Adverse Event (AD1)

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

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

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

1. Adverse event name:*(A1DESCPT)*

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

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

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

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

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

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

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

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

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

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

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

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

Comments:*(AD1COMM)*

Additional Selection Options for AD1

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

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

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

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Serious Adverse Event Summary (AD2)

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

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

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

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

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

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

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

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

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

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

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

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

6. Follow-up:*(A2FOLLUP)*

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

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

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

Additional Selection Options for AD2

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

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Serious Adverse Event Medical Reviewer (AD3)

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

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

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

Assessed by:*(A3ASRID)* (initials)

Reviewed by:*(A3REVID)* (initials)

Comments:*(A3COMM)*

Additional Selection Options for AD3

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

Alcohol and Substance Use History (ASU)

Web Version: 1.0; 6.00; 04-03-19

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

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

Alcohol Use History

1. In your entire life, have you had at least 1 drink of any kind of alcohol, not counting small tastes or sips?*(AUALCLFT)* ☐ 0-No ☐ 1-Yes

   If "Yes", think about the **first time** you had a drink of an alcoholic beverage. How old were you the **first time** you had a drink of an alcoholic beverage? Please do not include any time when you only had a sip or two from a drink.*(AUALCAGE)* _____ *(xx)* years

Substance Use History

@2**Substance**	@2**Have you EVER used any of these medicines or drugs?**	@2**If "Yes", specify substance type(s)**	@2 How old were you when you FIRST used? *(years)*
1. Sedatives: (e.g., sleeping pills, barbiturates, Seconal®, Quaaludes, or Chloral Hydrate)	*(AUSEDLFT)* ☐ 0-No ☐ 1-Yes	*(AUSEDLSP)*	*(AUSEDAGE)* *(xx)*
2. Tranquilizers or anti-anxiety drugs: (e.g., Valium®, Librium®, muscle relaxants, or Xanax®)	*(AUTNQLFT)* ☐ 0-No ☐ 1-Yes	*(AUTNQLSP)*	*(AUTRQAGE)* *(xx)*
3. Painkillers/Opioids: (e.g., Codeine, Darvon®, Percodan®, Oxycontin®, Dilaudid®, Demerol®, Celebrex® or Vioxx®)	*(AUPNKLFT)* ☐ 0-No ☐ 1-Yes	*(AUPNKLSP)*	*(AUPNKAGE)* *(xx)*
4. Methamphetamine:	*(AUMETLFT)* ☐ 0-No ☐ 1-Yes		*(AUMETAGE)* *(xx)*
5. Stimulants: (e.g., Preludin®, Benzedrine®, Ritalin®, uppers, or speed)	*(AUSTMLFT)* ☐ 0-No ☐ 1-Yes	*(AUSTMLSP)*	*(AUSTMAGE)* *(xx)*
6. Marijuana, hash, THC, grass, or cannabis:	*(AUTHCLFT)* ☐ 0-No ☐ 1-Yes	*(AUTHCLSP)*	*(AUTHCAGE)* *(xx)*
7. @2Cocaine or crack:	*(AUCOCLFT)* ☐ 0-No ☐ 1-Yes	*(AUCOCLSP)*	*(AUCOCAGE)* *(xx)*
8. Hallucinogens: (e.g., Ecstasy/MDMA, LSD, mescaline, psilocybin, PCP, angel dust, or peyote)	*(AUHALLFT)* ☐ 0-No ☐ 1-Yes	*(AUHALLSP)*	*(AUHALAGE)* *(xx)*
9. Inhalants or solvents: (e.g., amyl nitrite, nitrous oxide, glue, toluene, or gasoline)	*(AUINHLFT)* ☐ 0-No ☐ 1-Yes	*(AUINHLSP)*	*(AUINHAGE)* *(xx)*
10. Heroin:	*(AUHERLFT)* ☐ 0-No ☐ 1-Yes		*(AUHERAGE)* *(xx)*
11. Any OTHER medicines, drugs, or substances: (e.g., methadone, Elavil®, steroids, Thorazine®, or Haldol®)	*(AUOTHLFT)* ☐ 0-No ☐ 1-Yes	*(AUOTHLSP)*	*(AUOTHAGE)* *(xx)*

Comments:*(ASUCOMM)*

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

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

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

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

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

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

Comments:*(CHPCOMM)*

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Demographics (DEM)

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

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

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

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

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

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

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

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

Asian:*(DEASIAN)* 1-

Asian Indian:*(DEASAIND)* 1-

Chinese:*(DECHINA)* 1-

Filipino:*(DEFILIPN)* 1-

Japanese:*(DEJAPAN)* 1-

Korean:*(DEKOREA)* 1-

Vietnamese:*(DEVIETNM)* 1-

Specify other Asian:*(DEASIAOT)*

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

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

Native Hawaiian:*(DENATHAW)* 1-

Guamanian or Chamorro:*(DEGUAM)* 1-

Samoan:*(DESAMOAN)* 1-

Specify other Pacific Islander:*(DEPACISO)*

White:*(DEWHITE)* 1-

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

-or-

Don't know:*(DERACEDK)* 1-

Refused:*(DERACERF)* 1-

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

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

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

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

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

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

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

Comments:*(DEMCOMM)*

Additional Selection Options for DEM

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

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

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

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

DSM-5 Checklist (DSM)

