

Adverse Event (AD1)

Version: 1.01; 12-10-20

Adverse event onset date (AEDATE):
Sequence number (AESEQNO):

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

For the purpose of this protocol, Adverse Events are captured on the Targeted Safety Events form. Only Serious Adverse Events are reported on this form.

1. Adverse event name:(A1DESCPT)

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

 (mm/dd/yyyy)

3. Severity of event:(A1SEVRTY)

- 01-Grade 1 - Mild
- 02-Grade 2 - Moderate
- 03-Grade 3 - Severe

4. Is there a reasonable possibility that study medication caused the event?(A1STDMED)

 0-No 1-Yes

a. If "Yes", action taken with study medication:(A1MEDACT)

- 00-None
- 01-Decreased drug
- 02-Increased drug
- 03-Temporarily stopped drug
- 04-Permanently stopped drug
- 05-Participant terminated from study

5. If not caused by the study medication, alternative etiology:(A1ALTEI)

- 00-None apparent
- 01-Study disease
- 02-Concomitant medication
- 03-Other pre-existing disease or condition
- 04-Accident, trauma, or external factors
- *Additional Options Listed Below

a. If "Other", Specify:(A1ALTSP)

6. Outcome of event:(A1OUTCM)

- 01-Recovering/resolving
- 02-Recovered/resolved
- 03-Recovered/resolved with sequelae
- 04-Not recovered/not resolved
- 05-Fatal
- 97-Unknown

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

 (mm/dd/yyyy)

A response of "Yes" to any of the following 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.

8. Was this event associated with:

If more than one option applies, select the most serious.

a. Is the adverse event associated with a congenital anomaly or birth defect?(A1ANOM)

 0-No 1-Yes

b. Did the adverse event result in persistent or significant disability or incapacity?
(A1DISABL)

 0-No 1-Yes

c. Did the adverse event result in death?(A1DTH)

 0-No 1-Yes

1. If "Yes", date of death:(A1DTHDT)

 (mm/dd/yyyy)

d. Did the adverse event result in initial or prolonged hospitalization for the participant?
(A1HOSP)

 0-No 1-Yes

If "Yes",

1. Date of hospital admission:(A1HOSPAD)

 (mm/dd/yyyy)

2. Date of hospital discharge:(A1HOSPDC)

 (mm/dd/yyyy)

e. Is the adverse event life threatening?(A1LIFETH)

 0-No 1-Yes

f. Is the adverse event an "other serious" event (Important Medical Event)?(A1OTCRIT)

 0-No 1-Yes

Comments:(AD1COMM)

Additional Selection Options for AD1

Sequence 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 study medication, alternative etiology:

- 05-Concurrent illness/condition (not pre-existing)
- 06-Study procedures
- 07-Naloxone challenge
- 99-Other

Serious Adverse Event Summary (AD2)

Version: 3.00; 07-02-21

Adverse event onset date (AEDATE):
Sequence number (AESEQNO):

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)

00-No 01-Yes 97-Unknown

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

3. Medications at the time of the event:(A2SAEMED)

00-No 01-Yes 97-Unknown

Be sure to assess for dosage and date of last dose for the study medication, and any prior/concomitant medications as needed.

Medication (Generic Name)	Indication
a. (A2_01DNM) <input type="text"/>	(A2_01DIN) <input type="text"/>
b. (A2_02DNM) <input type="text"/>	(A2_02DIN) <input type="text"/>
c. (A2_03DNM) <input type="text"/>	(A2_03DIN) <input type="text"/>
d. (A2_04DNM) <input type="text"/>	(A2_04DIN) <input type="text"/>
e. (A2_05DNM) <input type="text"/>	(A2_05DIN) <input type="text"/>
f. (A2_06DNM) <input type="text"/>	(A2_06DIN) <input type="text"/>
g. (A2_07DNM) <input type="text"/>	(A2_07DIN) <input type="text"/>
h. (A2_08DNM) <input type="text"/>	(A2_08DIN) <input type="text"/>
i. (A2_09DNM) <input type="text"/>	(A2_09DIN) <input type="text"/>
j. (A2_10DNM) <input type="text"/>	(A2_10DIN) <input type="text"/>

