

Adverse Events (AD1)

Adverse event onset date (AEDATE):

Event number (AESEQNUM):

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

For the purposes of this protocol, Grade 1 (mild) unrelated adverse events should not be reported in Advantage EDC.

1. Adverse event name: (A1DESCPT)

2. Adverse event name: (A1SPINAE)

Respiratory depression-Respiratory depression
 Alcohol intoxication-Alcohol intoxication
 Hepatic impairment-Hepatic impairment
 Drug withdrawal syndrome-Drug withdrawal syndrome (from abrupt discontinuation of suboxone)
 Depressed level of consciousness-Depressed level of consciousness
 Hypersensitivity-Hypersensitivity
 Oral reaction to Suboxone film-Oral reaction to Suboxone film
 Peripheral edema-Peripheral edema
 Increased intracranial pressure-Increased intracranial pressure
 Unintentional pediatric exposure-Unintentional pediatric exposure
 99-Other

If "Other", specify: (A1DESCPT)

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

(mm/dd/yyyy)

4. Severity of event: (A1SEVRTY)

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

5. Is there a reasonable possibility that the extended-release naltrexone caused the event? (A1RDRUG1)

If "Yes", action taken with extended-release naltrexone: (A1ADRUG1)

No Yes

0-None
 1-Decreased drug
 2-Increased drug
 3-Temporarily stopped drug
 4-Permanently stopped drug

6. Is there a reasonable possibility that BUP-NX (Suboxone) caused the event? (A1RDRUG2)

If "Yes", action taken with buprenorphine: (A1ADRUG2)

No Yes

0-None
 1-Decreased drug
 2-Increased drug
 3-Temporarily stopped drug
 4-Permanently stopped drug

7. If "Unrelated" to the study drug(s), alternative etiology: (A1ALTESD)

0-None apparent
 1-Study disease
 2-Concomitant medication
 3-Other pre-existing disease or condition
 4-Accident, trauma, or external factors
 *Additional Options Listed Below

If "Other," specify: (A1AEPSP)

8. Outcome of event: (A1OUTCM)

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

9. 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.

10. Was this event associated with: (A1ASSOC)

- 0-None of the following
- 1-Death
- 2-Life-threatening event
- 3-Inpatient admission to hospital or prolongation of existing hospitalization
- 4-Persistent or significant incapacity
- 5-Congenital anomaly or birth defect
- 6-Important medical event that required intervention to prevent any of the above
- 7-Seizure
- 8-Hospitalization for a medical event

a. If "Death", date of death: (A1DTHDT)

(mm/dd/yyyy)

b. If "Inpatient admission to hospital or prolongation of hospitalization":

Date of hospital admission: (A1HOSPAD)

(mm/dd/yyyy)

Date of hospital discharge: (A1HOSPCD)

(mm/dd/yyyy)

Comments: (AD1COMM)

Additional Selection Options for AD1

Event number (AESEQNUM) (key field):

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

If "Unrelated" to the study drug(s), alternative etiology:

5-Concurrent illness/condition (not pre-existing)
6-Study procedures
7-Naloxone challenge
99-Other

Serious Adverse Event Summary (AD2)

Adverse event onset date (AEDATE):

Event number (AESEQNUM):

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

1. Initial narrative description of serious adverse event:

(A2SUMM)

2. Relevant past medical history: (A2SAEMHX) No Yes Unknown

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

(A2MEDHX)

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

Medication (Generic Name)	Indication
(A2_01DNM) <input type="text"/>	(A2_01DIN) <input type="text"/>
(A2_02DNM) <input type="text"/>	(A2_02DIN) <input type="text"/>
(A2_03DNM) <input type="text"/>	(A2_03DIN) <input type="text"/>
(A2_04DNM) <input type="text"/>	(A2_04DIN) <input type="text"/>
(A2_05DNM) <input type="text"/>	(A2_05DIN) <input type="text"/>
(A2_06DNM) <input type="text"/>	(A2_06DIN) <input type="text"/>
(A2_07DNM) <input type="text"/>	(A2_07DIN) <input type="text"/>
(A2_08DNM) <input type="text"/>	(A2_08DIN) <input type="text"/>
(A2_09DNM) <input type="text"/>	(A2_09DIN) <input type="text"/>
(A2_10DNM) <input type="text"/>	(A2_10DIN) <input type="text"/>

4. Treatments for the event: (A2SAETRTR) No Yes Unknown

Treatment	Indication	Date Treated (mm/d/yyyy)
(A2_1TNME) <input type="text"/>	(A2_1TIND) <input type="text"/>	(A2_1LTDT) <input type="text"/>
(A2_2TNME) <input type="text"/>	(A2_2TIND) <input type="text"/>	(A2_2LTDT) <input type="text"/>
(A2_3TNME) <input type="text"/>	(A2_3TIND) <input type="text"/>	(A2_3LTDT) <input type="text"/>
(A2_4TNME) <input type="text"/>	(A2_4TIND) <input type="text"/>	(A2_4LTDT) <input type="text"/>
(A2_5TNME) <input type="text"/>	(A2_5TIND) <input type="text"/>	(A2_5LTDT) <input type="text"/>

5. Labs/tests performed in conjunction with this event: (A2SAELAB) No Yes Unknown

Lab/Test	Findings	Date of Test (mm/d/yyyy)
(A2_1LBNM) <input type="text"/>	(A2_1LBIN) <input type="text"/>	(A2_1LBDT) <input type="text"/>
(A2_2LBNM) <input type="text"/>	(A2_2LBIN) <input type="text"/>	(A2_2LBDT) <input type="text"/>
(A2_3LBNM) <input type="text"/>	(A2_3LBIN) <input type="text"/>	(A2_3LBDT) <input type="text"/>
(A2_4LBNM) <input type="text"/>	(A2_4LBIN) <input type="text"/>	(A2_4LBDT) <input type="text"/>

(A2_5LBNM)

(A2_5LBIN)

(A2_5LBDT)

6. Follow-up:

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

(A2FOLLUP)

7. Additional information requested by the Medical Monitor:

(A2ADDINF)

Have all Medical Monitor requests been addressed? (A2RQADDR)

Yes

Additional Selection Options for AD2

Event number (*AESEQNUM*) (key field):

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

Serious Adverse Event Medical Reviewer (AD3)

Adverse event onset date (AEDATE):

Event number (AESEQNUM):

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

- No Yes
- No Yes
- No Yes
- No Yes
- No Yes
- No Yes
- No Yes
- No Yes

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

Assessed by: (A3ASRID)

 (initials)

Reviewed by: (A3REVID)

 (initials)

Comments: (A3COMM)

Additional Selection Options for AD3

Event number (*AESEQNUM*) (key field):

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

CTN-ASI Lite v1.0: Drug/Alcohol Use (ASD)

Segment (PROTSEG): B

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):	(ADALB0D) <input type="text"/> (xx)	-	(ADALICOM) <input type="text"/>
D3 Heroin	(ADHER30D) <input type="text"/> (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 (ADHERRTE)	(ADHERCOM) <input type="text"/>
D4 Methadone/LAAM (prescribed):	(ADM DP30D) <input type="text"/> (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 (ADM DP RTE)	(ADM DP COM) <input type="text"/>
D4a Methadone/LAAM (illicit):	(ADM DI30D) <input type="text"/> (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 (ADM DIR TE)	(ADM DICOM) <input type="text"/>
D5 Other Opiates/Analgesics:	(ADOPI30D) <input type="text"/> (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 (ADOPI RTE)	(ADOPICOM) <input type="text"/>
D6 Barbiturates:	(ADBAR30D) <input type="text"/> (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 (ADBAR RTE)	(ADBARCOM) <input type="text"/>

D7 Other Sedatives/ Hypnotics/Tranquilizers:	(ADSH T30D) <input type="text"/> (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 (ADSH TRTE)	(ADSH TCOM) <input type="text"/>
D8 Cocaine:	(ADCO C30D) <input type="text"/> (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 (ADCO CRTE)	(ADCO CCOM) <input type="text"/>
D9 Amphetamines:	(ADAMP30D) <input type="text"/> (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 (ADAMP RTE)	(ADAMP COM) <input type="text"/>
D9a Methamphetamine:	(ADMET30D) <input type="text"/> (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 (ADMET RTE)	(ADMET COM) <input type="text"/>
D10 Cannabis:	(ADTHC30D) <input type="text"/> (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 (ADTH CRTE)	(ADTH CCOM) <input type="text"/>
D11 Hallucinogens:	(ADHAL30D) <input type="text"/> (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 (ADHAL RTE)	(ADHAL COM) <input type="text"/>
D12 Inhalants:	(ADINH30D) <input type="text"/> (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 (ADINH RTE)	(ADINH COM) <input type="text"/>
D36 Nicotine:	(ADNIC30D) <input type="text"/> (xx)		
D13 More than 1 substance per day (including alcohol, excluding nicotine):	(ADGT130D) <input type="text"/> (xx)	-	(ADGT1COM) <input type="text"/>

D14 Currently, which substance is the major problem?

- Interviewers 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/LAAM (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 and one or more drugs
- 16-16 - More than one drug, but no alcohol

(ADMALDRG)

OR

(ADMJGNA) (97) Not answered

Comments:(ADMJGCM)

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

- Delirium Tremens (DTs): 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:

(ADALCRT) (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.

(ADDEETOX) (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) \$ (xx,xxx)

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 AA/NA

(ADOUTPAT) (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) Slightly
- 2-(2) Moderately
- 3-(3) Considerably
- 4-(4) Extremely

(ADAP130D)

OR

(ADAI30NA) (97) Not answered

Comments:(ADAI30CM)

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

(ADDP130D)

OR

(ADDI30NA) (97) Not answered

Comments:(ADDI30CM)

Confidence Ratings: Is the above information significantly distorted by:

D34 Participants misrepresentation?

(ADMISREP) (0) No (1) Yes

D35 Participants inability to understand?

(ADUNDRST) (0) No (1) Yes

Comments: (ASDCOMM)

CTN-ASI Lite v1.0: Employment/Support Status (ASE)

Web Version: 1.0; 1.00; 12-17-13

Segment (PROTSEG): B

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:(AEEDCPM)

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.

(AETECPT) (xx) months

OR

(AETECPTNA) (97) Not answered

Comments:(AETECPTM)

E4 Do you have a valid driver's license?

- Valid license; not suspended/revoked.

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

(AEDRVLSC)

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.

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

(AEAUTOAV)

Comments:(AEAUTOVM)

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.

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

(AE SUPPRT)

Comments:(AE SUPPCM)

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

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

(AE PAID) (xx) days

OR

(AE PAIDNA) (97) Not answered

Comments:(AE PAIDCM)

For questions E12-E17: How much money did you receive from the following sources in the past 30 days?

Max. = \$9999

E12 Employment (net income):

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

(AE EMPNY) \$ (xx,xxx)

OR

(AE EMPYNA) (97) Not answered

Comments:(AE EMPNYCM)

E13 Unemployment compensation:

(AE UNEMNY) \$ (xxxx)

OR

(AE UNEMYNA) (97) Not answered

Comments:(AEUMNYCM)

E14 Welfare:

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

(AEWLFMNY) \$ (xxxx)

OR

(AEWMNYNA) (97) Not answered

Comments:(AEWMNYCM)

E15 Pensions, benefits, or Social Security:

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

(AEPENMY) \$ (xxxx)

OR

(AEPMYNA) (97) Not answered

Comments:(AEPMYCM)

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.

(AEMATMY) \$ (xxxx)

OR

(AEMMYNA) (97) Not answered

Comments:(AEMMYCM)

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.

(AEILLMY) \$ (xxxx)

OR

(AEIMYNA) (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

(AEEP30CM)

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

The participants 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?

- If the participant has been incarcerated or detained during the past 30 days, they cannot have employment problems.

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

(AEEBP30D)

OR

(AEEBP30NA) (96) Not applicable (97) Not answered

Comments: (AEEBP30CM)

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

(AEEC30D)

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 v1.0: Family/Social Relationships (ASF)

Segment (PROTSEG): B

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:(AFMRTLST)

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

(AFMSAT)

Comments:(AFMSAT)

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:(AFLIVARR)

F6 Are you satisfied with these arrangements?

- Refers to response in question F4.