Web Version: 1.0; 4.00; 03-15-19

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

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

	Opioids	Alcohol	Amphetamines	Methamphetamine	Cannabis	Cocaine	Sedatives
1. Have you used [insert substance] in the past 12 months?	*(DSOPI12M)* 0-No 1-Yes	*(DSALC12M)* 0-No 1-Yes	*(DSAMP12M)* 0-No 1-Yes	*(DSMET12M)* 0-No 1-Yes	*(DSTHC12M)* 0-No 1-Yes	*(DSCOC12M)* 0-No 1-Yes	*(DSSED12M)* 0-No 1-Yes
2. Have you often found that when you started using [insert substance], you ended up taking more than you intended to? For example, you planned to have a small amount of [insert substance], but you ended up having much more; or you ended up using for a longer period than intended?	*(DSOPIDOS)* 0-No 1-Yes	*(DSALCDOS)* 0-No 1-Yes	*(DSAMPDOS)* 0-No 1-Yes	*(DSMETDOS)* 0-No 1-Yes	*(DSTHCDOS)* 0-No 1-Yes	*(DSCOCDOS)* 0-No 1-Yes	*(DSSEDDOS)* 0-No 1-Yes
3. Have you wanted to stop or cut down or control your use of [insert substance]?	*(DSOPICUT)* 0-No 1-Yes	*(DSALCCUT)* 0-No 1-Yes	*(DSAMPCUT)* 0-No 1-Yes	*(DSMETCUT)* 0-No 1-Yes	*(DSTHCCUT)* 0-No 1-Yes	*(DSCOCCUT)* 0-No 1-Yes	*(DSSEDCUT)* 0-No 1-Yes
4. Have you spent a lot of time getting or using [insert substance]? Or has it taken a lot of time for you to get over the effect?	*(DSOPITIM)* 0-No 1-Yes	*(DSALCTIM)* 0-No 1-Yes	*(DSAMPTIM)* 0-No 1-Yes	*(DSMETTIM)* 0-No 1-Yes	*(DSTHCTIM)* 0-No 1-Yes	*(DSCOCTIM)* 0-No 1-Yes	*(DSSEDTIM)* 0-No 1-Yes
5. Have you had a strong desire or urge to use [insert substance] in between those times when you were using? Has there been a time when you had such strong cravings or urges to use that you had trouble thinking about anything else?	*(DSOPICRA)* 0-No 1-Yes	*(DSALCCRA)* 0-No 1-Yes	*(DSAMPCRA)* 0-No 1-Yes	*(DSMETCRA)* 0-No 1-Yes	*(DSTHCCRA)* 0-No 1-Yes	*(DSCOCCRA)* 0-No 1-Yes	*(DSSEDCRA)* 0-No 1-Yes
6. Have you missed work or school or often arrived late because you were intoxicated, high or recovering from the night before? How about not taking care of things at home because of your use?	*(DSOPIOBL)* 0-No 1-Yes	*(DSALCOBL)* 0-No 1-Yes	*(DSAMPOBL)* 0-No 1-Yes	*(DSMETOBL)* 0-No 1-Yes	*(DSTHCOBL)* 0-No 1-Yes	*(DSCOCOBL)* 0-No 1-Yes	*(DSSEDOBL)* 0-No 1-Yes
7. Has your use of [insert substance] caused problems with other people such as with family members, friends or people at work? Do you get into arguments about your use or fights when you are using? Did you keep using despite these problems?	*(DSOPICON)* 0-No 1-Yes	*(DSALCCON)* 0-No 1-Yes	*(DSAMPCON)* 0-No 1-Yes	*(DSMETCON)* 0-No 1-Yes	*(DSTHCCON)* 0-No 1-Yes	*(DSCOCCON)* 0-No 1-Yes	*(DSSEDCON)* 0-No 1-Yes
8. Have you had to give up or spend less time working, enjoying hobbies, or being with others because of your drug use?	*(DSOPIACT)* 0-No 1-Yes	*(DSALCACT)* 0-No 1-Yes	*(DSAMPACT)* 0-No 1-Yes	*(DSMETACT)* 0-No 1-Yes	*(DSTHCACT)* 0-No 1-Yes	*(DSCOCACT)* 0-No 1-Yes	*(DSSEDACT)* 0-No 1-Yes
9. Have you ever gotten high before doing something that requires coordination or concentration like driving, boating, climbing a ladder, or operating heavy machinery? Would you say your use affected your coordination or concentration so that it was more likely that you or someone else could have been hurt?	*(DSOPIHAZ)* 0-No 1-Yes	*(DSALCHAZ)* 0-No 1-Yes	*(DSAMPHAZ)* 0-No 1-Yes	*(DSMETHAZ)* 0-No 1-Yes	*(DSTHCHAZ)* 0-No 1-Yes	*(DSCOCHAZ)* 0-No 1-Yes	*(DSSEDHAZ)* 0-No 1-Yes
10. Have you continued to use even though you knew that the drug caused you problems like making you depressed, anxious, agitated or irritable? Has your use ever caused physical problems like heart palpitations, trouble breathing or constipation?	*(DSOPISOC)* 0-No 1-Yes	*(DSALCSOC)* 0-No 1-Yes	*(DSAMPSOC)* 0-No 1-Yes	*(DSMETSOC)* 0-No 1-Yes	*(DSTHCSOC)* 0-No 1-Yes	*(DSCOCSOC)* 0-No 1-Yes	*(DSSEDSOC)* 0-No 1-Yes
11. Have you found you needed to use much more [insert substance] to get the same effect that you did when you first started taking it?	*(DSOPITOL)* 0-No 1-Yes	*(DSALCTOL)* 0-No 1-Yes	*(DSAMPTOL)* 0-No 1-Yes	*(DSMETTOL)* 0-No 1-Yes	*(DSTHCTOL)* 0-No 1-Yes	*(DSCOCTOL)* 0-No 1-Yes	*(DSSEDTOL)* 0-No 1-Yes
12. Have you had withdrawal symptoms or felt sick when you cut down or stopped using (aches, shaking, fever, weakness, diarrhea, nausea, sweating, heart pounding, difficulty sleeping, or feel agitated, anxious, irritable, or depressed)? Did you use again to keep yourself from getting sick?	*(DSOPIWIT)* 0-No 1-Yes	*(DSALCWIT)* 0-No 1-Yes	*(DSAMPWIT)* 0-No 1-Yes	*(DSMETWIT)* 0-No 1-Yes	*(DSTHCWIT)* 0-No 1-Yes	*(DSCOCWIT)* 0-No 1-Yes	*(DSSEDWIT)* 0-No 1-Yes
	Opioids	Alcohol	Amphetamines	Methamphetamine	Cannabis	Cocaine	Sedatives
Severity of Substance Use Disorder:	*(DSOPISCO)* 1-Severe 2-Moderate 3-Mild 4-None	*(DSALCSCO)* 1-Severe 2-Moderate 3-Mild 4-None	*(DSAMPSCO)* 1-Severe 2-Moderate 3-Mild 4-None	*(DSMETSCO)* 1-Severe 2-Moderate 3-Mild 4-None	*(DSTHCSCO)* 1-Severe 2-Moderate 3-Mild 4-None	*(DSCOCSCO)* 1-Severe 2-Moderate 3-Mild 4-None	*(DSSEDSCO)* 1-Severe 2-Moderate 3-Mild 4-None

Comments:*(DSMCOMM)*

Electrocardiogram (ECG) Results (ECG)

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

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

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

12-Lead Electrocardiogram (ECG)

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

Results Relating to Eligibility Criteria

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

12. Does the participant have evidence of second or third degree heart block, atrial fibrillation, atrial flutter, or prolongation of the QTc (results relating to eligibility criteria)?*(ECGELIG1)* ☐ 0-No ☐ 1-Yes

Additional ECG Findings

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

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

14. Does the participant have any other finding on the screening ECG that, in the opinion of the study medical clinician, would preclude safe participation in the study?*(ECGELIG2)* ☐ 0-No ☐ 1-Yes

Comments:*(ECGCOMM)*

0068A (ENR)

Web Version: 1.0; 1.00; 04-06-17

1. Date informed consent signed:*(STARTDT)* *(mm/dd/yyyy)*
2. Did the participant consent to the genetic blood sample?*(S4CNSTGN)* ☐ 0-No ☐ 1-Yes

