D31 How important to you **now** is treatment for these drug problems?

- 0-(0) Not at all
- 1-(1) Slightly
- 2-(2) Moderately
- 3-(3) Considerably
- 4-(4) Extremely

(ADDPI30D)

OR

(ADDI30NA) ☐ (97) Not Answered

Comments: (ADDI30CM)

Confidence Ratings: Is the above information **significantly** distorted by:

D34 Participant's misrepresentation?

(ADMISREP) ☐ (0) No ☐ (1) Yes

D35 Participant's inability to understand?

(ADUNDRST) ☐ (0) No ☐ (1) Yes

Comments: (ASDCOMM)

NIDA Clinical Trials Network

CTN-ASI Lite v. 1: Employment/Support Status (ASE)

Web Version: 1.0; 4.01; 06-05-12

Segment (*PROTSEG*):

Visit Number (*VISNO*):

CTN-ASI Lite v. 1 Follow-Up: Employment/Support Status

E1 Education completed since your last ASI:

- *GED = 12 years*
- *Include formal education only.*

(*AEEDCPYR*) (xx) a. years

(*AEEDCPMT*) (xx) b. months

OR

(*AEEDCPNA*) ☐ (97) Not Answered

Comments: (*AEEDCPCM*)

E2 Training or technical education completed since your last ASI:

- *Formal/organized training only. For military training, only include training that can be used in civilian life, i.e., electronics or computers.*

(*AETECPMT*) (xx) months

OR

(*AETECPNA*) ☐ (97) Not Answered

Comments: (AETECPCM)

E4 Do you have a valid driver's license?

- Valid license; not suspended/revoked.

(AEDRVLSC)

0-(0) No
1-(1) Yes
97-(97) Not answered

Comments: (AEDRVLSCM)

E5 Do you have an automobile available?

- If answer to E4 is "No", then E5 must be "No". Does not require ownership, only requires availability on a regular basis.

(AEAUTOAV)

0-(0) No
1-(1) Yes
97-(97) Notanswered

Comments: (AEAUTOCM)

E7 Usual (or last) occupation since your last ASI?

- Use Hollingshead Categories Reference Sheet.

1-(1) Higher Executive, Major Professionals, Owner of Large Business
2-(2) Business Manager, Owner (medium sized business), Other Professional
3-(3) Administrative Personnel, Manager, Owner/Proprietor of Small Business
4-(4) Clerical and Sales, Technician, Owner of Small Business
5-(5) Skilled Manual - usually having had training
6-(6) Semi-skilled
7-(7) Unskilled/Unemployed
8-(8) Homemaker
9-(9) Student/No Occupation/Disabled

(AE OCCUPT)

Specify:

(AE OCCPSP)

OR

(AE OCCPNA) ☐ (97) Not Answered

Comments: (AE OCCPCM)

E9 Does someone contribute the majority of your support?

- Is participant receiving any regular support (i.e., cash, food, housing) from family/friend?
- Include spouse's contribution; exclude support by an institution.

O-(0) No
1-(1) Yes
96-(96) Not applicable
97-(97) Not answered

(AESUPPRT)

Comments: (AESUPPCM)

E11 How many days were you paid for working in the past 30 days?

- Include "under the table" work, paid sick days, and vacation.

(AEPAID) (xx) days

OR

(AEPAIDNA) ☐ (97) Not Answered

Comments:(AEPaidCM)

For questions E12-E17: How much money did you receive from the following sources in the past 30 days?
Max. = \$99999

E12 Employment (net income):

- Net or "take home" pay, include any "under the table" money.

(AEEMPMNY) \$ (xxxxx)

OR

(AEEMNYNA) ☐ (97) Not Answered

Comments:(AEEMNYCM)

E13 Unemployment compensation:

(AEUNEMNY) \$ (xxxxx)

OR

(AEUMNYNA) ☐ (97) Not Answered

Comments:(AEUMNYCM)

E14 Welfare:

- Include food stamps, transportation money provided by an agency to go to and from treatment.

(AEWLFMNY) \$ (xxxxx)

OR

(AEWMNYNA) ☐ (97) Not Answered

Comments:(AEWMNYCM)

E15 Pensions, benefits, or Social Security:

- Include disability, pensions, retirement, veteran's benefits, SSI & workers' compensation.

(AEPENMNY) \$ (xxxxx)

OR

(AEPMNYNA) ☐ (97) Not Answered

Comments:(AEPMNYCM)

E16 Mate, family or friends:

- *Money for personal expenses, (i.e., clothing), include unreliable sources of income (e.g., gambling). Record **cash** payments only, include windfalls (unexpected), money from loans, gambling, inheritance, tax returns, etc.*

(AEMATMNY) \$ (xxxx)

OR

(AEMMNYNA) ☐ (97) Not Answered

Comments:(AEMMNYCM)

E17 Illegal:

- **Cash** obtained from drug dealing, stealing, fencing stolen goods, gambling, prostitution, etc.
- **Do not** attempt to convert drugs exchanged to a dollar value.

(AEILLMNY) \$ (xxxx)

OR

(AEIMNYNA) ☐ (97) Not Answered

Comments:(AEIMNYCM)

E18 How many people depend on you for the majority of their food, shelter, etc.?

- *Must be regularly depending on participant; do include alimony/child support; do not include the participant or self-supporting spouse, etc.*

(AEDEPEND) (xx) max = 99

OR

(AEDPNDNA) ☐ (97) Not Answered

Comments:(AEDPNDCM)

E19 How many days have you experienced employment problems in the past 30 days?

- *Include inability to find work, if they are actively looking for work, or problems with present job in which that job is jeopardized.*
- *If the participant has not had the opportunity to work, due to incarceration or other controlled environment, the appropriate answer to E19 is NA and the participant rating in E20 should also be NA as it depends on the problem day question.*

(AEEP30D) (xx) days

OR

(AEEP30NA) ☐ (96) Not applicable ☐ (97) Not answered

Comments:(AEEP30CM)

For questions E20-E21: Please ask participant to use the Participant Rating Scale.

The participant's ratings in questions E20 and E21 refer to question E19. Stress help in finding or preparing for a job, not giving them a job.

E20 How troubled or bothered have you been by these employment problems in the past 30 days?

0-(0) Not at all
1-(1) Slightly
2-(2) Moderately
3-(3) Considerably
4-(4) Extremely

(AEEBP30D)

OR

(AEEB30NA) ☐ (96) Not applicable ☐ (97) Not answered

Comments:(AEEB30CM)

E21 How important to you **now** is counseling for these employment problems?

0-(0) Not at all
1-(1) Slightly
2-(2) Moderately
3-(3) Considerably
4-(4) Extremely

(AEEC130D)

OR

(AEEC30NA) ☐ (97) Not Answered

Comments:(AEEC30CM)

Confidence Ratings: Is the above information **significantly** distorted by:

E23 Participant's misrepresentation?

(AEMISREP) ☐ (0) No ☐ (1) Yes

E24 Participant's inability to understand?

(AEUNDRST) ☐ (0) No ☐ (1) Yes

Comments:(ASECOMM)

CTN-ASI Lite v. 1: Family/Social Relationships (ASF)

Web Version: 1.0; 3.00; 03-09-12

Segment (PROTSEG):

Visit Number (VISNO):

CTN-ASI Lite v. 1 Follow-Up: Family/Social Relationships

F1 Marital status:

- Common-law marriage = 1: Specify in Comments.

1-(1) Married
2-(2) Remarried
3-(3) Widowed
4-(4) Separated
5-(5) Divorced
6-(6) Never married
97-(97) Not answered

(AFMRTLST)

Comments:(AFMRLCM)

F3 Are you satisfied with this situation?

- Satisfied= Generally liking the situation. Refers to question F1.

0-(0) No
1-(1) Indifferent
2-(2) Yes
97-(97) Not answered

(AFMSSAT)

Comments:(AFMSATCM)

F4 Usual living arrangements (*since your last ASI*):

- 1-(1) With sexual partner and children
2-(2) With sexual partner alone
3-(3) With children alone
4-(4) With parents
5-(5) With family
6-(6) With friends
7-(7) Alone
8-(8) Controlled environment
9-(9) No stable arrangements
97-(97) Not answered

(AFLIVARR)

Comments:(AFLVARCM)

F6 Are you satisfied with these arrangements?

- Refers to response in question F4.

- 0-(0) No
1-(1) Indifferent
2-(2) Yes
97-(97) Notanswered

(AFLSSAT)

Comments:(AFLSATCM)

Do you live with anyone who:

F7 Has a current alcohol problem?

0-(0) No
1-(1) Yes
97-(97) Not answered

(AFLIVALC)

Comments:(AFLVALCM)

F8 Uses non-prescribed drugs?

0-(0) No
1-(1) Yes
97-(97) Not answered

(AFLIVDRG)

Comments:(AFLVDGCM)

F9 With whom do you spend most of your free time?

- If a girlfriend/boyfriend is considered as family by participant, then they must refer to them as family throughout this section, not as a friend. Family is not to be referred to as "friend."

1-(1) Family

2-(2) Friends

3-(3) Alone

97-(97) Not answered

(AFFREETM)

Comments:(AFFREETCM)

F10 Are you satisfied with spending your free time this way?

- A satisfied response must indicate that the person generally likes the situation. Refers to question F9.

0-(0) No

1-(1) Indifferent

2-(2) Yes

97-(97) Notanswered

(AFFTMSAT)

Comments:(AFSFRETCM)

Have you had significant periods in which you have experienced serious problems getting along with:

- "Serious problems" mean those that endangered the relationship.
- A "problem" requires contact of some sort, either by telephone or in person. Indicate "Not applicable" if there was no contact.

	A Past 30 Days	
--	----------------	--

F18 Mother:	<div> <div> O-(0) No 1-(1) Yes 96-(96) Not applicable 97-(97) Not answered </div> <div>(AFMTR30D)</div> </div>
F19 Father:	<div> <div> O-(0) No 1-(1) Yes 96-(96) Not applicable 97-(97) Not answered </div> <div>(AFFTR30D)</div> </div>
F20 Brothers/sisters:	<div> <div> O-(0) No 1-(1) Yes 96-(96) Not applicable 97-(97) Not answered </div> <div>(AFSIB30D)</div> </div>
F21 Sexual partner/spouse:	<div> <div> O-(0) No 1-(1) Yes 96-(96) Not applicable 97-(97) Not answered </div> <div>(AFSPS30D)</div> </div>
F22 Children:	<div> <div> O-(0) No 1-(1) Yes 96-(96) Not applicable 97-(97) Not answered </div> <div>(AFCHD30D)</div> </div>
F23 Other significant family (<i>specify</i>): <div style="border: 1px solid black; height: 150px; width: 280px; margin-top: 10px;"></div> (AFOSFMSP)	<div> <div> O-(0) No 1-(1) Yes 96-(96) Not applicable 97-(97) Not answered </div> <div>(AFOSF30D)</div> </div>
F24 Close friends:	<div> <div> O-(0) No 1-(1) Yes 96-(96) Not applicable 97-(97) Not answered </div> <div>(AFFRD30D)</div> </div>
F25 Neighbors:	<div> <div> O-(0) No 1-(1) Yes 96-(96) Not applicable 97-(97) Not answered </div> <div>(AFNBR30D)</div> </div>

F26 Co-workers:	<div> <div> 0-(0) No 1-(1) Yes 96-(96) Not applicable 97-(97) Not answered </div> <div>(AFCWK30D)</div> </div>
Did anyone abuse you? (F18-F26)	A Past 30 Days
F28 Physically <i>(caused you physical harm)?</i>	<div> <div> 0-(0) No 1-(1) Yes 97-(97) Not answered </div> <div>(AFPAB30D)</div> </div>
F29 Sexually <i>(forced sexual advances/acts)?</i>	<div> <div> 0-(0) No 1-(1) Yes 97-(97) Not answered </div> <div>(AFSAB30D)</div> </div>
<div> <div> <div>Comments:(AFPRBLCM)</div> <div></div> </div> </div>	

F30 How many days in the past 30 have you had serious conflicts with your family?

(AFFMC30D) (xx) days

OR

(AFFC30NA) ☐ (97) Not Answered

Comments:(AFFC30CM)

For questions F32 and F34, please ask participant to use the Participant Rating Scale.

F32 How troubled or bothered have you been in the past 30 days by these family problems?

- 0-(0) Not at all
- 1-(1) Slightly
- 2-(2) Moderately
- 3-(3) Considerably
- 4-(4) Extremely

(AFFCB30D)

OR

(AFFB30NA) ☐ (97) Not Answered

Comments:(AFFB30CM)

F34 How important to you now is treatment or counseling for these family problems?
Participant is rating his/her need for counseling for family problems, not whether the family would be willing to attend.

- 0-(0) Not at all
- 1-(1) Slightly
- 2-(2) Moderately
- 3-(3) Considerably
- 4-(4) Extremely

(AFFCI30D)

OR

(AFFI30NA) ☐ (97) Not Answered

Comments:(AFFI30CM)

F31 How many days in the past 30 have you had serious conflicts with other people (*excluding family*)?

(AFSCC30D) (xx) days

OR

(AFSC30NA) ☐ (97) Not Answered

Comments: (AFSC30CM)

For questions F33 and F35, please ask participant to use the Participant Rating Scale.

F33 How troubled or bothered have you been in the past 30 days by these social problems?

0-(0) Not at all
1-(1) Slightly
2-(2) Moderately
3-(3) Considerably
4-(4) Extremely

(AFSPB30D)

OR

(AFSB30NA) ☐ (97) Not Answered

Comments: (AFSB30CM)

F35 How important to you now is treatment or counseling for these social problems?

- Include participant's need to seek treatment for such social problems as loneliness, inability to socialize, and dissatisfaction with friends. Participant rating should refer to dissatisfaction, conflicts, or other serious problems. Exclude problems that would be eliminated if participant had no substance abuse.

0-(0) Not at all
1-(1) Slightly
2-(2) Moderately
3-(3) Considerably
4-(4) Extremely

(AFSPI30D)

OR

(AFS30NA) ☐ (97) Not Answered

Comments: (AFSI30CM)

Confidence Ratings: Is the above information **significantly** distorted by:

F37 Participant's misrepresentation?

(AFMISREP) ☐ (0) No ☐ (1) Yes

F38 Participant's inability to understand?

(AFUNDRST) ☐ (0) No ☐ (1) Yes

Comments: (ASF COMM)

NIDA Clinical Trials Network

CTN-ASI Lite v. 1: General Information (ASG)

Web Version: 1.0; 3.00; 05-18-12

Segment (*PROTSEG*):

Visit Number (*VISNO*):

CTN-ASI Lite v. 1 Follow-Up: General Information

G9 Contact code:

1-(1) In person
2-(2) Telephone (Intake ASI must be in person)
3-(3) Mail
97-(97) Not Answered

(AGCONTACT)

G12 Special:

1-(1) Participant terminated
2-(2) Participant refused
3-(3) Participant unable to respond
96-(96) Not Applicable

(AGSPECIAL)

G19 Have you been in a controlled environment in the past 30 days? (*A place, theoretically, without access to drugs/alcohol*)

1-(1) No
2-(2) Jail
3-(3) Alcohol or drug treatment
4-(4) Medical treatment
5-(5) Psychiatric treatment
6-(6) Other
97-(97) Not answered

(AGCENTENV)

Other (specify):(AGCENVSP)

Comments:(AGCENVCM)

G20 How many days? (Refers to total number of days detained in the past 30 days)

- Not applicable if question G 19 is "No."

(AGCEDAYS) (xx) days

OR

(AGCEDSNA) ☐ (96) Not applicable ☐ (97) Not answered

Comments:(AGCEDSCM)

Comments:(ASGCOMM)

NIDA Clinical Trials Network

CTN-ASI Lite v. 1 (ASI)

Web Version: 1.0; 3.00; 05-16-12

Segment (*PROTSEG*):

Visit Number (*VISNO*):

CTN-ASI Lite v. 1 Follow-Up

Date of assessment: (*ASASMTDT*)

(mm/dd/yyyy) [Click here to view calendar](#)

Introducing the CTN-ASI Lite v. 1 Follow-Up

Seven potential problem areas: Medical, Employment/Support Status, Alcohol, Drug, Legal, Family/Social, and Psychological.

All clients receive this same **standard** interview. All information gathered is **confidential**.

There are **two time periods** we will discuss:

1. The past 30 days
2. Lifetime Data

Participant Rating Scale: Participant input is important. For each area, I will ask you to use this scale to let me know how bothered you have been by any problems in each section. I will also ask you how important treatment is for you for the area being discussed.

Please refer to the Participant Rating Scale in the adjacent key.

If you are uncomfortable giving an answer, then don't answer.

Please do not give inaccurate information!

Key: Participant Rating Scale
0=Not at all
1=Slightly
2=Moderately
3=Considerably
4=Extremely

Interviewer Instructions

1. Leave no blanks.
2. Make plenty of comments (*if another person reads this ASI, they should have a relatively complete picture of the client's perceptions of his/her problems*).
3. Throughout the ASI, please note if not answered or not applicable in the appropriate box.
4. Terminate interview if client misrepresents two or more sections.
5. When noting comments, please write the question number.

HALF TIME RULE:

If a question asks the number of months, round up periods of 14 days or more to 1 month.

Round up 6 months or more to 1 year.

CONFIDENCE RATINGS:

Last two items in each section.

Do not over interpret.

Denial does not warrant misrepresentation.

Misrepresentation = overt contradiction in information.

Probe and make plenty of comments!

CTN-ASI Lite v. 1: Hollingshead Categories

1 = Higher Executive, Major Professionals, Owner of Large Business

2 = Business Manager, Owner (*medium sized business*), **Other Professional** (*nurse, optician, pharmacist, social worker, teacher*)

3 = Administrative Personnel, Manager, Owner/Proprietor of Small Business (*bakery, car dealership, engraving business, plumbing business, florist, decorator, actor, reporter, travel agent*)

4 = Clerical and Sales, Technician, Owner of Small Business (*bank teller, bookkeeper, clerk, draftsman, timekeeper, secretary, car salesperson*)

5 = Skilled Manual - usually having had training (*baker, barber, brakeman, chef, electrician, fireman, lineman, machinist, mechanic, paperhanger, painter, repairman, tailor, welder, police officer, plumber*)

6 = Semi-skilled (*hospital aide, painter, bartender, bus driver, cutter, cook, drill press, garage guard, checker, waiter, spot welder, machine operator*)

7 = Unskilled (*attendant, janitor, construction help, unspecified labor, porter*). **Include Unemployed.**

8 = Homemaker

9 = Student/No Occupation/Disabled

List of Commonly Used Drugs

Alcohol:	Beer, wine, liquor
Methadone:	Dolophine, LAAM
Opiates:	Pain killers = Morphine, Dilaudid, Demerol, Percocet, Darvon, Talwin, Codeine, Tylenol 2, 3, 4 Syrups = Robitussin, Fentanyl
Barbiturates:	Nembutal, Seconal, Tuinol, Amytal, Pentobarbital, Secobarbital, Phenobarbital, Fiorinol
Sed/Hyp/Tranq:	Benzodiazepines = Valium, Librium, Ativan, Serax, Tranxene, Dalmane, Halcion, Xanax, Miltown, Other = Chloral Hydrate (Noctex), Quaaludes
Cocaine:	Cocaine Crystal, Free-Base Cocaine or "Crack", and "Rock Cocaine"
Amphetamines:	Monster, Crank, Benzedrine, Dexedrine, Ritalin, Preludin
Methamphetamine:	Speed, Ice, Crystal
Cannabis:	Marijuana, Hashish
Hallucinogens:	LSD (Acid), Mescaline, Mushrooms (Psilocybin), Peyote, Green, PCP (Phencyclidine), Angel Dust, Ecstasy
Inhalants:	Nitrous Oxide, Amyl Nitrate (Whippits, Poppers), Glue, Solvents, Gasoline, Toluene, etc.
Just note if these are used:	Antidepressants, Ulcer Meds = Zantac, Tagamet Asthma Meds = Ventoline Inhaler, Theodur Other meds = Antipsychotics, Lithium

Alcohol/Drug Section Instructions

The following questions look at two time periods: the past 30 days and lifetime. Lifetime refers to the time prior to the last 30 days. However, if the client has been incarcerated for more than 1 year, you would only gather lifetime information, unless the client admits to significant alcohol/drug use during incarceration. This guideline only applies to the Alcohol/Drug Section.

30 day questions only require the number of days used.

Lifetime use is asked to determine extended periods of use.

Regular use = 3+ times per week, binges, or problematic irregular use in which normal activities are compromised.

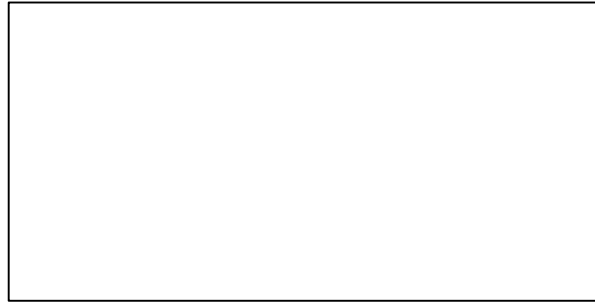
Alcohol to intoxication does not necessarily mean "drunk;" use the words "felt the effects," "got a buzz," "high," etc., instead of intoxication. As a rule of thumb, 3+ drinks in one setting, or within a brief period of time, or 5+ drinks in one day defines "intoxication."

How to ask these questions:

"How many days in the past 30 have you used...?"

"How many years in your life have you regularly used...?"

Comments: (ASCOMM)



CTN-ASI Lite v. 1: Legal Status (ASL)

Web Version: 1.0; 4.01; 06-05-12

Segment (PROTSEG):
Visit Number (VISNO):

CTN-ASI Lite v. 1 Follow-Up: Legal Status

L2 Are you on parole or probation?

- Note duration and level in comments.

0-(0) No, neither
1-(1) Yes, parole or postrelease supervision
2-(2) Yes, probation or pre-sentencing diversion
97-(97) Not answered

(ALPROBAT)

Comments:(ALPRBTCM)

How many times since your last ASI have you been arrested and charged with the following:
Include total numbers of counts, not just convictions. Do not include juvenile [under age 18] crimes, unless they were charged as an adult. Include formal charges only.

L3 Shoplifting/vandalism:

(ALSHPLFT)
| (xx)

OR (ALSLFTNA) ☐ (97) (ALSLFTCM)
Not Answered

Comments:

L4 Parole/probation violations:

(ALPPVIOL)
 (xx)

OR (ALPPVLNA) (97)
Not Answered

(ALPPVLCM)

L5 Drug Charges:

(ALDRGCHR)
 (xx)

OR (ALDCHRNA) (97)
Not Answered

(ALDCHRCM)

L6 Forgery:

(ALFORGER)
 (xx)

OR (ALFORGNA) (97)
Not Answered

(ALFORGCM)

L7 Weapons offense:

(ALWEAPON)
 (xx)

OR (ALWEAPNA) (97)
Not Answered

(ALWEAPCM)

L8 Burglary/larceny/B&E:

(ALBURGLR)
_____(xx)

OR (ALBURGNA) ☐ (97)
Not Answered

(ALBURGCM)

L9 Robbery:

(ALROBBRY)
_____(xx)

OR (ALROBBNA) ☐ (97)
Not Answered

(ALROBBCM)

L10 Assault:

(ALASSLT)
_____(xx)

OR (ALASLTNA) ☐ (97)
Not Answered

(ALASLTCM)

L11 Arson:

(ALARSON)
_____(xx)

OR (ALARSNNA) ☐ (97)
Not Answered

(ALARSNCM)

L12 Rape:

(ALRAPE)

(xx)

OR (ALRAPENA) ☐ (97)
Not Answered

(ALRAPECM)

L13 Homicide/manslaughter:

(ALMURDER)

(xx)

OR (ALMRDRNA) ☐ (97)
Not Answered

(ALMRDRCM)

L14 Prostitution:

(ALPROST)

(xx)

OR (ALPRSTNA) ☐ (97)
Not Answered

(ALPRSTCM)

L15 Contempt of court:

(ALCONTMP)

(xx)

OR (ALCNTPNA) ☐ (97)
Not Answered

(ALCNTPCM)

L16 Other (specify):

(ALOTHARR)
(xx)

OR (ALOARRNA) ☐ (97)
Not Answered

Comments:(ALARSTCM)

If "Other", specify:(ALOTHASP)

Comments:(ALARSTCM)

L17 How many of these charges resulted in convictions?