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

(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

(AFLVDRG)

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
98-(97) Not answered

(AFFRETM)

Comments:(AFFRECM)

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) Not answered

(AFFTMSAT)

Comments:(AFSFRECM)

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:	0-(0) No 1-(1) Yes 96-(96) Not applicable 97-(97) Not answered (AFMTR30D)
F19 Father:	0-(0) No 1-(1) Yes 96-(96) Not applicable 97-(97) Not answered (AFFTR30D)

F20 Brothers/sisters:	<input type="text"/> <small>(AFSIB30D)</small>	0-(0) No 1-(1) Yes 96-(96) Not applicable 97-(97) Not answered
F21 Sexual partner/s spouse:	<input type="text"/> <small>(AFSPS30D)</small>	0-(0) No 1-(1) Yes 96-(96) Not applicable 97-(97) Not answered
F22 Children:	<input type="text"/> <small>(AFCHD30D)</small>	0-(0) No 1-(1) Yes 96-(96) Not applicable 97-(97) Not answered
F23 Other significant family (specify): <small>(AFOSFMS P)</small>	<input type="text"/> <small>(AFOSF30D)</small>	0-(0) No 1-(1) Yes 96-(96) Not applicable 97-(97) Not answered
F24 Close friends:	<input type="text"/> <small>(AFFRD30D)</small>	0-(0) No 1-(1) Yes 96-(96) Not applicable 97-(97) Not answered
F25 Neighbors:	<input type="text"/> <small>(AFNBR30D)</small>	0-(0) No 1-(1) Yes 96-(96) Not applicable 97-(97) Not answered
F26 Co-workers:	<input type="text"/> <small>(AFCWK30D)</small>	0-(0) No 1-(1) Yes 96-(96) Not applicable 97-(97) Not answered
Did anyone abuse you? <small>(F18-F26)</small>	A Past 30 Days	
F28 Physically (caused you physical harm)?	<input type="text"/> <small>(AFFAB30D)</small>	0-(0) No 1-(1) Yes 97-(97) Not answered
F29 Sexually (forced sexual advances/acts)?	<input type="text"/> <small>(AFSAB30D)</small>	0-(0) No 1-(1) Yes 97-(97) Not answered
Comments: <small>(AFPRBLCM)</small>	<input type="text"/>	

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

(AFFC30D)

OR

(AFFI30NA) (97) Not answered

Comments:(AFR30CM)

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

(AFSPB0D)

OR

(AFS30NA) (97) Not answered

Comments:(AFSB0CM)

Confidence Ratings: Is the above information significantly distorted by:

F37 Participant's misrepresentation?

(AFMISREP) (0) No (1) Yes

F38 Participant's inability to understand?

(AFUNDRS 7) (0) No (1) Yes

Comments: (ASF COMM)

CTN-ASI Lite v1.0: General Information (ASG)

Web Version: 1.0; 1.00; 01-08-14

Segment (PROTSEG): B

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

(AGCONTCT)

G12 Special:

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

(AGSPCIAL)

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
- 99-(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 G19 is "No."

(AGCEDAYS) (xx) days

OR

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

Comments: (AGCEDSCM)

Comments: (ASGCOMM)

CTN ASI-Lite v1.0 (ASI)

Web Version: 1.0; 1.00; 12-17-13

Segment (PROTSEG): B

Visit number (VISNO):

CTN-ASI Lite v. 1 Follow-Up

Date of assessment (ASIASMDT)

 (mm/dd/yyyy)

Date of birth (ASBRTHDT)

 (mm/dd/yyyy)

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 clients 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, L AAM
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, Florinol
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"
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, Theodor 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:(ASICOMM)

CTN-ASI Lite v1.0: Legal Status (ASL)

Segment (PROTSEG): B
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 post release supervision
2-(2) Yes, probation or pre-sentencing diversion
97-(97) Not answered

(ALPROBAT)

Comments:(ALPRB TCM)

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

			Comments:
L3 Shoplifting/vandalism:	(ALSHPLFT) <input type="text"/> (xx)	OR (ALSLFTNA) <input type="checkbox"/> (97) Not answered	(ALSLFTCM) <input type="text"/>
L4 Parole/probation violations:	(ALPPVIOL) <input type="text"/> (xx)	OR (ALPPVLNA) <input type="checkbox"/> (97) Not answered	(ALPPVLCM) <input type="text"/>
L5 Drug Charges:	(ALDRGCHR) <input type="text"/> (xx)	OR (ALDCHRNA) <input type="checkbox"/> (97) Not answered	(ALDCHRCM) <input type="text"/>
L6 Forgery:	(ALFORGER) <input type="text"/> (xx)	OR (ALFORGNA) <input type="checkbox"/> (97) Not answered	(ALFORGCM) <input type="text"/>
L7 Weapons offense:	(ALWEAPON) <input type="text"/> (xx)	OR (ALWEAPNA) <input type="checkbox"/> (97) Not answered	(ALWEAPCM) <input type="text"/>
L8 Burglary/larceny/B&E:	(ALBURGLR) <input type="text"/> (xx)	OR (ALBURGNA) <input type="checkbox"/> (97) Not answered	(ALBURGCM) <input type="text"/>
L9 Robbery:	(ALROBBRY) <input type="text"/> (xx)	OR (ALROBBNA) <input type="checkbox"/> (97) Not answered	(ALROBBCM) <input type="text"/>
L10 Assault:	(ALASLT) <input type="text"/> (xx)	OR (ALASLTNA) <input type="checkbox"/> (97) Not answered	(ALASLTCM) <input type="text"/>
L11 Arson:	(ALARSON) <input type="text"/> (xx)	OR (ALARSNNA) <input type="checkbox"/> (97) Not answered	(ALARSNCM) <input type="text"/>
L12 Rape:	(ALRAPE) <input type="text"/> (xx)	OR (ALRAPENA) <input type="checkbox"/> (97) Not answered	(ALRAPECM) <input type="text"/>
L13 Homicide/manslaughter:	(ALMURDER) <input type="text"/> (xx)	OR (ALMRDRNA) <input type="checkbox"/> (97) Not answered	(ALMRDRCM) <input type="text"/>
L14 Prostitution:	(ALPROST) <input type="text"/> (xx)	OR (ALPRSTNA) <input type="checkbox"/> (97) Not answered	(ALPRSTCM) <input type="text"/>

L15 Contempt of court:

(ALCONTMP) (xx) OR (ALCNTPNA) (97) Not answered

(ALCNTPCM)

L16 Other (specify):

(ALOTHA RR) (xx) OR (ALOARRNA) (97) Not answered

(ALOARRCM)

If "Other", specify: (ALOTHA SP)

L17 How many of these charges resulted in convictions?

• Do not include misdemeanor offenses from questions L18-L20 below. Convictions include fines, probation, incarcerations, suspended sentences, and guilty pleas.

• If L3-L16 = 00, then L17 = 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.

(ALINCRMT) (xx) months

OR

(ALINCRNA) (97) Not answered

Comments: (ALINRCM)

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

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

(ALCHTRSE)

L25 What for (refer 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
- 99-16 = 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) Slightly
- 2-(2) Moderately
- 3-(3) Considerably
- 4-(4) Extremely

(ALLPSS30D)

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) Slightly
2-(2) Moderately
3-(3) Considerably
4-(4) Extremely

(ALLC130D)

OR

(ALLJ30NA) (97) Not answered

Comments:(ALLB0CM)

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)

CTN-ASI Lite v1.0: Medical Status (ASM)

Web Version: 1.0; 1.00; 12-17-13

Segment (PROTSEG): B

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.

(AMRXPHYS)

If "Yes", specify:(AMRXPHSP)

Comments:

(AMRXPHCM)

M5 Do you receive a pension for a physical disability?

- *Include Workers' Compensation, exclude psychiatric disability.*

(AMPENSPD)

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

(AMPR30NA) (97) Not answered

Comments:(AMPR30CM)

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.*

(AMPBR30D)

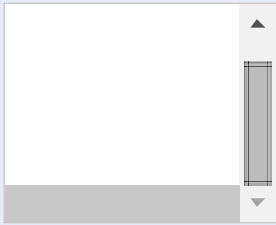
OR

(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.



(AMMTI30D)

OR

(AMMI30NA) (97) Not answered

Comments:(AMMI30CM)



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:(ASMCOMM)



CTN-ASI Lite v1.0: Psychiatric Status (ASP)

Web Version: 1.0; 1.00; 12-17-13

Segment (PROTSEG): B

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?

(APPHSPX) (xx)

OR

(APHPNA) (97) Not answered

Comments:(APPHCM)

P2 Outpatient/private patient?

(APPOHSPX) (xx)

OR

(APPOHPNA) (97) Not answered

Comments:(APPOHCM)

P3 Do you receive a pension for a psychiatric disability?

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

(APPENPSY)

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?	0-(0) No 1-(1) Yes 97-(97) Not answered (APDEP30D)	(APDEPCM) <input type="text"/>
P5 Experienced serious anxiety/tension-uptight, unreasonably worried, inability to feel relaxed?	0-(0) No 1-(1) Yes 97-(97) Not answered (APANX30D)	(APANXCM) <input type="text"/>
P6 Experienced hallucinations-saw things or heard voices that other people did not see or hear?	0-(0) No 1-(1) Yes 97-(97) Not answered (APHL30D)	(APHLPCM) <input type="text"/>

P7 Experienced trouble understanding, concentrating, or remembering?

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

(APCNC30D)

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

Comments

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

(APVLT30D)

P9 Experienced serious thoughts of suicide?
• Participant seriously considered a plan for taking his/her life.

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

(APTO30D)

P10 Attempted suicide?
• Include actual suicidal gestures or attempts.

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

(APASU30D)

P11 Been prescribed medications for any psychological/emotional problem?
• Prescribed for the participant by M.D.
Record "Yes" if a medication was prescribed even if the participant is not taking it.

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

(APMED30D)

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.

(APPR30D) (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

(APPR30NA) (97) Not answered

Comments: (APPR30CM)

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

(APPT130D)

OR

(APPT130NA) (97) Not answered

Comments: (APPT130CM)

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)

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

Segment (PROTSEG): B

Visit number (VISNO):

Date of assessment (CHPA SMDT)

 (mm.ttd/yyyy)

Please rate the extent to which each of the following statements describes how you have been feeling or acting in the past week.

For example, if you feel the statement very accurately describes how you have been feeling in the past week, you would give a rating of "Strongly Agree." If you feel the statement is not at all how you have been feeling in the past week, you would give a rating of "Strongly Disagree."

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

Comments (CHPCOMM)

BUP-NX Dose Log (D51)

Segment (PROTSEG): B

Visit number (VISNO):

Date of visit: (D51DSED T)

 (mm dd/yyyy)

1. Visit type: (D51VSTYP)

1-Induction
2-Dispensing
3-Non-dispensing
4-Participant not yet inducted

2. Prescribed daily dose: (D51DOSE)

 (xx)

3. Number of days with a missed dose since the last visit: (D51MSDSE)

 (xx)

4. Were films returned? (D51RTRNY)

 No Yes

a. Number of 4mg films returned: (D51N4FR T)

 (xxx)

b. Number of 8mg films returned: (D51N8FR T)

 (xxx)

5. Was medication dispensed? (D51BUPDD)

 No Yes

a. Number of 4 mg films dispensed: (D51NM4FD)

 (xxx)

b. Number of 8 mg films dispensed: (D51NM8FD)

 (xxx)

Comments: (D51COMM)

NIDA Clinical Trials Network

Demographics (DEM)

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

1. Date of birth:(DEBRTHDT)

(mm/dd/yyyy)

2. Age:(DEAGE)

(xx)

3. Gender:(DEGENDER)

Male Female Don't know Refused

4. Does the participant consider him or herself to be Hispanic/Latino?(DEHISPNC)

No Yes Don't know Refused

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

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

5. What race does the participant consider him or herself to represent:

(Check all that apply)

White: (DEWHITE)

Black/ African American: (DEBLACK)

Indian (American): (DEAMEIND)

Alaska native: (DEALASKA)

Native Hawaiian: (DEHAWAII)

Guamanian: (DEGUAM)

Samoan: (DESAMOAN)

Other Pacific Islander: (DEPACISL) Specify: (DEPACISO)

Asian Indian: (DEASAIND)

Chinese: (DECHINA)

Filipino: (DEFILIPN)

Japanese: (DEJAPAN)

Korean: (DEKOREA)

Vietnamese: (DEVIETNM)

Other Asian: (DEASIAN) Specify: (DEASIAOT)

Some other race: (DERACEOT) Specify: (DERACESP)

-OR- ---

Don't know:(DERACEDK)

Refused: (DERACERF)

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

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

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

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

If "Other", specify: (DEJOBSP)

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

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

Comments: (DEMCOMM)

Additional Selection Options for DEM

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

- 6-Cuban
- 7-Cuban American
- 8-Central or South American
- 9-Other Latin American
- 99-Other Hispanic
- 98-Refused
- 97-Don't know

What is the highest grade or level of school the participant has completed or the highest degree they have received?

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

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

- 06-Keeping house
- 07-Student
- 99-Other

Is the participant married, widowed, divorced, separated, never married, or living with a partner?