Comments:*(S4COMM)*

Main Study Consent

Original main consent

IRB approval date of ICF:*(S4IRBDT)* *(mm/dd/yyyy)*

Main study re-consent

IRB approval date of ICF:*(S4IRB2DT)* *(mm/dd/yyyy)*

Date informed consent signed:*(S4CST2DT)* *(mm/dd/yyyy)*

Main study re-consent

IRB approval date of ICF:*(S4IRB3DT)* *(mm/dd/yyyy)*

Date informed consent signed:*(S4CST3DT)* *(mm/dd/yyyy)*

Main study re-consent

IRB approval date of ICF:*(S4IRB4DT)* *(mm/dd/yyyy)*

Date informed consent signed:*(S4CST4DT)* *(mm/dd/yyyy)*

Other Consents

Other consent 1

Type of consent:*(S4CST2TY)*

1-Genetics
2-Ancillary
3-HIPAA
4-Medical release
99-Other

If "Other", specify:*(S4CST1OT)*

IRB approval date of ICF:*(S4IRB5DT)* *(mm/dd/yyyy)*

Date informed consent signed:*(S4CST5DT)* *(mm/dd/yyyy)*

Re-consent

IRB approval date of ICF:*(S4IRB6DT)* *(mm/dd/yyyy)*

Date informed consent signed:*(S4CST6DT)* *(mm/dd/yyyy)*

Other consent 2

Type of consent:*(S4CST3TY)*

1-Genetics
2-Ancillary
3-HIPAA
4-Medical release
99-Other

If "Other", specify:*(S4CST2OT)*

IRB approval date of ICF:*(S4IRB7DT)* *(mm/dd/yyyy)*

Date informed consent signed:*(S4CST7DT)* *(mm/dd/yyyy)*

Re-consent

IRB approval date of ICF:*(S4IRB8DT)* *(mm/dd/yyyy)*

Date informed consent signed:*(S4CST8DT)* *(mm/dd/yyyy)*

Final Screening Visit Status (FSV)

Web Version: 1.0; 1.01; 05-22-18

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

1. Was the participant positive for methamphetamine in 2 out of 3 urine drug screens within a ten day period during screening? ***(Must be "Yes" to proceed.)****(FSUDSMET)* ☐ 0-No ☐ 1-Yes
2. Was the participant negative for opiates (2000ng and 300 ng) at today's urine drug screen? ***(Must be "Yes" to proceed.)****(FSUDSOPI)* ☐ 0-No ☐ 1-Yes
3. Does the participant self-report no clinically significant opioid use (i.e., at any level that could constitute a potential risk of precipitating opioid withdrawal upon naltrexone administration) in the 7-10 days prior, as measured using the Timeline Followback and by the Prior and Concomitant Medication assessment? ***(Must be "Yes" to proceed.)****(FSOPINEG)* ☐ 0-No ☐ 1-Yes

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Can the participant proceed with the Final Screening Visit?*(FSVISOK)* ☐ 0-No ☐ 1-Yes

Comments:*(FSVCOMM)*

Self-Report of HIV Testing (HIV)

Web Version: 1.0; 1.02; 08-16-18

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

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

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

1. Have you ever been tested for HIV?*(HIHIVTST)*
   - 0-No
   - 1-Yes
   - 97-Don't know
   - 98-Refuse to answer

2. When did you have your most recent HIV test?*(HITESTMO)* _____ *(xx)* month *(HITESTYR)*/ _____ *(xxxx)* year

3. What was the result of your most recent HIV test?*(HIRESULT)*
   - 0-Negative
   - 1-Positive
   - 4-Indeterminate
   - 3-Never obtained results
   - 98-Refused to answer
   - *Additional Options Listed Below

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

Comments:*(HIVCOMM)*

Additional Selection Options for HIV

What was the result of your most recent HIV test?
97-Don't know

Clinical Laboratory Tests (LAB)

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

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

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

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

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

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

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

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

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

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

26. Does the participant have any elevated bilirubin test value per laboratory criteria OR any other liver function test (LFT) value > 5 times the upper limit of normal per laboratory criteria?*(LAELIGIB)* 0-No 1-Yes

Comments:*(LABCOMM)*

Medical and Psychiatric History (MHX)