- Do not include misdemeanor offenses from questions L18-L20 below. Convictions include fines, probation, incarceration, suspended sentences, and guilty pleas.
- If L3-L 16 = 00, then L 17 = Not applicable

(ALCONVCT) (xx)

OR

(ALCNVTNA) ☐ (96) Not applicable ☐ (97) Not answered

Comments:(ALCNVTCM)

How many times since your last ASI have you been charged with the following:

L18 Disorderly conduct, vagrancy, public intoxication:

(ALDISCND) (xx)

OR

(ALDCNDNA) ☐ (97) Not Answered

Comments: (ALDCNDCM)

L19 Driving while intoxicated (DWI):

(ALDWI) (xx)

OR

(ALDWINA) ☐ (97) Not Answered

Comments: (ALDWICM)

L20 Major driving violations:

- *Moving violations: speeding, reckless driving, no license, etc.*

(ALDRVOL) (xx)

OR

(ALDRVINA) ☐ (97) Not Answered

Comments: (ALDRVLCM)

L21 How many months were you incarcerated since your last ASI?

- If incarcerated **2 weeks or more**, round this up to 1 month. List total number of months incarcerated (up to 99). If more than 99, code 99 and enter the number in comments.

(ALINCRM T) (xx) months

OR

(ALINCRNA) ☐ (97) Not Answered

Comments: (ALINRCRM)

L24 Are you presently awaiting charges, trial, or sentence ?

0-(0) No
1-(1) Yes
97-(97) Not answered

(ALCHTRSE)

L25 What for (refers to L24)?

- Use code 03-16, 18-20. If more than one, choose most severe. Don't include civil cases, unless a criminal offense is involved.

03-03 = Shoplifting
04-04 = Probation violation
05-05 = Drug
06-06 = Forgery
07-07 = Weapons
08-08 = Burglary
09-09 = Robbery
10-10 = Assault
11-11 = Arson
12-12 = Rape
13-13 = Homicide
14-14 = Prostitution
15-15 = Contempt
16-16 = Other
18-18 = Disorderly conduct
19-19 = DWI
20-20 = Major driving violation

(ALCTSSP)

OR

(ALCTSPNA) ☐ (96) Not applicable ☐ (97) Not answered

Comments: (ALCTSPCM)

L26 How many days in the past 30 were you detained or incarcerated?

- *Include being arrested and released on the same day.*

(ALIN30D) (xx) days

OR

(ALIN30NA) ☐ (97) Not Answered

Comments: (ALIN30CM)

L27 How many days in the past 30 have you engaged in illegal activities for profit?

- *Exclude simple drug possession. Include drug dealing, prostitution, selling stolen goods, etc. May be cross checked with question E17 under Employment/Family Support section.*

(ALIP30D) (xx) days

OR

(ALIP30NA) ☐ (97) Not Answered

Comments: (ALIP30CM)

For questions L28-29: Please ask participant to use the Participant Rating Scale.

L28 How serious do you feel your present legal problems are?

- Exclude civil problems

0-(0) Not at all
1-(1) S lightly
2-(2) Moderately
3-(3) Considerably
4-(4) Extremely

(ALLPS30D)

OR

(ALLP30NA) ☐ (97) Not Answered

Comments: (ALLP30CM)

L29 How important to you **now** is counseling or referral for these legal problems?

- Participant is rating a need for **additional** referral to legal counsel for defense against criminal charges.

0-(0) Not at all
1-(1) S lightly
2-(2) Moderately
3-(3) Considerably
4-(4) Extremely

(ALLCI30D)

OR

(ALLI30NA) ☐ (97) Not Answered

Comments: (ALLI30CM)

Confidence Ratings: Is the above information **significantly** distorted by:

L31 Participant's misrepresentation?

(ALMISREP) ☐ (0) No ☐ (1) Yes

L32 Participant's inability to understand?

(ALUNDRST) ☐ (0) No ☐ (1) Yes

Comments: (ALCOMM)

NIDA Clinical Trials Network

CTN-ASI Lite v. 1: Medical Status (ASM)

Web Version: 1.0; 3.00; 05-29-12

Segment (*PROTSEG*):

Visit Number (*VISNO*):

CTN-ASI Lite v. 1 Follow-Up: Medical Status

M1 Since your last ASI, how many times have you been hospitalized for medical problems?

- Include O.D.'s and D.T.'s. Exclude detox, alcohol/drug, psychiatric treatment and childbirth (if no complications).
- Enter the number of **overnight** hospitalizations for medical problems.

(AMHOSPTM) (xx) times

OR

(AMHOSPNA) ☐ (97) Not Answered

Comments: (AMHOSPCM)

M4 Are you taking any prescribed medication on a regular basis for a physical problem?

- Medication prescribed by a M.D. for medical conditions; **not psychiatric medicines**.
- Include medicines prescribed, whether or not the participant is currently taking them.
- The intent is to verify chronic medical problems.

0-(0) No
1-(1) Yes
97-(97) Notanswered

(AMRXPHYS)

If "Yes", specify:(AMRXPHSP)

Comments: (AMRXPHCM)

M5 Do you receive a pension for a physical disability?

- Include Workers' Compensation, exclude psychiatric disability.

(AMPENSPD)

O-(0) No
1-(1) Yes
97-(97) Not answered

If "Yes", specify:(AMPNPDSP)

Comments: (AMPNDCM)

M6 How many days have you experienced medical problems in the past 30 days?

- Do not include ailments directly caused by drugs/alcohol.
- Include flu, colds, etc. Include serious ailments related to drugs/alcohol, which would continue even if the participant were abstinent (e.g., cirrhosis of liver, abscesses from needles, etc.).

(AMPRB30D) (xx) days

OR

(AMPB30NA) ☐ (97) Not Answered

Comments: (AMPB30CM)

For questions M7 & M8, please ask participant to use the Participant Rating Scale.

M7 How troubled or bothered have you been by these medical problems in the past 30 days?

- Restrict response to problem days of question M6.

0-(0) Not at all
1-(1) Slightly
2-(2) Moderately
3-(3) Considerably
4-(4) Extremely

(AMPBR30D)

OR

(AMPB30NA) ☐ (97) Not Answered

Comments: (AMPB30CM)

M8 How important to you **now** is treatment for these medical problems?

- Refers to the need for new or additional medical treatment by the participant.

0-(0) Not at all
1-(1) S lightly
2-(2) Moderately
3-(3) Considerably
4-(4) Extremely

(AMM TI30D)

OR

(AMM I30NA) ☐ (97) Not Answered

Comments: (AMM I30CM)

Confidence Ratings: Is the above information **significantly** distorted by:

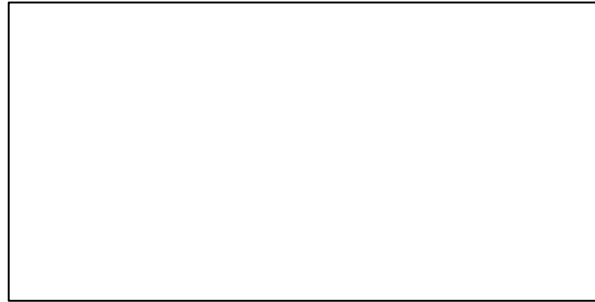
M10 Participant's misrepresentation?

(AMMISREP) ☐ (0) No ☐ (1) Yes

M11 Participant's inability to understand?

(AMUNDRST) ☐ (0) No ☐ (1) Yes

Comments: (AMCOMM)

A large, empty rectangular box with a thin black border, likely intended for a signature or stamp.

NIDA Clinical Trials Network

CTN-ASI Lite v. 1: Psychiatric Status (ASP)

Web Version: 1.0; 3.00; 04-09-12

Segment (*PROTSEG*):

Visit Number (*VISNO*):

CTN-ASI Lite v. 1 Follow-Up: Psychiatric Status

How many times since your last ASI have you been treated for any psychological or emotional problems?

- Do not include substance abuse, employment, or family counseling. Treatment episode = a series of more or less continuous visits or treatment days, not the number of visits or treatment days. Enter diagnosis in Comments if known.

P1 In a hospital or inpatient setting?

(*APPIHSPX*) (xx)

OR

(*APPIHPNA*) ☐ (97) Not Answered

Comments: (*APPIHCM*)

P2 Outpatient/private patient?

(*APPOHSPX*) (xx)

OR

(*APPOHPNA*) ☐ (97) Not Answered

Comments: (APPOHPCM)

P3 Do you receive a pension for a psychiatric disability?

(APPENPSY)

O-(0) No
1-(1) Yes
97-(97) Not answered

Comments: (APPENPCM)

Have you had a significant period of time (that was not a direct result of drug/alcohol use) in which you have:

A Past 30 Days

Comments

P4 Experienced serious depression-sadness, hopelessness, loss of interest, difficulty with daily function?

(APDEP30D)

O-(0) No
1-(1) Yes
97-(97) Not answered

(APDEPCM)

P5 Experienced serious anxiety/tension-up tight, unreasonably worried, inability to feel relaxed?

(APANX30D)

O-(0) No
1-(1) Yes
97-(97) Not answered

(APANXCM)

P6 Experienced hallucinations-saw things or heard voices that other people did not see or hear?

(APHLC30D)

0-(0) No

1-(1) Yes

97-(97) Not answered

(APHLCCM)

P7 Experienced trouble understanding, concentrating, or remembering?

(APCNC30D)

0-(0) No

1-(1) Yes

97-(97) Not answered

(APCNCCM)

For questions P8-P10, participant could have been under the influence of alcohol/drugs

P8 Experienced trouble controlling violent behavior including episodes of rage, or violence?

- Participant can be under the influence of alcohol/drugs.

A Past 30 Days

(APVL T30D)

0-(0) No

1-(1) Yes

97-(97) Not answered

Comments

(APVLTCM)

P9 Experienced serious thoughts of suicide?

- Participant seriously considered a plan for taking his/her life.

(APTOS30D)

0-(0) No

1-(1) Yes

97-(97) Not answered

(APTOSCM)

P10 Attempted suicide?

- Include actual suicidal gestures or attempts.

(APASU30D)

0-(0) No

1-(1) Yes

97-(97) Not answered

(APASUCM)

P11 Been prescribed medications for any psychological/emotional problem?

- Prescribed for the participant by MD.
Record "Yes" if a medication was prescribed **even if** the participant is not taking it.

(APMED30D)

0-(0) No

1-(1) Yes

97-(97) Not answered

(APMEDCM)

P12 How many days in the past 30 have you experienced these psychological or emotional problems?

- This refers to problems noted in questions P4-P10.

(APPRB30D) (xx) days

OR

(APPR30NA) ☐ (97) Not Answered

Comments:(APPR30CM)

For questions P13-P14, please ask participant to use the Participant Rating Scale.

P13 How much have you been troubled or bothered by these psychological or emotional problems in the past 30 days?

- Participant should be rating the problem days from question P12.

0-(0) Not at all
1-(1) Slightly
2-(2) Moderately
3-(3) Considerably
4-(4) Extremely

(APPR30D)

OR

(APPB30NA) ☐ (97) Not Answered

Comments:(APPB30CM)

P14 How important to you **now** is treatment for these psychological or emotional problems?

0-(0) Not at all
1-(1) Slightly
2-(2) Moderately
3-(3) Considerably
4-(4) Extremely

(APPT30D)

OR

(APPI30NA) ☐ (97) Not Answered

Comments:(APPI30CM)

Confidence Ratings: Is the above information **significantly** distorted by:

P22 Participant's misrepresentation?

(APMISREP) ☐ (0) No ☐ (1) Yes

P23 Participant's inability to understand?

(APUNDRST) ☐ (0) No ☐ (1) Yes

Comments:(APCOMM)

NIDA Clinical Trials Network

Buprenorphine/PLB and Naltrexone Blood Levels (BBL)

Web Version: 1.0; 2.02; 03-09-12

Segment (*PROTSEG*):

Visit Number (*VISNO*):

Date of assessment: (*BBLASMDT*)

(mm/dd/yyyy) [Click here for calendar](#)

1. Was a blood sample collected for the purpose of a buprenorphine/placebo and naltrexone pharmacokinetic analysis? (*BBBLDCLT*)

☐ No ☐ Yes

If "no", why? (*BBNBLDSP*)

2. Collection date: (*BBCLTDT*)

(mm/dd/yyyy) [Click here for calendar](#)

3. Collection time (24-hour format): (*BBCL TTM*)

(hh:mm)

4. Accession Number: (*BBPKACC*)

5. Date of last BUP/PLB dose: (*BBBUPDT*)

(mm/dd/yyyy) [Click here for calendar](#)

6. Time of last BUP/PLB dose (24 - hour format): (*BBBUP TM*)

(hh:mm)

a. Number of 2mg (small) tabs: (*BBBUP2MG*)

(x)

b. Number of 8mg (large) tabs: (*BBBUP8MG*)

(x)

7. Date of last XR-NTX dose: (*BBVVTLDT*)

(mm/dd/yyyy) [Click here for calendar](#)

8. Time of last XR-NTX dose (24 - hour format): (*BBVV TL TM*)

(hh:mm)

9. Was PK Primary Sample (3.6mL Pink Cap) shipped for analysis? (*BBPK1SHP*)

☐ No ☐ Yes

If "No", reason: (*BBPK1NSP*)

If "Yes", date shipped: (*BBPK1SDT*)

(mm/dd/yyyy) [Click here for calendar](#)

10. Was PK Secondary Sample (3.6mL Brown Cap) shipped for analysis? (*BBPK2SHP*)

☐ No ☐ Yes

If "Yes", reason: (*BBPK2NSP*)

If "Yes", date shipped: (*BBPK2SDT*)

(mm/dd/yyyy) [Click here for calendar](#)

Comments: (*BBLCOMM*)

NIDA Clinical Trials Network

Beck Depression Inventory (BDI)

Web Version: 1.0; 1.02; 06-14-12

Segment (*PROTSEG*):

Visit Number (*VISNO*):

Date of assessment (*BDCOMDT*):

(mm/dd/yyyy) [Click here for calendar](#)

INSTRUCTIONS: On this questionnaire are groups of statements. Please read each group carefully. Then pick out the one statement in each group which best describes the way you have been feeling. Click on the statement you picked in the box. Be sure to read all the statements in each group before making your choice.

1. (*BDSAD*)

0-I do not feel sad.
1-I feel sad.
2-I am sad all the time and I can't snap out of it.
3-I am so sad or unhappy that I can't stand it.

2. (*BDDISCOU*)

0-I am not particularly discouraged about my future.
1-I feel discouraged about the future.
2-I feel I have nothing to look forward to.
3-I feel that the future is hopeless and that things cannot improve.

3. (*BDFAILUR*)

0-I do not feel like a failure.
1-I feel I have failed more than the average person.
2-As I look back on my life all I can see is a lot of failures.
3-I feel I am a complete failure as a person.

4. (*BDSATISF*)

0-I get as much satisfaction out of things as I used to.
1-I don't enjoy things the way I used to.
2-I don't get real satisfaction out of anything anymore.
3-I am dissatisfied or bored with everything.

5. (*BDGUILTY*)

0-I don't feel particularly guilty.
1-I feel guilty a good part of the time.
2-I feel quite guilty most of the time.
3-I feel guilty all the time.

6. (*BDPUNISH*)

0-I don't feel I am being punished.
1-I feel I may be punished.
2-I expect to be punished.
3-I feel I am being punished.

7.(BDDISA PP)

0-I don't feel disappointed in myself.
1-I am disappointed in myself.
2-I am disgusted with myself.
3-I hate myself.

8.(BDBLM SLF)

0-I don't feel I am any worse than anybody else.
1-I am critical of myself for my weaknesses or mistakes.
2-I blame myself all the time for my faults.
3-I blame myself for everything bad that happens.

9.(BDSUICID)

0-I don't have any thoughts of killing myself.
1-I have thoughts of killing myself but I would not carry them out.
2-I would like to kill myself.
3-I would kill myself if I had the chance.

10.(BDCRY)

0-I don't cry more than usual.
1-I cry more than I used to.
2-I cry all the time now.
3-I used to be able to cry but now I can't cry even though I want to.

11.(BDIRRITA)

0-I am no more irritated now than I ever am.
1-I get annoyed or irritated more easily than I used to.
2-I feel irritated all the time now.
3-I don't get irritated at all by the things that used to irritate me.

12.(BDINTRST)

0-I have not lost interest in other people.
1-I am less interested in other people than I used to be.
2-I have lost most of my interest in other people.
3-I have lost all of my interest in other people.

13.(BDDECSN)

0-I make decisions about as well as I ever could.
1-I put off making decisions more than I used to.
2-I have greater difficulty in making decisions than before.
3-I can't make decisions at all any more.

14.(BDAPPEAR)

0-I don't feel I look worse than I used to.
1-I am worried that I am looking old or unattractive.
2-I feel that there are permanent changes in my appearance that make me look unattractive.
3-I believe that I look ugly.

15.(BDWORK)

0-I work about as well as before.
1-It takes extra effort to get started at doing something.
2-I have to push myself very hard to do anything.
3-I can't do any work at all.

16. (BDSL EEP)

0-I can sleep as well as usual.
1-I don't sleep as well as I used to.
2-I wake up 1-2 hours earlier than usual and find it hard to get back to sleep.
3-I wake up several hours earlier than I used to and cannot get back to sleep.

17. (BDT IRED)

0-I don't get any more tired than usual.
1-I get tired more easily than I used to.
2-I get tired from doing almost anything.
3-I am too tired to do anything.

18. (BDHUNGER)

0-My appetite is no worse than usual.
1-My appetite is not as good as it used to be.
2-My appetite is much worse now.
3-I have no appetite at all anymore.

19. (BDWEIGHT)

0-I haven't lost much weight, if any, lately.
1-I have lost more than 5 pounds.
2-I have lost more than 10 pounds.
3-I have lost more than 15 pounds.

20. I am purposely trying to lose weight by eating less. (BDEATING)

0-No
1-Yes

21. (BDWORRIE)

0-I am no more worried about my health than usual.
1-I am worried about physical problems such as aches and pains; or upset stomach; or constipation.
2-I am very worried about physical problems and it's hard to think of much else.
3-I am so worried about my physical problems, I can't think of anything else.

22. (BDSEX)

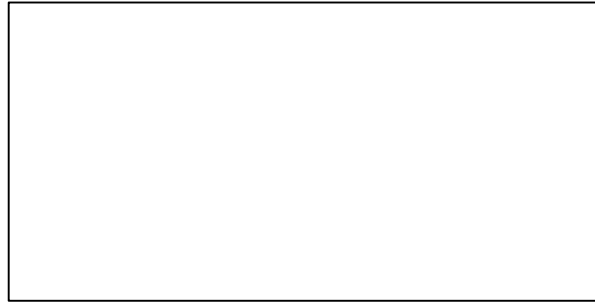
0-I have not noticed any recent change in my interest in sex.
1-I am less interested in sex than I used to be.
2-I am much less interested in sex now.
3-I have lost interest in sex completely.

23. (BDRLTSHP)

0-I am in a long term relationship/marriage.
1-My partner/spouse is not interested in sex.
2-I do not have a partner but I am interested in finding one.
3-I do not have a partner and I am not interested in finding one.

Total score: (BDSCORE)

Comments: (BD/COMM)



NIDA Clinical Trials Network

CBT Attendance Log (CBT)

Web Version: 1.0; 3.00; 08-20-12

Segment (PROTSEG):

Visit Number (VISNO):

Week	Start Date	End Date	Did a CBT session occur?	If "Yes", what was the date?	If "No", why?
Week 1	(CBWK1SRT) <input type="text"/>	(CBWK1END) <input type="text"/>	(CBWK1SES) <input type="checkbox"/> No <input type="checkbox"/> Yes	(CBWK1DT) <input type="text"/> (mm/dd/yyyy) Calendar	(CBWK1WHY) <input type="text"/>
Week 2	(CBWK2SRT) <input type="text"/>	(CBWK2END) <input type="text"/>	(CBWK2SES) <input type="checkbox"/> No <input type="checkbox"/> Yes	(CBWK2DT) <input type="text"/> (mm/dd/yyyy) Calendar	(CBWK2WHY) <input type="text"/>
Week 3	(CBWK3SRT) <input type="text"/>	(CBWK3END) <input type="text"/>	(CBWK3SES) <input type="checkbox"/> No <input type="checkbox"/> Yes	(CBWK3DT) <input type="text"/> (mm/dd/yyyy) Calendar	(CBWK3WHY) <input type="text"/>
Week 4	(CBWK4SRT) <input type="text"/>	(CBWK4END) <input type="text"/>	(CBWK4SES) <input type="checkbox"/> No <input type="checkbox"/> Yes	(CBWK4DT) <input type="text"/> (mm/dd/yyyy) Calendar	(CBWK4WHY) <input type="text"/>
Week 5	(CBWK5SRT) <input type="text"/>	(CBWK5END) <input type="text"/>	(CBWK5SES) <input type="checkbox"/> No <input type="checkbox"/> Yes	(CBWK5DT) <input type="text"/> (mm/dd/yyyy) Calendar	(CBWK5WHY) <input type="text"/>
Week 6	(CBWK6SRT) <input type="text"/>	(CBWK6END) <input type="text"/>	(CBWK6SES) <input type="checkbox"/> No <input type="checkbox"/> Yes	(CBWK6DT) <input type="text"/> (mm/dd/yyyy) Calendar	(CBWK6WHY) <input type="text"/>
Week 7	(CBWK7SRT) <input type="text"/>	(CBWK7END) <input type="text"/>	(CBWK7SES) <input type="checkbox"/> No <input type="checkbox"/> Yes	(CBWK7DT) <input type="text"/> (mm/dd/yyyy) Calendar	(CBWK7WHY) <input type="text"/>
Week 8	(CBWK8SRT) <input type="text"/>	(CBWK8END) <input type="text"/>	(CBWK8SES) <input type="checkbox"/> No <input type="checkbox"/> Yes	(CBWK8DT) <input type="text"/> (mm/dd/yyyy) Calendar	(CBWK8WHY) <input type="text"/>

Comments: (CBTCOMM)

NIDA Clinical Trials Network

Clinical Lab Tests (CLT)

Web Version: 1.0; 2.01; 06-14-12

Segment (*PROTSEG*):

Visit Number (*VISNO*):

Date of assessment: (*CLASMDT*)

(mm/dd/yyyy) [Click here for calendar](#)

1. Were clinical lab tests collected at this visit? (*CLLABS*)

☐ No ☐ Yes

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

2. Collection Date: (*CLTESTDT*)

(mm/dd/yyyy) [Click here for calendar](#)

3. Collection Time: (*CLTESTTM*)

(hh:mm) (24-hour clock)

4. Accession number: (*CLACSNUM*)

5. Was a sample submitted for PT w/INR, PTT (3.6mL Blue Cap)? (*CLPTINR*)

☐ No ☐ Yes If "No", reason: (*CLPTINNO*)

6. Was a sample submitted for Chemistry (6mL Plain Cap)? (*CLCHEMST*)

☐ No ☐ Yes If "No", reason: (*CLCHEMNO*)