- 06-Living with partner
- 98-Refused
- 99-Don't know

End of Medication (EOM)

Segment (PROTSEG): B

1. Did the participant discontinue study medication early?(EOEARLY)
Primary reason for not completing study medication:(EOSTOP51)

No Yes

- 1-Participant became pregnant
- 2-Participant unable to tolerate side effects
- 3-Participant continued to experience intolerable side effects after a dose reduction
- 4-Contraindicated concomitant medication
- 5-Participant refused, non-specific
- *Additional Options Listed Below

(mm/dd/yyyy)

If "Other", specify:(EOSTOPSP)

2. Date of last taken buprenorphine dose:(EODRUGDT)

Comments:(EOMCOMM)

Additional Selection Options for EOM

Primary reason for not completing study medication:

- 6-Participant left study and never returned
- 7-Clinical deterioration: new onset of psychiatric or medical condition
- 8-Physical illness or condition that precludes taking study medication
- 9-Participant feels study treatment no longer necessary, cured
- 10-Participant feels study treatment no longer necessary, not working
- 11-Participant became incarcerated
- 12-Participant withdrew consent
- 13-Participant moved from area
- 14-Participant deceased
- 15-Participant met criteria for relapse
- 99-Other

0051B (ENR)

Date of assessment (R1ASMDT)

 (mm/dd/yyyy)

Inclusion Criteria

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

- Participant is 18 years of age or older? (R1PTAGE)

No Yes Unknown
- Participant meets DSM-5 criteria for opioid-use disorder (heroin and/or prescription opioids)? (R1OPIDEP)

No Yes Unknown
- Participant has used opioids other than as specifically prescribed within thirty days prior to consent? (R1OPIUSE)

No Yes Unknown
- Participant is seeking treatment for opioid dependence and willing to accept "agonist-based" or "antagonist-based" therapy? (R1SEKTX)

If "No", specify: (R1THRSPSP)

No Yes Unknown
- Participant is female of childbearing potential, and agrees to use acceptable birth control methods during participation in the study? (R1BCUSE)

No Yes Not assessed Not applicable
- Participant is in good-enough health, as determined by the study physician on the basis of medical history, review of systems, physical exam and laboratory assessments, to permit treatment with XR-NTX or BUP-NX? (R1HEALTH)

No Yes Unknown
- Participant is able to provide written informed consent? (R1INFORM)

No Yes Unknown
- Participant is able to speak English sufficiently to understand the study procedures and provide written informed consent to participate in the study? (R1ENGLISH)

No Yes Unknown

- 0-Participant did not want medication
- 1-Participant did not want buprenorphine
- 2-Participant did not want naltrexone
- 3-Participant preferred another treatment

Exclusion Criteria

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

- Participant has a serious medical, psychiatric or substance use disorder that, in the opinion of the study physician, would make study participation hazardous to the participant, or compromise study findings or would prevent the participant from completing the study?

Examples include:
 (a) Disabling or terminal medical illness (e.g., uncompensated heart failure, cirrhosis or end-stage liver disease) as assessed by medical history, review of systems, physical exam and/or laboratory assessments
 (b) Severe, untreated or inadequately treated mental disorder (e.g., active psychosis, uncontrolled manic-depressive illness) as assessed by history and/or clinical interview
 (c) Current severe alcohol, benzodiazepine, or other depressant or sedative hypnotic use likely to require a complicated medical detoxification (routine alcohol and sedative detoxifications may be included) (R1PSYCH)

No Yes Unknown
- Participant has LFTs greater than 5 times upper limit of normal? (R1LFTS)

No Yes Unknown
- Participant has suicidal or homicidal ideation that requires immediate attention? (R1SUICDE)

No Yes Unknown
- Participant has a known allergy or sensitivity to buprenorphine, naloxone, naltrexone, polylactide-co-glycolide, carboxymethylcellulose, or other components of the Vivitrol® diluent? (R1ALLERGY)

No Yes Unknown
- Participant is on maintenance of methadone at doses of 30mg or greater at the time of signing consent? (R1MTDMNT)

No Yes Unknown
- Participant has presence of pain of sufficient severity as to require ongoing pain management with opioids? (R1PAIN)

No Yes Unknown
- Participant has pending legal action or other reasons that might prevent an individual from completing the study? (R1LEGAL)

No Yes Unknown
- Participant is female of child bearing potential and currently pregnant, breastfeeding, or planning on conception? (R1PREGNT)

No Yes Not assessed Not applicable
- Participant has a body habitus that, in the judgment of the study physician, precludes safe intramuscular injection of XR-NTX (e.g., BMI>40, excess fat tissue over the buttocks, emaciation)? (R1HABTUS)

No Yes Unknown

Eligibility for Randomization

- Did the participant complete the screening visit? (R1CMPSCR)

If "No", specify: (R1NCMPSP)

No Yes

If "Other", specify: (R1NCMOTH)

 - 0-Participant dropped out of CTP
 - 1-Participant did not meet eligibility criteria
 - 2-Participant did not want research
 - 99-Other
- Is the participant eligible for the study? (R1ELGTY)

No Yes

 - In the 7 day period prior to detox admission, on average how many bags (or equivalent) of IV heroin per day did the participant report using? (R1HERBAG)

< 6 bags >= 6 bags
 - Last (licit or illicit) opioid use prior to randomization entered on the Detoxification Utilization Summary form? (R1LSTOPP)

No Yes
- Will the participant be randomized? (R1ELGRDM)

No Yes

If "No", specify: (R1NORSP)

If "Other", specify: (R1OTHRSP)

4. Have all eligibility criteria been reviewed by the study physician? (R1PHYREV)

If "Yes", review date: (R1HRVDT)

Comments: (R1COMM)

0-Participant dropped out of CTP
1-Participant did not meet eligibility criteria
2-Participant did not want research
99-Other

No Yes

(mm.dd/yyyy)

The Hamilton Rating Scale for Depression (HAM)

Segment (PROTSEG): B

Visit number (VISNO):

Date of assessment (HAMASMDT)

(mm.ttd/yyyy)

To rate the severity of depression, administer this questionnaire. The higher the score, the more severe the depression.

1. DEPRESSED MOOD (Sadness, hopeless, helpless, worthless)

- 0-(0) Absent
- 1-(1) These feeling states indicated only on questioning
- 2-(2) These feeling states spontaneously reported verbally
- 3-(3) Communicates feeling states non-verbally- i.e., through facial expression, posture, voice, and t
- 4-(4) Patient reports VIRTUALLY ONLY these feeling states in his spontaneous verbal and non-verbal com

(HADPMOOD)

2. FEELINGS OF GUILT

- 0-(0) Absent
- 1-(1) Self reproach, feels he has let people down
- 2-(2) Ideas of guilt or rumination over past errors or sinful deeds
- 3-(3) Present illness is a punishment. Delusions of guilt
- 4-(4) Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations

(HAGUILT)

3. SUICIDE

- 0-(0) Absent
- 1-(1) Feels life is not worth living
- 2-(2) Wishes he were dead or any thoughts of possible death to self
- 3-(3) Suicide ideas or gesture
- 4-(4) Attempts at suicide (any serious attempt rates 4)

(HASUIUDE)

4. INSOMNIA EARLY

- 0-(0) No difficulty falling asleep
- 1-(1) Complains of occasional difficulty falling asleep - i.e., more than 1/2 hour
- 2-(2) Complains of nightly difficulty falling asleep

(HAINSMER)

5. INSOMNIA MIDDLE

- 0-(0) No difficulty
- 1-(1) Participant complains of being restless and disturbed during the night
- 2-(2) Waking during the night - any getting out of bed rates 2 (except for purposes of voiding)

(HAINSMMD)

6. INSOMNIA LATE

- 0-(0) No difficulty
- 1-(1) Waking in early hours of the morning but goes back to sleep
- 2-(2) Unable to fall asleep again if he gets out of bed

(HAINSMLT)

7. WORK AND ACTIVITIES

- 0-(0) No difficulty
- 1-(1) Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies
- 2-(2) Loss of interest in activity; hobbies or work-either directly reported by patient, or indirect i
- 3-(3) Decrease in actual time spent in activities or decrease in productivity
- 4-(4) Stopped working because of present illness

(HAWRKACT)

8. RETARDATION: PSYCHOMOTOR

(Slowness of thought and speech; impaired ability to concentrate; decreased motor activity)

- 0-(0) Normal speech and thought
- 1-(1) Slight retardation at interview
- 2-(2) Obvious retardation at interview
- 3-(3) Interview difficult
- 4-(4) Complete stupor

(HAPSYCHM)

9. **AGITATION**

- 0-(0) None
- 1-(1) Fidgetiness
- 2-(2) Playing with hands, hair, etc.
- 3-(3) Moving about, can't sit still
- 4-(4) Hand wringing, nail biting, hair-pulling, biting of lips

(HAAGITAN)

10. **ANXIETY (PSYCHOLOGICAL)**

- 0-(0) No difficulty
- 1-(1) Subjective tension and irritability
- 2-(2) Worrying about minor matters
- 3-(3) Apprehensive attitude apparent in face or speech
- 4-(4) Fears expressed without questioning

(HAANXPSY)

11. **ANXIETY SOMATIC:** Psychological concomitants of anxiety, (i.e., effects of autonomic overactivity, "butterflies," indigestion, stomach cramps, belching, diarrhea, palpitations, hyperventilation, paresthesia, sweating, flushing, tremor, headache, urinary frequency). Avoid asking about possible medication side effects (i.e., dry mouth, constipation)

- 0-(0) Absent
- 1-(1) Mild
- 2-(2) Moderate
- 3-(3) Severe
- 4-(4) Incapacitating

(HAANXSOM)

12. **SOMATIC SYMPTOMS (GASTROINTESTINAL)**

- 0-(0) None
- 1-(1) Loss of appetite but eating without encouragement from others. Food intake about normal
- 2-(2) Difficulty eating without urging from others. Marked reduction of appetite and food intake

(HASOMGAS)

13. **SOMATIC SYMPTOMS GENERAL**

- 0-(0) None
- 1-(1) Heaviness in limbs, back and head. Backaches, headache, muscle aches. Loss of energy and fatigab
- 2-(2) Any clear-cut symptom rates 2

(HASOMGEN)

14. **GENITAL SYMPTOMS** (Symptoms such as: loss of libido; impaired sexual performance; menstrual disturbances)

- 0-(0) Absent
- 1-(1) Mild
- 2-(2) Severe

(HAGENSYM)

15. **HYPOCHONDRIASIS**

- 0-(0) Not present
- 1-(1) Self-absorption (bodily)
- 2-(2) Preoccupation with health
- 3-(3) Frequent complaints, requests for help, etc.
- 4-(4) Hypochondriacal delusions

(HAHYPOCH)

16. **LOSS OF WEIGHT**

A. When rating by history:

- 0-(0) No weight loss
- 1-(1) Probably weight loss associated with present illness
- 2-(2) Definite (according to participant) weight loss

(HAWEIGHT)

17. **INSIGHT**

- 0-(0) Acknowledges being depressed and ill
- 1-(1) Acknowledges illness but attributes cause to bad food, climate, overwork, virus, need for rest
- 2-(2) Denies being ill at all

(HAINSIGHT)



Injection Site Abnormality (INA)

Segment (PROTSEG): B

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

Abnormal Event If "Other", specify in comments	Event Start Date (mm/dd/yyyy)	Severity	Treatment	Event Resolution Date (mm/dd/yyyy)	Comments
1-Pain 2-Tenderness 3-Induration 4-Swelling 5-Erythema (redness) *Additional Options Listed Below 1. (NETYP1)	(NESDT1) <input type="text"/>	(INESVR1) <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	(NETRT1) <input type="text"/>	(INERDT1) <input type="text"/>	(INECOM1) <input type="text"/>
1-Pain 2-Tenderness 3-Induration 4-Swelling 5-Erythema (redness) *Additional Options Listed Below 2. (NETYP2)	(NESDT2) <input type="text"/>	(INESVR2) <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	(NETRT2) <input type="text"/>	(INERDT2) <input type="text"/>	(INECOM2) <input type="text"/>
1-Pain 2-Tenderness 3-Induration 4-Swelling 5-Erythema (redness) *Additional Options Listed Below 3. (NETYP3)	(NESDT3) <input type="text"/>	(INESVR3) <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	(NETRT3) <input type="text"/>	(INERDT3) <input type="text"/>	(INECOM3) <input type="text"/>
1-Pain 2-Tenderness 3-Induration 4-Swelling 5-Erythema (redness) *Additional Options Listed Below 4. (NETYP4)	(NESDT4) <input type="text"/>	(INESVR4) <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	(NETRT4) <input type="text"/>	(INERDT4) <input type="text"/>	(INECOM4) <input type="text"/>
1-Pain 2-Tenderness 3-Induration 4-Swelling 5-Erythema (redness) *Additional Options Listed Below 5. (NETYP5)	(NESDT5) <input type="text"/>	(INESVR5) <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	(NETRT5) <input type="text"/>	(INERDT5) <input type="text"/>	(INECOM5) <input type="text"/>
1-Pain 2-Tenderness 3-Induration 4-Swelling 5-Erythema (redness) *Additional Options Listed Below 6. (NETYP6)	(NESDT6) <input type="text"/>	(INESVR6) <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	(NETRT6) <input type="text"/>	(INERDT6) <input type="text"/>	(INECOM6) <input type="text"/>
1-Pain 2-Tenderness 3-Induration 4-Swelling 5-Erythema (redness) *Additional Options Listed Below 7. (NETYP7)	(NESDT7) <input type="text"/>	(INESVR7) <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	(NETRT7) <input type="text"/>	(INERDT7) <input type="text"/>	(INECOM7) <input type="text"/>
1-Pain 2-Tenderness 3-Induration 4-Swelling 5-Erythema (redness) *Additional Options Listed Below 8. (NETYP8)	(NESDT8) <input type="text"/>	(INESVR8) <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	(NETRT8) <input type="text"/>	(INERDT8) <input type="text"/>	(INECOM8) <input type="text"/>