Web Version: 1.0; 6.00; 02-20-19

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

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

Medical and Psychiatric History

Medical Condition	History of the Condition	If "Yes", specify:	Condition Present Currently	Medication Taken Currently
1. Eye disorders:	*(MHEYEH)* 0-No 1-Yes	*(MHEYESP)*	*(MHEYEC)* 0-No 1-Yes	*(MHEYEM)* 0-No 1-Yes
2. Ear disorders:	*(MHEARH)* 0-No 1-Yes	*(MHEARSP)*	*(MHEARC)* 0-No 1-Yes	*(MHEARM)* 0-No 1-Yes
3. Respiratory and throat disorders:	*(MHRESPH)* 0-No 1-Yes	*(MHRESPSP)*	*(MHRESPC)* 0-No 1-Yes	*(MHRESPM)* 0-No 1-Yes
4. Cardiovascular disorders:	*(MHCARDH)* 0-No 1-Yes	*(MHCARDSP)*	*(MHCARDC)* 0-No 1-Yes	*(MHCARDM)* 0-No 1-Yes
5. Liver and gallbladder disorders:	*(MHLIVRH)* 0-No 1-Yes	*(MHLIVRSP)*	*(MHLIVRC)* 0-No 1-Yes	*(MHLIVRM)* 0-No 1-Yes
6. Other gastrointestinal disorders:	*(MHGIH)* 0-No 1-Yes	*(MHGISP)*	*(MHGIC)* 0-No 1-Yes	*(MHGIM)* 0-No 1-Yes
7. Skin disorders:	*(MHSKINH)* 0-No 1-Yes	*(MHSKINSP)*	*(MHSKINC)* 0-No 1-Yes	*(MHSKINM)* 0-No 1-Yes
8. Musculoskeletal disorders:	*(MHMUSCH)* 0-No 1-Yes	*(MHMUSCSP)*	*(MHMUSCC)* 0-No 1-Yes	*(MHMUSCM)* 0-No 1-Yes
9. Metabolic disorders:	*(MHMETAH)* 0-No 1-Yes	*(MHMETASP)*	*(MHMETAC)* 0-No 1-Yes	*(MHMETAM)* 0-No 1-Yes
10. Endocrine disorders:	*(MHENDOH)* 0-No 1-Yes	*(MHENDOSP)*	*(MHENDOC)* 0-No 1-Yes	*(MHENDOM)* 0-No 1-Yes
11. Renal and urinary tract disorders:	*(MHRENLH)* 0-No 1-Yes	*(MHRENLSP)*	*(MHRENLC)* 0-No 1-Yes	*(MHRENLM)* 0-No 1-Yes
12. Reproductive system and breast disorders:	*(MHREPOH)* 0-No 1-Yes	*(MHREPOSP)*	*(MHREPOC)* 0-No 1-Yes	*(MHREPOM)* 0-No 1-Yes
13. Epilepsy or seizure disorder:	*(MHELPYH)* 0-No 1-Yes	*(MHELPYSP)*	*(MHELPYC)* 0-No 1-Yes	*(MHELPYM)* 0-No 1-Yes
14. Clinically significant neurological damage:	*(MHNEURH)* 0-No 1-Yes	*(MHNEURSP)*	*(MHNEURC)* 0-No 1-Yes	*(MHNEURM)* 0-No 1-Yes
15. Other nervous system disorders:	*(MHNERVH)* 0-No 1-Yes	*(MHNERVSP)*	*(MHNERVC)* 0-No 1-Yes	*(MHNERVM)* 0-No 1-Yes
Psychiatric Condition	**History of the Condition**	**If "Yes", specify:**	**Condition Present Currently**	**Medication Taken Currently**
16. Anxiety or panic disorder:	*(MHANXH)* 0-No 1-Yes	*(MHANXSP)*	*(MHANXC)* 0-No 1-Yes	*(MHANXM)* 0-No 1-Yes
17. Attention Deficit Hyperactivity Disorder:	*(MHADHDH)* 0-No 1-Yes	*(MHADHDSP)*	*(MHADHDC)* 0-No 1-Yes	*(MHADHDM)* 0-No 1-Yes
18. Bipolar Disorder:	*(MHBPLRH)* 0-No 1-Yes	*(MHBPLRSP)*	*(MHBPLRC)* 0-No 1-Yes	*(MHBPLRM)* 0-No 1-Yes
19. Eating Disorder:	*(MHEATH)* 0-No 1-Yes	*(MHEATSP)*	*(MHEATC)* 0-No 1-Yes	*(MHEATM)* 0-No 1-Yes
20. Major Depressive Disorder:	*(MHMDDH)* 0-No 1-Yes	*(MHMDDSP)*	*(MHMDDC)* 0-No 1-Yes	*(MHMDDM)* 0-No 1-Yes
21. Schizophrenia:	*(MHSCHZH)* 0-No 1-Yes	*(MHSCHZSP)*	*(MHSCHZC)* 0-No 1-Yes	*(MHSCHZM)* 0-No 1-Yes
22. Suicidal ideation:	*(MHSIDH)* 0-No 1-Yes	*(MHSIDSP)*	*(MHSIDC)* 0-No 1-Yes	*(MHSIDM)* 0-No 1-Yes
23. Suicidal behavior:	*(MHSBEHH)* 0-No 1-Yes	*(MHSBEHSP)*	*(MHSBEHC)* 0-No 1-Yes	*(MHSBEHM)* 0-No 1-Yes
24. Homicidal ideation:	*(MHHIDH)* 0-No 1-Yes	*(MHHIDSP)*	*(MHHIDC)* 0-No 1-Yes	*(MHHIDM)* 0-No 1-Yes
25. Homicidal behavior:	*(MHHBEHH)* 0-No 1-Yes	*(MHHBEHSP)*	*(MHHBEHC)* 0-No 1-Yes	*(MHHBEHM)* 0-No 1-Yes
26. Violent behavior:	*(MHVBEHH)* 0-No 1-Yes	*(MHVBEHSP)*	*(MHVBEHC)* 0-No 1-Yes	*(MHVBEHM)* 0-No 1-Yes
27. Psychotic episodes not specified above:	*(MHPSYEH)* 0-No 1-Yes	*(MHPSYESP)*	*(MHPSYEC)* 0-No 1-Yes	*(MHPSYEM)* 0-No 1-Yes
28. Other psychiatric disorder:	*(MHPSYOH)* 0-No 1-Yes	*(MHPSYOSP)*	*(MHPSYOC)* 0-No 1-Yes	*(MHPSYOM)* 0-No 1-Yes

Other Conditions Not Listed Above	Specific Details	Condition Present Currently	Medication Taken Currently
29. *(MHOTHR1)*	*(MHOTH1SP)*	*(MHOTHR1C)* 0-No 1-Yes	*(MHOTHR1M)* 0-No 1-Yes
30. *(MHOTHR2)*	*(MHOTH2SP)*	*(MHOTHR2C)* 0-No 1-Yes	*(MHOTHR2M)* 0-No 1-Yes
31. *(MHOTHR3)*	*(MHOTH3SP)*	*(MHOTHR3C)* 0-No 1-Yes	*(MHOTHR3M)* 0-No 1-Yes

Surgical/Medical Procedure History

32. Does the participant have a history of surgical and/or medical procedures?*(MHSURGRY)* 0-No 1-Yes

If the participant has had major surgery, provide most important/significant surgical event data below, including date of surgery.
If the participant remembers only the year, then record "06" for the month and "15" for the day. If the participant remembers only the month and year, then record "15" for the day.

Type of Surgery and/or Medical Procedure	Surgery/Procedure Date
a.*(MHSRG1)*	*(MHSRG1DT)*
b.*(MHSRG2)*	*(MHSRG2DT)*
c.*(MHSRG3)*	*(MHSRG3DT)*
d.*(MHSRG4)*	*(MHSRG4DT)*
e.*(MHSRG5)*	*(MHSRG5DT)*

Specific Study Eligibility Criteria

33. Does the participant have an acute medical or psychiatric disorder that would, in the judgment of the study medical clinician, make participation difficult or unsafe?*(MHMEDCON)* ☐ 0-No ☐ 1-Yes

34. Does the participant have suicidal or homicidal ideation that requires immediate attention?*(MHCIDE)* ☐ 0-No ☐ 1-Yes

35. Does the participant have a history of epilepsy, seizure disorder, or head trauma with neurological sequelae (e.g., loss of consciousness that required hospitalization); current anorexia nervosa or bulimia; or any other conditions that increase seizure risk in the opinion of the study medical clinician?*(MHMEDCO2)* ☐ 0-No ☐ 1-Yes

36. Does the participant have a known allergy or sensitivity to bupropion, naloxone, naltrexone, PLG (polyactide-co-glycolide), carboxymethylcellulose or any other component of the XR-NTX diluents? *(MHALGDRG)* ☐ 0-No ☐ 1-Yes

37. Does the participant receive ongoing treatment with tricyclic antidepressants, xanthines (i.e., theophylline and aminophylline), systemic corticosteroids, nelfinavir, efavirenz, chlorpromazine, MAOIs, central nervous system stimulants (e.g., Adderall, Ritalin, etc.), or any medication that, in the judgment of the study medical clinician, could interact adversely with study medications?*(MHADVDRG)* ☐ 0-No ☐ 1-Yes

38. Does the participant require treatment with opioid-containing medications (e.g., opioid analgesics) during the study period?*(MHOPIMED)* ☐ 0-No ☐ 1-Yes

39. Does the participant have a surgery planned or scheduled during the study period?*(MHSRGSCH)* ☐ 0-No ☐ 1-Yes

Comments:*(MHXCOMM)*

Naloxone Challenge (NXC)

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

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

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

First Dose

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

Second Dose (if applicable)

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

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

Third Dose (if applicable)

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

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

Results

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

Comments:*(NXCCOMM)*

Additional Selection Options for NXC

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

Pregnancy and Birth Control Assessment (PBC)

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

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

Complete this form only for females.