7. Was a sample submitted for Hematology (2mL Lavender Cap/EDT A)? (*CLHEMAT*)

☐ No ☐ Yes If "No", reason: (*CLHEMANO*)

8. Was a sample submitted for Urinalysis (10mL Yellow Cap)? (*CLURINE*)

☐ No ☐ Yes If "No", reason: (*CLURNNO*)

9. Was a sample submitted for Hepatitis (6mL Yellow Cap)? (*CLHEP*)

☐ No ☐ Yes

a. If "Yes", accession number: (*CLHEPACC*)

b. If "No", reason: (*CLHEPNO*)

1-Participant did not consent
2-Participant was not randomized
9-Other

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

10. Was a sample submitted for HIV Antibody (6mL Blue Cap)? (*CLHIV*)

☐ No ☐ Yes

a. If "Yes", accession number: (*CLHIVACC*)

b. If "No", reason: (*CLHIVNO*)

1-Participant did not consent
2-Participant was not randomized
9-Other

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

11. Was a retest needed for any of these samples? (*CLRETEST*)

☐ Yes

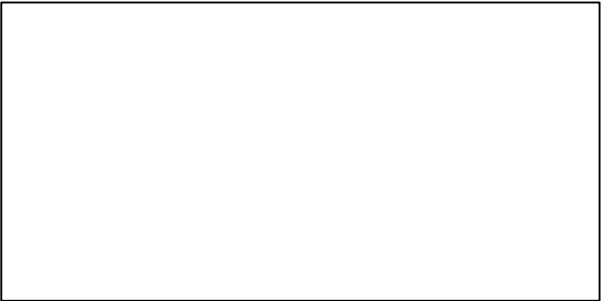
a. If "Yes", for which sample type(s):

PT w/INR, PTT: (*CLRTP TIR*) ☐ Chemistry: (*CLRTCHEM*) ☐ Hematology: (*CLRTHEM*) ☐

Urinalysis: (*CLRTURIN*) ☐ Hepatitis: (*CLRTHEP*) ☐ HIV Antibody: (*CLRTHIV*) ☐

b. If "Yes", accession number of the retest kit: (*CLACNUM2*)

Comments:(CL TCOMM)



Demographics (DEM)

Web Version: 1.0; 1.00; 06-03-11

1. Date of birth:(DEBRTHDT)

(mm/dd/yyyy)

2. Sex:(DEGENDER)

☐ Male

☐ Female

☐ Participant chooses not to answer

3. Ethnicity:(DEETHNIC)

☐ Hispanic or Latino

☐ Not Hispanic or Latino

☐ Participant chooses not to answer

4. Race:

American Indian or Alaska Native(DEAMEIND)

Asian(DEASIAN)

Black or African American(DEBLACK)

Native Hawaiian or Pacific Islander(DEHAWAII)

White(DEWHITE)

Other(DEOTHER)

If "Yes", specify:(DEOTHRSP)

☐ No

☐ Yes

☐ No

☐ Yes

☐ No

☐ Yes

☐ No

☐ Yes

☐ No

☐ Yes

☐ No

☐ Yes

OR

Unknown(DEUNKNOWN)

Participant chooses not to provide their race(DENORACE)

☐ Yes

☐ Yes

Comments:(DEMMCOMM)

NIDA Clinical Trials Network

BUP (or PLB) Dose Log (DL1)

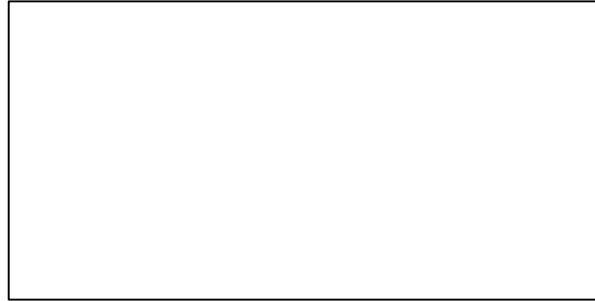
Web Version: 1.0; 1.00; 05-10-12

Segment (PROTSEG):

Visit Number (VISNO):

Day	Date	Dose Dispensed 2mg (# of pills)	Dose Dispensed 8mg (# of pills)	Location Dose Dispensed for:	Dose Taken 2mg (# of pills)	Dose Taken 8mg (# of pills)	Comments
Day 1 Ramp Up	(L1D1DT) 11/30/2010	(L11D2DSP) 0-0 1-1 2-2	(L11D8DSP) 0-0 1-1 2-2	(L11DLOCT) 1-In clinic 2-Take home	(L11D2TKN)	(L11D8TKN)	(L11DCOMM)
Day 2 Ramp Up	(L1D2DT) 12/1/2010	(L12D2DSP) 0-0 1-1 2-2	(L12D8DSP) 0-0 1-1 2-2	(L12DLOCT) 1-In clinic 2-Take home	(L12D2TKN)	(L12D8TKN)	(L12DCOMM)
Day 3	(L1D3DT) 12/2/2010	(L13D2DSP) 0-0 1-1 2-2	(L13D8DSP) 0-0 1-1 2-2	(L13DLOCT) 1-In clinic 2-Take home	(L13D2TKN)	(L13D8TKN)	(L13DCOMM)
Day 4	(L1D4DT) 12/3/2010	(L14D2DSP) 0-0 1-1 2-2	(L14D8DSP) 0-0 1-1 2-2	(L14DLOCT) 1-In clinic 2-Take home	(L14D2TKN)	(L14D8TKN)	(L14DCOMM)
Day 5	(L1D5DT) 12/4/2010	(L15D2DSP) 0-0 1-1 2-2	(L15D8DSP) 0-0 1-1 2-2	(L15DLOCT) 1-In clinic 2-Take home	(L15D2TKN)	(L15D8TKN)	(L15DCOMM)
Day 6	(L1D6DT) 12/5/2010	(L16D2DSP) 0-0 1-1 2-2	(L16D8DSP) 0-0 1-1 2-2	(L16DLOCT) 1-In clinic 2-Take home	(L16D2TKN)	(L16D8TKN)	(L16DCOMM)
Day 7	(L1D7DT) 12/6/2010	(L17D2DSP) 0-0 1-1 2-2	(L17D8DSP) 0-0 1-1 2-2	(L17DLOCT) 1-In clinic 2-Take home	(L17D2TKN)	(L17D8TKN)	(L17DCOMM)

Comments: *(DL1COMM)*



NIDA Clinical Trials Network

Week 2 BUP (or PLB) Dose Log (DL2)

Web Version: 1.0; 1.00; 05-10-12

Segment (PROTSEG):

Visit Number (VISNO):

Day	Date	Dose Dispensed 2mg (# of pills)	Dose Dispensed 8mg (# of pills)	Location Dose Dispensed for:	Dose Taken 2mg (# of pills)	Dose Taken 8mg (# of pills)	Comments
Day 8	(L2D1DT) 11/12/2010	(L21D2DSP) 0-0 1-1 2-2	(L21D8DSP) 0-0 1-1 2-2	(L21DLOCT) 1-In clinic 2-Take home	(L21D2TKN)	(L21D8TKN)	(L21DCOMM)
Day 9	(L2D2DT) 11/13/2010	(L22D2DSP) 0-0 1-1 2-2	(L22D8DSP) 0-0 1-1 2-2	(L22DLOCT) 1-In clinic 2-Take home	(L22D2TKN)	(L22D8TKN)	(L22DCOMM)
Day 10	(L2D3DT) 11/14/2010	(L23D2DSP) 0-0 1-1 2-2	(L23D8DSP) 0-0 1-1 2-2	(L23DLOCT) 1-In clinic 2-Take home	(L23D2TKN)	(L23D8TKN)	(L23DCOMM)
Day 11	(L2D4DT) 11/15/2010	(L24D2DSP) 0-0 1-1 2-2	(L24D8DSP) 0-0 1-1 2-2	(L24DLOCT) 1-In clinic 2-Take home	(L24D2TKN)	(L24D8TKN)	(L24DCOMM)
Day 12	(L2D5DT) 11/16/2010	(L25D2DSP) 0-0 1-1 2-2	(L25D8DSP) 0-0 1-1 2-2	(L25DLOCT) 1-In clinic 2-Take home	(L25D2TKN)	(L25D8TKN)	(L25DCOMM)
Day 13	(L2D6DT) 11/17/2010	(L26D2DSP) 0-0 1-1 2-2	(L26D8DSP) 0-0 1-1 2-2	(L26DLOCT) 1-In clinic 2-Take home	(L26D2TKN)	(L26D8TKN)	(L26DCOMM)
Day 14	(L2D7DT) 11/18/2010	(L27D2DSP) 0-0 1-1 2-2	(L27D8DSP) 0-0 1-1 2-2	(L27DLOCT) 1-In clinic 2-Take home	(L27D2TKN)	(L27D8TKN)	(L27DCOMM)

Comments: (DL2COMM)



NIDA Clinical Trials Network

Week 3 BUP (or PLB) Dose Log (DL3)

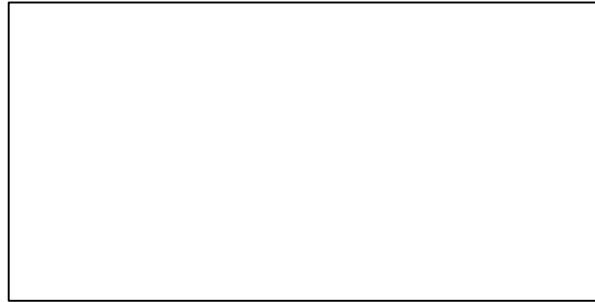
Web Version: 1.0; 1.00; 05-10-12

Segment (PROTSEG):

Visit Number (VISNO):

Day	Date	Dose Dispensed 2mg (# of pills)	Dose Dispensed 8mg (# of pills)	Location Dose Dispensed for:	Dose Taken 2mg (# of pills)	Dose Taken 8mg (# of pills)	Comments
Day 15	(L3D1DT) 12/9/2010	(L31D2DSP) 0-0 1-1 2-2	(L31D8DSP) 0-0 1-1 2-2	(L31DLOCT) 1-In clinic 2-Take home	(L31D2TKN)	(L31D8TKN)	(L31DCOMM)
Day 16	(L3D2DT) 12/10/2010	(L32D2DSP) 0-0 1-1 2-2	(L32D8DSP) 0-0 1-1 2-2	(L32DLOCT) 1-In clinic 2-Take home	(L32D2TKN)	(L32D8TKN)	(L32DCOMM)
Day 17	(L3D3DT) 12/11/2010	(L33D2DSP) 0-0 1-1 2-2	(L33D8DSP) 0-0 1-1 2-2	(L33DLOCT) 1-In clinic 2-Take home	(L33D2TKN)	(L33D8TKN)	(L33DCOMM)
Day 18	(L3D4DT) 12/12/2010	(L34D2DSP) 0-0 1-1 2-2	(L34D8DSP) 0-0 1-1 2-2	(L34DLOCT) 1-In clinic 2-Take home	(L34D2TKN)	(L34D8TKN)	(L34DCOMM)
Day 19	(L3D5DT) 12/13/2010	(L35D2DSP) 0-0 1-1 2-2	(L35D8DSP) 0-0 1-1 2-2	(L35DLOCT) 1-In clinic 2-Take home	(L35D2TKN)	(L35D8TKN)	(L35DCOMM)
Day 20	(L3D6DT) 12/14/2010	(L36D2DSP) 0-0 1-1 2-2	(L36D8DSP) 0-0 1-1 2-2	(L36DLOCT) 1-In clinic 2-Take home	(L36D2TKN)	(L36D8TKN)	(L36DCOMM)
Day 21	(L3D7DT) 12/15/2010	(L37D2DSP) 0-0 1-1 2-2	(L37D8DSP) 0-0 1-1 2-2	(L37DLOCT) 1-In clinic 2-Take home	(L37D2TKN)	(L37D8TKN)	(L37DCOMM)

Comments: (DL3COMM)



NIDA Clinical Trials Network

Week 4 BUP (or PLB) Dose Log (DL4)

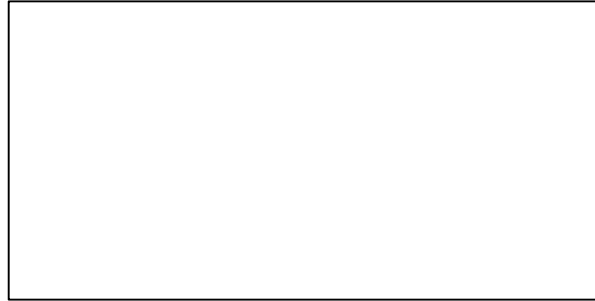
Web Version: 1.0; 1.00; 05-10-12

Segment (PROTSEG):

Visit Number (VISNO):

Day	Date	Dose Dispensed 2mg (# of pills)	Dose Dispensed 8mg (# of pills)	Location Dose Dispensed for:	Dose Taken 2mg (# of pills)	Dose Taken 8mg (# of pills)	Comments
Day 22	(L4D1DT) 12/21/2010	(L41D2DSP) 0-0 1-1 2-2	(L41D8DSP) 0-0 1-1 2-2	(L41DLOCT) 1-In clinic 2-Take home	(L41D2TKN)	(L41D8TKN)	(L41DCOMM)
Day 23	(L4D2DT) 12/22/2010	(L42D2DSP) 0-0 1-1 2-2	(L42D8DSP) 0-0 1-1 2-2	(L42DLOCT) 1-In clinic 2-Take home	(L42D2TKN)	(L42D8TKN)	(L42DCOMM)
Day 24	(L4D3DT) 12/23/2010	(L43D2DSP) 0-0 1-1 2-2	(L43D8DSP) 0-0 1-1 2-2	(L43DLOCT) 1-In clinic 2-Take home	(L43D2TKN)	(L43D8TKN)	(L43DCOMM)
Day 25	(L4D4DT) 12/24/2010	(L44D2DSP) 0-0 1-1 2-2	(L44D8DSP) 0-0 1-1 2-2	(L44DLOCT) 1-In clinic 2-Take home	(L44D2TKN)	(L44D8TKN)	(L44DCOMM)
Day 26	(L4D5DT) 12/25/2010	(L45D2DSP) 0-0 1-1 2-2	(L45D8DSP) 0-0 1-1 2-2	(L45DLOCT) 1-In clinic 2-Take home	(L45D2TKN)	(L45D8TKN)	(L45DCOMM)
Day 27	(L4D6DT) 12/26/2010	(L46D2DSP) 0-0 1-1 2-2	(L46D8DSP) 0-0 1-1 2-2	(L46DLOCT) 1-In clinic 2-Take home	(L46D2TKN)	(L46D8TKN)	(L46DCOMM)
Day 28	(L4D7DT) 12/27/2010	(L47D2DSP) 0-0 1-1 2-2	(L47D8DSP) 0-0 1-1 2-2	(L47DLOCT) 1-In clinic 2-Take home	(L47D2TKN)	(L47D8TKN)	(L47DCOMM)

Comments: *(DL4COMM)*



NIDA Clinical Trials Network

Week 5 BUP (or PLB) Dose Log (DL5)

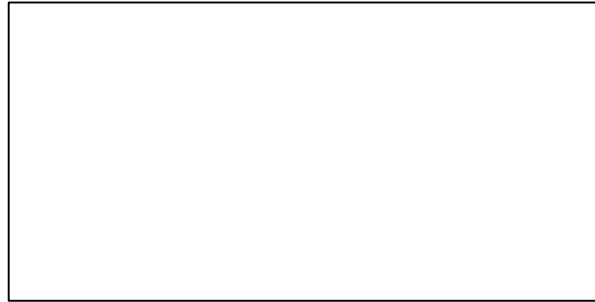
Web Version: 1.0; 1.00; 05-10-12

Segment (PROTSEG):

Visit Number (VISNO):

Day	Date	Dose Dispensed 2mg (# of pills)	Dose Dispensed 8mg (# of pills)	Location Dose Dispensed for:	Dose Taken 2mg (# of pills)	Dose Taken 8mg (# of pills)	Comments
Day 29	(L5D1DT) 12/28/2010	(L51D2DSP) 0-0 1-1 2-2	(L51D8DSP) 0-0 1-1 2-2	(L51DLOCT) 1-In clinic 2-Take home	(L51D2TKN)	(L51D8TKN)	(L51DCOMM)
Day 30	(L5D2DT) 12/29/2010	(L52D2DSP) 0-0 1-1 2-2	(L52D8DSP) 0-0 1-1 2-2	(L52DLOCT) 1-In clinic 2-Take home	(L52D2TKN)	(L52D8TKN)	(L52DCOMM)
Day 31	(L5D3DT) 12/30/2010	(L53D2DSP) 0-0 1-1 2-2	(L53D8DSP) 0-0 1-1 2-2	(L53DLOCT) 1-In clinic 2-Take home	(L53D2TKN)	(L53D8TKN)	(L53DCOMM)
Day 32	(L5D4DT) 12/31/2010	(L54D2DSP) 0-0 1-1 2-2	(L54D8DSP) 0-0 1-1 2-2	(L54DLOCT) 1-In clinic 2-Take home	(L54D2TKN)	(L54D8TKN)	(L54DCOMM)
Day 33	(L5D5DT) 1/1/2011	(L55D2DSP) 0-0 1-1 2-2	(L55D8DSP) 0-0 1-1 2-2	(L55DLOCT) 1-In clinic 2-Take home	(L55D2TKN)	(L55D8TKN)	(L55DCOMM)
Day 34	(L5D6DT) 1/2/2011	(L56D2DSP) 0-0 1-1 2-2	(L56D8DSP) 0-0 1-1 2-2	(L56DLOCT) 1-In clinic 2-Take home	(L56D2TKN)	(L56D8TKN)	(L56DCOMM)
Day 35	(L5D7DT) 1/3/2011	(L57D2DSP) 0-0 1-1 2-2	(L57D8DSP) 0-0 1-1 2-2	(L57DLOCT) 1-In clinic 2-Take home	(L57D2TKN)	(L57D8TKN)	(L57DCOMM)

Comments: (DL5COMM)



NIDA Clinical Trials Network

Week 6 BUP (or PLB) Dose Log (DL6)

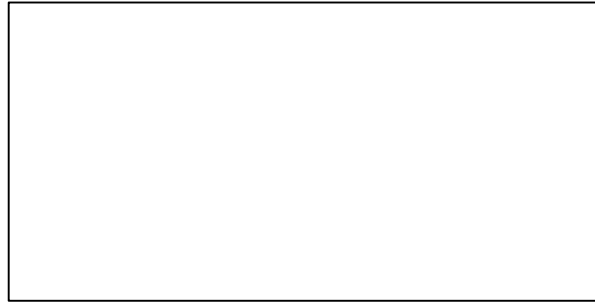
Web Version: 1.0; 1.00; 05-10-12

Segment (PROTSEG):

Visit Number (VISNO):

Day	Date	Dose Dispensed 2mg (# of pills)	Dose Dispensed 8mg (# of pills)	Location Dose Dispensed for:	Dose Taken 2mg (# of pills)	Dose Taken 8mg (# of pills)	Comments
Day 36	(L6D1DT) 1/4/2011	(L61D2DSP) 0-0 1-1 2-2	(L61D8DSP) 0-0 1-1 2-2	(L61DLOCT) 1-In clinic 2-Take home	(L61D2TKN)	(L61D8TKN)	(L61DCOMM)
Day 37	(L6D2DT) 1/5/2011	(L62D2DSP) 0-0 1-1 2-2	(L62D8DSP) 0-0 1-1 2-2	(L62DLOCT) 1-In clinic 2-Take home	(L62D2TKN)	(L62D8TKN)	(L62DCOMM)
Day 38	(L6D3DT) 1/6/2011	(L63D2DSP) 0-0 1-1 2-2	(L63D8DSP) 0-0 1-1 2-2	(L63DLOCT) 1-In clinic 2-Take home	(L63D2TKN)	(L63D8TKN)	(L63DCOMM)
Day 39	(L6D4DT) 1/7/2011	(L64D2DSP) 0-0 1-1 2-2	(L64D8DSP) 0-0 1-1 2-2	(L64DLOCT) 1-In clinic 2-Take home	(L64D2TKN)	(L64D8TKN)	(L64DCOMM)
Day 40	(L6D5DT) 1/8/2011	(L65D2DSP) 0-0 1-1 2-2	(L65D8DSP) 0-0 1-1 2-2	(L65DLOCT) 1-In clinic 2-Take home	(L65D2TKN)	(L65D8TKN)	(L65DCOMM)
Day 41	(L6D6DT) 1/9/2011	(L66D2DSP) 0-0 1-1 2-2	(L66D8DSP) 0-0 1-1 2-2	(L66DLOCT) 1-In clinic 2-Take home	(L66D2TKN)	(L66D8TKN)	(L66DCOMM)
Day 42	(L6D7DT) 1/10/2011	(L67D2DSP) 0-0 1-1 2-2	(L67D8DSP) 0-0 1-1 2-2	(L67DLOCT) 1-In clinic 2-Take home	(L67D2TKN)	(L67D8TKN)	(L67DCOMM)

Comments: (DL6COMM)



NIDA Clinical Trials Network

Week 7 BUP (or PLB) Dose Log (DL7)

Web Version: 1.0; 1.00; 05-10-12

Segment (PROTSEG):

Visit Number (VISNO):

Day	Date	Dose Dispensed 2mg (# of pills)	Dose Dispensed 8mg (# of pills)	Location Dose Dispensed for:	Dose Taken 2mg (# of pills)	Dose Taken 8mg (# of pills)	Comments
Day 43	(L7D1DT) 1/11/2011	(L71D2DSP) 0-0 1-1 2-2	(L71D8DSP) 0-0 1-1 2-2	(L71DLOCT) 1-In clinic 2-Take home	(L71D2TKN)	(L71D8TKN)	(L71DCOMM)
Day 44	(L7D2DT) 1/12/2011	(L72D2DSP) 0-0 1-1 2-2	(L72D8DSP) 0-0 1-1 2-2	(L72DLOCT) 1-In clinic 2-Take home	(L72D2TKN)	(L72D8TKN)	(L72DCOMM)
Day 45	(L7D3DT) 1/13/2011	(L73D2DSP) 0-0 1-1 2-2	(L73D8DSP) 0-0 1-1 2-2	(L73DLOCT) 1-In clinic 2-Take home	(L73D2TKN)	(L73D8TKN)	(L73DCOMM)
Day 46	(L7D4DT) 1/14/2011	(L74D2DSP) 0-0 1-1 2-2	(L74D8DSP) 0-0 1-1 2-2	(L74DLOCT) 1-In clinic 2-Take home	(L74D2TKN)	(L74D8TKN)	(L74DCOMM)
Day 47	(L7D5DT) 1/15/2011	(L75D2DSP) 0-0 1-1 2-2	(L75D8DSP) 0-0 1-1 2-2	(L75DLOCT) 1-In clinic 2-Take home	(L75D2TKN)	(L75D8TKN)	(L75DCOMM)
Day 48	(L7D6DT) 1/16/2011	(L76D2DSP) 0-0 1-1 2-2	(L76D8DSP) 0-0 1-1 2-2	(L76DLOCT) 1-In clinic 2-Take home	(L76D2TKN)	(L76D8TKN)	(L76DCOMM)
Day 49	(L7D7DT) 1/17/2011	(L77D2DSP) 0-0 1-1 2-2	(L77D8DSP) 0-0 1-1 2-2	(L77DLOCT) 1-In clinic 2-Take home	(L77D2TKN)	(L77D8TKN)	(L77DCOMM)

Comments: (DL7COMM)



NIDA Clinical Trials Network

Week 8 BUP (or PLB) Dose Log (DL8)

Web Version: 1.0; 1.00; 05-10-12

Segment (PROTSEG):

Visit Number (VISNO):