<p>1-Pain 2-Tenderness 3-Induration 4-Swelling 5-Erythema (redness) *Additional Options Listed Below</p> <p>9. (NETYP9)</p>	<p>(NESDT9) <input type="text"/></p>	<p>(INESVR9) <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe</p>	<p>(NETRT9) <input type="text"/></p>	<p>(INERDT9) <input type="text"/></p>	<p>(INECOM9) <input type="text"/></p>
<p>1-Pain 2-Tenderness 3-Induration 4-Swelling 5-Erythema (redness) *Additional Options Listed Below</p> <p>10. (NETYP10)</p>	<p>(NESDT10) <input type="text"/></p>	<p>(INESVR10) <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe</p>	<p>(NETRT10) <input type="text"/></p>	<p>(INERDT10) <input type="text"/></p>	<p>(INECOM10) <input type="text"/></p>
<p>1-Pain 2-Tenderness 3-Induration 4-Swelling 5-Erythema (redness) *Additional Options Listed Below</p> <p>11. (NETYP11)</p>	<p>(NESDT11) <input type="text"/></p>	<p>(INESV11) <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe</p>	<p>(NETRT11) <input type="text"/></p>	<p>(INERDT11) <input type="text"/></p>	<p>(INECOM11) <input type="text"/></p>
<p>1-Pain 2-Tenderness 3-Induration 4-Swelling 5-Erythema (redness) *Additional Options Listed Below</p> <p>12. (NETYP12)</p>	<p>(NESDT12) <input type="text"/></p>	<p>(INESV12) <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe</p>	<p>(NETRT12) <input type="text"/></p>	<p>(INERDT12) <input type="text"/></p>	<p>(INECOM12) <input type="text"/></p>

Comments: (INACOMM)

Additional Selection Options for INA

Event 1 type

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

Induction Failure (INF)

Date induction failed: (INFAILDT)

 (mm.Bd/yyyy)

1. Why was the participant not induced into a treatment? (INREASON)

- 0-Participant could not tolerate detoxification
- 1-Participant failed naloxone challenge
- 2-Participant failed to provide a negative urine sample
- 3-Participant left prior to induction
- 4-Participant rejected treatment assignment
- *Additional Options Listed Below

Comments: (INFCOMM)

Additional Selection Options for INF

Why was the participant not induced into a treatment?

5-Participant met criteria for relapse

6-Participant reached end of induction window

XR-NTX Administration (INJ)

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

Date of injection: (INJNJD)

(mm.ttd/yyyy)

1. Location of previous injection: (INPREV)

Right buttock Left buttock

2. Injection location: (ININLOC)

Right buttock Left buttock

3. Time injection given (24 - hour format): (ININTM)

(hh:mm)

4. Did you experience difficulty with XR-NTX administration? (INDIFFCT)

No Yes

If "Yes", describe: (INDIPRES)

Comments: (INICOMM)

Additional Selection Options for INJ

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

- 1-1
- 2-2
- 3-3
- 4-4
- 5-5
- 6-6
- 7-7

Injection Site Examination (INX)

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

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

Date of examination: (INXASMDT)

(mm.dd/yyyy)

Location of previous injection: (INJPREV)

Right buttock Left buttock

1. Location of injection: (INJLOC)

Right buttock Left buttock

2. Is this injection site normal? (INJOK)

No Yes

If the injection site is "abnormal", complete the Injection Site Abnormality Log.

Note: If this event is an SAE, you must complete the AE forms.

Comments: (INXCOMM)

Additional Selection Options for INX

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

- 1-1
- 2-2
- 3-3
- 4-4
- 5-5
- 6-6
- 7-7

Clinical Laboratory Tests (LAB)

Segment (PROTSEG): B

Visit number (VISNO):

Lab collection date (LABDATE)

 (mm/dd/yyyy)

Test	Result	Date of Collection (mm/dd/yyyy)	Abstracted from Medical Record
LFTs			
1. Aspartate Aminotransferase (AST/SGOT)	(LAAST) <input type="text"/> (xx.xx.x) IU/L	(LAASDT) <input type="text"/>	(LAASTMR) <input type="checkbox"/> Yes
2. Alanine Aminotransferase (ALT/SGPT)	(LAALT) <input type="text"/> (xxxx.x) U/L	(LAALTD) <input type="text"/>	(LAALTM) <input type="checkbox"/> Yes
3. Albumin	(LAALBUMN) <input type="text"/> (x.x) g/dL	(LAALBD) <input type="text"/>	(LAALBM) <input type="checkbox"/> Yes
4. Total Bilirubin	(LABLRBT) <input type="text"/> (xx.x) mg/dL	(LABLDT) <input type="text"/>	(LABLMR) <input type="checkbox"/> Yes
Hepatitis			
5. Hep B surface antigen (HBsAg)	(LAHBSAG) <input type="checkbox"/> Negative <input type="checkbox"/> Positive	(LAHBAGD) <input type="text"/>	(LAHBAGMR) <input type="checkbox"/> Yes
6. Hep B surface antibody (HBsAb)	(LAHBSAB) <input type="checkbox"/> Negative <input type="checkbox"/> Positive	(LAHBABD) <input type="text"/>	(LAHBABMR) <input type="checkbox"/> Yes
7. Hep C antibody	(LAHEPC) <input type="checkbox"/> Negative <input type="checkbox"/> Positive	(LAHEPCD) <input type="text"/>	(LAHEPCMR) <input type="checkbox"/> Yes
HIV			
8. HIV antibody	(LAHIVAB) <input type="checkbox"/> Negative <input type="checkbox"/> Positive	(LAHIVD) <input type="text"/>	(LAHIVMR) <input type="checkbox"/> Yes

Comments (LABCOMM)

MM Community Treatment (MMC)

Segment (PROTSEG): B

Visit number (VISNO):

Date of assessment (MMCASMDT)

(mm.ttd/yyyy)

1. Is the participant continuing to receive treatment in the community as planned? (MMTXPLAN)

No Yes Not applicable

2. What treatment(s) is the participant engaging in:

No Yes

a. Medication assisted treatment (MAT) with buprenorphine maintenance: (MMBUP)

No Yes

b. Medication assisted treatment (MAT) with injectable naltrexone: (MMVIVTRL)

No Yes

c. Medication assisted treatment (MAT) with oral naltrexone: (MMVIVORL)

No Yes

d. Medication assisted treatment (MAT) with methadone maintenance: (MMMTDMNT)

No Yes

e. Medication assisted treatment (MAT) with inpatient detox: (MMINPDTX)

No Yes

f. Psychosocial: (MMPSYCH)

No Yes

g. Referral to other community-based treatment: (MMCOMTRT)

No Yes

If "Yes", specify: (MMPSYCSP)

-OR-

Declined further treatment: (MMDCLNTR)

Comments: (MMC COMM)

Medical Management Log (MML)

Segment (PROTSEG): B

Scheduled Medical Management Visit(s)

Week	Medical Management	Date of Visit (mm/dd/yyyy)	Comments
0	(M MYNWK00) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MMDT00) <input type="text"/>	(MMCOMM00) <input type="text"/>
1	(M MYNWK01) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MMDT01) <input type="text"/>	(MMCOMM01) <input type="text"/>
2	(M MYNWK02) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MMDT02) <input type="text"/>	(MMCOMM02) <input type="text"/>
3	(M MYNWK03) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MMDT03) <input type="text"/>	(MMCOMM03) <input type="text"/>
4	(M MYNWK04) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MMDT04) <input type="text"/>	(MMCOMM04) <input type="text"/>
6	(M MYNWK06) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MMDT06) <input type="text"/>	(MMCOMM06) <input type="text"/>
8	(M MYNWK08) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MMDT08) <input type="text"/>	(MMCOMM08) <input type="text"/>
10	(M MYNWK10) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MMDT10) <input type="text"/>	(MMCOMM10) <input type="text"/>
12	(M MYNWK12) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MMDT12) <input type="text"/>	(MMCOMM12) <input type="text"/>
14	(M MYNWK14) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MMDT14) <input type="text"/>	(MMCOMM14) <input type="text"/>
16	(M MYNWK16) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MMDT16) <input type="text"/>	(MMCOMM16) <input type="text"/>
20	(M MYNWK20) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MMDT20) <input type="text"/>	(MMCOMM20) <input type="text"/>
24	(M MYNWK24) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MMDT24) <input type="text"/>	(MMCOMM24) <input type="text"/>
EOT	(M MYNEOT) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MMDTEOT) <input type="text"/>	(MMCOM EOT) <input type="text"/>

Un-scheduled Medical Management Visit(s)

Date of Visit (mm/dd/yyyy)	Reason If 'Other', specify in Comments section	Comments
(M MUSDT01) <input type="text"/>	0-BUP dose adjustment 1-BUP medication replacement 2-XR-NTX off cycle injection 3-XR-NTX injection site reaction 5-AE/SAE *Additional Options Listed Below (M MUSRS01)	(M MUSCM01) <input type="text"/>
(M MUSDT02) <input type="text"/>	0-BUP dose adjustment 1-BUP medication replacement 2-XR-NTX off cycle injection 3-XR-NTX injection site reaction 5-AE/SAE *Additional Options Listed Below (M MUSRS02)	(M MUSCM02) <input type="text"/>
(M MUSDT03) <input type="text"/>	0-BUP dose adjustment 1-BUP medication replacement 2-XR-NTX off cycle injection 3-XR-NTX injection site reaction 5-AE/SAE *Additional Options Listed Below (M MUSRS03)	(M MUSCM03) <input type="text"/>

(MMUSDT04) <input type="text"/>	(MMUSRS04) 0-BUP dose adjustment 1-BUP medication replacement 2-XR-NTX off cycle injection 3-XR-NTX injection site reaction 5-AE/SAE *Additional Options Listed Below	(MMUSCM04) <input type="text"/>
(MMUSDT05) <input type="text"/>	(MMUSRS05) 0-BUP dose adjustment 1-BUP medication replacement 2-XR-NTX off cycle injection 3-XR-NTX injection site reaction 5-AE/SAE *Additional Options Listed Below	(MMUSCM05) <input type="text"/>
(MMUSDT06) <input type="text"/>	(MMUSRS06) 0-BUP dose adjustment 1-BUP medication replacement 2-XR-NTX off cycle injection 3-XR-NTX injection site reaction 5-AE/SAE *Additional Options Listed Below	(MMUSCM06) <input type="text"/>
(MMUSDT07) <input type="text"/>	(MMUSRS07) 0-BUP dose adjustment 1-BUP medication replacement 2-XR-NTX off cycle injection 3-XR-NTX injection site reaction 5-AE/SAE *Additional Options Listed Below	(MMUSCM07) <input type="text"/>
(MMUSDT08) <input type="text"/>	(MMUSRS08) 0-BUP dose adjustment 1-BUP medication replacement 2-XR-NTX off cycle injection 3-XR-NTX injection site reaction 5-AE/SAE *Additional Options Listed Below	(MMUSCM08) <input type="text"/>
(MMUSDT09) <input type="text"/>	(MMUSRS09) 0-BUP dose adjustment 1-BUP medication replacement 2-XR-NTX off cycle injection 3-XR-NTX injection site reaction 5-AE/SAE *Additional Options Listed Below	(MMUSCM09) <input type="text"/>
(MMUSDT10) <input type="text"/>	(MMUSRS10) 0-BUP dose adjustment 1-BUP medication replacement 2-XR-NTX off cycle injection 3-XR-NTX injection site reaction 5-AE/SAE *Additional Options Listed Below	(MMUSCM10) <input type="text"/>

Comments: (MMLCOMM)

Additional Selection Options for MML

Unsch 1 med mgmt reason

99-Other

Medical Management Termination (MMT)

Segment (PROTSEG): B

Medical Management study treatment (Medical Management visits) ends in the event of the week 24 visit (treatment phase is completed), if the participant meets the primary outcome of an opioid relapse event and is referred to community treatment, or MM treatment ends for other reasons. Note: participants may discontinue study medications for valid reasons, continue MM visits, and not meet relapse criteria, and complete the study treatment phase. Medication use is tracked elsewhere.

1. Date Medical Management ended: (MMENDDT)

 (mm/dd/yyyy)

2. Why did Medical Management (MM) treatment end? (MTE NDRSN)

- 1-End of study treatment period
- 2-Relapse (positive urines or self-report)
- 3-Relapse (missing urines)
- 4-Adverse event
- 5-Participant declined further MM study treatment visits
- *Additional Options Listed Below

If "Other", specify: (MTENDOSP)

3. What treatment plan has been established for the participant at his/her termination from study treatment?

a. Medication assisted treatment (MAT) with buprenorphine maintenance: (MTBUP)

 No Yes

b. Medication assisted treatment (MAT) with injectable naltrexone: (MTVIVTRL)

 No Yes

c. Medication assisted treatment (MAT) with oral naltrexone: (MTVIVORL)

 No Yes

d. Medication assisted treatment (MAT) with methadone maintenance: (MTM TDMNT)

 No Yes

e. Medication assisted treatment (MAT) with inpatient detox: (MTINPDTX)

 No Yes

f. Psychosocial: (MTPSYCH)

 No Yes

g. Referral to other community-based treatment: (MTCOMTRT)

 No Yes

-OR-

Declined further treatment: (MTDCLNTR)

-OR-

Failed to return to establish a treatment plan: (MTNOTRMT)

Comments: (MM TCOMM)

If "Yes", specify: (MTPSYCSP)

Additional Selection Options for MMT

Why did Medical Management (MM) treatment end?