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

1. Is the participant of childbearing potential?*(PBCHILD)* ☐ 0-No ☐ 1-Yes
2. Is the participant breastfeeding?*(PBBSTFED)* ☐ 0-No ☐ 1-Yes
3. Does the participant agree to use an acceptable method of birth control?*(PBUSEBC)* ☐ 0-No ☐ 1-Yes

If "Yes", select all that apply:

a. Oral contraceptives:*(PBORALCN)* ☐ 0-No ☐ 1-Yes
b. Contraceptive patch:*(PBPATCH)* ☐ 0-No ☐ 1-Yes
c. Barrier (diaphragm or condom):*(PBBARRIR)* ☐ 0-No ☐ 1-Yes
d. Levonorgestrel implant:*(PBLEVIMP)* ☐ 0-No ☐ 1-Yes
e. Medroxyprogesterone acetate injection:*(PBMEDINJ)* ☐ 0-No ☐ 1-Yes
f. Complete abstinence from sexual intercourse:*(PBABSTIN)* ☐ 0-No ☐ 1-Yes
g. Hormonal vaginal contraceptive ring:*(PBRING)* ☐ 0-No ☐ 1-Yes
h. Surgical sterilization:*(PBSURGSZ)* ☐ 0-No ☐ 1-Yes
i. Intrauterine contraceptive device (IUD):*(PBINTDEV)* ☐ 0-No ☐ 1-Yes
j. Other:*(PBBCOTH)* ☐ 0-No ☐ 1-Yes

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

4. Date of the first day of the participant's last period:*(PBPRDDT)* _____ *(mm/dd/yyyy)*
5. Was a pregnancy test performed?*(PBPRGTST)* ☐ 0-No ☐ 1-Yes

a. Date of pregnancy test:*(PBPTSTDT)* _____ *(mm/dd/yyyy)*
b. Result of pregnancy test:*(PBRESULT)* ☐ 0-Negative ☐ 1-Positive

Comments:*(PBCCOMM)* _____

Prior and Concomitant Medications (PCM)

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

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

1. Indication for use:*(PCINDICT)*

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

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

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

☐ 0-No ☐ 1-Yes

3. Is medication ongoing?*(PCONGOIN)*

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

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

Comments:*(PCMCOMM)*

Additional Selection Options for PCM

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

NIDA Clinical Trials Network

Psychiatric Diagnostic Screening Questionnaire (PDQ)

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

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

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

*This questionnaire contains items about emotions, moods, thoughts, and behaviors. Select **"Yes"** or **"No"** next to each question to indicate whether it describes how you have been acting, feeling, or thinking. If the item does not apply to you then select "No".*
PLEASE ANSWER EVERY QUESTION.
Note: Please answer "Yes" only if your symptoms were not due to drug or alcohol use.

DURING THE PAST 2 WEEKS...	Yes	No
1. Did you feel sad or depressed?	*(PDSAD)* ☐	☐
2. Did you feel sad or depressed for most of the day, nearly every day of the past 2 weeks?	*(PDSADMT)* ☐	☐
3. Did you get less joy or pleasure from almost all of the things you normally enjoy?	*(PDLESJOY)* ☐	☐
4. Were you less interested in almost all of the activities you are usually interested in?	*(PDLESACT)* ☐	☐
5. Was your appetite significantly lower than usual nearly every day of the past 2 weeks?	*(PDAPTL)* ☐	☐
6. Was your appetite significantly greater than usual nearly every day of the past 2 weeks?	*(PDAPTG)* ☐	☐
7. Did you sleep at least 1-2 hours less than usual nearly every day of the past 2 weeks?	*(PDSLPL)* ☐	☐
8. Did you sleep at least 1-2 hours more than usual nearly every day of the past 2 weeks?	*(PDSLPM)* ☐	☐
9. Did you feel very jumpy and physically restless, and have a lot of trouble sitting calmly in a chair, nearly every day of the past 2 weeks?	*(PDRSTLS)* ☐	☐
10. Did you feel tired out nearly every day of the past 2 weeks?	*(PDTIRED)* ☐	☐
11. Did you frequently feel guilty about things you have done?	*(PDGUILTY)* ☐	☐
12. Did you put yourself down and have negative thoughts about yourself nearly every day of the past 2 weeks?	*(PDNEG)* ☐	☐
13. Did you feel like a failure nearly every day of the past 2 weeks?	*(PDFAIL)* ☐	☐
14. Did you have problems concentrating nearly every day of the past 2 weeks?	*(PDCNCT)* ☐	☐
15. Was decision making more difficult than normal nearly every day of the past 2 weeks?	*(PDDECSN)* ☐	☐

DURING THE PAST 2 YEARS...	Yes	No
16. Did you feel sad or down on most days of the past two years?	*(PDSAD2Y)* ☐	☐
17. Did you have a poor appetite or overeat on most days of the past two years?	*(PDAPT2Y)* ☐	☐
18. Did you have difficulty with not sleeping enough or with oversleeping on most days of the past two years?	*(PDSLP2Y)* ☐	☐
19. Did you feel tired out on most days of the past two years?	*(PDTRD2Y)* ☐	☐
20. Did you have problems concentrating or making decisions on most days of the past two years?	*(PDCNCT2Y)* ☐	☐
21. Did you have low self-esteem on most days of the past two years?	*(PDESTM2Y)* ☐	☐
22. Did you feel hopeless about the future on most days of the past two years?	*(PDHLPS2Y)* ☐	☐

23. Have you ever experienced a traumatic event such as combat, rape, assault, sexual abuse, or any other extremely upsetting event?*(PDTRMEXP)*	☐ 1-Yes ☐ 2-No
24. Have you ever witnessed a traumatic event such as rape, assault, someone dying in an accident, or any other extremely upsetting event?*(PDTRMWIT)*	☐ 1-Yes ☐ 2-No
DURING THE PAST 2 WEEKS...	
25. Did thoughts about a traumatic event frequently pop into your mind?*(PDTRMA)*	☐ 1-Yes ☐ 2-No
26. Did you frequently get upset because you were thinking about a traumatic event?*(PDUPSET)*	☐ 1-Yes ☐ 2-No
27. Were you frequently still bothered by memories or dreams of a traumatic event?*(PDBOTHR)*	☐ 1-Yes ☐ 2-No
28. Did reminders of a traumatic event cause you to feel intense distress?*(PDRMDR)*	☐ 1-Yes ☐ 2-No
29. Did you try to block out thoughts or feelings related to a traumatic event?*(PDBLOCK)*	☐ 1-Yes ☐ 2-No
30. Did you try to avoid activities, places, or people that reminded you of a traumatic event?*(PDAVOID)*	☐ 1-Yes ☐ 2-No
31. Did you have "flashbacks," where it felt like you were reliving a traumatic event?*(PDFLASH)*	☐ 1-Yes ☐ 2-No
32. Did reminders of a traumatic event make you shake, break out into a sweat, or have a racing heart?*(PDSWEAT)*	☐ 1-Yes ☐ 2-No
33. Did you feel distant and cutoff from other people because of having experienced a traumatic event?*(PDDISTNT)*	☐ 1-Yes ☐ 2-No
34. Did you feel emotionally numb because of having experienced a traumatic event?*(PDNUMB)*	☐ 1-Yes ☐ 2-No
35. Did you give up on goals for the future because of having experienced a traumatic event?*(PDNOGOAL)*	☐ 1-Yes ☐ 2-No
36. Did you keep your guard up because of having experienced a traumatic event?*(PDGUARD)*	☐ 1-Yes ☐ 2-No
37. Were you jumpy and easily startled because of having experienced a traumatic event?*(PDJUMPY)*	☐ 1-Yes ☐ 2-No