Day	Date	Dose Dispensed 2mg (# of pills)	Dose Dispensed 8mg (# of pills)	Location Dose Dispensed for:	Dose Taken 2mg (# of pills)	Dose Taken 8mg (# of pills)	Comments
Day 50	(L8D1DT) 1/18/2011	(L81D2DSP) 0-0 1-1 2-2	(L81D8DSP) 0-0 1-1 2-2	(L81DLOCT) 1-In clinic 2-Take home	(L81D2TKN)	(L81D8TKN)	(L81DCOMM)
Day 51	(L8D2DT) 1/19/2011	(L82D2DSP) 0-0 1-1 2-2	(L82D8DSP) 0-0 1-1 2-2	(L82DLOCT) 1-In clinic 2-Take home	(L82D2TKN)	(L82D8TKN)	(L82DCOMM)
Day 52	(L8D3DT) 1/20/2011	(L83D2DSP) 0-0 1-1 2-2	(L83D8DSP) 0-0 1-1 2-2	(L83DLOCT) 1-In clinic 2-Take home	(L83D2TKN)	(L83D8TKN)	(L83DCOMM)
Day 53	(L8D4DT) 1/21/2011	(L84D2DSP) 0-0 1-1 2-2	(L84D8DSP) 0-0 1-1 2-2	(L84DLOCT) 1-In clinic 2-Take home	(L84D2TKN)	(L84D8TKN)	(L84DCOMM)
Day 54	(L8D5DT) 1/22/2011	(L85D2DSP) 0-0 1-1 2-2	(L85D8DSP) 0-0 1-1 2-2	(L85DLOCT) 1-In clinic 2-Take home	(L85D2TKN)	(L85D8TKN)	(L85DCOMM)
Day 55 Taper	(L8D6DT) 1/23/2011	(L86D2DSP) 0-0 1-1 2-2	(L86D8DSP) 0-0 1-1 2-2	(L86DLOCT) 1-In clinic 2-Take home	(L86D2TKN)	(L86D8TKN)	(L86DCOMM)
Day 56 Taper	(L8D7DT) 1/24/2011	(L87D2DSP) 0-0 1-1 2-2	(L87D8DSP) 0-0 1-1 2-2	(L87DLOCT) 1-In clinic 2-Take home	(L87D2TKN)	(L87D8TKN)	(L87DCOMM)

Comments: (DL8COMM)



NIDA Clinical Trials Network

Electrocardiogram (ECG) Results (ECG)

Web Version: 1.0; 1.06; 07-17-12

Segment (*PROTSEG*):

Visit Number (*VISNO*):

Date of assessment: (*ECASMDT*)

(mm/dd/yyyy) [Click here to view calendar](#)

12-Lead Electrocardiogram (ECG)

1. Normal sinus rhythm? (*ECSINRTM*)

☐ No ☐ Yes

2. Ventricular Rate: (*ECVENTRT*)

(bpm)

3. QTc interval: (*ECQTC*)

(ms)

4. PR interval: (*ECPR*)

(ms)

5. QRS duration: (*ECQRS*)

(ms)

6. PRT Axis: (*EC1PRXS*)

(*EC2PRXS*) (*EC3PRXS*)

Results Relating to Eligibility Criteria (automatically excludes)

	Not Present	Present
a. QTc Prolongation (<i>ECQTCPLG</i>)	<input type="checkbox"/>	<input type="checkbox"/>
b. Atrial Fibrillation (<i>ECATFIB</i>)	<input type="checkbox"/>	<input type="checkbox"/>
c. Atrial Flutter (<i>ECATFLR</i>)	<input type="checkbox"/>	<input type="checkbox"/>
d. 2nd Degree A-V Block (<i>EC2A VBLK</i>)	<input type="checkbox"/>	<input type="checkbox"/>
e. 3rd Degree A-V Block (<i>EC3A VBLK</i>)	<input type="checkbox"/>	<input type="checkbox"/>

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

0-Normal
1-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 (<i>ECQRSINC</i>)	<input type="checkbox"/>	<input type="checkbox"/>	u. Supraventricular Premature Beat (<i>ECSVPB</i>)	<input type="checkbox"/>	<input type="checkbox"/>
g. Left Atrial Hypertrophy (<i>ECLAHYPY</i>)	<input type="checkbox"/>	<input type="checkbox"/>	v. Ventricular Premature Beat (<i>ECVPB</i>)	<input type="checkbox"/>	<input type="checkbox"/>
h. Right Atrial Hypertrophy (<i>ECRAHYPY</i>)	<input type="checkbox"/>	<input type="checkbox"/>	w. Supraventricular Tachycardia (<i>ECSPVTTY</i>)	<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	(EACTINF) <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	(ECOTHIVB) <input type="checkbox"/>	<input type="checkbox"/>
q. Poor R-Wave Progression	(ECPRWPG) <input type="checkbox"/>	<input type="checkbox"/>	ff. Other abnormal result	(ECOTH) <input type="checkbox"/>	<input type="checkbox"/>
r. Other nonspecific ST/T	(ECOTHSTT) <input type="checkbox"/>	<input type="checkbox"/>	If "Other abnormal result", specify:		
s. Sinus Tachycardia	(ECSTACHY) <input type="checkbox"/>	<input type="checkbox"/>	(ECOTHSP) <input type="text"/>		
t. Sinus Bradycardia	(ECSBRADY) <input type="checkbox"/>	<input type="checkbox"/>			

8. ECG summary: (refer to ECG for details)(ECSUMRY)

0-Normal
1-Abnormal

If normal, skip the "ECG Findings" grid [questions a-ff] .

ECG Findings (include borderline)

	Not Present	Present		Not Present	Present
a. Increased QRS Voltage	(ECQRSINC) <input type="checkbox"/>	<input type="checkbox"/>	q. Supraventricular Premature Beat	(ECVVPB) <input type="checkbox"/>	<input type="checkbox"/>
b. QTc Prolongation	(ECQTCPLG) <input type="checkbox"/>	<input type="checkbox"/>	r. Ventricular Premature Beat	(ECVPB) <input type="checkbox"/>	<input type="checkbox"/>
c. Left Atrial Hypertrophy	(ECLAHYPY) <input type="checkbox"/>	<input type="checkbox"/>	s. Supraventricular Tachycardia	(ECSPVTTY) <input type="checkbox"/>	<input type="checkbox"/>
d. Right Atrial Hypertrophy	(ECRAHYPY) <input type="checkbox"/>	<input type="checkbox"/>	t. Ventricular Tachycardia	(ECVTTY) <input type="checkbox"/>	<input type="checkbox"/>
e. Left Ventricular Hypertrophy	(ECLVHYPY) <input type="checkbox"/>	<input type="checkbox"/>	u. Atrial Fibrillation	(ECATFIB) <input type="checkbox"/>	<input type="checkbox"/>
f. Right Ventricular Hypertrophy	(ECRVHYP) <input type="checkbox"/>	<input type="checkbox"/>	v. Atrial Flutter	(ECATFLR) <input type="checkbox"/>	<input type="checkbox"/>
g. Acute Infarction	(EACTINF) <input type="checkbox"/>	<input type="checkbox"/>	w. Other Rhythm Abnormalities	(ECOTHRA) <input type="checkbox"/>	<input type="checkbox"/>
h. Subacute Infarction	(ECSATINF) <input type="checkbox"/>	<input type="checkbox"/>	x. Implanted Pacemaker	(ECPACEMK) <input type="checkbox"/>	<input type="checkbox"/>
i. Old Infarction	(ECINFOLD) <input type="checkbox"/>	<input type="checkbox"/>	y. 1st Degree A-V Block	(EC1AVBLK) <input type="checkbox"/>	<input type="checkbox"/>
j. Myocardial Ischemia	(ECMYISCH) <input type="checkbox"/>	<input type="checkbox"/>	z. 2nd Degree A-V Block	(EC2AVBLK) <input type="checkbox"/>	<input type="checkbox"/>
k. Digitalis Effect	(ECDGTEFT) <input type="checkbox"/>	<input type="checkbox"/>	aa. 3rd Degree A-V Block	(EC3AVBLK) <input type="checkbox"/>	<input type="checkbox"/>
l. Symmetrical T-Wave Inversions	(ECSTWI) <input type="checkbox"/>	<input type="checkbox"/>	bb. LBB Block	(ECLBBBLK) <input type="checkbox"/>	<input type="checkbox"/>
m. Poor R-Wave Progression	(ECPRWPG) <input type="checkbox"/>	<input type="checkbox"/>	cc. RBB Block	(ECRBBBLK) <input type="checkbox"/>	<input type="checkbox"/>
n. Other nonspecific ST/T	(ECOTHSTT) <input type="checkbox"/>	<input type="checkbox"/>	dd. Pre-excitation syndrome	(ECPES) <input type="checkbox"/>	<input type="checkbox"/>

o. Sinus Tachycardia	(ECSTACHY) <input type="checkbox"/>	<input type="checkbox"/>	ee. Other Intraventricular Conduction Delay	(ECOTHIVB) <input type="checkbox"/>	<input type="checkbox"/>
p. Sinus Bradycardia	(ECSBRADY) <input type="checkbox"/>	<input type="checkbox"/>	ff. Other abnormal result	(ECOTH) <input type="checkbox"/>	<input type="checkbox"/>

If "Other abnormal result", Specify: (ECOTHSP)

9. Does the participant have evidence of second or third degree heart block, atrial fibrillation, atrial flutter, prolongation of the QTc (results relating to eligibility criteria grid); in addition, have any other finding on the screening ECG that, in the opinion of the medical clinician, would preclude safe participation in the study and would also be exclusionary?(ECGELIG) ☐ No ☐ Yes

10. Based on the ECG, is there anything, in the opinion of the medical clinician, that would preclude continued participation in the study?(ECCNTPPT) ☐ No ☐ Yes

Comments:(ECGCOMM)

NIDA Clinical Trials Network

End of Medication (EOM)

Web Version: 1.0; 2.00; 07-10-12

Segment (PROTSEG):

- Date of assessment:(EOASMTDT)
1. Did the participant discontinue study medication early?(EOMEDERL)
Primary reason for not completing study medication:(EOSTPRSN)
- If "Other", specify:(EOSTPMSP)
2. Was end-of-medication visit scheduled?(EOMSCHED)
3. Was end-of-medication visit completed?(EOMCOMPL)
4. Date of last Vivitrol administration:(EOVTRLDT)
5. Date of last Suboxone and/or Placebo dose:(EOSBXNDT)
6. Was last Suboxone and/or Placebo dose verified by participant self-report?(EOSBVRFY)
- Comments:(EOMCOMM)

(mm/dd/yyyy) [Click here for calendar](#)

☐ No ☐ Yes

1-Participant became pregnant
20-Participant experienced intolerable side effects
2-Participant continued to experience intolerable side effects after a dose reduction
3-Clinical deterioration: Initiation or recurrence of risky behaviors
4-Clinical deterioration: Overdose
*Additional Options Listed Below

☐ No ☐ Yes

☐ No ☐ Yes

(mm/dd/yyyy) [Click here for calendar](#)

(mm/dd/yyyy) [Click here for calendar](#)

Location:(EOSBXLCT)

☐ No ☐ Yes

1-In clinic
2-Take home

Additional Selection Options for EOM

Primary reason for not completing study medication:

- 5-Clinical deterioration: Emergence of psychiatric impairment or dangerous behavior
- 6-Clinical deterioration: Evidence of medical deterioration
- 7-Clinical deterioration: New onset of psychiatric or medical condition
- 8-Physical illness or condition that precludes taking study medication(s)
- 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-Participant discharged for administrative reasons (behavioral problems, noncompliance)
- 95-Investigator chose to discontinue medication for other reasons
- 94-Participant chose to discontinue medication for other reasons
- 21-Participant chose to discontinue medication for unspecified reasons
- 99-Other

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End of Study (EOS)

Web Version: 1.0; 1.01; 04-05-13

1. Date of assessment: *(EOTRMDT)*

(mm/dd/yyyy) [Click here for calendar](#)

2. Is data reporting for this participant complete? *(EOCOMPLT)*

☐ Yes

Comments: *(EOSCOMM)*

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 or designee: *(TRPISIGN)*

Date: *(TRPISGDT)*

(mm/dd/yyyy)

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0048B (ENR)

Web Version: 1.0; 1.01; 06-08-12

Date of assessment: (R4ASMTDT)

(mm/dd/yyyy) [Click here for calendar](#)

Inclusion Criteria

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

- | | | | |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|------------------------------|----------------------------------|
| 1. Is between the ages of 18 and 65? (R4PTAGE) | <input type="checkbox"/> No | <input type="checkbox"/> Yes | <input type="checkbox"/> Unknown |
| 2. Is in good general health? (R4HEALTH) | <input type="checkbox"/> No | <input type="checkbox"/> Yes | <input type="checkbox"/> Unknown |
| 3. Meets DSM-IV criteria for cocaine dependence? (R4COPDEP) | <input type="checkbox"/> No | <input type="checkbox"/> Yes | <input type="checkbox"/> Unknown |
| 4. Has either past-year opioid abuse or dependence (DSM-IV) or past-year opioid use and a history of opioid dependence during the lifetime (DSM-IV Addendum)? (R4PYOPUS) | <input type="checkbox"/> No | <input type="checkbox"/> Yes | <input type="checkbox"/> Unknown |
| 5. Is interested in receiving treatment for cocaine dependence? (R4SKTRT) | <input type="checkbox"/> No | <input type="checkbox"/> Yes | <input type="checkbox"/> Unknown |
| 6. Provided a negative urine drug screen for opioids immediately prior to naloxone challenge? (R4NEGUDS) | <input type="checkbox"/> No | <input type="checkbox"/> Yes | <input type="checkbox"/> Unknown |
| 7. Meets objective or subjective definition of being "opioid detoxified" as per study medical clinician's determination? (R4DETOX) | <input type="checkbox"/> No | <input type="checkbox"/> Yes | <input type="checkbox"/> Unknown |
| 8. Is able to tolerate induction onto oral naltrexone and XR-NTX? (R4TOLNAL) | <input type="checkbox"/> No | <input type="checkbox"/> Yes | <input type="checkbox"/> Unknown |
| 9. If female of childbearing potential, is willing to practice an effective method of birthcontrol for the duration of participation in the study? (R4BCUSE) | <input type="checkbox"/> No | <input type="checkbox"/> Yes | <input type="checkbox"/> Unknown |
| 10. Is able to speak English sufficiently to understand the study procedures and provide written informed consent to participate in the study? (R4OKCSNT) | <input type="checkbox"/> No | <input type="checkbox"/> Yes | <input type="checkbox"/> Unknown |

☐ N/A

Exclusion Criteria

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

- | | | | |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------|------------------------------|----------------------------------|
| 1. Shows evidence of an acute psychiatric disorder as assessed by the study medical clinician that would make participation difficult or unsafe? (R4PSYCH) | <input type="checkbox"/> No | <input type="checkbox"/> Yes | <input type="checkbox"/> Unknown |
| 2. Exhibits suicidal or homicidal ideation that requires immediate attention? (R4SUICDE) | <input type="checkbox"/> No | <input type="checkbox"/> Yes | <input type="checkbox"/> Unknown |
| 3. Has a known allergy or sensitivity to buprenorphine, naloxone, naltrexone, PLG (polyactide-co-glycolide), carboxymethylcellulose or any other component of the XR-NTX diluent? (R4ALGY) | <input type="checkbox"/> No | <input type="checkbox"/> Yes | <input type="checkbox"/> Unknown |
| 4. Has a serious medical illness that, in the opinion of the medical clinician, would make participation medically hazardous? (R4MEDILN) | <input type="checkbox"/> No | <input type="checkbox"/> Yes | <input type="checkbox"/> Unknown |
| 5. 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 the participant from participating safely in the study will also be exclusionary)? (R4HEART) | <input type="checkbox"/> No | <input type="checkbox"/> Yes | <input type="checkbox"/> Unknown |
| 6. Has any LFT values > 5 times the upper limit of normal as per laboratory criteria? (R4LFTVAL) | <input type="checkbox"/> No | <input type="checkbox"/> Yes | <input type="checkbox"/> Unknown |
| 7. Has INR >1.5 or platelet count <100k? (R4INR) | <input type="checkbox"/> No | <input type="checkbox"/> Yes | <input type="checkbox"/> Unknown |
| 8. Has a body habitus that precludes gluteal intramuscular injection of naltrexone with provided needle? (R4NOIMU) | <input type="checkbox"/> No | <input type="checkbox"/> Yes | <input type="checkbox"/> Unknown |
| 9. Has taken an investigational drug study within 30 days of study consent? (R4PTO THS) | <input type="checkbox"/> No | <input type="checkbox"/> Yes | <input type="checkbox"/> Unknown |
| 10. Is receiving ongoing treatment with tricyclic antidepressants, chlorpromazine, modafinil, disulfuram, or any medication that, in the judgment of the study medical clinician, could interact adversely with study drugs? (R4MEDAE) | <input type="checkbox"/> No | <input type="checkbox"/> Yes | <input type="checkbox"/> Unknown |

11. Has participated in a methadone maintenance program within 15 days of study consent?(R4MTHMPG)

☐ No☐ Yes☐ Unknown
12. Has participated in a buprenorphine maintenance treatment within 30 days of study consent?(R4BUPMTN)

☐ No☐ Yes☐ Unknown
13. Has pending legal action or other reasons that might prevent the individual from remaining in the area for the duration of the study?(R4NOMOVE)

☐ No☐ Yes☐ Unknown
14. Has a surgery planned or scheduled during the study period?(R4SURGRY)

☐ No☐ Yes☐ Unknown
15. Requires therapy with opioid-containing medicines (e.g., opioid analgesics) during the study period?(R4NDMEDS)

☐ No☐ Yes☐ Unknown
16. Has a current pattern of alcohol, benzodiazepine, or sedative-hypnotic use, as determined by the study medical clinician which would preclude safe participation in the study?(R4DEPRUS)

☐ No☐ Yes☐ Unknown
17. If female, is currently pregnant or breastfeeding?(R4PREGNT)

☐ No☐ Yes☐ Unknown☐ N/A

Eligibility for Randomization

1. Is the participant eligible for the study?(R4ELGSTY)

☐ No☐ Yes
2. Is the participant eligible for randomization?(R4ELGRDM)

☐ No☐ Yes
- If "No", specify:(R4NORSP)

2-Declined study participation

3-Death

4-Judgement of CTP/research staff

5-Failed to return to clinic prior to randomization

9-Other

If "Judgment of research staff", specify:(R4JGTSP)

If "Other", specify:(R4OTHRSP)

Opioid Use

- Ever injected an opioid?(R4OPINJ)

☐ No☐ Yes☐ Unknown
- Greater than or equal to 2 years of regular opioid use?(R42YRUSE)

☐ No☐ Yes☐ Unknown
- Opioid use on 20 or more days in the month preceding screening?(R45XWKUS)

☐ No☐ Yes☐ Unknown
3. Opioid use level:(R4OPUSLV)

☐ Low☐ High☐ Unknown

Comments:(R4COMM)

NIDA Clinical Trials Network

Fagerstrom Test for Nicotine Dependence (FTD)

Web Version: 1.0; 1.03; 06-14-12

Segment (*PROTSEG*):

Visit Number (*VISNO*):

Date of assessment: (*FDA SMTDT*)

(mm/dd/yyyy) [Click here for calendar](#)

Do you currently smoke cigarettes? (*FDSMOKE*)

☐ No ☐ Yes

If "Yes", please read each question below. For each question enter the answer choice which best describes your responses.

1. How soon after you wake up do you smoke your first cigarette? (*FTFSTCIG*)

3-(3) Within 5 minutes
2-(2) 6 - 30 minutes
1-(1) 31 - 60 minutes
0-(0) After 60 minutes

2. Do you find it difficult to refrain from smoking in places where it is forbidden, e.g., in church, at the library, in cinema, etc.? (*FDFORBID*)

1-(1) Yes
0-(0) No

3. Which cigarette would you hate most to give up? (*FDGIVEUP*)

1-(1) The first one in the morning
0-(0) All others

4. How many cigarettes/day do you smoke? (*FDPERDAY*)

0-(0) 10 or less
1-(1) 11-20
2-(2) 21-30
3-(3) 31 or more

5. Do you smoke more frequently during the first hours after waking than during the rest of the day? (*FDFREQ*)

1-(1) Yes
0-(0) No

6. Do you smoke if you are so ill that you are in bed most of the day? (*FDILL*)

1-(1) Yes
0-(0) No

Comments: (FTDCOMM)



Heatherton TF; Kozlowski LT; Frecker RC; The Fagerström Test for Nicotine Dependence: a revision of the Fagerström Tolerance Questionnaire. *Br J Addict* (1991), 86, 119-1127.

NIDA Clinical Trials Network

Genetics Consent and Shipping Confirmation (GEN)

Web Version: 1.0; 2.02; 06-14-12

Segment (PROTSEG):

Date of assessment(*GENASMDT*)

(mm/dd/yyyy) [Click here for calendar](#)

1. Did the participant agree to participate in the Genetics Study? (*GECNST*)

☐ No ☐ Yes

a. If "Yes", what date was consent given? (*GECNSTDT*)

(mm/dd/yyyy) [Click here for calendar](#)

b. If "Yes", what is the genetics study ID? (*GEGENID*)

XXX-XXXXXX

c. If "Yes", what is the alternate ID? (*GEALTID*)

XXXXXXXX

2. Was a sample collected? (*GESAMPLE*)

☐ No ☐ Yes

a. If "Yes", what type of sample was collected? (*GESMPLTP*)

1-Blood
2-Saliva

b. If "Yes", what date was the sample collected? (*GETAKNDT*)

(mm/dd/yyyy) [Click here for calendar](#)

c. If "Yes", what date was the sample shipped? (*GESHIPDT*)

(mm/dd/yyyy) [Click here for calendar](#)

d. If a saliva sample was given, was a blood sample collected at a later date? (*GE2NDBLD*)

☐ No ☐ Yes

1. If "Yes", what date was the blood sample collected? (*GE2NDDT*)

(mm/dd/yyyy) [Click here for calendar](#)

2. If "Yes", what date was the blood sample shipped? (*GE2SH PDT*)

(mm/dd/yyyy) [Click here for calendar](#)

3. Did the participant withdraw consent from the genetics study? (*GECNSTWD*)

☐ Yes

If "Yes", what date was consent withdrawn? (*GEQNWDDT*)

(mm/dd/yyyy) [Click here for calendar](#)

Comments: (*GENCOMM*)

NIDA Clinical Trials Network

Medication / Supply Inventory (INV)

Web Version: 1.0; 4.01; 06-07-12

Date of Inventory (INVTRYDT):

	Current Inventory Level	Expiration Date Earliest Date (mm/dd/yyyy)
<u>Biological Assessments</u>		
1. QuickTox Urine Drug Screen	(INUDSEA) <input type="text"/> (xxx) Each	(INUDSEX) <input type="text"/> Calendar
2. QuickTox Urine Drug Screen	(INUDSEA) <input type="text"/> (xxx) Full Case(s)	(INUDSEX) <input type="text"/> Calendar
3. Opiate 300ng Urine Drug Screen	(INOPIEA) <input type="text"/> (xxx) Each	(INOPIEX) <input type="text"/> Calendar
4. Urine Adulterant Test Strips	(INADLTEA) <input type="text"/> (xxx) Each	(INADLTEX) <input type="text"/> Calendar
5. Urine Adulterant Test Strips	(INADLTEA) <input type="text"/> (xxx) Full Bottle(s)	(INADLTEX) <input type="text"/> Calendar
6. Pregnancy Tests	(INPREGEA) <input type="text"/> (xxx) Each	(INPREGEX) <input type="text"/> Calendar
7. Urine Cups with Temp Strips	(INTEMPEA) <input type="text"/> (xxx) Each	N/A
<u>Lab Supplies</u>		
1. Screening Kit	(INSCRNKT) <input type="text"/> (xx) Kit(s)	(INSCRNEX) <input type="text"/> Calendar
2. Hepatitis & HIV Testing Kit	(INHHPHVKT) <input type="text"/> (xx) Kit(s)	(INHHPHVEX) <input type="text"/> Calendar
3. Week 4 (Visit 401) Safety Kit	(INWK4KT) <input type="text"/> (xx) Kit(s)	(INWK4EX) <input type="text"/> Calendar
4. Week 5 (Visit 501) PK Kit	(INWK5KT) <input type="text"/> (xx) Kit(s)	(INWK5EX) <input type="text"/> Calendar
5. Week 8 (End of Treatment/Visit 803) PK Kit	(INWK8KT) <input type="text"/> (xx) Kit(s)	(INWK8EX) <input type="text"/> Calendar
6. Week 8 (End of Treatment/Visit 803) Safety Kit	(INEOTSFY) <input type="text"/> (xx) Kit(s)	(INETSFEX) <input type="text"/> Calendar
7. End of Medication Visit Safety Kit	(INEOMSFY) <input type="text"/> (xx) Kit(s)	(INEMSFEX) <input type="text"/> Calendar
8. Unscheduled/Retest Kit	(INRETTKT) <input type="text"/> (xx) Kit(s)	(INRETTEx) <input type="text"/> Calendar
9. Prescription Vials	(INRXVIAL) <input type="text"/> (xxx) Each	N/A
10. Butterfly Needles	(INBFLYEA) <input type="text"/> (xxx) Each	N/A
11. Needle Holders	(INNHLDEA) <input type="text"/> (xxx) Each	N/A

<u>Medication</u>		
1. Naltrexone (Vivitrol) IM Injection Kit	(INVIVTEA) <input type="text"/> (xx) Each	(INVIVTEX) <input type="text"/> Calendar
<u>Miscellaneous</u>		
1. CBT Participant Manual	(INCBTEA) <input type="text"/> (xx) Each	N/A

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

Comments: (INVCOMM)

NIDA Clinical Trials Network

Injection Site Examination (INX)

Web Version: 1.0; 1.00; 07-21-11

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

Date of assessment: (*INXASMDT*)

(mm/dd/yyyy) [Click here for calendar](#)

1. Location of injection: (*INJ1LOC*)

☐ Right buttock ☐ Left buttock

2. Is the initial injection site normal? (*INJ00OK*)

☐ No ☐ Yes

3. Is the second injection site normal? (*INJ502OK*)

☐ 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- 1st Injection
2- 2nd Injection

NIDA Clinical Trials Network

Injection Site Abnormality Log (ISA)

Web Version: 1.0; 1.03; 11-15-12

Segment (PROTSEG):
Injection Number (INJNUM):

Note: If SAE, complete SAE CRFs.