99-Other (e.g., other safety concerns, PI discretion)

Missed Visit Form (MVF)

Segment (PROTSEG): B

Visit number (VISNO):

Reason for missed visit: (MVREASON)

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

If "Other", specify: (MVOTHRSP)

Comments: (MVFCOMM)

Additional Selection Options for MVF

Reason for missed visit:

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

Non-CTP / Study Medical and Other Services (NMS)

Segment (PROTSEG): B

Visit number (VISNO):

Date of assessment (NMSASMDT)

 (mm/dd/yyyy)

When did the participant last complete this form (NMLSTFDI)

 (mm/dd/yyyy)

The following questions are about the services you've received in the past 30 days, besides what you've received in this research study.

1. Are you currently receiving substance abuse treatment services from this substance abuse treatment program (CTP)? (NMCTPSE)

No Yes
2. Have you participated in an (other) outpatient treatment program for drug or alcohol problems? (Do not include your participation in this study or the services directly related to this study or services received from this substance abuse treatment program.) (NMOUSER)

a. How many days have you participated? (NMOUDAY) (xx) days

b. How many hours do you attend the program in a typical week? (NMOUHR) (xx) hours

c. Are you, or have you been, required by the criminal justice system to attend treatment? (NMOUTCJ) No Yes
3. Have you been admitted into a residential program for detox or for other services? (NMRDTX)

a. How many admissions? (NMRDTXNO) (xx) admissions

b. How many nights altogether for all stays? (NMRDTXNG) (xx) nights
4. Have you been admitted into a hospital for detox? (NMHDTX)

a. How many admissions? (NMHDTXNO) (xx) admissions

b. How many nights altogether for all stays? (NMHDTXNG) (xx) nights
5. Have you been admitted to the hospital for any other reason? (NMHSPTL)

a. How many times were you admitted? (NMHSPNO) (xx) admissions

b. Were any admissions for psychiatric or emotional reasons? (NMHSPSY) No Yes

c. How many nights altogether for all stays? (NMHSPNG) (xx) nights
6. Have you visited an emergency room and not been admitted to the hospital? (NMER)

How many times did you visit the emergency room? (NMERNO) (xx) visits
7. Outside of the services or programs mentioned above, have you seen a therapist, that is a psychiatrist, psychologist, counselor, or social worker for psychological or emotional problems? (NMMTHLTH)

How many times did you see a psychiatrist, psychologist, counselor or social worker? (NMMTHLNO) (xx) times
8. Outside of the services or programs mentioned above, have you seen a therapist, that is a psychiatrist, psychologist, counselor, or social worker for alcohol or drug problems? (NMMDRG)

How many times did you see a psychiatrist, psychologist, counselor or social worker? (NMMDGNO) (xx) times
9. Have you visited a medical office, not including your therapist? (Include all visits to a physician, nurse, nurse practitioner, or physician's assistant.) (NMMEDOFF)

a. How many visits to a medical office have you had? (NMMEDVNO) (xx) visits

b. How many of these visits did you see a doctor? (NMMEDSEE) (xx) visits
10. Have you attended AA, NA, or CA meetings? (NMAA)

For how many days? (NMAADAY) (xx) days
11. Are you currently prescribed any medication for the treatment of substance abuse? (NMRXMED)

a. If "Yes", which of the following medications have you been prescribed?

 - Depot Naltrexone (NMRXVTD) No Yes
 - Naltrexone (NMRXVTL) No Yes
 - Suboxone (NMRXSBX) No Yes
 - Subutex (NMRXSBTX) No Yes
 - Methadone (NMRXETH) No Yes
 - Buprenorphine (NMRXBUP) No Yes
 - Acamprosate (NMRXACS) No Yes

Abuse/Disulfiram (NMRXD SM)

No Yes

Other (NMRXOTR)

No Yes

Specify: (NMRXOTSP)

b. How many total days did you take this/these medications? (NMEDDAY)

(xx)

12. Have you had health insurance? (NMINSURE)

No Yes

a. Did you have Medicaid? (NMINSMED)

No Yes

b. Did you have other public insurance? (NMINSPUB)

No Yes

c. Do you have private health insurance? (NMINSPRV)

No Yes

d. Have you spent time uninsured? (NMINSN0)

No Yes

13. Have you had a job? This includes any job for which you have been paid (including under-the-table work.) (NMWORKIN)

No Yes

a. How many days have you been paid for working? (NMWRKDAY)

(xx) days

b. Including overtime, how many hours per week do you work on this job? (NMWRKHS)

(xxx) hours

c. Including tips and bonuses, what is your hourly rate on this job, before taxes? (NMWRKTE)

(\$\$\$.\$\$) per hour

Note: I would like to ask you some questions about your legal status. I want to remind you all information is kept strictly confidential. Legal information will not be available to anyone outside this research study.

14. How many days have you participated in criminal activities (excluding drug use)? (NMCRACT)

(xx) days

15. How many days were you detained or incarcerated (spent overnight in jail)? (NMCRCM INC)

(xx) days

Have you committed, been charged with, or been convicted of (answer all questions below):

	Committed	If "Yes", Number of Days: (xx)	Charged	Convicted
16. Drug charges (not drug dealing)	N/A	N/A	(NMDCCCHAR) <input type="checkbox"/> No <input type="checkbox"/> Yes	(NMDCCONV) <input type="checkbox"/> No <input type="checkbox"/> Yes
17. Drug dealing	(NMDCCOMT) <input type="checkbox"/> No <input type="checkbox"/> Yes	(NMDCCDAYS) <input type="text"/>	(NMDCCCHAR) <input type="checkbox"/> No <input type="checkbox"/> Yes	(NMDCCONV) <input type="checkbox"/> No <input type="checkbox"/> Yes
18. Shoplifting/retail theft	(NMSLCOMT) <input type="checkbox"/> No <input type="checkbox"/> Yes	(NMSLDAYS) <input type="text"/>	(NMSLCHAR) <input type="checkbox"/> No <input type="checkbox"/> Yes	(NMSLCONV) <input type="checkbox"/> No <input type="checkbox"/> Yes
19. Theft/non-retail	(NMTFCOMT) <input type="checkbox"/> No <input type="checkbox"/> Yes	(NMTFDAYS) <input type="text"/>	(NMTFCHAR) <input type="checkbox"/> No <input type="checkbox"/> Yes	(NMTFCONV) <input type="checkbox"/> No <input type="checkbox"/> Yes
20. Robbery	(NMRBCOMT) <input type="checkbox"/> No <input type="checkbox"/> Yes	(NMRBDAYS) <input type="text"/>	(NMRBCHAR) <input type="checkbox"/> No <input type="checkbox"/> Yes	(NMRBCONV) <input type="checkbox"/> No <input type="checkbox"/> Yes
21. Household burglary	(NMHHCOMT) <input type="checkbox"/> No <input type="checkbox"/> Yes	(NMHHDAYS) <input type="text"/>	(NMHHCHAR) <input type="checkbox"/> No <input type="checkbox"/> Yes	(NMHHCONV) <input type="checkbox"/> No <input type="checkbox"/> Yes
22. Auto theft	(NMATCOMT) <input type="checkbox"/> No <input type="checkbox"/> Yes	(NMATDAYS) <input type="text"/>	(NMATCHAR) <input type="checkbox"/> No <input type="checkbox"/> Yes	(NMATCONV) <input type="checkbox"/> No <input type="checkbox"/> Yes
23. Aggravated assault	(NMAACOMT) <input type="checkbox"/> No <input type="checkbox"/> Yes	(NMAADAYS) <input type="text"/>	(NMAACHAR) <input type="checkbox"/> No <input type="checkbox"/> Yes	(NMAACONV) <input type="checkbox"/> No <input type="checkbox"/> Yes
24. Sexual assault	(NMSACOMT) <input type="checkbox"/> No <input type="checkbox"/> Yes	(NMSADAYS) <input type="text"/>	(NMSACHAR) <input type="checkbox"/> No <input type="checkbox"/> Yes	(NMSACONV) <input type="checkbox"/> No <input type="checkbox"/> Yes
25. Driving while intoxicated	(NMDICOMT) <input type="checkbox"/> No <input type="checkbox"/> Yes	(NMDIDAYS) <input type="text"/>	(NMDICCHAR) <input type="checkbox"/> No <input type="checkbox"/> Yes	(NMDICONV) <input type="checkbox"/> No <input type="checkbox"/> Yes
26. Other, specify: (NMOTCRSP) <input type="text"/>	(NMOTCOMT) <input type="checkbox"/> No <input type="checkbox"/> Yes	(NMOTDAYS) <input type="text"/>	(NMOTCHAR) <input type="checkbox"/> No <input type="checkbox"/> Yes	(NMOTCONV) <input type="checkbox"/> No <input type="checkbox"/> Yes

Comments: (NMSCOMM)

Naloxone Challenge (NXC)

Segment (PROTSEG): B

Visit number (VISNO):

Challenge number (NXC_CHNO):

Date of last XR-NTX injection: (NXRNTDT)

 (mm.Bd/yyyy)

Date of naloxone administration: (NXDOSED1)

 (mm.Bd/yyyy)

First Dose

1. Time of administration: (NXDOSTM1)

 (hh:mm) (24-hour clock)

2. Total dose: (NXDOSE1)

 (x.xx) mg

3. Route of administration: (NXROUTE1)

1-I.V. (Intravenous)
2-I.M. (Intramuscular injection)
3-S.C. (Subcutaneous injection)

Second Dose (if applicable)

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

4. Time of administration: (NXDOSTM2)

 (hh:mm) (24-hour clock)

5. Total dose: (NXDOSE2)

 (x.xx) mg

6. Route of administration: (NXROUTE2)

1-I.V. (Intravenous)
2-I.M. (Intramuscular injection)
3-S.C. (Subcutaneous injection)

Results

7. Result of naloxone challenge: (NXRESULT)

Negative Positive

8. Proceed with administration of study medication? (NXADMED)

No Yes

Comments: (NXCCOMM)

Additional Selection Options for NXC

Challenge number (*NXC_CHNO*) (key field):

1-1
2-2
3-3
4-4
5-5
6-6
7-7

Naloxone Withdrawal Symptoms (NXW)

Segment (PROTSEG): B

Visit number (VISNO):

Challenge number (NXC_CHNO):

Date of assessment (NXWASMDT)

(mm dd/yyyy)

Vital Signs

Timeframe	Pulse:	Respiration Rate:	Blood Pressure: (Systolic/Diastolic)	
Pre-injection	(NXPULSPR) <input type="text"/> (xxx)	(NXRESPPR) <input type="text"/> (xx)	(NXSYSTPR) <input type="text"/> (xxx)	(NXDSTPR) / <input type="text"/> (xxx) mmHg
10-30 minutes post-injection	(NXPULSPT) <input type="text"/> (xxx)	(NXRESPTT) <input type="text"/> (xx)	(NXSYSTPT) <input type="text"/> (xxx)	(NXDSTPT) / <input type="text"/> (xxx) mmHg

Event Grading Scale

- Grade 1 Mild Transient or mild discomfort (< 48 hours), no or minimal medical intervention/therapy required, hospitalization not necessary (non prescription or single use prescription therapy may be employed to relieve symptoms, e.g., aspirin for simple headache, acetaminophen for post-surgical pain)
- Grade 2 Moderate Mild to moderate limitation in activity some assistance may be needed; no or minimal intervention/therapy required, hospitalization possible.
- Grade 3 Severe Marked limitation in activity, some assistance usually required; medical intervention/therapy required hospitalization possible.