DURING THE PAST 2 WEEKS...	Yes	No
38. Did you often go on eating binges (eating a very large amount of food very quickly over a short period of time)?	*(PDETBNG)* ☐	☐
39. Did you often feel you could not control how much you were eating during an eating binge?	*(PDETCNTL)* ☐	☐
40. Did you go on eating binges during which you ate so much that you felt uncomfortably full?	*(PDETFULL)* ☐	☐
41. Did you go on eating binges during which you ate a large amount of food even when you didn't feel hungry?	*(PDETHUNG)* ☐	☐
42. Did you eat alone during an eating binge because you were embarrassed by how much you were eating?	*(PDETEMB)* ☐	☐
43. Did you go on eating binges and then feel disgusted with yourself after overeating?	*(PDETDISG)* ☐	☐
44. Were you very upset with yourself because you were going on eating binges?	*(PDETUPST)* ☐	☐
45. To prevent gaining weight from an eating binge did you go on strict diets, or exercise excessively?	*(PDETDIET)* ☐	☐
46. To prevent gaining weight from an eating binge did you force yourself to vomit, or use laxatives or water pills?	*(PDETVMT)* ☐	☐
47. Was your weight or the shape of your body one of the most important things that affected your opinion of yourself?	*(PDETOPIN)* ☐	☐

DURING THE PAST 2 WEEKS...	Yes	No
48. Did you worry obsessively about dirt, germs, or chemicals?	*(PDWYDRT)* ☐	☐
49. Did you worry obsessively that something bad would happen because you forgot to do something important - like locking the door, turning off the stove, pulling out the electrical cords of appliances, etc.?	*(PDWYBAD)* ☐	☐
50. Did you worry obsessively that you would act or speak violently when you really didn't want to?	*(PDWYVLNT)* ☐	☐

51. Were there things you felt compelled to do over and over (for at least 1/2 hour per day) that you could not stop doing when you tried? *(PDCOMPL)*

52. Were there things you felt compelled to do over and over even though it interfered with getting other things done? *(PDINTRF)*

53. Did you wash and clean yourself or things around you obsessively and excessively? *(PDCLEAN)*

54. Did you obsessively and excessively check or repeat things over and over again? *(PDCHECK)*

55. Did you count things obsessively and excessively? *(PDCOUNT)*

DURING THE PAST 2 WEEKS...		Yes	No
56.	Did you get very scared because your heart was beating fast?	*(PDHRBEAT)*	
57.	Did you get very scared because you were short of breath?	*(PDBREATH)*	
58.	Did you get very scared because you were feeling shaky or faint?	*(PDSHAKY)*	
59.	Did you get sudden attacks of very intense anxiety or fear that came on from out of the blue, for no reason at all?	*(PDANXNRS)*	
60.	Did you get sudden attacks of very intense anxiety or fear during which you thought something terrible might happen, such as you might die, go crazy, or lose control?	*(PDANXATT)*	
61.	Did you have sudden, unexpected attacks of anxiety during which you had 3 or more of the following symptoms: heart racing or pounding, sweating, shakiness, shortness of breath, nausea, dizziness, or feeling faint?	*(PDANXPHY)*	
62.	Did you worry a lot about having unexpected anxiety attacks?	*(PDWRYANX)*	
63.	Did you have attacks of anxiety that caused you to avoid certain situations or to change your behavior or normal routine?	*(PDANXAVD)*	

DURING THE PAST 2 WEEKS...		Yes	No
64.	Did you feel excessively cheerful and happy, much more than usual, and the good mood lasted most of the day for at least several days?	*(PDHAPPY)*	
65.	Did you feel extremely self-confident, much more than usual?	*(PDCONFD)*	
66.	Did you have so much positive energy that you needed less sleep than usual to feel rested?	*(PDPOSITV)*	
67.	Did you talk much more than usual, or feel a pressure to talk constantly?	*(PDTALK)*	
68.	Did you take on new projects or responsibilities because you thought you could do everything?	*(PDNEW)*	
69.	Did you do impulsive things that are out of character for you like going on spending sprees, investing money, or doing things sexually that are unusual for you?	*(PDIMPUL)*	

DURING THE PAST 2 WEEKS...		Yes	No
70.	Did things happen that you knew were true, but other people told you were your imagination?	*(PDIMGN)*	
71.	Were you convinced that other people were watching you, talking about you, or spying on you?	*(PDSPY)*	
72.	Did you think that you were in danger because someone was plotting to hurt you?	*(PDDANGR)*	
73.	Did you think that you had special powers other people didn't have?	*(PDPOWER)*	
74.	Did you think that some force or power from the outside was controlling your body or mind?	*(PDCONTRL)*	
75.	Did you hear voices that other people didn't hear, or see things that other people didn't see?	*(PDVOICE)*	

DURING THE PAST 6 MONTHS...		Yes	No
76.	Did you regularly avoid any situations because you were afraid you'd have an anxiety attack in the situation?	*(PDAVDT6M)*	
77.	Did any of the following make you feel fearful, anxious, or nervous because you were afraid you'd have an anxiety attack in the situation?		
a.	Going outside far away from home.	*(PDOUT6M)*	
b.	Being in crowded places.	*(PDCRD6M)*	
c.	Standing in long lines.	*(PDLINE6M)*	
d.	Being on a bridge or in a tunnel.	*(PDBRTN6M)*	
e.	Traveling in a bus, train, or plane.	*(PDTRVL6M)*	
f.	Driving or riding in a car.	*(PDCAR6M)*	
g.	Being home alone.	*(PDHOME6M)*	
h.	Being in wide open spaces (like a park).	*(PDOPEN6M)*	
78.	Did you almost always get very anxious as soon as you were in any of the above situations?	*(PDAWY16M)*	
79.	Did you avoid any of the above situations because they made you feel anxious or fearful?	*(PDAVD16M)*	