Abnormal Event If "Other", specify in comments	Event Start Date (mm/dd/yyyy)	Severity	Treatment	Date of Event Resolution (mm/dd/yyyy)	Comments
1. (ISE1TYP) <div> 1-Pain 2-Tenderness 3-Induration 4-Swelling 5-Erythema *A additional Options Listed Below </div>	(ISE1SDT) <div>Calendar</div>	(ISE1SVR) <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	(ISE1TRT)	(ISE1RDT) <div>Calendar</div>	(ISE1COM)
2. (ISE2TYP) <div> 1-Pain 2-Tenderness 3-Induration 4-Swelling 5-Erythema *A additional Options Listed Below </div>	(ISE2SDT) <div>Calendar</div>	(ISE2SVR) <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	(ISE2TRT)	(ISE2RDT) <div>Calendar</div>	(ISE2COM)
3. (ISE3TYP) <div> 1-Pain 2-Tenderness 3-Induration 4-Swelling 5-Erythema *A additional Options Listed Below </div>	(ISE3SDT) <div>Calendar</div>	(ISE3SVR) <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	(ISE3TRT)	(ISE3RDT) <div>Calendar</div>	(ISE3COM)
4. (ISE4TYP) <div> 1-Pain 2-Tenderness 3-Induration 4-Swelling 5-Erythema *A additional Options Listed Below </div>	(ISE4SDT) <div>Calendar</div>	(ISE4SVR) <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	(ISE4TRT)	(ISE4RDT) <div>Calendar</div>	(ISE4COM)
5. (ISE5TYP)	(ISE5SDT) <div>Calendar</div>	(ISE5SVR) <input type="checkbox"/> Mild <input type="checkbox"/> Moderate	(ISE5TRT)	(ISE5RDT) <div>Calendar</div>	(ISE5COM)

1-Pain 2-Tenderness 3-Induration 4-Swelling 5-Erythema *Additional Options Listed Below		<input type="checkbox"/> Severe			
6. (ISE6TYP) 1-Pain 2-Tenderness 3-Induration 4-Swelling 5-Erythema *Additional Options Listed Below	(ISE6SDT) Calendar	(ISE6SVR) <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	(ISE6TRT) 	(ISE6RDT) Calendar	(ISE6COM)
7. (ISE7TYP) 1-Pain 2-Tenderness 3-Induration 4-Swelling 5-Erythema *Additional Options Listed Below	(ISE7SDT) Calendar	(ISE7SVR) <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	(ISE7TRT) 	(ISE7RDT) Calendar	(ISE7COM)
8. (ISE8TYP) 1-Pain 2-Tenderness 3-Induration 4-Swelling 5-Erythema *Additional Options Listed Below	(ISE8SDT) Calendar	(ISE8SVR) <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	(ISE8TRT) 	(ISE8RDT) Calendar	(ISE8COM)
9. (ISE9TYP) 1-Pain 2-Tenderness 3-Induration 4-Swelling 5-Erythema *Additional Options Listed Below	(ISE9SDT) Calendar	(ISE9SVR) <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	(ISE9TRT) 	(ISE9RDT) Calendar	(ISE9COM)
10. (ISE10TYP) 1-Pain 2-Tenderness 3-Induration 4-Swelling 5-Erythema *Additional Options Listed Below	(ISE10SDT) Calendar	(ISE10SVR) <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	(ISE10TRT) 	(ISE10RDT) Calendar	(ISE10COM)
11. (ISE11TYP)	(ISE11SDT) Calendar	(ISE11SVR) <input type="checkbox"/> Mild <input type="checkbox"/> Moderate	(ISE11TRT) 	(ISE11RDT) Calendar	(ISE11COM)

<div>1-Pain</div> <div>2-Tenderness</div> <div>3-Induration</div> <div>4-Swelling</div> <div>5-Erythema</div> <div>*Additional Options Listed Below</div>		<div><input type="checkbox"/></div> <div>Severe</div>			
<div>12. (ISE12 TYP)</div> <div>1-Pain</div> <div>2-Tenderness</div> <div>3-Induration</div> <div>4-Swelling</div> <div>5-Erythema</div> <div>*Additional Options Listed Below</div>	<div>(ISE12SDT)</div> <div><div>Calendar</div></div>	<div>(ISE12SVR)</div> <div><div><input type="checkbox"/> Mild</div><div><input type="checkbox"/> Moderate</div><div><input type="checkbox"/> Severe</div></div>	<div>(ISE12 TRT)</div> <div></div>	<div>(ISE12RDT)</div> <div><div>Calendar</div></div>	<div>(ISE12COM)</div> <div></div>

Comments: (ISACOMM)

Additional Selection Options for ISA

Injection Number (*INJNUM*) (key field):

- 1- 1st Injection
- 2-2nd Injection

Event 1 type

- 6-Bruising
- 7-Pruritus
- 8-Hematoma
- 9-Abscess
- 10-Necrosis
- 11-Redness
- 12-Nodule
- 99-Other

NIDA Clinical Trials Network

Missed Visit Form (MVF)

Web Version: 1.0; 3.01; 05-31-13

Segment (*PROTSEG*):

Visit Number (*VISNO*):

Reason for missed visit (*MVREASON*)

8-Participant failed to return to clinic and unable to contact
10-Participant unable to attend visit (e.g. no childcare, transportation, schedule conflict)
11-Participant on vacation
12-Participant in hospital, in-patient or residential treatment
13-Participant moved from area
*Additional Options Listed Below

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

Additional Selection Options for MVF

- Reason for missed visit:**
14-Participant incarcerated
15-CTP closed
16-Participant withdrew consent
17-Participant deceased
99-Other

NIDA Clinical Trials Network

Naloxone Dose Log (NDL)

Web Version: 1.0; 1.00; 07-18-11

Segment (*PROTSEG*):

Visit Number (*VISNO*):

First Naloxone Challenge

Dose Number	Date Dose Administered (mm/d/yyyy)	Calendar	Time 24-hour (00:00)	Dose (X.XX mg)	Route
1.	(NDA1DSDT) <input type="text"/>	Calendar	(NDA1DSTM) <input type="text"/>	(NDA1DOSE) <input type="text"/>	<div style="border: 1px solid black; padding: 2px;"> 1-I.V. (Intravenous) 2-I.M. (Intramuscular injection) 3-S.C. (Subcutaneous injection) </div> (NDA1RTE)
2.	(NDA2DSDT) <input type="text"/>	Calendar	(NDA2DSTM) <input type="text"/>	(NDA2DOSE) <input type="text"/>	<div style="border: 1px solid black; padding: 2px;"> 1-I.V. (Intravenous) 2-I.M. (Intramuscular injection) 3-S.C. (Subcutaneous injection) </div> (NDA2RTE)
3.	(NDA3DSDT) <input type="text"/>	Calendar	(NDA3DSTM) <input type="text"/>	(NDA3DOSE) <input type="text"/>	<div style="border: 1px solid black; padding: 2px;"> 1-I.V. (Intravenous) 2-I.M. (Intramuscular injection) 3-S.C. (Subcutaneous injection) </div> (NDA3RTE)
4.	(NDA4DSDT) <input type="text"/>	Calendar	(NDA4DSTM) <input type="text"/>	(NDA4DOSE) <input type="text"/>	<div style="border: 1px solid black; padding: 2px;"> 1-I.V. (Intravenous) 2-I.M. (Intramuscular injection) 3-S.C. (Subcutaneous injection) </div> (NDA4RTE)
5.	(NDA5DSDT) <input type="text"/>	Calendar	(NDA5DSTM) <input type="text"/>	(NDA5DOSE) <input type="text"/>	<div style="border: 1px solid black; padding: 2px;"> 1-I.V. (Intravenous) 2-I.M. (Intramuscular injection) 3-S.C. (Subcutaneous injection) </div> (NDA5RTE)
6.	(NDA6DSDT) <input type="text"/>	Calendar	(NDA6DSTM) <input type="text"/>	(NDA6DOSE) <input type="text"/>	<div style="border: 1px solid black; padding: 2px;"> 1-I.V. (Intravenous) 2-I.M. (Intramuscular injection) 3-S.C. (Subcutaneous injection) </div> (NDA6RTE)

Second Naloxone Challenge

Dose Number	Date Dose Administered (mm/d/yyyy)	Time 24-hour (00:00)	Dose (X.XX mg)	Route
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1.	(NDB1DSDT) <input type="text"/> Calendar	(NDB1DSTM) <input type="text"/>	(NDB1DOSE) <input type="text"/>	<div>(NDB1RTE)</div> <div> 1-I.V. (Intravenous) 2-I.M. (Intramuscular injection) 3-S.C. (Subcutaneous injection) </div>
2.	(NDB2DSDT) <input type="text"/> Calendar	(NDB2DSTM) <input type="text"/>	(NDB2DOSE) <input type="text"/>	<div>(NDB2RTE)</div> <div> 1-I.V. (Intravenous) 2-I.M. (Intramuscular injection) 3-S.C. (Subcutaneous injection) </div>
3.	(NDB3DSDT) <input type="text"/> Calendar	(NDB3DSTM) <input type="text"/>	(NDB3DOSE) <input type="text"/>	<div>(NDB3RTE)</div> <div> 1-I.V. (Intravenous) 2-I.M. (Intramuscular injection) 3-S.C. (Subcutaneous injection) </div>
4.	(NDB4DSDT) <input type="text"/> Calendar	(NDB4DSTM) <input type="text"/>	(NDB4DOSE) <input type="text"/>	<div>(NDB4RTE)</div> <div> 1-I.V. (Intravenous) 2-I.M. (Intramuscular injection) 3-S.C. (Subcutaneous injection) </div>
5.	(NDB5DSDT) <input type="text"/> Calendar	(NDB5DSTM) <input type="text"/>	(NDB5DOSE) <input type="text"/>	<div>(NDB5RTE)</div> <div> 1-I.V. (Intravenous) 2-I.M. (Intramuscular injection) 3-S.C. (Subcutaneous injection) </div>
6.	(NDB6DSDT) <input type="text"/> Calendar	(NDB6DSTM) <input type="text"/>	(NDB6DOSE) <input type="text"/>	<div>(NDB6RTE)</div> <div> 1-I.V. (Intravenous) 2-I.M. (Intramuscular injection) 3-S.C. (Subcutaneous injection) </div>

Comments: (NDL COMM)

NIDA Clinical Trials Network

Naltrexone (XR-NTX) Dose Log (NXL)

Web Version: 1.0; 1.00; 07-27-11

Segment (*PROTSEG*):

Visit Number (*VISNO*):

Date of assessment: (*NXLASMDT*)

(mm/dd/yyyy) [Click here for calendar](#)

Location of first 380mg XR-NTX dose administered by deep intramuscular injection into a gluteal muscle: ☐ Left buttock ☐ Right buttock
(*NX1STINJ*)

1. Was a 380mg XR-NTX dose administered by deep intramuscular injection into a gluteal muscle?
(*NXIMINJ*) ☐ No ☐ Yes

2. Was a second 380mg XR-NTX dose administered by deep intramuscular injection into a gluteal muscle?
(*NXIMINJ*) ☐ No ☐ Yes

a. If "Yes", what was the location? (*NXINJLOC*)

☐ Left buttock ☐ Right buttock

b. If "Yes", what time was the injection given (24 - hour format): (*NXINJTM*)

(hh:mm)

3. Did you experience difficulty with XR-NTX administration? (*NXINDIF*)

☐ No ☐ Yes

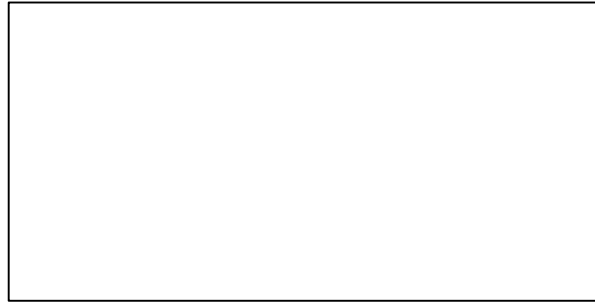
If "Yes", describe: (*NXDIFSP*)

4. Administered by: (*NXADMNBY*)

1-Physician
2-Physician's Assistant
3-Nurse Practitioner
4-Registered Nurse
9-Other

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

Comments: (NXLCOMM)



NIDA Clinical Trials Network

Oral Naltrexone Dose Log (ONX)

Web Version: 1.0; 1.00; 07-12-11

Segment (PROTSEG):

Visit Number (VISNO):

First Oral Naltrexone Induction

Dose Number	Date Dose Taken (mm/dd/yyyy)	Time 24-hour (00:00)	Dose of Tablet (XX mg)	Number of Tablets Dispensed (X.XX)	Total Dose (mg)	Administered for
1.	(ONA1DSDT) <input type="text"/> Calendar	(ONA1DSTM) <input type="text"/>	(ONA1DOSE) <input type="text"/>	(ONA1 TABS) <input type="text"/>	(ONA1DSTL) <input type="text"/>	(ONA1DSLCL) <div>1-In clinic 2-Take home</div>
2.	(ONA2DSDT) <input type="text"/> Calendar	(ONA2DSTM) <input type="text"/>	(ONA2DOSE) <input type="text"/>	(ONA2 TABS) <input type="text"/>	(ONA2DSTL) <input type="text"/>	(ONA2DSLCL) <div>1-In clinic 2-Take home</div>
3.	(ONA3DSDT) <input type="text"/> Calendar	(ONA3DSTM) <input type="text"/>	(ONA3DOSE) <input type="text"/>	(ONA3 TABS) <input type="text"/>	(ONA3DSTL) <input type="text"/>	(ONA3DSLCL) <div>1-In clinic 2-Take home</div>
4.	(ONA4DSDT) <input type="text"/> Calendar	(ONA4DSTM) <input type="text"/>	(ONA4DOSE) <input type="text"/>	(ONA4 TABS) <input type="text"/>	(ONA4DSTL) <input type="text"/>	(ONA4DSLCL) <div>1-In clinic 2-Take home</div>
5.	(ONA5DSDT) <input type="text"/> Calendar	(ONA5DSTM) <input type="text"/>	(ONA5DOSE) <input type="text"/>	(ONA5 TABS) <input type="text"/>	(ONA5DSTL) <input type="text"/>	(ONA5DSLCL) <div>1-In clinic 2-Take home</div>
6.	(ONA6DSDT) <input type="text"/> Calendar	(ONA6DSTM) <input type="text"/>	(ONA6DOSE) <input type="text"/>	(ONA6 TABS) <input type="text"/>	(ONA6DSTL) <input type="text"/>	(ONA6DSLCL) <div>1-In clinic 2-Take home</div>

Second Oral Naltrexone Induction

Dose Number	Date Dose Taken (mm/dd/yyyy)	Time 24-hour (00:00)	Dose of Tablet (XX mg)	Number of Tablets Dispensed (X.XX)	Total Dose (mg)	Administered for
1.	(ONB1DSDT) <input type="text"/> Calendar	(ONB1DSTM) <input type="text"/>	(ONB1DOSE) <input type="text"/>	(ONB1 TABS) <input type="text"/>	(ONB1DSTL) <input type="text"/>	(ONB1DSLCL) <div>1-In clinic 2-Take home</div>
2.	(ONB2DSDT) <input type="text"/> Calendar	(ONB2DSTM) <input type="text"/>	(ONB2DOSE) <input type="text"/>	(ONB2 TABS) <input type="text"/>	(ONB2DSTL) <input type="text"/>	(ONB2DSLCL) <div>1-In clinic 2-Take home</div>

3.	(ONB3DSDT) <input type="text"/> Calendar	(ONB3DSTM) <input type="text"/>	(ONB3DOSE) <input type="text"/>	(ONB3TABS) <input type="text"/>	(ONB3DSTL) <input type="text"/>	(ONB3DSLC) <div>1-In clinic 2-Take home</div>
4.	(ONB4DSDT) <input type="text"/> Calendar	(ONB4DSTM) <input type="text"/>	(ONB4DOSE) <input type="text"/>	(ONB4TABS) <input type="text"/>	(ONB4DSTL) <input type="text"/>	(ONB4DSLC) <div>1-In clinic 2-Take home</div>
5.	(ONB5DSDT) <input type="text"/> Calendar	(ONB5DSTM) <input type="text"/>	(ONB5DOSE) <input type="text"/>	(ONB5TABS) <input type="text"/>	(ONB5DSTL) <input type="text"/>	(ONB5DSLC) <div>1-In clinic 2-Take home</div>
6.	(ONB6DSDT) <input type="text"/> Calendar	(ONB6DSTM) <input type="text"/>	(ONB6DOSE) <input type="text"/>	(ONB6TABS) <input type="text"/>	(ONB6DSTL) <input type="text"/>	(ONB6DSLC) <div>1-In clinic 2-Take home</div>

Comments: (ONXCOMM)

NIDA Clinical Trials Network

Pregnancy and Birth Control Assessment (PBC)

Web Version: 1.0; 3.00; 06-13-12

Segment (*PROTSEG*):

Visit Number (*VISNO*):

Complete this form only for females.

Date of assessment: (*PBASMDT*)

(mm/dd/yyyy) [Click here for calendar](#)

1. Is participant continuing to use an effective method of birth control? (*PBUSEBC*)

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

☐ No ☐ Yes

2. Was a pregnancy test performed? (*PBPRGTST*)

a. Date of pregnancy test: (*PBPTSTDY*)

b. Result of pregnancy test: (*PBRESULT*)

☐ No ☐ Yes

(mm/dd/yyyy) [Click here for calendar](#)

☐ Negative ☐ Positive

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

Comments: (*PBCCOMM*)

NIDA Clinical Trials Network

Prior and Concomitant Medications (PCM)

Web Version: 1.0; 2.03; 01-18-12

Is the participant currently taking any prescribed medications or has the participant taken any prescribed medications within the past 7 days?(CMMEDNY) ☐ No ☐ Yes

In addition to prescription medications, please also record over the counter Zantac, ranitidine, Wal-zan, or Tritec, or anything that is intended to substitute for these. If you are unsure about a medication, please make note of it and find out if it is in fact a substitute for these; if not, you can correct later. If you are asked why we are interested in these medications, please explain that we have found that they are a category of medication that we are interested in tracking for the study, just as we are tracking prescription medications.