	Pre-injection	10 - 30 Minutes Post-injection
Were all symptoms assessed and were none reported?	(NXNOSYPR) <input type="checkbox"/> No <input type="checkbox"/> Yes	(NXNOSYPT) <input type="checkbox"/> No <input type="checkbox"/> Yes
Symptom	Severity of Symptom:	Maximum Severity of Symptom:
Rhinorrhea	(NXRHINPR) 0-Absent 1-Grade 1- Mild 2-Grade 2- Moderate 3-Grade 3- Severe	(NXRHINPT) 0-Absent 1-Grade 1- Mild 2-Grade 2- Moderate 3-Grade 3- Severe
Lacrimation	(NXLACRPR) 0-Absent 1-Grade 1- Mild 2-Grade 2- Moderate 3-Grade 3- Severe	(NXLACRPT) 0-Absent 1-Grade 1- Mild 2-Grade 2- Moderate 3-Grade 3- Severe
Mydriasis	(NXMYDRPR) 0-Absent 1-Grade 1- Mild 2-Grade 2- Moderate 3-Grade 3- Severe	(NXMYDRPT) 0-Absent 1-Grade 1- Mild 2-Grade 2- Moderate 3-Grade 3- Severe
Piloerection	(NXPILOPR) 0-Absent 1-Grade 1- Mild 2-Grade 2- Moderate 3-Grade 3- Severe	(NXPILOPT) 0-Absent 1-Grade 1- Mild 2-Grade 2- Moderate 3-Grade 3- Severe
Diaphoresis	(NXDIPHPR) 0-Absent 1-Grade 1- Mild 2-Grade 2- Moderate 3-Grade 3- Severe	(NXDIPHPT) 0-Absent 1-Grade 1- Mild 2-Grade 2- Moderate 3-Grade 3- Severe
Chills	(NXCHILPR) 0-Absent 1-Grade 1- Mild 2-Grade 2- Moderate 3-Grade 3- Severe	(NXCHILPT) 0-Absent 1-Grade 1- Mild 2-Grade 2- Moderate 3-Grade 3- Severe

Anxiety	0-Absent 1-Grade 1- Mild 2-Grade 2- Moderate 3-Grade 3- Severe (NXANXTPR)	0-Absent 1-Grade 1- Mild 2-Grade 2- Moderate 3-Grade 3- Severe (NXANXTP T)
Yawning	0-Absent 1-Grade 1- Mild 2-Grade 2- Moderate 3-Grade 3- Severe (NXYWNP R)	0-Absent 1-Grade 1- Mild 2-Grade 2- Moderate 3-Grade 3- Severe (NXYWNPT)
Tremulousness	0-Absent 1-Grade 1- Mild 2-Grade 2- Moderate 3-Grade 3- Severe (NXTREM PR)	0-Absent 1-Grade 1- Mild 2-Grade 2- Moderate 3-Grade 3- Severe (NXTREMP T)
Stomach cramps	0-Absent 1-Grade 1- Mild 2-Grade 2- Moderate 3-Grade 3- Severe (NXSTMCPR)	0-Absent 1-Grade 1- Mild 2-Grade 2- Moderate 3-Grade 3- Severe (NXSTMCPT)

Comments: (NXWCOMM)

Additional Selection Options for NXW

Challenge number (NXC_CHNO) (key field):

1-1
2-2
3-3
4-4
5-5
6-6
7-7

Pregnancy and Birth Control Assessment (PBC)

Segment (PROTSEG): B

Visit number (VISNO):

Complete this form only for females.

Date of assessment (PBCASMDT)

 (mm/dd/yyyy)

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

 No Yes

2. Was a pregnancy test performed?(PBPRGTST)

 No Yes

a. Date of pregnancy test (PBPTSDDT)

 (mm/dd/yyyy)

b. Result of pregnancy test:(PBRESULT)

 Negative Positive

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

Comments:(PBCCOMM)

Psychosocial Counseling Participation Log (PCL)

Segment (PROTSEG): B

Week	Did counseling occur?	If "Yes", how much (hours/week)				If "No", primary reason why not:
		Individual (xx)	Group (xx)	AA/NA (xx)	Other (xx)	
1	(PC1CNLSL) <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unk no wn	(PC1DHR) <input type="text"/>	(PC1GRHR) <input type="text"/>	(PC1AAHR) <input type="text"/>	(PC1OTHR) <input type="text"/>	1-Did not want to 2-Too busy 3-Too inconvenient 4-Don't think it helps me 99-Other (PC1NSP)
2	(PC2CNLSL) <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unk no wn	(PC2DHR) <input type="text"/>	(PC2GRHR) <input type="text"/>	(PC2AAHR) <input type="text"/>	(PC2OTHR) <input type="text"/>	1-Did not want to 2-Too busy 3-Too inconvenient 4-Don't think it helps me 99-Other (PC2NSP)
3	(PC3CNLSL) <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unk no wn	(PC3DHR) <input type="text"/>	(PC3GRHR) <input type="text"/>	(PC3AAHR) <input type="text"/>	(PC3OTHR) <input type="text"/>	1-Did not want to 2-Too busy 3-Too inconvenient 4-Don't think it helps me 99-Other (PC3NSP)
4	(PC4CNLSL) <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unk no wn	(PC4DHR) <input type="text"/>	(PC4GRHR) <input type="text"/>	(PC4AAHR) <input type="text"/>	(PC4OTHR) <input type="text"/>	1-Did not want to 2-Too busy 3-Too inconvenient 4-Don't think it helps me 99-Other (PC4NSP)
5	(PC5CNLSL) <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unk no wn	(PC5DHR) <input type="text"/>	(PC5GRHR) <input type="text"/>	(PC5AAHR) <input type="text"/>	(PC5OTHR) <input type="text"/>	1-Did not want to 2-Too busy 3-Too inconvenient 4-Don't think it helps me 99-Other (PC5NSP)
6	(PC6CNLSL) <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unk no wn	(PC6DHR) <input type="text"/>	(PC6GRHR) <input type="text"/>	(PC6AAHR) <input type="text"/>	(PC6OTHR) <input type="text"/>	1-Did not want to 2-Too busy 3-Too inconvenient 4-Don't think it helps me 99-Other (PC6NSP)
7	(PC7CNLSL) <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unk no wn	(PC7DHR) <input type="text"/>	(PC7GRHR) <input type="text"/>	(PC7AAHR) <input type="text"/>	(PC7OTHR) <input type="text"/>	1-Did not want to 2-Too busy 3-Too inconvenient 4-Don't think it helps me 99-Other (PC7NSP)
8	(PC8CNLSL) <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unk no wn	(PC8DHR) <input type="text"/>	(PC8GRHR) <input type="text"/>	(PC8AAHR) <input type="text"/>	(PC8OTHR) <input type="text"/>	1-Did not want to 2-Too busy 3-Too inconvenient 4-Don't think it helps me 99-Other (PC8NSP)
9	(PC9CNLSL) <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unk no wn	(PC9DHR) <input type="text"/>	(PC9GRHR) <input type="text"/>	(PC9AAHR) <input type="text"/>	(PC9OTHR) <input type="text"/>	1-Did not want to 2-Too busy 3-Too inconvenient 4-Don't think it helps me 99-Other (PC9NSP)

10	(PC10CNLSL) <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown	(PC10IDHR) <input type="text"/>	(PC10GRHR) <input type="text"/>	(PC10AAHR) <input type="text"/>	(PC10OTHR) <input type="text"/>	<p>1-Did not want to 2-Too busy 3-Too inconvenient 4-Don't think it helps me 99-Other</p> <p>(PC10NSP)</p>
11	(PC11CNLSL) <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown	(PC11IDHR) <input type="text"/>	(PC11GRHR) <input type="text"/>	(PC11AAHR) <input type="text"/>	(PC11OTHR) <input type="text"/>	<p>1-Did not want to 2-Too busy 3-Too inconvenient 4-Don't think it helps me 99-Other</p> <p>(PC11NSP)</p>
12	(PC12CNLSL) <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown	(PC12IDHR) <input type="text"/>	(PC12GRHR) <input type="text"/>	(PC12AAHR) <input type="text"/>	(PC12OTHR) <input type="text"/>	<p>1-Did not want to 2-Too busy 3-Too inconvenient 4-Don't think it helps me 99-Other</p> <p>(PC12NSP)</p>
13	(PC13CNLSL) <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown	(PC13IDHR) <input type="text"/>	(PC13GRHR) <input type="text"/>	(PC13AAHR) <input type="text"/>	(PC13OTHR) <input type="text"/>	<p>1-Did not want to 2-Too busy 3-Too inconvenient 4-Don't think it helps me 99-Other</p> <p>(PC13NSP)</p>
14	(PC14CNLSL) <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown	(PC14IDHR) <input type="text"/>	(PC14GRHR) <input type="text"/>	(PC14AAHR) <input type="text"/>	(PC14OTHR) <input type="text"/>	<p>1-Did not want to 2-Too busy 3-Too inconvenient 4-Don't think it helps me 99-Other</p> <p>(PC14NSP)</p>
15	(PC15CNLSL) <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown	(PC15IDHR) <input type="text"/>	(PC15GRHR) <input type="text"/>	(PC15AAHR) <input type="text"/>	(PC15OTHR) <input type="text"/>	<p>1-Did not want to 2-Too busy 3-Too inconvenient 4-Don't think it helps me 99-Other</p> <p>(PC15NSP)</p>
16	(PC16CNLSL) <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown	(PC16IDHR) <input type="text"/>	(PC16GRHR) <input type="text"/>	(PC16AAHR) <input type="text"/>	(PC16OTHR) <input type="text"/>	<p>1-Did not want to 2-Too busy 3-Too inconvenient 4-Don't think it helps me 99-Other</p> <p>(PC16NSP)</p>
17	(PC17CNLSL) <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown	(PC17IDHR) <input type="text"/>	(PC17GRHR) <input type="text"/>	(PC17AAHR) <input type="text"/>	(PC17OTHR) <input type="text"/>	<p>1-Did not want to 2-Too busy 3-Too inconvenient 4-Don't think it helps me 99-Other</p> <p>(PC17NSP)</p>
18	(PC18CNLSL) <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown	(PC18IDHR) <input type="text"/>	(PC18GRHR) <input type="text"/>	(PC18AAHR) <input type="text"/>	(PC18OTHR) <input type="text"/>	<p>1-Did not want to 2-Too busy 3-Too inconvenient 4-Don't think it helps me 99-Other</p> <p>(PC18NSP)</p>
19	(PC19CNLSL) <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown	(PC19IDHR) <input type="text"/>	(PC19GRHR) <input type="text"/>	(PC19AAHR) <input type="text"/>	(PC19OTHR) <input type="text"/>	<p>1-Did not want to 2-Too busy 3-Too inconvenient 4-Don't think it helps me 99-Other</p> <p>(PC19NSP)</p>
20	(PC20CNLSL) <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown	(PC20IDHR) <input type="text"/>	(PC20GRHR) <input type="text"/>	(PC20AAHR) <input type="text"/>	(PC20OTHR) <input type="text"/>	<p>1-Did not want to 2-Too busy 3-Too inconvenient 4-Don't think it helps me 99-Other</p> <p>(PC20NSP)</p>
21	(PC21CNLSL) <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown	(PC21IDHR) <input type="text"/>	(PC21GRHR) <input type="text"/>	(PC21AAHR) <input type="text"/>	(PC21OTHR) <input type="text"/>	<p>1-Did not want to 2-Too busy 3-Too inconvenient 4-Don't think it helps me 99-Other</p> <p>(PC21NSP)</p>

22	(PC22 CNSL) <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown	(PC22 IDHR) <input type="text"/>	(PC22 GRHR) <input type="text"/>	(PC22 AAHR) <input type="text"/>	(PC22 OTHR) <input type="text"/>	1-Did not want to 2-Too busy 3-Too inconvenient 4-Don't think it helps me 99-Other (PC22NSP)
23	(PC23 CNSL) <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown	(PC23 IDHR) <input type="text"/>	(PC23 GRHR) <input type="text"/>	(PC23 AAHR) <input type="text"/>	(PC23 OTHR) <input type="text"/>	1-Did not want to 2-Too busy 3-Too inconvenient 4-Don't think it helps me 99-Other (PC23NSP)
24	(PC24 CNSL) <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown	(PC24 IDHR) <input type="text"/>	(PC24 GRHR) <input type="text"/>	(PC24 AAHR) <input type="text"/>	(PC24 OTHR) <input type="text"/>	1-Did not want to 2-Too busy 3-Too inconvenient 4-Don't think it helps me 99-Other (PC24NSP)

Comments:(PCLCOMM)

Protocol Deviation Review (PDR)

Web Version: 1.0; 3.00; 03-17-16

Date of deviation (*PDDATE*):

Protocol deviation number (*PDSEQNUM*):

Completed by Protocol Specialist:

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

2. Does the report of this deviation require site staff retraining?
(*PDTRAIN*)

No Yes

If "Yes", specify plan for retraining:(*PDPLATRA*)

3. Deviation was discussed with Lead Investigative Team on:
(*PDDISCDT*)

(*mm/dd/yyyy*)

4. Deviation is categorized as:(*PDCATGRY*)

Major Minor

5. Deviation assessment by Protocol Specialist complete:
(*PDPSCMP*)

No Yes

Protocol Specialist reviewer:(*PDPSRVID*)

(initials)

Protocol Specialist comments:(*PDPSCOMM*)

Completed by Protocol Monitor:

6. Corrective action for this deviation was completed and documented on-site as described:(*PDACTDOC*)

No Yes

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

7. Deviation was reported to the IRB as required:
(*PDIRBRPT*)

No Yes

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

8. Preventive action plan related to this event was completed and documented on-site as described:
(*PDPREVNT*)

No Yes

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

No Yes

Protocol Monitor reviewer:(*PDPMRVID*)

(initials)

Protocol Monitor comments:(*PVCOMM*)