DURING THE PAST 6 MONTHS...		Yes	No
80.	Did you worry a lot about embarrassing yourself in front of others?	*(PDEMB6M)*	
81.	Did you worry a lot that you might do something to make people think that you were stupid or foolish?	*(PDDO6M)*	
82.	Did you feel very nervous in situations where people might pay attention to you?	*(PDATT6M)*	
83.	Were you extremely nervous in social situations?	*(PDSOC6M)*	
84.	Did you regularly avoid any situations because you were afraid you'd say or do something to embarrass yourself?	*(PDAVDE6M)*	
85.	Did you worry a lot about doing or saying something to embarrass yourself in any of the following siutations?		
a.	Public speaking.	*(PDSPK6M)*	
b.	Eating in front of other people.	*(PDEAT6M)*	
c.	Using public restrooms.	*(PDREST6M)*	
d.	Writing in front of others.	*(PDWRT6M)*	
e.	Saying something stupid when you're with a group of people.	*(PDSAY6M)*	
f.	Asking a question when in a group of people.	*(PDQUST6M)*	
g.	Business meetings.	*(PDMEET6M)*	
h.	Parties or other social gatherings.	*(PDPRTY6M)*	
86.	Did you almost always get very anxious as soon as you were in any of the above situations?	*(PDAWY26M)*	
87.	Did you avoid any of the above situations because they made you feel anxious or fearful?	*(PDAVD26M)*	

DURING THE PAST 6 MONTHS...		Yes	No
88.	Were you a nervous person on most days of the past 6 months?	*(PDPRSN6M)*	
89.	Did you worry a lot that bad things might happen to you or someone close to you?	*(PDHAPN6M)*	
90.	Did you worry about things that other people said you shouldn't worry about?	*(PDNOWY6M)*	
91.	Were you worried or anxious about a number of things in your daily life on most days of the past 6 months?	*(PDNUM6M)*	
92.	Did you often feel restless or on edge because you were worrying?	*(PDRSTL6M)*	

93. Did you often have problems falling asleep because you were worrying about things? *(PDSLP6M)*

94. Did you often feel tension in your muscles because of anxiety or stress? *(PDTENS6M)*

95. Did you often have difficulty concentrating because your mind was on your worries? *(PDCNCT6M)*

96. Were you often snappy or irritable because you were worrying or feeling stressed out? *(PDIRR6M)*

97. Was it hard for you to control or stop your worrying on most days of the past 6 months? *(PDNCNT6M)*

DURING THE PAST 6 MONTHS...		Yes	No
98. Have you had a lot of stomach and intestinal problems such as nausea, vomiting, excessive gas, stomach bloating, or diarrhea?	*(PDSTM6M)*	☐	☐
99. Have you been bothered by aches and pains in many different parts of your body?	*(PDACHE6M)*	☐	☐
100. Do you get sick more than most people?	*(PDSICK6M)*	☐	☐
101. Has your physical health been poor most of your life?	*(PDHLTH6M)*	☐	☐
102. Are your doctors usually not able to find a physical cause for your physical symptoms?	*(PDNOPY6M)*	☐	☐

DURING THE PAST 6 MONTHS...		Yes	No
103. Did you often worry that you might have a serious physical illness?	*(PDSERS6M)*	☐	☐
104. Was it hard to stop worrying that you might have a serious physical illness?	*(PDSTP6M)*	☐	☐
105. Did your doctor say you didn't have a serious illness but it was still hard to stop thinking about it?	*(PDTHNK6M)*	☐	☐
106. Did you worry so much about having a serious illness that it interfered with your activities or it caused you problems?	*(PDPROB6M)*	☐	☐
107. Did you visit the doctor a lot because you were worried that you had a serious physical illness?	*(PDVIST6M)*	☐	☐

Comments:*(PDQCOMM)*

Protocol Deviation (PDV)

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

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

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

If "Yes", how many participants?*(PDPRELNO)*

01-1
02-2
03-3
04-4
05-5
*Additional Options Listed Below

Select related participants:

Participant ID 1:*(PDPPT01)* 9999999999999-DUMMYPARTICIPANTID

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3. Deviation type:*(PDTYPE)*

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

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

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

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

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

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

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

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

If "No", date of actual submission:*(PDIRBADT)* *(mm/dd/yyyy)*

Comments:*(PDVCOMM)*

Additional Selection Options for PDV

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

If "Yes", how many participants?
06-6
07-7
08-8
09-9
10-10
11-11
12-12
13-13
14-14
15-15
16-16
17-17
18-18
19-19
20-20

Deviation type:
01E--- Informed consent/assent process not properly conducted and/or documented
01Z--- Other informed consent/assent procedures issues (specify)
020-INCLUSION/EXCLUSION CRITERIA
02A--- Ineligible participant randomized/inclusion/exclusion criteria not met
02B--- Ineligible participant enrolled/inclusion/exclusion criteria not met
02Z--- Other inclusion/exclusion criteria issues (specify)
040-LABORATORY ASSESSMENTS
04A--- Biologic specimen not collected/processed as per protocol
04Z--- Other laboratory assessments issues (specify)
050-STUDY PROCEDURES/ASSESSMENTS
05A--- Protocol required visit/assessment not scheduled or conducted
05B--- Study assessments not completed/followed as per protocol
05C--- Inappropriate unblinding
05Z--- Other study procedures/assessments issues (specify)
060-ADVERSE EVENT
06A--- AE not reported
06B--- SAE not reported
06C--- AE/SAE reported out of protocol specified reporting timeframe
06D--- AE/SAE not elicited, observed and/or documented as per protocol
06E--- Safety assessment (e.g. labs, ECG, clinical referral to care) not conducted per protocol
06Z--- Other adverse events issues (specify)
070-RANDOMIZATION PROCEDURES
07A--- Stratification error
07Z--- Other randomization procedures issues (specify)
080-STUDY MEDICATION MANAGEMENT
08A--- Medication dispensed to ineligible participant
08B--- Medication dispensed to incorrect participant
08C--- Medication dosing errors (protocol specified dose not dispensed)
08D--- Participant use of protocol prohibited medication
08Z--- Other study medication management issues (specify)
090-STUDY BEHAVIORAL INTERVENTION
09A--- Study behavioral intervention was not provided/performed as per protocol
09Z--- Other study behavioral intervention issues (specify)
100-STUDY DEVICES
10A--- Study devices dispensed to ineligible participant
10Z--- Other study devices issues (specify)
110-SAFETY EVENT
11A--- Safety event not reported
11B--- Safety event reported out of protocol specified reporting timeframe
11C--- Safety event not elicited, observed and/or documented as per protocol
11D--- Safety event assessment not conducted per protocol
11Z--- Other safety event issues (specify)
990-OTHER SIGNIFICANT DEVIATIONS
99A--- Destruction of study materials without prior authorization from sponsor
99B--- Breach of Confidentiality
99Z--- Other significant deviations issues (specify)

Physical Examination (PEX)