	Medication Name	Indication	Medication Start Date	Ongoing?	Medication Stop Date	Used to Treat an AE
1.	(CM_01DNM) <input type="text"/>	(CM_01DIN) 1-Analgesic/NSAID/Antipyretic 2-Anesthetic 3-Antacid 4-Ant-asthma/Bronchodilator 5-Antibiotic/Anti-infective/Anti-parasite/Anti-fungal/Anti-inflammatory/Ant-microbial *Additional Options Listed Below	(CM_01SDT) (m m/dd/yyyy) <input type="text"/>	(CM_01ONG) 0-No 1-Yes 2-Yes (continuing at protocol completion or study termination)	(CM_01PDT) (mm/dd/yyyy) <input type="text"/>	(CM_01TAE) 0-No 1-Yes
2.	(CM_02DNM) <input type="text"/>	(CM_02DIN) 1-Analgesic/NSAID/Antipyretic 2-Anesthetic 3-Antacid 4-Ant-asthma/Bronchodilator 5-Antibiotic/Anti-infective/Anti-parasite/Anti-fungal/Anti-inflammatory/Ant-microbial *Additional Options Listed Below	(CM_02SDT) (m m/dd/yyyy) <input type="text"/>	(CM_02ONG) 0-No 1-Yes 2-Yes (continuing at protocol completion or study termination)	(CM_02PDT) (mm/dd/yyyy) <input type="text"/>	(CM_02TAE) 0-No 1-Yes
3.	(CM_03DNM) <input type="text"/>	(CM_03DIN) 1-Analgesic/NSAID/Antipyretic 2-Anesthetic 3-Antacid 4-Ant-asthma/Bronchodilator 5-Antibiotic/Anti-infective/Anti-parasite/Anti-fungal/Anti-inflammatory/Ant-microbial *Additional Options Listed Below	(CM_03SDT) (m m/dd/yyyy) <input type="text"/>	(CM_03ONG) 0-No 1-Yes 2-Yes (continuing at protocol completion or study termination)	(CM_03PDT) (mm/dd/yyyy) <input type="text"/>	(CM_03TAE) 0-No 1-Yes
4.	(CM_04DNM) <input type="text"/>	(CM_04DIN) 1-Analgesic/NSAID/Antipyretic 2-Anesthetic 3-Antacid 4-Ant-asthma/Bronchodilator 5-Antibiotic/Anti-infective/Anti-parasite/Anti-fungal/Anti-inflammatory/Ant-microbial *Additional Options Listed Below	(CM_04SDT) (m m/dd/yyyy) <input type="text"/>	(CM_04ONG) 0-No 1-Yes 2-Yes (continuing at protocol completion or study termination)	(CM_04PDT) (mm/dd/yyyy) <input type="text"/>	(CM_04TAE) 0-No 1-Yes
5.	(CM_05DNM) <input type="text"/>	(CM_05DIN) 1-Analgesic/NSAID/Antipyretic 2-Anesthetic 3-Antacid 4-Ant-asthma/Bronchodilator 5-Antibiotic/Anti-infective/Anti-parasite/Anti-fungal/Anti-inflammatory/Ant-microbial *Additional Options Listed Below	(CM_05SDT) (m m/dd/yyyy) <input type="text"/>	(CM_05ONG) 0-No 1-Yes 2-Yes (continuing at protocol completion or study termination)	(CM_05PDT) (mm/dd/yyyy) <input type="text"/>	(CM_05TAE) 0-No 1-Yes
6.	(CM_06DNM) <input type="text"/>	(CM_06DIN) 1-Analgesic/NSAID/Antipyretic 2-Anesthetic 3-Antacid 4-Ant-asthma/Bronchodilator 5-Antibiotic/Anti-infective/Anti-parasite/Anti-fungal/Anti-inflammatory/Ant-microbial *Additional Options Listed Below	(CM_06SDT) (m m/dd/yyyy) <input type="text"/>	(CM_06ONG) 0-No 1-Yes 2-Yes (continuing at protocol completion or study termination)	(CM_06PDT) (mm/dd/yyyy) <input type="text"/>	(CM_06TAE) 0-No 1-Yes
7.	(CM_07DNM) <input type="text"/>	(CM_07DIN) 1-Analgesic/NSAID/Antipyretic 2-Anesthetic 3-Antacid 4-Ant-asthma/Bronchodilator 5-Antibiotic/Anti-infective/Anti-parasite/Anti-fungal/Anti-inflammatory/Ant-microbial *Additional Options Listed Below	(CM_07SDT) (m m/dd/yyyy) <input type="text"/>	(CM_07ONG) 0-No 1-Yes 2-Yes (continuing at protocol completion or study termination)	(CM_07PDT) (mm/dd/yyyy) <input type="text"/>	(CM_07TAE) 0-No 1-Yes

8.	(CM_08DNM) <input type="text"/>	(CM_08DIN) 1-Analgesic/NSAID/Antipyretic 2-Anesthetic 3-Antacid 4-Ant-asthma/Bronchodilator 5-Antibiotic/Anti-infective/Anti-parasite/Anti-fungal/Anti-inflammatory/Ant-microbial *Additional Options Listed Below	(CM_08SDT) <input type="text"/> (m m/dd/yyyy)	(CM_08ONG) 0-No 1-Yes 2-Yes (continuing at protocol completion or study termination)	(CM_08PDT) <input type="text"/> (mm/dd/yyyy)	(CM_08TAE) 0-No 1-Yes
9.	(CM_09DNM) <input type="text"/>	(CM_09DIN) 1-Analgesic/NSAID/Antipyretic 2-Anesthetic 3-Antacid 4-Ant-asthma/Bronchodilator 5-Antibiotic/Anti-infective/Anti-parasite/Anti-fungal/Anti-inflammatory/Ant-microbial *Additional Options Listed Below	(CM_09SDT) <input type="text"/> (m m/dd/yyyy)	(CM_09ONG) 0-No 1-Yes 2-Yes (continuing at protocol completion or study termination)	(CM_09PDT) <input type="text"/> (mm/dd/yyyy)	(CM_09TAE) 0-No 1-Yes
10.	(CM_10DNM) <input type="text"/>	(CM_10DIN) 1-Analgesic/NSAID/Antipyretic 2-Anesthetic 3-Antacid 4-Ant-asthma/Bronchodilator 5-Antibiotic/Anti-infective/Anti-parasite/Anti-fungal/Anti-inflammatory/Ant-microbial *Additional Options Listed Below	(CM_10SDT) <input type="text"/> (m m/dd/yyyy)	(CM_10ONG) 0-No 1-Yes 2-Yes (continuing at protocol completion or study termination)	(CM_10PDT) <input type="text"/> (mm/dd/yyyy)	(CM_10TAE) 0-No 1-Yes
11.	(CM_11DNM) <input type="text"/>	(CM_11DIN) 1-Analgesic/NSAID/Antipyretic 2-Anesthetic 3-Antacid 4-Ant-asthma/Bronchodilator 5-Antibiotic/Anti-infective/Anti-parasite/Anti-fungal/Anti-inflammatory/Ant-microbial *Additional Options Listed Below	(CM_11SDT) <input type="text"/> (m m/dd/yyyy)	(CM_11ONG) 0-No 1-Yes 2-Yes (continuing at protocol completion or study termination)	(CM_11PDT) <input type="text"/> (mm/dd/yyyy)	(CM_11TAE) 0-No 1-Yes
12.	(CM_12DNM) <input type="text"/>	(CM_12DIN) 1-Analgesic/NSAID/Antipyretic 2-Anesthetic 3-Antacid 4-Ant-asthma/Bronchodilator 5-Antibiotic/Anti-infective/Anti-parasite/Anti-fungal/Anti-inflammatory/Ant-microbial *Additional Options Listed Below	(CM_12SDT) <input type="text"/> (m m/dd/yyyy)	(CM_12ONG) 0-No 1-Yes 2-Yes (continuing at protocol completion or study termination)	(CM_12PDT) <input type="text"/> (mm/dd/yyyy)	(CM_12TAE) 0-No 1-Yes
13.	(CM_13DNM) <input type="text"/>	(CM_13DIN) 1-Analgesic/NSAID/Antipyretic 2-Anesthetic 3-Antacid 4-Ant-asthma/Bronchodilator 5-Antibiotic/Anti-infective/Anti-parasite/Anti-fungal/Anti-inflammatory/Ant-microbial *Additional Options Listed Below	(CM_13SDT) <input type="text"/> (m m/dd/yyyy)	(CM_13ONG) 0-No 1-Yes 2-Yes (continuing at protocol completion or study termination)	(CM_13PDT) <input type="text"/> (mm/dd/yyyy)	(CM_13TAE) 0-No 1-Yes
14.	(CM_14DNM) <input type="text"/>	(CM_14DIN) 1-Analgesic/NSAID/Antipyretic 2-Anesthetic 3-Antacid 4-Ant-asthma/Bronchodilator 5-Antibiotic/Anti-infective/Anti-parasite/Anti-fungal/Anti-inflammatory/Ant-microbial *Additional Options Listed Below	(CM_14SDT) <input type="text"/> (m m/dd/yyyy)	(CM_14ONG) 0-No 1-Yes 2-Yes (continuing at protocol completion or study termination)	(CM_14PDT) <input type="text"/> (mm/dd/yyyy)	(CM_14TAE) 0-No 1-Yes
15.	(CM_15DNM) <input type="text"/>	(CM_15DIN) 1-Analgesic/NSAID/Antipyretic 2-Anesthetic 3-Antacid 4-Ant-asthma/Bronchodilator 5-Antibiotic/Anti-infective/Anti-parasite/Anti-fungal/Anti-inflammatory/Ant-microbial *Additional Options Listed Below	(CM_15SDT) <input type="text"/> (m m/dd/yyyy)	(CM_15ONG) 0-No 1-Yes 2-Yes (continuing at protocol completion or study termination)	(CM_15PDT) <input type="text"/> (mm/dd/yyyy)	(CM_15TAE) 0-No 1-Yes
16.	(CM_16DNM) <input type="text"/>	(CM_16DIN) 1-Analgesic/NSAID/Antipyretic 2-Anesthetic 3-Antacid 4-Ant-asthma/Bronchodilator 5-Antibiotic/Anti-infective/Anti-parasite/Anti-fungal/Anti-inflammatory/Ant-microbial *Additional Options Listed Below	(CM_16SDT) <input type="text"/> (m m/dd/yyyy)	(CM_16ONG) 0-No 1-Yes 2-Yes (continuing at protocol completion or study termination)	(CM_16PDT) <input type="text"/> (mm/dd/yyyy)	(CM_16TAE) 0-No 1-Yes
17.	(CM_17DNM) <input type="text"/>	(CM_17DIN)	(CM_17SDT) <input type="text"/> (m m/dd/yyyy)	(CM_17ONG) 0-No 1-Yes 2-Yes (continuing at protocol completion or study termination)	(CM_17PDT) <input type="text"/> (mm/dd/yyyy)	(CM_17TAE) 0-No 1-Yes

		1-Analgesic/NSAID/Antipyretic 2-Anesthetic 3-Antacid 4-Ant-asthma/Bronchodilator 5-Antibiotic/Anti-infective/Anti-parasite/Anti-fungal/Anti-inflammatory/Ant-microbial *Additional Options Listed Below				
18.	(CM_18DNM)	(CM_18DIN) 1-Analgesic/NSAID/Antipyretic 2-Anesthetic 3-Antacid 4-Ant-asthma/Bronchodilator 5-Antibiotic/Anti-infective/Anti-parasite/Anti-fungal/Anti-inflammatory/Ant-microbial *Additional Options Listed Below	(CM_18SDT) (m m/dd/yyyy)	(CM_18ONG) 0-No 1-Yes 2-Yes (continuing at protocol completion or study termination)	(CM_18PDT) (mm/dd/yyyy)	(CM_18TAE) 0-No 1-Yes
19.	(CM_19DNM)	(CM_19DIN) 1-Analgesic/NSAID/Antipyretic 2-Anesthetic 3-Antacid 4-Ant-asthma/Bronchodilator 5-Antibiotic/Anti-infective/Anti-parasite/Anti-fungal/Anti-inflammatory/Ant-microbial *Additional Options Listed Below	(CM_19SDT) (m m/dd/yyyy)	(CM_19ONG) 0-No 1-Yes 2-Yes (continuing at protocol completion or study termination)	(CM_19PDT) (mm/dd/yyyy)	(CM_19TAE) 0-No 1-Yes
20.	(CM_20DNM)	(CM_20DIN) 1-Analgesic/NSAID/Antipyretic 2-Anesthetic 3-Antacid 4-Ant-asthma/Bronchodilator 5-Antibiotic/Anti-infective/Anti-parasite/Anti-fungal/Anti-inflammatory/Ant-microbial *Additional Options Listed Below	(CM_20SDT) (m m/dd/yyyy)	(CM_20ONG) 0-No 1-Yes 2-Yes (continuing at protocol completion or study termination)	(CM_20PDT) (mm/dd/yyyy)	(CM_20TAE) 0-No 1-Yes
21.	(CM_21DNM)	(CM_21DIN) 1-Analgesic/NSAID/Antipyretic 2-Anesthetic 3-Antacid 4-Ant-asthma/Bronchodilator 5-Antibiotic/Anti-infective/Anti-parasite/Anti-fungal/Anti-inflammatory/Ant-microbial *Additional Options Listed Below	(CM_21SDT) (m m/dd/yyyy)	(CM_21ONG) 0-No 1-Yes 2-Yes (continuing at protocol completion or study termination)	(CM_21PDT) (mm/dd/yyyy)	(CM_21TAE) 0-No 1-Yes
22.	(CM_22DNM)	(CM_22DIN) 1-Analgesic/NSAID/Antipyretic 2-Anesthetic 3-Antacid 4-Ant-asthma/Bronchodilator 5-Antibiotic/Anti-infective/Anti-parasite/Anti-fungal/Anti-inflammatory/Ant-microbial *Additional Options Listed Below	(CM_22SDT) (m m/dd/yyyy)	(CM_22ONG) 0-No 1-Yes 2-Yes (continuing at protocol completion or study termination)	(CM_22PDT) (mm/dd/yyyy)	(CM_22TAE) 0-No 1-Yes
23.	(CM_23DNM)	(CM_23DIN) 1-Analgesic/NSAID/Antipyretic 2-Anesthetic 3-Antacid 4-Ant-asthma/Bronchodilator 5-Antibiotic/Anti-infective/Anti-parasite/Anti-fungal/Anti-inflammatory/Ant-microbial *Additional Options Listed Below	(CM_23SDT) (m m/dd/yyyy)	(CM_23ONG) 0-No 1-Yes 2-Yes (continuing at protocol completion or study termination)	(CM_23PDT) (mm/dd/yyyy)	(CM_23TAE) 0-No 1-Yes
24.	(CM_24DNM)	(CM_24DIN) 1-Analgesic/NSAID/Antipyretic 2-Anesthetic 3-Antacid 4-Ant-asthma/Bronchodilator 5-Antibiotic/Anti-infective/Anti-parasite/Anti-fungal/Anti-inflammatory/Ant-microbial *Additional Options Listed Below	(CM_24SDT) (m m/dd/yyyy)	(CM_24ONG) 0-No 1-Yes 2-Yes (continuing at protocol completion or study termination)	(CM_24PDT) (mm/dd/yyyy)	(CM_24TAE) 0-No 1-Yes
25.	(CM_25DNM)	(CM_25DIN) 1-Analgesic/NSAID/Antipyretic 2-Anesthetic 3-Antacid 4-Ant-asthma/Bronchodilator 5-Antibiotic/Anti-infective/Anti-parasite/Anti-fungal/Anti-inflammatory/Ant-microbial *Additional Options Listed Below	(CM_25SDT) (m m/dd/yyyy)	(CM_25ONG) 0-No 1-Yes 2-Yes (continuing at protocol completion or study termination)	(CM_25PDT) (mm/dd/yyyy)	(CM_25TAE) 0-No 1-Yes
26.	(CM_26DNM)	(CM_26DIN) 1-Analgesic/NSAID/Antipyretic 2-Anesthetic 3-Antacid 4-Ant-asthma/Bronchodilator 5-Antibiotic/Anti-infective/Anti-parasite/Anti-fungal/Anti-inflammatory/Ant-microbial *Additional Options Listed Below	(CM_26SDT) (m m/dd/yyyy)	(CM_26ONG) 0-No 1-Yes 2-Yes (continuing at protocol completion or study termination)	(CM_26PDT) (mm/dd/yyyy)	(CM_26TAE) 0-No 1-Yes

		1-Analgesic/NSAID/Antipyretic 2-Anesthetic 3-Antacid 4-Ant-asthma/Bronchodilator 5-Antibiotic/Anti-infective/Anti-parasite/Anti-fungal/Anti-inflammatory/Ant-microbial *Additional Options Listed Below				
27.	(CM_27DNM)	(CM_27DIN) 1-Analgesic/NSAID/Antipyretic 2-Anesthetic 3-Antacid 4-Ant-asthma/Bronchodilator 5-Antibiotic/Anti-infective/Anti-parasite/Anti-fungal/Anti-inflammatory/Ant-microbial *Additional Options Listed Below	(CM_27SDT) (m m/dd/yyyy)	(CM_27ONG) 0-No 1-Yes 2-Yes (continuing at protocol completion or study termination)	(CM_27PDT) (mm/dd/yyyy)	(CM_27TAE) 0-No 1-Yes
28.	(CM_28DNM)	(CM_28DIN) 1-Analgesic/NSAID/Antipyretic 2-Anesthetic 3-Antacid 4-Ant-asthma/Bronchodilator 5-Antibiotic/Anti-infective/Anti-parasite/Anti-fungal/Anti-inflammatory/Ant-microbial *Additional Options Listed Below	(CM_28SDT) (m m/dd/yyyy)	(CM_28ONG) 0-No 1-Yes 2-Yes (continuing at protocol completion or study termination)	(CM_28PDT) (mm/dd/yyyy)	(CM_28TAE) 0-No 1-Yes
29.	(CM_29DNM)	(CM_29DIN) 1-Analgesic/NSAID/Antipyretic 2-Anesthetic 3-Antacid 4-Ant-asthma/Bronchodilator 5-Antibiotic/Anti-infective/Anti-parasite/Anti-fungal/Anti-inflammatory/Ant-microbial *Additional Options Listed Below	(CM_29SDT) (m m/dd/yyyy)	(CM_29ONG) 0-No 1-Yes 2-Yes (continuing at protocol completion or study termination)	(CM_29PDT) (mm/dd/yyyy)	(CM_29TAE) 0-No 1-Yes
30.	(CM_30DNM)	(CM_30DIN) 1-Analgesic/NSAID/Antipyretic 2-Anesthetic 3-Antacid 4-Ant-asthma/Bronchodilator 5-Antibiotic/Anti-infective/Anti-parasite/Anti-fungal/Anti-inflammatory/Ant-microbial *Additional Options Listed Below	(CM_30SDT) (m m/dd/yyyy)	(CM_30ONG) 0-No 1-Yes 2-Yes (continuing at protocol completion or study termination)	(CM_30PDT) (mm/dd/yyyy)	(CM_30TAE) 0-No 1-Yes
31.	(CM_31DNM)	(CM_31DIN) 1-Analgesic/NSAID/Antipyretic 2-Anesthetic 3-Antacid 4-Ant-asthma/Bronchodilator 5-Antibiotic/Anti-infective/Anti-parasite/Anti-fungal/Anti-inflammatory/Ant-microbial *Additional Options Listed Below	(CM_31SDT) (m m/dd/yyyy)	(CM_31ONG) 0-No 1-Yes 2-Yes (continuing at protocol completion or study termination)	(CM_31PDT) (mm/dd/yyyy)	(CM_31TAE) 0-No 1-Yes
32.	(CM_32DNM)	(CM_32DIN) 1-Analgesic/NSAID/Antipyretic 2-Anesthetic 3-Antacid 4-Ant-asthma/Bronchodilator 5-Antibiotic/Anti-infective/Anti-parasite/Anti-fungal/Anti-inflammatory/Ant-microbial *Additional Options Listed Below	(CM_32SDT) (m m/dd/yyyy)	(CM_32ONG) 0-No 1-Yes 2-Yes (continuing at protocol completion or study termination)	(CM_32PDT) (mm/dd/yyyy)	(CM_32TAE) 0-No 1-Yes
33.	(CM_33DNM)	(CM_33DIN) 1-Analgesic/NSAID/Antipyretic 2-Anesthetic 3-Antacid 4-Ant-asthma/Bronchodilator 5-Antibiotic/Anti-infective/Anti-parasite/Anti-fungal/Anti-inflammatory/Ant-microbial *Additional Options Listed Below	(CM_33SDT) (m m/dd/yyyy)	(CM_33ONG) 0-No 1-Yes 2-Yes (continuing at protocol completion or study termination)	(CM_33PDT) (mm/dd/yyyy)	(CM_33TAE) 0-No 1-Yes
34.	(CM_34DNM)	(CM_34DIN) 1-Analgesic/NSAID/Antipyretic 2-Anesthetic 3-Antacid 4-Ant-asthma/Bronchodilator 5-Antibiotic/Anti-infective/Anti-parasite/Anti-fungal/Anti-inflammatory/Ant-microbial *Additional Options Listed Below	(CM_34SDT) (m m/dd/yyyy)	(CM_34ONG) 0-No 1-Yes 2-Yes (continuing at protocol completion or study termination)	(CM_34PDT) (mm/dd/yyyy)	(CM_34TAE) 0-No 1-Yes
35.	(CM_35DNM)	(CM_35DIN) 	(CM_35SDT) (m m/dd/yyyy)	(CM_35ONG) 0-No 1-Yes 2-Yes (continuing at protocol completion or study termination)	(CM_35PDT) (mm/dd/yyyy)	(CM_35TAE) 0-No 1-Yes

		1-Analgesic/NSAID/Antipyretic 2-Anesthetic 3-Antacid 4-Ant-asthma/Bronchodilator 5-Antibiotic/Anti-infective/Anti-parasite/Anti-fungal/Anti-inflammatory/Ant-microbial *Additional Options Listed Below					
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Comments: (CM COMM)

Additional Selection Options for PCM

- Medication purpose/ind 01
- 6-Anticoagulant/Haemostatic/Anti-hemorrhagic
 - 7-Anti-co nvulsant
 - 8-Antidepressant
 - 9-Antidiabetic
 - 33-Antifungal
 - 10-Antihistamine
 - 11-Antihypertensive
 - 32-Antiretroviral
 - 12-Cardiovascular Agent, Other Than Hyperlipidemic/HTN
 - 13-Contraceptive
 - 14-Dermatologic Agent
 - 15-Emergency/Support Agent
 - 16-Endocrine/Metabolic Agent
 - 17-GI Agent/Antidiarrheal/Antiemetic/Antispasmodic/Laxative
 - 18-Growth Factor
 - 19-Herbal/Homeopathic Product
 - 20-Hormone/Steroid/Anti-inflammatory Steroid/Corticosteroid
 - 21-Immunomodulatory Agent
 - 22-OTC Cold and Flu/Sleep Aid
 - 23-Sedative
 - 24-Skeletal Muscle Relaxant
 - 25-Therapeutic Agent/Remedy for Eyes
 - 26-Therapeutic Agent/Remedy for Mouth/Teeth
 - 27-Vaccine/Prophylaxis
 - 28-Vitamin/Mineral/Food Supplement/Electrolyte Replacement
 - 29-Antipsychotic
 - 30-Mood Stabilizer
 - 31-Other CNS-acting Agent
 - 99-Other, Specify

NIDA Clinical Trials Network

Physical Examination (PEX)

Web Version: 1.0; 1.01; 12-12-11

Segment (*PROTSEG*):

Visit Number (*VISNO*):

Date of assessment: (*PEASMDT*)

(mm/dd/yyyy) [Click here for calendar](#)

1. Height: (*PEHGHTIN*)

in: (xx) - or - (*PEHGHTCM*) cm: (xxx)

2. Weight: (*PEWGHTLB*)

lbs: (xxx.x) - or - (*PEWGHTKG*) kg: (xxx.x)

3. BMI: (*PEBMI*)

4. General Appearance: (*PEGENAPP*)

1-Normal
2-A bnormal, Not Clinicially S ignificant
3-A bnormal, C linically Significant
4-N ot Assessed

Comments: (*PEGASP*)

5. Skin, Hair, and Nails: (*PESKHRNA*)

1-Normal
2-A bnormal, Not Clinicially S ignificant
3-A bnormal, C linically Significant
4-N ot Assessed

Comments:(PESHNSP)

6. Head and Neck:(PEHDNK)

1-Normal
2-A bnormal, Not Clinicially S ignificant
3-A bnormal, C linically Significant
4-Not Assessed

Comments:(PEHDNKSP)

7. Ears, Eyes, Nose, and Throat:(PEEENT)

1-Normal
2-A bnormal, Not Clinicially S ignificant
3-A bnormal, C linically Significant
4-Not Assessed

Comments:(PEENTSP)

8. Cardiovascular:(PECARD)

1-Normal
2-A bnormal, Not Clinicially S ignificant
3-A bnormal, C linically Significant
4-Not Assessed

Comments:(*PECARDSP*)

9. **Respiratory**:(*PERESP*)

1-Normal
2-A bnormal, Not Clinicially S ignificant
3-A bnormal, C linically Significant
4-Not Assessed

Comments:(*PERESPSP*)

10. **Gastrointestinal**:(*PEGAST*)

1-Normal
2-A bnormal, Not Clinicially S ignificant
3-A bnormal, C linically Significant
4-Not Assessed

Comments:(*PEGASTSP*)

11. **Extremities**:(*PEEXTR*)

1-Normal
2-A bnormal, Not Clinicially S ignificant
3-A bnormal, C linically Significant
4-Not Assessed

Comments:(PEEXTRSP)

12. Lymph Nodes:(PELYMP)

1-Normal
2-A bnormal, Not Clinicially S ignificant
3-A bnormal, C linically Significant
4-Not Assessed

Comments:(PELYMPSP)

13. Musculoskeletal:(PEMUSC)

1-Normal
2-A bnormal, Not Clinicially S ignificant
3-A bnormal, C linically Significant
4-Not Assessed

Comments:(PEMUSCSP)

14. Neurological:(PENEUR)

1-Normal
2-A bnormal, Not Clinicially S ignificant
3-A bnormal, C linically Significant
4-Not Assessed

Comments:(PENEURSP)

15. Injection Site Assessment: (PEINJS)

1-Normal
2-Abnormal, Not Clinically Significant
3-Abnormal, Clinically Significant
4-Not Assessed

Comments:(PEINJSSP)