Additional Selection Options for PDR

Protocol deviation number (*PDSEQNUM*) (key field):

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

Protocol Deviation (PDV)

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

1. Date deviation identified: (PDVDATE)

 (mm/dd/yyyy)

2. Deviation type: (PDTYPE)

Z01-INFORMED CONSENT PROCEDURES
01A--- No consent/assent obtained
01B--- Invalid/incomplete informed consent form
01C--- Unauthorized assessments and/or procedures conducted prior to obtaining informed consent
01D--- Non IRB approved/outdated/obsolete informed consent documents used
*Additional Options Listed Below

If "Other", specify: (PDTYPEPSP)

3. Brief description of what occurred: (PDES CPT)

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

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

6. Is this deviation reportable to your IRB? (PDIRBREP)

No Yes

If "Yes", will the IRB be notified at the time of continuing review? (PDIRBCOM)

No Yes

If "Yes", date of planned submission: (PDIRBPD T)

 (mm/dd/yyyy)

If "No", date of actual submission: (PDIRBAD T)

 (mm/dd/yyyy)

Comments: (PDVCOMM)

Additional Selection Options for PDV

Protocol deviation number (PDSEQNUM) (key field):

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

Deviation type:

01E--- Informed consent process not properly conducted and/or documented
01Z--- Other (specify)
Z02-INCLUSION/EXCLUSION CRITERIA
02A--- Ineligible participant randomized/inclusion/exclusion criteria not met
02Z--- Other (specify)
Z04-LABORATORY ASSESSMENTS
04A--- Biologic specimen not collected/processed as per protocol
04Z--- Other (specify)
Z05-STUDY PROCEDURES/ASSESSMENTS
05A--- Protocol required visit/assessment not scheduled or conducted
05B--- Study assessments not completed/failed as per protocol
05C--- Inappropriate unblinding
05Z--- Other (specify)
Z06-ADVERSE EVENT
06A--- AE not reported
06B--- SAE not reported
06C--- AE/SAE reported out of protocol specified reporting time frame
06D--- AE/SAE not elicited, observed and/or documented as per protocol
06E--- Safety assessment (e.g. labs, ECG, clinical referral to care) not conducted per protocol
06Z--- Other (specify)
Z07-RANDOMIZATION PROCEDURES
07A--- Stratification error
07Z--- Other (specify)
Z08-STUDY MEDICATION MANAGEMENT
08A--- Medication dispensed to ineligible participant
08B--- Medication dispensed to incorrect participant
08C--- Medication dosing errors (protocol specified dose not dispensed)
08D--- Participant use of protocol prohibited medication
08Z--- Other (specify)
Z09-STUDY BEHAVIORAL INTERVENTION
09A--- Study behavioral intervention was not provided/performed as per protocol
09Z--- Other (specify)
Z99-OTHER SIGNIFICANT DEVIATIONS
99A--- Destruction of study materials without prior authorization from sponsor
99B--- Breach of Confidentiality
99Z--- Other (specify)

Physical Examination (PEX)

Segment (PROTSEG): B

Visit number (VISNO):

Date of assessment (PEXASMDT)

 (mm.dd/yyyy)

Date of assessment (PEXASMDT)

 (mm.dd/yyyy)

Comments

General appearance:	1-Normal 2-Abnormal, not clinically significant 3-Abnormal, clinically significant 97-Not assessed (PEGENAP)	(PEGASP)	
Skin, hair, and nails:	1-Normal 2-Abnormal, not clinically significant 3-Abnormal, clinically significant 97-Not assessed (PESKHRNA)	(PESHNSP)	
Head and neck:	1-Normal 2-Abnormal, not clinically significant 3-Abnormal, clinically significant 97-Not assessed (PEHDNK)	(PEHDNKSP)	
Ears, eyes, nose, and throat:	1-Normal 2-Abnormal, not clinically significant 3-Abnormal, clinically significant 97-Not assessed (PEEENT)	(PEENTSP)	
Cardiovascular:	1-Normal 2-Abnormal, not clinically significant 3-Abnormal, clinically significant 97-Not assessed (PECARD)	(PECARDSP)	
Respiratory:	1-Normal 2-Abnormal, not clinically significant 3-Abnormal, clinically significant 97-Not assessed (PERESP)	(PERESPSP)	
Gastrointestinal:	1-Normal 2-Abnormal, not clinically significant 3-Abnormal, clinically significant 97-Not assessed (PEGAST)	(PEGASTSP)	
Extremities:	1-Normal 2-Abnormal, not clinically significant 3-Abnormal, clinically significant 97-Not assessed (PEEXTR)	(PEEXTRSP)	
Lymph nodes:	1-Normal 2-Abnormal, not clinically significant 3-Abnormal, clinically significant 97-Not assessed (PELYMP)	(PELYMPSP)	
Musculoskeletal:	1-Normal 2-Abnormal, not clinically significant 3-Abnormal, clinically significant 97-Not assessed (PEMUSC)	(PEMUSCSP)	

Neurological:

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

(PENEUR)

(PENEURSP)

Injection site assessment

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

(PEINUS)

(PEINJSSP)

Other (specify in comments):

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

(PEOTHER)

(PEOTHERSP)

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

No Yes

Comments:(PEHLTHSP)

Comments:(PEXCOMM)

Pregnancy Outcome 1 (PO1)

Pregnancy number (PGSEQNUM):

Newborn Information

- 1. Gender: (PO1GENDR)
- 2. Gestational age at delivery: (PO1GESWK)
- 3. Weight at delivery: (PO1WTLBS)
- 4. Apgar score at 1 minute: (PO1APG1M)
- 5. Apgar score at 5 minutes: (PO1APG5M)
- 6. Normal infant? (PO1NORML)
If "No", is there a congenital anomaly? (PO1CONAN)
If "Yes", specify abnormality and contributing factors: (PO1ABNSP)

Male Female Unknown
[] (xx) Weeks (PO1GESDY) | [] (x) Days (PO1GESUN) OR Unknown
[] (xx) Lbs (PO1WTOZ) | [] (xx) Oz (PO1WTUNK) OR Unknown
[] (xx) (PO1APUK) OR Unknown
[] (xx) (PO15APUK) OR Unknown
 No Yes
 No Yes Unknown

[]

[]

Comments: (PO1COMM)

Additional Selection Options for PO1

Pregnancy number (*PGSEQNUM*) (key field):

- 01-1st Pregnancy
- 02-2nd Pregnancy
- 03-3rd Pregnancy
- 04-4th Pregnancy

Confirmed Pregnancy and Outcome (PRG)

Pregnancy number (PGSEQNUM):

Information About Pregnancy

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

 (mm.Bd/yyyy)

2. How was the pregnancy confirmed? (select all that apply)

- a. Urine pregnancy test result:(PRURICNF)
- b. Serum pregnancy test result:(PRSERCNF)
- c. Ultrasound result:(PRULTCNF)
- d. Other:(PROTHCNF)
If "Other", specify:(PROTCNSP)

 No Yes
 No Yes
 No Yes
 No Yes

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

 (mm.Bd/yyyy)

4. Action taken with study drug:(PRACTIND)

 (mm.Bd/yyyy)
 0-None
 1-Decreased drug
 2-Increased drug
 3-Temporarily stopped drug
 4-Permanently stopped drug

5. Approximate due date:(PRAPXDDT)

 (mm.Bd/yyyy) (PRDDTUNKOR) Unknown

6. Outcome of pregnancy:(PROUTCME)

 (mm.Bd/yyyy)
 1-Vaginal delivery
 2-Cesarean delivery
 3-Miscarriage
 4-Termination
 99-Other
 *Additional Options Listed Below

If "Other", specify:(PROTCMSP)

7. Date of pregnancy outcome:(PROTCMDT)

 (mm.Bd/yyyy)

8. Number of live births:(PRNMLIVB)

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

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

Comments:(PRGCOMM)

Additional Selection Options for PRG

Pregnancy number (PGSEQNUM) (key field):

- 01-1st Pregnancy
- 02-2nd P pregnancy
- 03-3rd Pregnancy
- 04-4th Pregnancy

Outcome of pregnancy:

- 97-Unknown

Number of live births:

- 99-Other
- 97-Unknown

EuroQoL Questionnaire (QLE)

Segment (PROTSEG): B

Visit number (VISNO):

Date of assessment (OLEASMDT)

(mm.ttd/yyyy)

Check the answer that best describes your current health state today.

1. Mobility: (QLMOBIL)

1-1 have no problems in walking about
2-1 have some problems in walking about
3-1 am confined to bed

2. Self-care: (QLSLFCAR)

1-1 have no problems with self-care
2-1 have some problems washing or dressing myself
3-1 am unable to wash or dress myself

3. Usual activities (e.g., work, study, housework, family or leisure activities): (QLACTIVE)

1-1 have no problems with performing my usual activities
2-1 have some problems with performing my usual activities
3-1 am unable to perform my usual activities

4. Pain/discomfort: (QLPAIN)

1-1 have no pain or discomfort
2-1 have moderate pain or discomfort
3-1 have extreme pain or discomfort

5. Anxiety/depression: (QLANXDEP)

1-1 am not anxious or depressed
2-1 am moderately anxious or depressed
3-1 am extremely anxious or depressed

Use the paper EuroQoL Questionnaire Thermometer to indicate how good or bad your health is currently.

6. Health state today: (QLHLTHST)

(xxx)

Comments: (QLECOMM)

Risk Assessment Battery (RAB)

Segment (PROTSEG): B

Visit number (VISNO):

Date of assessment (RABASMDT)

 (mm/dd/yyyy)

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.

A. 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)?	(RASPEDBL) <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)?	(RAHERINJ) <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)?	(RASNRTHR) <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)?	(RASMOKHR) <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)?	(RACOCINJ) <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)?	(RASNRTCO) <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?	(RASMOKCO) <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?	(RASPDINJ) <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?	(RASNRTP) <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?	(RASMOKSP) <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?	(RAUSEDBZ) <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)?	(RAUSEDPK) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Which types of painkillers did you use? (RAPKSP) <input type="text"/>				
13. In the past month, how often have you injected Dilaudid?	(RADILINJ) <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?	(RAUSDLSD) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. In the past month, how often have you used marijuana?	(RAUSDCAN) <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?	(RADRANK) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

B. Needle Use

17. In the past month, have you injected drugs? (RADRGINJ)

No Yes

18. In the past month, have you shared needles or works? (RASHNDLE)

No or I have not shot up in the past month Yes

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

- 0-Zero or I have not shot up in the past month
- 1-1 other person
- 2-2 or 3 different people
- 3-4 or more different people

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

- 0-Never or I have not shot up or shared in the past month
- 1-A few times (1 or 2 times)
- 2-About once a week (3 or 4 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 or I have not shot up or shared in the past month
- 1-A few times (1 or 2 times)
- 2-About once a week (3 or 4 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 or I have not shot up or shared in the past month
- 1-A few times (1 or 2 times)
- 2-About once a week (3 or 4 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. I have not shot up in the past month (RANDLNOT) No Yes
- b. From a diabetic (RANDLBT) No Yes
- c. On the street (RANDLSRT) No Yes
- d. Drugstore (RANDLDST) No Yes
- e. Shooting gallery or other place where users go to shoot up (RANDLSGY) No Yes
- f. Needle Exchange Program (RANDEXC) No Yes
- g. Other, specify: (RANDLOSP) (RANDLOTH) No Yes

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 few times (1 or 2 times)
- 2-About once a week (3 or 4 times)
- 3-More than once a week (5 or more times)

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

- 0-Never
- 1-A few times (1 or 2 times)
- 2-About once a week (3 or 4 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. If you cleaned your needles and works in the past month, how did you clean them?

- a. I have not shot up in the past month (RANLNOT) No Yes
- b. Soap and water only (RANLSOAP) No Yes
- c. Alcohol (RANLALCH) No Yes
- d. Bleach (RANLBLCH) No Yes
- e. Boiling water (RANLDWTR) No Yes
- f. Other, specify: (RANLCOSP) (RANLOTHC) No Yes
- g. I did not clean my needles in the past month (RANOTCLN) No Yes
- h. I ALWAYS used new needles in the past month (RALWAYS) No Yes

	Never or I have not shot up or shared in the past month	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. In the past month, how often have you shared rinse-water?	(RA RH20SH) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
29. In the past month, how often have you shared a cooker?	(RA COKRSH) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
30. In the past month, how often have you shared cotton?	(RAC TNSH) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
31. In the past month, how often have you 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)?	(RA BCKLD) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

C. Sexual Practices

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
- 1-1
- 2-2 or 3
- 3-4 or more

men/man

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

- 0-0
- 1-1
- 2-2 or 3
- 3-4 or more

women/woman

	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. In the past month, how often have you had sex so you could get drugs? (RASEX4DG)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
36. In the past month, how often 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. In the past month, how often were you paid money to have sex with someone? (RAPOSTUT)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
38. In the past month, how often 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. In the past month, how often 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? (RASEXFEE)

- 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. In the past 30 days, how many times did you have penetrative sex (vaginal or anal sex)? (RASEXPE N)

(xx)

42. In the past 30 days, how many times did you have penetrative sex (vaginal or anal sex) without a condom? (RASEXUPR)

(xx)

D. Concerns About HIV and Testing

If you know that you are HIV positive, skip to question 46.