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

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

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

			Comments
1. General appearance:	*(PEGENAPP)*	1-Normal 2-Abnormal, not clinically significant 3-Abnormal, clinically significant 97-Not assessed	*(PEGASP)*
2. Skin, hair, and nails:	*(PESKHRNA)*	1-Normal 2-Abnormal, not clinically significant 3-Abnormal, clinically significant 97-Not assessed	*(PESHNSP)*
3. Head and neck:	*(PEHDNK)*	1-Normal 2-Abnormal, not clinically significant 3-Abnormal, clinically significant 97-Not assessed	*(PEHDNKSP)*
4. Ears, eyes, nose, and throat:	*(PEEENT)*	1-Normal 2-Abnormal, not clinically significant 3-Abnormal, clinically significant 97-Not assessed	*(PEENTSP)*
5. Cardiovascular:	*(PECARD)*	1-Normal 2-Abnormal, not clinically significant 3-Abnormal, clinically significant 97-Not assessed	*(PECARDSP)*
6. Respiratory:	*(PERESP)*	1-Normal 2-Abnormal, not clinically significant 3-Abnormal, clinically significant 97-Not assessed	*(PERESPSP)*
7. Gastrointestinal:	*(PEGAST)*	1-Normal 2-Abnormal, not clinically significant 3-Abnormal, clinically significant 97-Not assessed	*(PEGASTSP)*
8. Extremities:	*(PEEXTR)*	1-Normal 2-Abnormal, not clinically significant 3-Abnormal, clinically significant 97-Not assessed	*(PEEXTRSP)*
9. Lymph nodes:	*(PELYMP)*	1-Normal 2-Abnormal, not clinically significant 3-Abnormal, clinically significant 97-Not assessed	*(PELYMPSP)*
10. Musculoskeletal:	*(PEMUSC)*	1-Normal 2-Abnormal, not clinically significant 3-Abnormal, clinically significant 97-Not assessed	*(PEMUSCSP)*
11. Neurological:	*(PENEUR)*	1-Normal 2-Abnormal, not clinically significant 3-Abnormal, clinically significant 97-Not assessed	*(PENEURSP)*
12. Gluteal injection site:	*(PEINJSIT)*	1-Normal 2-Abnormal, not clinically significant 3-Abnormal, clinically significant 97-Not assessed	*(PEINJSSP)*
13. Other: *(specify in comments)*	*(PEOTHER)*	1-Normal 2-Abnormal, not clinically significant 3-Abnormal, clinically significant 97-Not assessed	*(PEOTHESP)*

14. Does participant have a body habitus that precludes gluteal intramuscular injection of XR-NTX in accordance with the administration equipment (needle) and procedures?*(PEBDYHBT)*
☐ 0-No ☐ 1-Yes ☐ 97-Not assessed

Comments:*(PEXCOMM)*

Patient Health Questionnaire (PHQ-9) (PHQ)

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

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

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

Please answer the following to the best of your ability.

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

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

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

Comments:*(PHQCOMM)*

Quality of Life (QLP)

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

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

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

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

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

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

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

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

Comments:*(QLPCOMM)*

Sexual Risk Behaviors (SRB)

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

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

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

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

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

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

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

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

How many of your male partners were:

a. HIV positive?*(SRMHIVPS)* _____ *(xx)*

b. HIV negative?*(SRMHIVNG)* _____ *(xx)*

c. You did not know their status?*(SRMHIVUK)* _____ *(xx)*

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

How many of your female partners were:

a. HIV positive?*(SRFHIVPS)* _____ *(xx)*

b. HIV negative?*(SRFHIVNG)* _____ *(xx)*

c. You did not know their status?*(SRFHIVUK)* _____ *(xx)*

4. With how many of your sexual partners have you been high (on alcohol or drugs) when having sex in the past 30 days? *(SR3ALSEX)* _____ *(xx)*

5. **During the past 30 days**, when you had sex with your male and/or female partners:

a. How many times did you have vaginal or anal sex with HIV negative partners?*(SRSHIVNG)* _____ *(xx)* times

Of these, how many times was a condom worn from start to finish?*(SR3CONDN)* _____ *(xx)* times

b. How many times did you have vaginal or anal sex with HIV positive or unknown partners?*(SRSHIVPU)* _____ *(xx)* times

Of these, how many times was a condom worn from start to finish?*(SR3CONDP)* _____ *(xx)* times

6. During the past 30 days, how many times did you have sex while you were **high on methamphetamine**?*(SR3MTSEX)* _____ *(xx)* times

7. During the past 30 days, how many times did you have sex while you were **high on alcohol or drugs other than methamphetamine**?*(SR3OTSEX)* _____ *(xx)* times

8. During the past 30 days, how many times did you **trade sex** for drugs, gifts, or money?*(SRTRADE)* _____ *(xx)* times

9. During the past 30 days, how many times did you use drugs, gifts, or money to purchase or get sex?*(SRPURCHS)* _____ *(xx)* times

Comments:*(SRBCOMM)*

Additional Selection Options for SRB

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

NIDA Clinical Trials Network

Timeline Followback (T68)

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

TFB week start date *(TFWKSTDT)*:

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

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

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

Comments: *(TFBCOMM)*

Additional Selection Options for T68

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

TLFB Assessment Period (TAP)

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

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

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

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

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

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

☐ 0-No ☐ 1-Yes

Comments:*(TAPCOMM)*

Treatment Effectiveness Assessment (TEA)

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

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

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

This assessment asks you to express what you think about how you are doing in four categories: substance use, health, lifestyle, and community. For each topic, think about what is going on in your life and how you are doing in those areas, then mark the result on the scale. Check the number that indicates how things are for you in each area, from 1 (poor) to 10 (great). You might want to type some remarks in each category to provide some details about why you checked a specific number on the scale.

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

Poor				Ok					Great
(TESUBUSE) ☐ 01-1	☐ 02-2	☐ 03-3	☐ 04-4	☐ 05-5	☐ 06-6	☐ 07-7	☐ 08-8	☐ 09-9	☐ 10-10

Remarks: *(TSSUBRM)*

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

Poor				Ok					Great
(TEHEALTH) ☐ 01-1	☐ 02-2	☐ 03-3	☐ 04-4	☐ 05-5	☐ 06-6	☐ 07-7	☐ 08-8	☐ 09-9	☐ 10-10

Remarks: *(TEHLTHRM)*

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

Poor				Ok					Great
(TELIFEST) ☐ 01-1	☐ 02-2	☐ 03-3	☐ 04-4	☐ 05-5	☐ 06-6	☐ 07-7	☐ 08-8	☐ 09-9	☐ 10-10

Remarks: *(TELIFERM)*

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

Poor				Ok					Great
(TECOMMUN) ☐ 01-1	☐ 02-2	☐ 03-3	☐ 04-4	☐ 05-5	☐ 06-6	☐ 07-7	☐ 08-8	☐ 09-9	☐ 10-10

Remarks: *(TECOMRM)*

Comments:*(TEACOMM)*

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Tobacco Use History (TUH)

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

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

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

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

Section A: Every-Day Smokers

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

Section B: Some-Day Smokers

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

Section C: Former Smokers

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

Comments:*(TUHCOMM)*

Urine Drug Screen (UDS)

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

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

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

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

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

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

1st Urine Drug Screen

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

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

2nd Urine Drug Screen

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

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

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

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

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

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

Comments:*(UDSCOMM)*

Visual Analog Craving Scale (VAS)

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

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

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

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

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

Comments:*(VASCOMM)*

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Vital Signs (VIT)

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

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

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

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

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

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

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

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

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

Comments:*(VITCOMM)*