16. Other (specify in comments): (PEOTHER)

1-Normal
2-Abnormal, Not Clinically Significant
3-Abnormal, Clinically Significant
4-Not Assessed

Comments:(PEOTHESP)

17. Does participant have a body habitus that precludes gluteal intramuscular injection of naltrexone with provided needle?(PEBDYHBT)

0-No
1-Yes

Comments:(PEBDHBSP)

18. Is the participant in good general health?(PEHEALTH)

0-No

1-Yes

Comments:(PEHLTHSP)

Comments:(PEXCOMM)

NIDA Clinical Trials Network

Pregnancy Outcome 1 (PO1)

Web Version: 1.0; 1.01; 01-29-13

Pregnancy Number (*PREGNO*):

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 (*PREGNO*) (key field):

- 1-1
- 2-2
- 3-3

NIDA Clinical Trials Network

Pregnancy Outcome 2 (PO2)

Web Version: 1.0; 2.01; 01-29-13

Pregnancy Number (PREGNO):

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 (*PREGNO*) (key field):

- 1-1
- 2-2
- 3-3

NIDA Clinical Trials Network

Pregnancy Outcome 3 (PO3)

Web Version: 1.0; 2.01; 01-29-13

Pregnancy Number (*PREGNO*):

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 (*PREGNO*) (key field):

- 1-1
- 2-2
- 3-3

NIDA Clinical Trials Network

Pregnancy Outcome 4 (PO4)

Web Version: 1.0; 2.01; 01-29-13

Pregnancy Number (PREGNO):

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 (*PREGNO*) (key field):

- 1-1
- 2-2
- 3-3

NIDA Clinical Trials Network

Confirmed Pregnancy and Outcome (PRG)

Web Version: 1.0; 3.00; 01-29-13

Pregnancy Number (PREGNO):

Information About Pregnancy

Date of assessment: (PRASMTDT)

(mm/dd/yyyy) [Click here for calendar](#)

1. Date on which study staff became aware of pregnancy: (PRAWARDT)

(mm/dd/yyyy) [Click here for calendar](#)

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)

(mm/dd/yyyy) [Click here for calendar](#)

3. Date on which the pregnancy was confirmed: (PRCNFMDT)

(mm/dd/yyyy) [Click here for calendar](#)

4. Action taken with study intervention: (PRACTIND)

1-None
2-Temporarily stopped intervention
3-Permanently stopped intervention
4-Participant terminated from study

5. Approximate due date: (PRADUEDT)

(mm/dd/yyyy) (PRDDTUNK)OR ☐ Unknown

6. Outcome of pregnancy: (PROUTCME)

1-Vaginal delivery
2-Cesarean delivery
3-Miscarriage
4-Termination
98-Other
*Additional Options Listed Below

If "Other", specify: (PROTCMSP)

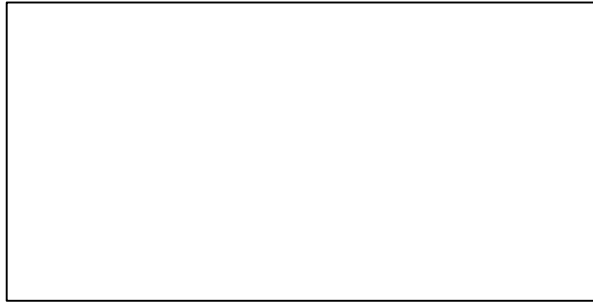
7. Date of pregnancy outcome: (PROTCMDT)

(mm/dd/yyyy) (PRODTUNK)OR ☐ Unknown

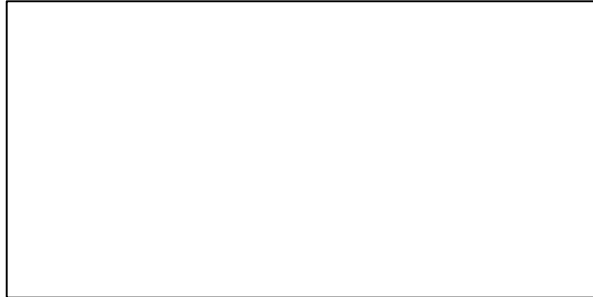
8. Number of live births: (PRNMLIVB)

0-0
1-1
2-2
3-3
4-4
*Additional Options Listed Below

If "0" live births, please indicate reason: *(PRRS0BSP)*

A large, empty rectangular box with a thin black border, intended for the user to provide a reason for reporting zero live births.

Comments: *(PRGCOMM)*

A large, empty rectangular box with a thin black border, intended for the user to provide additional comments or information.

Additional Selection Options for PRG

Pregnancy Number (*PREGNO*) (key field):

- 1-1
- 2-2
- 3-3

Outcome of pregnancy:

- 99-Unknown

Number of live births:

- 99-Other
- 98-Unknown

NIDA Clinical Trials Network

Participant Self-Report Measures (PS2)

Web Version: 1.0; 1.00; 03-25-11

Segment (*PROTSEG*):

Visit Number (*VISNO*):

Welcome!

You are about to answer some questions using this computer by clicking on checkboxes like this: (*PS1BOX*) ☐

When you're done, click on the "Save" button at the top or bottom of the screen.

Try it out!

Click this checkbox and then click on the "Save" button: (*PS2BOX*) ☐

NIDA Clinical Trials Network

PRISM Suicidal and Homicidal Intent (PSM)

Web Version: 1.0; 1.02; 06-14-12

Segment (*PROTSEG*):

Visit Number (*VISNO*):

Date of assessment: (*PSMASMDT*)

(mm/dd/yyyy) [Click here for calendar](#)

1. Recurrent Thoughts of Death

Assessment Questions

- Did you ever find yourself thinking about death or dying?
Do you think you would be better off dead?
Did you feel as though you wanted to die (did you wish you wouldn't wake up in the morning when you went to bed at night)?

UNCLEAR: Can you describe these thoughts/feelings? How often were you thinking about these things?

If YES: Do you still have these thoughts/feelings at the present time?

How often?

For how long have you been having these thoughts/feelings?

Qualifications for Rating

*Must have spent some time thinking about death at least three times in a week (not necessarily all day).
Include recurrent thoughts that s/he would be better off dead.
Include thoughts of death attributed to health problem or HIV status that occur without a change in health status.
Exclude if preoccupied with death when someone close is ill or dying, as long as preoccupation is at expected level.
Exclude normal fear of death.*

a. Rating Scale: (*PSDTHTH*)

0-Absent
1-Sub Threshold
2-Present
9-Not Answered

b. Most recent occurrence: (*PSDTHTHO*)

☐ Prior to the past 6 months ☐ In the past 6 months

2. Recurrent Suicidal Ideation

Assessment Questions

Did you ever think about suicide or killing yourself? (What did you think of? How often did you have that thought?)

If YES: Do you still think about killing yourself at the present time?

How often?

For how long have you been having these thoughts?

Qualifications for Rating

*Must have a thought about this at least three times in a week.
Must think actively of killing oneself, even if ambivalent.
Can have suicidal ideation without having a suicidal plan.*

a. Rating Scale:(PSSDIDEA)

0-Absent
1-Sub Threshold
2-Present
9-Not Answered

b. Most recent occurrence:(PSSDIDA O)

☐ Prior to the past 6 months ☐ In the past 6 months

3. Specific Suicide Plan

Assessment Questions

Did you ever think of any specific plan for committing suicide?
What did you think of doing?

IF YES: When was that?

For how long did you think of this plan?
How often would you think about this plan?

IF YES: Do you think of any specific plan for committing suicide at the present time?

What do you think of doing?
How often do you think about it?
For how long have you been thinking about this plan?

Qualifications for Rating

*Must be thinking of actual method of suicide.
Intent to carry out the plan is not required; formulation of a specific plan is enough.
Include even if fleeting plan.
Need not have been recurrent or feasible.*

a. Rating Scale:(PSSDPLN)

0-Absent
1-Sub Threshold
2-Present
9-Not Answered

b. Most recent occurrence:(PSSDPNO)

☐ Prior to the past 6 months ☐ In the past 6 months

4. Suicide Gesture

Assessment Questions

Did you start to do something in order to kill yourself, even if you changed your mind and stopped, or if someone else stopped you?
What did you do?
What happened then?
What were you thinking of when you did that?

IF YES: When was that?

How many times did this happen?

Qualifications for Rating

*Must be thinking about suicide at the time of act but believe that the extent of action taken would not actually result in death.
Include apparent suicide gesture even if subject claims intent was only attention-seeking.
Exclude self-mutilation for tension relief.
Exclude preparation for attempt.*

a. Rating Scale:(PSSDGEST)

0-Absent
1-Sub T hreshold
2-Present
9-NotAnswered

b. Most recent occurrence:(PSSDGSTO)

☐ Prior to the past 6 months ☐ In the past 6 months

5. Suicide Attempt

Assessment Questions

Did you ever do anything to hurt or kill yourself?

Did you do anything on purpose that you knew could have killed you? (What did you do? What happened then? Did you think you could die as a result?)

IF YES: When was that?

How many times did you do anything to kill yourself?

Qualifications for Rating

Need not have been planned or pre-meditated; include totally impulsive attempts.

Very impulsive suicidal behavior can occur even when other death/suicide items are negative.

Include if completed act was believed to be lethal but subject was discovered and saved.

Must have believed that the act was lethal, regardless of objective reality.

a. Rating Scale:(PSSDTRY)

0-Absent
1-Present
9-NotAnswered

b. Most recent occurrence:(PSSDTRYO)

☐ Prior to the past 6 months ☐ In the past 6 months

6. Recurrent Homicidal Ideation

Assessment Questions

Did you ever think about harming or killing someone? (What did you think of? How often did you have that thought?)

IF YES: Do you still think about harming or killing someone at the present time?

How often?

For how long have you been having these thoughts?

Qualifications for Rating

Must think actively of harming or killing someone, even if ambivalent.

Can have homicidal ideation without having homicidal plan.

a. Rating Scale:(PSHMIDEA)

0-Absent
1-Sub T hreshold
2-Present
9-NotAnswered

b. Most recent occurrence:(PSHMIDA O)

☐ Prior to the past 6 months ☐ In the past 6 months

7. Specific Homicide Plan

Assessment Questions

Have you taken any steps toward carrying out this plan?

IF YES: What have you done?

Qualifications for Rating

*Must be thinking about actual method of harming or killing someone.
Intent to carry out the plan is not required; formulation of a specific plan is enough.
Include even if fleeting plan.
Need not have been recurrent or feasible.*

a. Rating Scale:(PSHMPLAN)

0-Absent
1-Present
9-NotAnswered

Comments:(PSMCOMM)

NIDA Clinical Trials Network

Protocol Violation Log (PVL)

Web Version: 1.0; 3.04; 10-04-12

Date of Violation (PVDATE):

Protocol Violation Number (PVSEQNUM):

To be filled in by person(s) reporting this protocol violation:

1. Violation type: (PV48TYPE)

Z01-INFORMED CONSENT PROCEDURES

O1A - No consent/assent obtained

O1C - Invalid/incomplete informed consent

O1D- Unauthorized assessments and/or procedures conducted prior to obtaining informed consent

O1E- HIPAA release not obtained

*Additional Options Listed Below

If "Other" is indicated, provide the specification: (PV48TPSP)

2. Description of violation: (PVDESC)

3. Has this protocol violation been resolved? (PVRESOL)

☐ No ☐ Yes

Protocol violation resolution and corrective action:(PVRSCASP)

4. Does this protocol violation require IRB reporting?(PVIRB)

☐ No ☐ Yes

If "Yes", provide date reported:(PVIRBDT)

 (mm/dd/yyyy) [Click here for calendar](#)

Comments:(PVLCOMM)

Additional Selection Options for PVL

Protocol Violation Number (*PVSEQNUM*) (key field):

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

Violation type:

01 F- Invalid/incomplete HIPAA
01 G- Invalid/incomplete Comprehension Quiz
01 H- Outdated/Obsolete consent documents used
01 I- Required re-consent not obtained or obtained late
01 J- Informed consent process not properly conducted and/or documented
01 K- Informed consent form/documents not securely and/or properly stored
01 Z- Other (specify)
Z02-INCLUSION/EXCLUSION CRITERIA
02 A- Improper documentation of study physician review and approval of participant eligibility
Z04-LABORATORY ASSESSMENTS/PROCEDURES
04 B- Testing completed outside window
04 C- Testing not completed as per protocol
04 D- Unauthorized test/procedure obtained
04 E- Testing results not reviewed and/or signed off in a timely manner, as per protocol
04 F- Clinical significance not assessed and/or documented for out of range values
04 Z- Other (specify)
Z05-STUDY PROCEDURES/ASSESSMENTS
05 B- Procedures/Assessments not completed as per protocol
05 C- Procedures/Assessments obtained outside the visit timeframes
05 D- Protocol required procedures not followed.
05 E- Protocol required visit/assessment not scheduled
05 F- Protocol required visit conducted outside visit window
05 Z- Other (specify)
Z06-ADVERSE EVENT
06 A- SAE not reported
06 B- SAE reported out of time window
06 C- SAE not recorded as per protocol
06 D- AE not reported
06 E- AE reported out of time window
06 F- AE not recorded as per protocol
06 G- AE/SAE follow-up not conducted and/or documented as per protocol
06 Z- Other (specify)
Z07-RANDOMIZATION PROCEDURES
07 A- Randomization procedures not followed (e.g., outside window, out of sequence, etc.)
07 B- Ineligible participant randomized
07 C- Improper unblinding procedures
07 E- Incorrect treatment assignment
07 F- Study physician didn't review/approve eligibility assessments prior to randomization
07 Z- Other (specify)
Z08-STUDY DRUG DOSING
08 A- Ineligible participant dispensed medication
08 B- Incorrect medication dispensed
08 C- Incorrect medication dosage or amount of medication dispensed
08 D- Induction, dosing, and/or taper procedure not followed per protocol
08 E- Medication prescribing, dispensing, and/or administration not properly documented
08 Z- Other (specify)
Z09-BEHAVORAL INTERVENTION
09 A- Intervention not provided per protocol schedule or visit window timeframe
09 Z- Other (specify)
Z99-OTHER SIGNIFICANT VIOLATIONS

- 99A- Destroying study materials prior to authorization from Lead Node
- 99B- Site starting the study prior to obtaining appropriate IRB(s) and/or CTM approvals
- 99C- Using advertising materials or brochures without prior IRB approval
- 99D- IRB approved compensation not provided to participant
- 99E- Departure from GCP guidelines or any applicable regulatory requirements
- 99Z- Other (specify)

NIDA Clinical Trials Network

Protocol Violation Review (PVR)

Web Version: 1.0; 1.02; 01-18-13

Date of Violation (PVDATE):
Protocol Violation Number (PVSEQNUM):

- 1. Is this event considered to be: (PVSEVER)
- 2. What section of the protocol does this event refer to? (PVSECTN)
- 3. Does this event require retraining? (PVTRAIN)
- 4. Does the protocol need to be modified based on this event? (PVPRTMOD)
- 5. Does the consent need to be modified based on this event? (PVCNTMOD)
- 6. Is the review of this event complete? (PVREVCMP)
If "No", what additional information is requested? (PVADTINF)

☐ Major ☐ Minor

☐ No ☐ Yes
☐ No ☐ Yes
☐ No ☐ Yes
☐ No ☐ Yes

Assessed by: (PVREVBV)

2-Ro Shauna Rothwell
3-Dikla (Dee) Blumberg
5-Maria Campanella
6-Matthew Wright

Comments: (PVCOMM)

Additional Selection Options for PVR

Protocol Violation Number (*PVSEQNUM*) (key field):

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

NIDA Clinical Trials Network

Risk Assessment Battery (30-day) (RAB)

Web Version: 1.0; 2.01; 06-18-12

Segment (*PROTSEG*):

Visit Number (*VISNO*):

Date of assessment: (*RAASMDT*)

(mm/dd/yyyy) [Click here for calendar](#)

Please read each of the following questions very carefully. As you will see, many of these questions are very personal. We understand this and have taken great care to protect the privacy of your answers. It is very important that you answer EVERY question honestly. In fact, it's better not to answer a question at all than to tell us something that is not accurate or true. Some questions may not seem to have an answer that is true for you. When this happens, you should simply choose the answer that is most right. Don't spend too much time on any one question. Remember, always ask for help if you're unsure about what to do. Thank you for your time and cooperation.

Past Month Drug and Alcohol Use

	Not At All	A Few Times	A Few Times Each Week	Everyday
1. In the past month, how often have you <u>Injected</u> cocaine and heroin together (Speedball)?	(<i>RASPEDBL</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. In the past month, how often have you <u>Injected</u> heroin (not mixed)?	(<i>RAHERINJ</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. In the past month, how often have you <u>Snorted</u> heroin (not mixed)?	(<i>RASNRTHR</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. In the past month, how often have you <u>Smoked</u> heroin (not mixed)?	(<i>RASMOKHR</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. In the past month, how often have you <u>Injected</u> cocaine (not mixed)?	(<i>RACOCINJ</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. In the past month, how often have you <u>Snorted</u> cocaine (not mixed)?	(<i>RASNRTCO</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. In the past month, how often have you <u>Smoked</u> crack, rock, or freebase cocaine?	(<i>RASMOKCO</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. In the past month, how often have you <u>Injected</u> amphetamines, methamphetamine, speed, crank, or crystal?	(<i>RASPDINJ</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. In the past month, how often have you <u>Snorted</u> amphetamines, methamphetamine, speed, crank, or crystal?	(<i>RASNRTSP</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. In the past month, how often have you <u>Smoked</u> amphetamines, methamphetamine, speed, crank, or crystal?	(<i>RASMOKSP</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. In the past month, how often have you used benzodiazepines (benzos, benzies) such as Xanax, Valium, Klonopin, or Ativan?	(<i>RAUSEDDBZ</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. In the past month, how often have you taken painkillers [pills such as Percodan, Percocet, Vicodin, Demerol, Dilaudid, Darvon, Darvocet, or syrup (Codeine)]?	(<i>RAUSEDPK</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Which types of painkillers did you use? (<i>RAPKSP</i>) <input type="text"/>				
13. In the past month, how often have you injected Dilaudid?	(<i>RADILINJ</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. In the past month, how often have you used acid, LSD, or other hallucinogens?	(<i>RAUSDLS</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. In the past month, how often have you used marijuana?	(<i>RAUSDCAN</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. In the past month, how often have you used beer, wine, or liquor?	(<i>RADRANK</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

17. In the past month, have you injected drugs?(RADRGINJ) ☐ No ☐ Yes

18. In the past month, have you shared needles or works?(RASHNDLE) ☐ Yes ☐ No or I have not shot up in the past month

19. With how many different people did you share needles in the past month?(RANDLWNO)

0-Z ero or I have notshot up in the pastmonth

1-1 other person

2-2 or 3 differentpeople

3-4 or more differentpeople

20. In the past month, how often have you used a needle after someone (with or without cleaning)?
(RAUSOTND)

0-Never

1-A fewtimes (1 or2 times)

2-A boutonce a week (3 or4 times)

3-More than once a week (5 or more times)

21. In the past month, how often have others used after you (with or without cleaning)?(RANDLEOT)

0-Never

1-A fewtimes (1 or2 times)

2-A boutonce a week (3 or4 times)

3-More than once a week (5 or more times)

22. In the past month, how often have you shared needles with someone you knew (or later found out) had
AIDS or was positive for HIV, the AIDS virus?(RAAIDSND)

0-Never

1-A fewtimes (1 or2 times)

2-A boutonce a week (3 or4 times)

3-More than once a week (5 or more times)

23. In the past month, did you get your needles from any of the following:

- a. A diabetic (RANDLDBT) ☐ No ☐ Yes
- b. On the street (RANDLSRT) ☐ No ☐ Yes
- c. Drugstore (RANDLDST) ☐ No ☐ Yes
- d. Shooting gallery or other place where users go to shoot up (RANDLSGY) ☐ No ☐ Yes
- e. Needle Exchange Program (RANDLEXC) ☐ No ☐ Yes
- f. Other (RANDLOTH) ☐ No ☐ Yes
- If "Other", specify: (RANDLOSP)

24. In the past month, how often have you been to a shooting gallery/house or other place where users go to
shoot up?(RASHTGLY)

0-Never

1-A fewtimes (1 or2 times)

2-A boutonce a week (3 or4 times)

3-More than once a week (5 or more times)

25. In the past month, how often have you been to a Crack House or other place where people go to smoke
crack?(RACRCKHS)

0-Never

1-A fewtimes (1 or2 times)

2-A boutonce a week (3 or4 times)

3-More than once a week (5 or more times)

26. Which statement best describes the way you cleaned your needles during the past month?(RANDLCLN)

0-I have not shot up in the past month

1-I ALWAYS use new needles

2-I ALWAYS clean my needle just BEFORE I shoot up

3-After I shoot up, I ALWAYS clean my needle

4-SOMETIMES I clean my needle, sometimes I don't

*Additional Options Listed Below

27. In the past month, have you cleaned your needles in any of the following ways:

a. Soap and water only

(RANLSOAP)

☐ No

☐ Yes

b. Alcohol

(RANLALCH)

☐ No

☐ Yes

c. Bleach

(RANLBLCH)

☐ No

☐ Yes

d. Boiling water

(RANDLWTR)

☐ No

☐ Yes

e. Other

(RANLOTHC)

☐ No

☐ Yes

If "Other", specify

(RANLCOSP)

In the past month, how often have you:

	Never	A Few Times (1 or 2 Times)	About Once a Week (3 or 4 Times)	More Than Once a Week (5 or More Times)
28. Shared rinse-water?	(RARH20SH) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
29. Shared a cooker?	(RACOKRSH) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
30. Shared cotton?	(RACTNSH) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
31. Divided or shared drugs with others by using one syringe (yours or someone else's) to squirt or load the drugs into the other syringe(s) (backloading, for example)?	(RABCKLD) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

32. How would you describe yourself?(RASEXPRF)

☐ Straight or Heterosexual

☐ Gay or Homosexual

☐ Bisexual

PLEASE NOTE: For the following questions, **sex** means any **vaginal intercourse**, **anal intercourse** (in the butt) or **oral sex** (blowjobs, for example).

33. With how many men have you had sex in the past month?(RASEXMEN)

0-0 men

1-1 man

2-2 or 3 men

3-4 or more men

34. With how many women have you had sex in the past month?(RASEXWMN)

0-0 women

1-1 woman

2-2 or 3 women

3-4 or more women

In the past month, how often:

	Never	A Few Times (1 or 2 Times)	About Once a Week (3 or 4 Times)	More Than Once a Week (5 or More Times)
35. Have you had sex so you could get drugs?	(RASEX4DG) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

36. Have you given drugs to someone so you could have sex with them?	(RADG4SEX) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
37. Have you been paid money to have sex with someone?	(RAPOSTUT) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
38. Did you give money to someone so you could have sex with them?	(RAPD4SEX) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
39. Have you had sex with someone you knew (or later found out) had AIDS or was positive for HIV, the AIDS virus?	(RASEXHIV) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

40. In the past month, how often did you use condoms when you had sex?(RASEXSFE)

0-I have not had sex in the past month

1-All the time

2-Most of the time

3-Some of the time

4-None of the time

41. Were you ever told that you had HIV, the AIDS virus?(RAHIVYES)

☐ No

☐ Yes

☐ I never got the results

42. How worried are you about getting HIV or AIDS?(RAGETHIV)

0-Not at all

1-Slightly

2-Moderately

3-Considerably

4-Extremely

43. How worried are you that you may have already been exposed to the HIV or AIDS virus? (RAEXPHIV)

0-Not at all

1-Slightly

2-Moderately

3-Considerably

4-Extremely

44. How many times have you had a blood test for the AIDS virus (HIV)?(RATSTHIV)

1-1

2-2

3-3

4-4

5-5

*Additional Options Listed Below

45. When were you last tested for HIV?(RALTMHIV)

(mm) / (RALTYPHIV)

(yyyy)

Comments:(RABCOMM)

Additional Selection Options for RAB

Which statement best describes the way you cleaned your needles during the past month?