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

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

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

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

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

- 0-Never
- 1-1
- 2-2
- 3-3
- 4-4
- *Additional Options Listed Below

46. When were you last tested for HIV? (RALTM HIV)

(mm) / (RALTYHIV) (yyyy)

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

47. Reason not tested for HIV: (RAN OTSRN)

- 1-You think you are at a low risk for HIV infection
- 2-You were afraid of finding out that you had HIV
- 3-You didn't have time
- 4-Some other reason
- 5-No particular reason
- 98-Refused to answer
- 97-Don't know

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

No Yes I never got the results

49. How was assessment completed? (RACMPLT)

- 0-Entered directly in ePRO
- 1-In-person visit, collected on paper source
- 2-Telephone visit, collected on paper source



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)?

5-5

6-6

7-7

8-8

9-9

10-10 or more times

The Subjective Opiate Withdrawal Scale (SOW)

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

Segment (PROTSEG): B

Visit number (VISNO):

Date of assessment (SOWASMDT)

(mm.ttd/yyyy)

Time of assessment (24-hour format) (SOWASMTM)

(hh:mm)

Please score each of the 16 items below according to [how you feel now](#)

Symptom	Not at All	A Little	Moderately	Quite a Bit	Extremely
1. I feel anxious	(SOANX) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. I feel like yawning	(SOYAWN) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. I am perspiring	(SOSWEAT) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. My eyes are teary	(SOOUTEAR) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. My nose is running	(SONOSRUN) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. I have goosebumps	(SOGOSBUM) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. I am shaking	(SOSHAKE) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. I have hot flushes	(SOHOT) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. I have cold flushes	(SOCOLD) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. My bones and muscles ache	(SOACHE) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. I feel restless	(SORESTLS) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. I feel nauseous	(SONAUS) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. I feel like vomiting	(SOVOMIT) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. My muscles twitch	(SOMUSTWT) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. I have stomach cramps	(SOSCHMP) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. I feel like using now	(SOUSENOW) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Range 0-64. Handelsman, L., Cochrane, K.J., Aronson, M.J. et al. (1987)

Two New Rating Scales for Opiate Withdrawal, *American Journal of Alcohol Abuse*, 13, 293-308.

Comments: (SOWCOMM)

Stroop Color and Word Test - Adult Version (STR)

Web Version: 1.0; 1.00; 07-22-13

Segment (PROTSEG): B

Visit number (VISNO):

Date of assessment (STRASMDT)

 (mm.ttd/yyyy)

1. Is the participant color-blind? (STRCLRBD)

If "Yes", leave the rest of this form blank.

 No Yes

2. Please complete the following fields based on the results of the Stroop Task:

	Raw Score
Word Score (W)	(STRWRAW) <input type="text"/> (xxx)
Color Score (C)	(STRCRAW) <input type="text"/> (xxx)
Color-Word Score (CW)	(STRCWRAW) <input type="text"/> (xxx)

Comments: (STRCOMM)

Study Termination (STT)

Segment (PROTSEG): B

1. Date of study completion or last attended study visit: (STTRMDT)

 (mm/dd/yyyy)

2. Did the participant complete the week 36 visit? (STCOMPLT)

 No Yes

If "No", select the primary reason for study termination (STTRMRES)

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

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

Comments: (STTCOMM)

Investigator's Signature

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

Principal Investigator: (STPISIGN)

Date: (STPSGDT)

 (mm/dd/yyyy)

Additional Selection Options for STT

If "No", select the primary reason for study termination:

6-Participant terminated for other clinical reasons

7-Participant had a significant psychiatric risk (suicidal, homicidal, psychotic)

8-Participant withdrew consent

9-Participant deceased

19-Participant terminated due to protocol deviation

99-Participant terminated for other reason

Timeline Followback (T51)

TFB week start date (TFWKSTD7):

Day	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Date	(TLDATE1) <input type="text"/>	(TLDATE2) <input type="text"/>	(TLDATE3) <input type="text"/>	(TLDATE4) <input type="text"/>	(TLDATE5) <input type="text"/>	(TLDATE6) <input type="text"/>	(TLDATE7) <input type="text"/>
1. Have any illicit substances or alcohol been used on this day?	(TLSUBAL1) <input type="checkbox"/> No <input type="checkbox"/> Yes	(TLSUBAL2) <input type="checkbox"/> No <input type="checkbox"/> Yes	(TLSUBAL3) <input type="checkbox"/> No <input type="checkbox"/> Yes	(TLSUBAL4) <input type="checkbox"/> No <input type="checkbox"/> Yes	(TLSUBAL5) <input type="checkbox"/> No <input type="checkbox"/> Yes	(TLSUBAL6) <input type="checkbox"/> No <input type="checkbox"/> Yes	(TLSUBAL7) <input type="checkbox"/> No <input type="checkbox"/> Yes
2. Alcohol number of standard drinks (xx):	(TLALCHL1) <input type="text"/>	(TLALCHL2) <input type="text"/>	(TLALCHL3) <input type="text"/>	(TLALCHL4) <input type="text"/>	(TLALCHL5) <input type="text"/>	(TLALCHL6) <input type="text"/>	(TLALCHL7) <input type="text"/>
3. Cannabinoids / Marijuana:	(TLTHCR1) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLTHCR2) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLTHCR3) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLTHCR4) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLTHCR5) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLTHCR6) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLTHCR7) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below
4. Cocaine:	(TLCOCR1) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLCOCR2) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLCOCR3) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLCOCR4) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLCOCR5) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLCOCR6) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLCOCR7) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below
5. Crack:	(TLCAKR1) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLCAKR2) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLCAKR3) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLCAKR4) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLCAKR5) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLCAKR6) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLCAKR7) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below
6. Amphetamine-type stimulants:	(TLAMPR1) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLAMPR2) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLAMPR3) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLAMPR4) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLAMPR5) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLAMPR6) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLAMPR7) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below
7. Buprenorphine:	(TLBUPR1) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLBUPR2) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLBUPR3) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLBUPR4) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLBUPR5) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLBUPR6) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLBUPR7) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below
8. Opioid analgesic:	(TLOPIR1) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLOPIR2) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLOPIR3) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLOPIR4) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLOPIR5) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLOPIR6) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLOPIR7) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below
9. Methadone:	(TLMTDR1)	(TLMTDR2)	(TLMTDR3)	(TLMTDR4)	(TLMTDR5)	(TLMTDR6)	(TLMTDR7)

Additional Selection Options for T 51

D1 cannabinoids

5-05-IV Injection

99-99-Other

TLFB Assessment Period (TAP)

Segment (PROTSEG): B

Visit number (VISNO):

Date of assessment (TAPASMDT)

(mm/dd/yyyy)

1. Assessment period start (TATFS TDT)

From: (mm/dd/yyyy)

(TATFENDT)

To: (mm/dd/yyyy)

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

No Yes

Comments: (TAPCOMM)

Trail Making Test (TRL)

Segment (PROTSEG): B

Visit number (VISNO):

Date of assessment (TRLASMDT)

 (mm.ttd/yyyy)

Record time (in seconds) required to complete each task.

1. Part A: (TRTMPRTA)

 (xxx) seconds

2. Part B: (TRTMPRTB)

 (xxx) seconds

Comments: (TRLCOMM)

Treatment Satisfaction (TXS)

Segment (PROTSEG): B

Visit number (VISNO):

Date of assessment (TXSASMDT)

(mm.dd/yyyy)

1. How helpful do you think the medication you received was in reducing your opioid use? (TXMEDEFT)

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

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

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

3. How was assessment completed? (TXCMPLT)

- 0-Entered directly in ePRO
- 1-In-person visit, collected on paper source
- 2-Telephone visit, collected on paper source

Comments: (TXSCOMM)

Urine Drug Screen (UDS)

Segment (PROTSEG): B

Visit number (VISNO):

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

If "No", reason:(UDNORSN)

If "Other", specify:(UDNOSP1)

No Yes

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

(mm/dd/yyyy)

No Yes

No Yes

1st Urine Drug Screen

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

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

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

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

Drug Name (Abbreviation)	Negative	Positive	Invalid
Benzodiazepines (BZO):	(UDBZO1) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Amphetamine (AMP):	(UDAMP1) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Marijuana (THC):	(UDTHC1) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Methamphetamine (MET):	(UDMET1) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Opiates (2000 ng) (OP I):	(UDOP11) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cocaine (COC):	(UDCOC1) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ecstasy (MDMA):	(UDMDA1) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Oxycodone (OXY):	(UDOXY1) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Methadone (MTD):	(UDMTD1) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Barbiturate (BAR):	(UDBAR1) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Opiates (300ng)(OP I):(UDOP1300)

Buprenorphine (BUP):(UDBUP1)

Negative Positive Invalid

Negative Positive Invalid

2nd Urine Drug Screen

6. If the 1st urine specimen was determined to be adulterated, was a second specimen collected?(UDTEST2)

If "No", reason:(UDNORSN2)

If "Other", specify:(UDNOSP2)

No Yes

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

No Yes

No Yes

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

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

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

Drug Name (Abbreviation)	Negative	Positive	Invalid
Benzodiazepines (BZO):	(UDBZO2) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Amphetamine (AMP):	(UDAMP2) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Marijuana (THC):	(UDTHC2) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Methamphetamine (MET):	(UDMET2) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Opiates (2000 ng) (OP I):	(UDOP12) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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

Opiates (300ng)(OPI): (UDOP2300)

Buprenorphine (BUP): (UDBUP2)

Comments: (UDSCOMM)

Negative Positive Invalid

Negative Positive Invalid

Visual Analog Scale (VAS)

Segment (PROTSEG): B

Visit number (VISNO):

Date of assessment (VASASMDT)

 (mm.dd/yyyy)

1. In the past week, how much did you crave **opiates**? (VACRVOPI)
2. In the past 4 weeks, how much did you crave **alcohol**? (VACRVALC)
3. In the past 4 weeks, how much did you crave **stimulants**? (VACRSTM)
4. In the past 4 weeks, how much did you crave **nicotine**? (VACRVNIC)
5. In the past 4 weeks, on average, how many **cigarettes** did you smoke per day? (VANUMCIG)

 (xxx) (xxx) (xxx) (xxx) (xxx)

Comments: (VASCOMM)

Vital Signs (VIS)

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

Segment (PROTSEG): B

Visit number (VISNO):

Date of assessment (VISASMDT)

(mm/dd/yyyy)

1. Heart rate: (VIPULSE)

(xxx) BPM

2. Blood pressure: (VIBPSYS1)

/ (VIBPDS1) Systolic/Diastolic (mmHg)

Comments: (VISCOMM)

Norwegian VAS (VNS)

Segment (PROTSEG): B

Visit number (VISNO):

Date of assessment (VNSASMDT)

 (mm.ttd/yyyy)

1. Have you used non-prescribed opiates during the past month? (VNOPIUSE)

 No Yes

If "Yes", which:
(Check all that apply)

- Methadone (Dolophine): (VNMETUSE) No Yes
- Oxycodone (Oxycontin, Percocet, Percodan, Roxycodone, others): (VNOXYUSE) No Yes
- Hydrocodone (Vicodin, Lorcet, Lortab): (VNH YC ODU) No Yes
- Heroin: (VNH ER USE) No Yes
- Non-study buprenorphine: (VNBUPNSU) No Yes
- Hydromorphone (Dilaudid): (VNH YM ORU) No Yes
- Oxymorphone (Numorphan, Opana): (VNO YM ORU) No Yes
- Meperidine (Demero): (VNM EP USE) No Yes
- Codeine (Tylenol 3): (VNC ODU SE) No Yes
- Fentanyl (Duragesic transdermal): (VNFEN USE) No Yes
- Morphine: (VNM OR USE) No Yes

When used opiates, answer for the time you got the greatest impact (most high).

2. Indicate how much you liked the feeling you got from opiate use: (VNOPIFEL)

 (xxx)

3. How much would you be willing to pay for the high described in question 2 above? (VNPAYHIG)

 (xxx)

Comments: (VNSCOMM)

Weekly Relapse Assessment (XRP)

Segment (PROTSEG): B

Visit number (VISNO):

Date of assessment (XRPASMDT)

 (mm.ttd/yyyy)

Has relapse event occurred? (XRRELA PS)

 No Yes

a. If "Yes", which was the criterion for the relapse event? (XRRLPCRT)

1-Four (4) consecutive opioid use weeks (starting day 21 or later) *
2-Seven (7) consecutive days of use by self-report (starting day 21 or later) **

* A use week is defined as any week during which a subject self-reports at least one day of use during that week, provides a urine sample positive for non-protocol opioids, or fails to provide a urine sample (e.g., missed weekly study visit).
** Self-report of opioid (i.e., heroin or non-study prescription opioids) and other substance use will be ascertained at each weekly study visit using the Time Line Follow-back for each day leading back to the previous visit.

Comments: (XRPCOMM)