5-I NEVER clean my needle

How many times have you had a blood test for the AIDS virus (HIV)?

6-6

7-7

8-8

9-9

10-10 or more times

0-Never

NIDA Clinical Trials Network

Self Help Assessment (SHA)

Web Version: 1.0; 1.02; 06-14-12

Segment (*PROTSEG*):

Visit Number (*VISNO*):

Date of assessment: (*SHAASMDT*)

(mm/dd/yyyy) [Click here to view calendar](#)

1. Have you ever attended any 12-Step self-help group such as AA, NA, CA, etc.? (*SHTSMATD*)

☐ No ☐ Yes

2. Since you started the study have you attended any 12-Step self-help group such as AA, NA, CA, etc.? (*SHTSMATD*)

☐ No ☐ Yes

3. Since you ended participation in the study, have you attended any 12-Step self-help group such as AA, NA, CA, etc.? (*SHTSMATD*)

☐ No ☐ Yes

4. How helpful are these groups? (*SHHELPFL*)

0-Not at all
1-S omewhat
2-V ery helpful

5. When did you first attend a self-help/12-Step meeting? (*SHTSMFMO*)

1-J anuary
2-F ebruary
3-M arch
4-A pril
5-M ay
*Additional Options Listed Below

(*SHTSMFYR*, Year (yyyy))

6. In the past 2 months, how frequently have you participated in 12-Step groups? (*SHTSMFRQ*)

0-N ever
1-L ess than 1/week
2-O nce a week
3-M ore than 1/week
4-D aily

7. Since you started the study, how frequently have you attended 12-Step self-help groups? (*SHTSMFRQ*)

1-L ess than 1/week
2-O nce a week
3-M ore than 1/week
4-D aily

8. Since you ended participation in the study, how frequently have you attended 12-Step self-help groups? (*SHTSMFRQ*)

1-L ess than 1/week
2-O nce a week
3-M ore than 1/week
4-D aily

9. Do you have a sponsor? (*SHSPONSR*)

☐ No ☐ Yes

10. In the past 2 months, how frequently have you talked with your sponsor?(SHSPSRTK)

- 0-Never
- 1-Less than 1/week
- 2-Once a week
- 3-More than 1/week
- 4-Daily

11. Since you started the study, how frequently have you talked with your sponsor?(SHSPSRTK)

- 0-Never
- 1-Less than 1/week
- 2-Once a week
- 3-More than 1/week
- 4-Daily

12. Since you ended participation in the study, how frequently have you talked with your sponsor?
(SHSPSRTK)

- 0-Never
- 1-Less than 1/week
- 2-Once a week
- 3-More than 1/week
- 4-Daily

13. Are you a sponsor?(SHUSPNSR)

☐ No

☐ Yes

14. Have you ever served the 12-step group in a role such as a meeting leader, meeting secretary, coffee maker, etc.?(SHGRROLE)

☐ No

☐ Yes

15. Since you started the study, have you served the 12-step group in a role such as a meeting leader, meeting secretary, coffee maker, etc.?(SHGRROLE)

☐ No

☐ Yes

16. Since you ended participation in the study, have you served the 12-step group in a role such as a meeting leader, meeting secretary, coffee maker, etc.?(SHGRROLE)

☐ No

☐ Yes

17. Have you ever celebrated a "birthday" at a 12-Step meeting?(SHBIRTHD)

☐ No

☐ Yes

18. Since you started the study, have you celebrated a "birthday" at a 12-Step meeting?(SHBIRTHD)

☐ No

☐ Yes

19. Since you ended participation in the study, have you celebrated a "birthday" at a 12-Step meeting?
(SHBIRTHD)

☐ No

☐ Yes

Comments:(SHACOMM)

Additional Selection Options for SHA

When did you first attend a self-help/12-Step meeting?

- 6-June
- 7-July
- 8-August
- 9-September
- 10-October
- 11-November
- 12-December

NIDA Clinical Trials Network

TLFB Assessment Period (TAP)

Web Version: 1.0; 1.04; 08-20-12

Segment (*PROTSEG*):

Visit Number (*VISNO*):

1. Date of assessment: (*TAASMTDT*)

(mm/dd/yyyy) [Click here to view calendar](#)

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

From: (mm/dd/yyyy) [Click here to view calendar](#)

To: (mm/dd/yyyy) [Click here to view calendar](#)

3. Have any illicit substances or alcohol been taken during this assessment period? (*TASUBALC*)

☐ No ☐ Yes

4. How many days during this 30 day assessment period prior to consent were **NO** opioids used? (*TAOPIATE*)

Opioids include oxycodone, methadone, opiates such as heroin, vicodin or codeine.

Opioids **do not** include sedatives or benzodiazepines.

NIDA Clinical Trials Network

Treatment Effect Assessment (TEA)

Web Version: 1.0; 1.02; 06-14-12

Segment (*PROTSEG*):

Visit Number (*VISNO*):

Date of assessment: (*TEASSMDT*)

(mm/dd/yyyy) [Click here for calendar](#)

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 circled 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
(<i>TESUBUSE</i>) <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
(<i>TEHEALTH</i>) <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

Time Line Follow Back (TFB)

Web Version: 1.0; 2.00; 08-20-12

Segment (*PROTSEG*):

TLFB Date (*TFASMTDT*):

1. Have any illicit substances or alcohol been taken on this day? (*TFSUBALC*)

☐ No ☐ Yes

2. Alcohol: (*TFALCOHL*)

a. Number of standard drinks: (*TFNMDRNK*)

☐ No ☐ Yes

(xx)

3. Cannabinoids/Marijuana: (*TFCANNAB*)

a. Route: (*TFCANROU*)

☐ No ☐ Yes

1-01-Oral
2-02-Nasal
3-03-Smoking
4-04-Non-IV Injection
5-05-IV Injection
*Additional Options Listed Below

4. Cocaine: (*TFCOCAIN*)

a. Route: (*TFCOCROU*)

☐ No ☐ Yes

1-01-Oral
2-02-Nasal
3-03-Smoking
4-04-Non-IV Injection
5-05-IV Injection
*Additional Options Listed Below

5. Amphetamines: (*TFAMPHET*)

a. Route: (*TFAMPROU*)

☐ No ☐ Yes

1-01-Oral
2-02-Nasal
3-03-Smoking
4-04-Non-IV Injection
5-05-IV Injection
*Additional Options Listed Below

6. Methamphetamine: (*TFMETAMP*)

a. Route: (*TFMETROU*)

☐ No ☐ Yes

1-01-Oral
2-02-Nasal
3-03-Smoking
4-04-Non-IV Injection
5-05-IV Injection
*Additional Options Listed Below

7. Oxycodone/Oxycontin: (TFOXYCOD)

a. Route: (TFOXYROU)

☐ No ☐ Yes

1-01-Oral
2-02-Nasal
3-03-Smoking
4-04-Non-IV Injection
5-05-IV Injection
*Additional Options Listed Below

8. Methadone: (TFMETHAD)

a. Route: (TFMTHROU)

☐ No ☐ Yes

1-01-Oral
2-02-Nasal
3-03-Smoking
4-04-Non-IV Injection
5-05-IV Injection
*Additional Options Listed Below

9. Opiates: (TFOPIATE)

a. Route: (TFOPIROU)

☐ No ☐ Yes

1-01-Oral
2-02-Nasal
3-03-Smoking
4-04-Non-IV Injection
5-05-IV Injection
*Additional Options Listed Below

10. Ecstasy (MDMA): (TFECSTAS)

a. Route: (TFECSROU)

☐ No ☐ Yes

1-01-Oral
2-02-Nasal
3-03-Smoking
4-04-Non-IV Injection
5-05-IV Injection
*Additional Options Listed Below

11. Barbiturates: (TFBARBIT)

a. Route: (TFBARROU)

☐ No ☐ Yes

1-01-Oral
2-02-Nasal
3-03-Smoking
4-04-Non-IV Injection
5-05-IV Injection
*Additional Options Listed Below

12. Benzodiazepines: (TFBENZOD)

a. Route: (TFBENROU)

☐ No ☐ Yes

1-01-Oral
2-02-Nasal
3-03-Smoking
4-04-Non-IV Injection
5-05-IV Injection
*Additional Options Listed Below

13. Other drugs:(*TFO THDRG*)
a. Number of other drugs (up to 9):(*TFNMOTH*)

☐ No ☐ Yes

(x)

Other Drug 1
b. Specify Other Drug 1:(*TFO TH1SP*)
c. Route Other Drug 1:(*TFOTH1RT*)

1-01 -O ral
2-02-Nasal
3-03-S moking
4-04-Non-IV Injection
5-05-IV Injection
*Additional Options Listed Below

Other Drug 2
d. Specify Other Drug 2:(*TFO TH2SP*)
e. Route Other Drug 2:(*TFOTH2RT*)

1-01 -O ral
2-02-Nasal
3-03-S moking
4-04-Non-IV Injection
5-05-IV Injection
*Additional Options Listed Below

Other Drug 3
f. Specify Other Drug 3:(*TFO TH3SP*)
g. Route Other Drug 3:(*TFOTH3RT*)

1-01 -O ral
2-02-Nasal
3-03-S moking
4-04-Non-IV Injection
5-05-IV Injection
*Additional Options Listed Below

Other Drug 4
h. Specify Other Drug 4:(*TFO TH4SP*)
i. Route Other Drug 4:(*TFOTH4RT*)

1-01 -O ral
2-02-Nasal
3-03-S moking
4-04-Non-IV Injection
5-05-IV Injection
*Additional Options Listed Below

Other Drug 5
j. Specify Other Drug 5:(*TFO TH5SP*)
k. Route Other Drug 5:(*TFOTH5RT*)

1-01 -O ral
2-02-Nasal
3-03-S moking
4-04-Non-IV Injection
5-05-IV Injection
*Additional Options Listed Below

Other Drug 6
l. Specify Other Drug 6:(*TFO TH6SP*)

m. Route Other Drug 6:(TFOTH6RT)

1-01-Oral

2-02-Nasal

3-03-Smoking

4-04-Non-IV Injection

5-05-IV Injection

*Additional Options Listed Below

Other Drug 7

n. Specify Other Drug 7:(TFOTH7SP)

o. Route Other Drug 7:(TFOTH7RT)

1-01-Oral

2-02-Nasal

3-03-Smoking

4-04-Non-IV Injection

5-05-IV Injection

*Additional Options Listed Below

Other Drug 8

p. Specify Other Drug 8:(TFOTH8SP)

q. Route Other Drug 8:(TFOTH8RT)

1-01-Oral

2-02-Nasal

3-03-Smoking

4-04-Non-IV Injection

5-05-IV Injection

*Additional Options Listed Below

Other Drug 9

r. Specify Other Drug 9:(TFOTH9SP)

s. Route Other Drug 9:(TFOTH9RT)

1-01-Oral

2-02-Nasal

3-03-Smoking

4-04-Non-IV Injection

5-05-IV Injection

*Additional Options Listed Below

Comments:(TFBCOMM)

Additional Selection Options for TFB

Route:
99-99-Other

NIDA Clinical Trials Network

Treatment Satisfaction (TXS)

Web Version: 1.0; 1.01; 10-13-11

Segment (*PROTSEG*):

Visit Number (*VISNO*):

Date of assessment: (*TXSASMDT*)

(mm/dd/yyyy) [Click here to view calendar](#)

1. How helpful do you think the medications (oral and injected) you received were in reducing your cocaine use? (*TXMEDEFT*)

4-Very helpful
3-Q uite helpful
2-Somewhat helpful
1-A little bit helpful
0-Not helpful

2. How helpful do you think the counseling you received was in reducing your cocaine use? (*TXCNLEFT*)

4-Very helpful
3-Q uite helpful
2-Somewhat helpful
1-A little bit helpful
0-Not helpful

3. Overall, how helpful do you think the treatment (oral medication, injected medication, and counseling) was in reducing your cocaine use? (*TXTRTHLP*)

4-Very helpful
3-Q uite helpful
2-Somewhat helpful
1-A little bit helpful
0-Not helpful

4. Which part of the treatment do you think was most helpful in reducing your cocaine use? (*TXBESTTR*)

1-Oral medication
2-Injected medication
3-Both oral and injected medication
4-Counseling
9-Other
5-None of the above

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

5. How satisfied are you with your overall experience in the study? (*TXSATFY*)

5-Very satisfied
4-Satisfied
3-Neither satisfied nor dissatisfied
2-Dissatisfied
1-Very dissatisfied

4-Placebo
3-Active medication - Low dose
2-Active medication - High dose
1-I am not sure

4-Definitely participate
3-Probably participate
2-Probably not participate
1-Definitely not participate

[illegible]

- If "Other", specify: (TXOTGDSP)

1-I liked the compensation/cash or gift cards
2-I liked the counseling
3-I liked how the medication made me feel
4-I didn't have to pay to participate in the study
5-The study/treatment helped me
*Additional Options Listed Below

[illegible]

- a. There was not enough compensation/cash or gift cards(*TXNOCASH*)
- b. I didn't like the counseling(*TXNOCNSL*)
- c. I didn't like how the medication made me feel(*TXNOMEDS*)
- d. The injected medication caused undesirable side effects(*TXNOINJ*)
- e. The oral medication caused undesirable side effects(*TXNO ORAL*)
- f. The study/treatment didn't help me(*TXNO TRT*)
- g. There were too many visits(*TXVVISITS*)
- h. There were too many procedures/visits that lasted too long(*TXLNGVST*)
- i. There wasn't enough counseling(*TXMRCNSL*)
- j. I would rather enroll in a usual treatment program(*TXTAUBTR*)
- k. The staff didn't treat me well(*TXBDSTAF*)
- l. Undesirable location/difficult to get to clinic(*TXBDLOC*)
- m. Inconvenient clinic hours/days(*TXBDHOUR*)

n. Other(TXBADOTH)
If "Other", specify:(TXBADSP)

9. What is the primary reason you would choose to not participate again?(TXBDPRIM)

If "Other", specify:(TXPRIMSP)

Comments:(TXSCOMM)

☐ No ☐ Yes

- 1-T here was not enough compensation/cash or gift cards
- 2-I didn't like the counseling
- 3-I didn't like how the medication made me feel
- 4-T he injected medication caused undesirable side effects
- 5-T he oral medication caused undesirable side effects
- *Additional Options Listed Below

Additional Selection Options for TXS

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/contribute to science
- 9-I liked coming to the clinic 3x per week
- 10-The staff treated me well
- 11-Desirable location/easy to get to clinic
- 12-Convenient clinic hours/days
- 99-Other

9. What is the primary reason you would choose to not participate again?

- 6-The study/treatment didn't help me
- 7-There were too many visits
- 8-There were too many procedures/visits lasted too long
- 9-There wasn't enough counseling
- 10-I would rather enroll in a usual treatment program
- 11-The staff didn't treat me well
- 12-Undesirable location/difficult to get to clinic
- 13-Inconvenient clinic hours/days
- 99-Other

NIDA Clinical Trials Network

Urine Drug Screen (UDS)

Web Version: 1.0; 5.00; 05-10-12

Segment (PROTSEG):
Visit Number (VISNO):

1. Was a urine drug screen performed? (UDTSTPRF)
a. If "No", provide reason: (UD1NCLRS)

b. If "Other", specify: (UD1NOCSP)

☐ No ☐ Yes

1-Participant reported being unable to provide sample
2-Participant refused to provide sample
3-Staff error
9-Other

1st Urine Drug Screen

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

(mm/dd/yyyy) [Click here for calendar](#)

3. Time 1st urine specimen collected (24 hour format): (UD1COLTM)

(hh:mm)

4. Was the 1st urine temperature within range? (90 - 100 °F) (UD1TMP)

☐ No ☐ Yes

5. Was the 1st urine specimen determined to be adulterated? (UD1ADULT)

☐ No ☐ Yes

1st Urine Drug Screen Results

6.	Drug Name (Abbreviation)	Negative	Positive	Invalid
	Benzodiazepines (BZO):	(UD1BZO) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Amphetamine (AMP):	(UD1AMP) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Marijuana (THC):	(UD1THC) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Methamphetamine (MET):	(UD1MET) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Opiates (2000 ng) (OPI):	(UD1OPI) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Cocaine (COC):	(UD1COC) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Ecstasy (MDMA):	(UD1MDMA) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Oxycodone (OXY):	(UD1OXY) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Methadone (MTD):	(UD1MTD) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Barbiturate (BAR):	(UD1BAR) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Opiates (300 ng) (OPI300): (UD1300OP)

☐ Negative ☐ Positive ☐ Invalid

Opiates (300 ng)(OPI300):(UD1300OP)

☐ Negative ☐ Positive ☐ Invalid

2nd Urine Drug Screen

7. If the 1st urine specimen was determined to be adulterated, was a second specimen collected?
(UD2COLNY)
a. If "No", provide reason: (UD2NCLRS)

b. If "Other", specify:(UD2NOCSP)

8. Time 2nd urine specimen collected (24 hour format):(UD2COLTM)

9. Was the 2nd urine temperature within range? (90 - 100 °F)(UD2TMP)

10. Was the 2nd urine specimen determined to be adulterated?(UD2ADULT)

2nd Urine Drug Screen Results

11.

Drug Name (Abbreviation)	Negative	Positive	Invalid
Benzodiazepines (BZO):	(UD2BZO) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Amphetamine (AMP):	(UD2AMP) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Marijuana (THC):	(UD2THC) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Methamphetamine (MET):	(UD2MET) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Opiates (2000 ng) (OPI):	(UD2OPI) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cocaine (COC):	(UD2COC) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ecstasy (MDMA):	(UD2MDMA) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Oxycodone (OXY):	(UD2OXY) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Methadone (MTD):	(UD2MTD) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Barbiturate (BAR):	(UD2BAR) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Opiates (300 ng) (OPI300):(UD2300OP)

Opiates (300 ng) (OPI300):(UD2300OP)

☐ No ☐ Yes

1-Participant reported being unable to provide sample

2-Participant refused to provide sample

3-Study staff error

9-Other

(hh:mm)

☐ No ☐ Yes

☐ No ☐ Yes

☐ Negative ☐ Positive ☐ Invalid

☐ Negative ☐ Positive ☐ Invalid

Comments:(UDSCOMM)

Visual Analog Scale (VAS)

Web Version: 1.0; 1.01; 06-14-12

Segment (PROTSEG):

Visit Number (VISNO):

Date of assessment: (VASASMDT)

(mm/dd/yyyy) [Click here to view calendar](#)

1. How much do you currently crave **opiates**? (VACRAVEO)

(xxx)

2. How much do you currently crave **cocaine**? (VACRAVEC)

(xxx)

Comments: (VASCOMM)

NIDA Clinical Trials Network

Vital Signs (VIS)

Web Version: 1.0; 3.01; 03-12-13

Segment (*PROTSEG*):

Visit Number (*VISNO*):

Date of assessment: (*VISASMDT*)

(mm/dd/yyyy) [Click here to view calendar](#)

1. Temperature: (*VITEMPFS*)

(xxx.x) °F - or - (*VITEMPCS*) (xx.x) °C

2. Respirations (1 min): (*VIRESPS*)

(xx)

Vital Signs Sitting

1. Time (24-hour format): (*VITIMES*)

(hh:mm)

2. Blood pressure: (*VIBPMGS*)

/ (*VIBPHGS*) mmHg

3. Pulse: (*VIPULSES*)

(xxx) bpm

4. Temperature: (*VITEMPFS*)

(xxx.x) °F - or - (*VITEMPCS*) (xx.x) °C

5. Respirations (1 min): (*VIRESPS*)

(xx)

Vital Signs Standing

1. Time (24-hour format): (*VITIMED*)

(hh:mm)

2. Blood pressure: (*VIBPMGD*)

/ (*VIBPHGD*) mmHg

3. Pulse: (*VIPULSED*)

(xxx) bpm

Comments: (*VISCOMM*)

NIDA Clinical Trials Network

WHO Quality of Life - BREF (WQL)

Web Version: 1.0; 1.02; 06-20-12

Segment (*PROTSEG*):

Visit Number (*VISNO*):

Date of assessment: (*WQLASMDT*)

(mm/dd/yyyy) [Click here to view calendar](#)

The following questions ask how you feel about your quality of life, health, or other areas of your life. **Please choose the answer that appears most appropriate.** If you are unsure about which response to give to a question, the first response you think of is often the best one.

Please keep in mind your standards, hopes, pleasures, and concerns. We ask that you think about your life **in the last 30 days**.

	Very Poor	Poor	Neither Poor Nor Good	Good	Very Good
1. How would you rate your quality of life in the past 30 days?	(<i>WQQUALF</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Very Dissatisfied	Dissatisfied	Neither Satisfied Nor Dissatisfied	Satisfied	Very Satisfied
2. How satisfied have you been with your health in the past 30 days?	(<i>WQHEALTH</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

The following questions ask about **how much** you have experienced certain things in the last 30 days.

	Not At All	A Little	A Moderate Amount	Very Much	An Extreme Amount
3. To what extent do you feel that physical pain prevented you from doing what you needed to do in the past 30 days?	(<i>WQPAINPV</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. How much did you need medical treatment to function in your daily life in the past 30 days?	(<i>WQMEDFCT</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. How much did you enjoy your life in the past 30 days?	(<i>WQENJYLF</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. To what extent do you feel your life to be meaningful in the past 30 days?	(<i>WQMEANLF</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Not At All	A Little	A Moderate Amount	Very Much	Extremely
7. How well were you able to concentrate in the past 30 days?	(<i>WQCONCEN</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. How safe did you feel in your daily life during the past 30 days?	(<i>WQSAFE</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. How healthy was your physical environment in the past 30 days?	(<i>WQENVIRO</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

The following questions ask about how completely you experience or were able to do certain things in the last 30 days.

	Not At All	A Little	Moderately	Mostly	Completely
10. Did you have enough energy for everyday life in the past 30 days?	(WQENERGY) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Were you able to accept your bodily appearance in the past 30 days?	(WQBODYOK) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Did you have enough money to meet your needs in the past 30 days?	(WQMONEYK) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. How available to you was the information that you needed in your day-to-day life in the past 30 days?	(WQINFOAV) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. To what extent did you have the opportunity for leisure activities in the past 30 days?	(WQLEISUR) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Very Poor	Poor	Neither Poor Nor Good	Good	Very Good
15. How well were you able to get around in the past 30 days?	(WQGETARN) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Very Dissatisfied	Dissatisfied	Neither Satisfied Nor Dissatisfied	Satisfied	Very Satisfied
16. How satisfied were you with your sleep in the past 30 days?	(WQSLEEPK) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. How satisfied were you with your ability to perform your daily living activities in the past 30 days?	(WQACTVOK) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. How satisfied were you with your capacity to work in the past 30 days?	(WQWORKOK) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. How satisfied were you with yourself in the past 30 days?	(WQSELFOK) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20. How satisfied were you with your personal relationships in the past 30 days?	(WQRELATK) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21. How satisfied were you with your sex life in the past 30 days?	(WQSEXOK) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22. How satisfied were you with the support you got from your friends in the past 30 days?	(WQFRIEND) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23. How satisfied were you with the living conditions of your place in the past 30 days?	(WQHOMEOK) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
24. How satisfied were you with your access to health services in the past 30 days?	(WQAXSMED) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
25. How satisfied were you with your transport in the past 30 days?	(WQTRANSK) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

The following question refers to how often you have felt or experienced certain things in the last 30 days.

	Never	Seldom	Quite Often	Very Often	Always
26. How often did you have negative feelings such as blue mood, despair, anxiety, depression in the past 30 days?	(WQNGTFEL) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments: (WQLCOMM)