4. Treatments for the event:(A2SAETRT)

00-No 01-Yes 97-Unknown

Treatment	Indication	Date Treated (mm/dd/yyyy)
a. (A2_1TNME) <input type="text"/>	(A2_1TIND) <input type="text"/>	(A2_1LTDT) <input type="text"/>
b. (A2_2TNME) <input type="text"/>	(A2_2TIND) <input type="text"/>	(A2_2LTDT) <input type="text"/>
c. (A2_3TNME) <input type="text"/>	(A2_3TIND) <input type="text"/>	(A2_3LTDT) <input type="text"/>
d. (A2_4TNME) <input type="text"/>	(A2_4TIND) <input type="text"/>	(A2_4LTDT) <input type="text"/>
e. (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)

00-No 01-Yes 97-Unknown

Lab/Test	Findings	Date of Test (mm/dd/yyyy)
a. (A2_1LBNM) <input type="text"/>	(A2_1LBIN) <input type="text"/>	(A2_1LBDT) <input type="text"/>
b. (A2_2LBNM) <input type="text"/>	(A2_2LBIN) <input type="text"/>	(A2_2LBDT) <input type="text"/>
c. (A2_3LBNM) <input type="text"/>	(A2_3LBIN) <input type="text"/>	(A2_3LBDT) <input type="text"/>
d. (A2_4LBNM) <input type="text"/>	(A2_4LBIN) <input type="text"/>	(A2_4LBDT) <input type="text"/>
e. (A2_5LBNM) <input type="text"/>	(A2_5LBIN) <input type="text"/>	(A2_5LBDT) <input type="text"/>

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)

a. Have all Medical Monitor requests been addressed?(A2RQADDR)

01-Yes

Additional Selection Options for AD2

Sequence 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



Serious Adverse Event Medical (AD3)

Version: 1.01; 12-10-20

Adverse event onset date (AEDATE):

Sequence number (AESEQNO):

1. Was this determined to be a serious adverse event?(A3SAE)

0-No 1-Yes

2. Was this event considered associated with the study medication?(A3RELDRG)

00-No 01-Yes 96-N/A

3. Was this event expected?(A3EXPECT)

0-No 1-Yes

4. Is this a standard expedited/reportable event (i.e., is it serious, unexpected and related to therapy)?(A3EXPFDA)

00-No 01-Yes 96-N/A

a. If "No", is this an expedited/reportable event for other reasons?(A3EXPOTH)

0-No 1-Yes

5. Does the protocol need to be modified based on this event?(A3MPROT)

0-No 1-Yes

6. Does the consent form need to be modified based on this event?(A3MCNST)

0-No 1-Yes

7. Is the review complete?(A3REVDNE)

0-No 1-Yes

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

Assessed by:(A3ASRID)

(initials)

Reviewed by:(A3REVID)

(initials)

Comments:(A3COMM)

Additional Selection Options for AD3

Sequence number (*AESQNO*) (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

Concomitant Medications (CMX)

Version: 1.01; 05-19-21

Segment (PROTSEG): B, E
Visit Number (VISNO):

Date of assessment:(CMXASMDT) (mm/dd/yyyy)

Please use this form to capture concomitant medications taken in the past week other than MOUD.

Medications

- 1.(CMMED01)
- 2.(CMMED02)
- 3.(CMMED03)
- 4.(CMMED04)
- 5.(CMMED05)
- 6.(CMMED06)
- 7.(CMMED07)
- 8.(CMMED08)
- 9.(CMMED09)
- 10.(CMMED10)

Comments:(CMXCOMM)

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Clinic Urine Toxicology (CUT)

Version: 1.01; 02-15-22

Segment (*PROTSEG*): B, C, D, E
 Sequence number (*SEQNUM2*):

Date of assessment:(*CUTASMDT*)

(mm/dd/yyyy)

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

0-No 1-Yes

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

01-Participant reported being unable to provide sample
 02-Participant refused to provide sample
 04-Study staff error
 92-COVID-19: Illness
 93-COVID-19: Public health measures
 94-COVID-19: Other
 99-Other

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

(mm/dd/yyyy)

2. Date urine specimen collected:(*UDCOLDT*)

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

00-No 01-Yes 97-Not measured

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

00-No 01-Yes 97-Not measured

5. Urine Drug Screen Result(s):

Drug Name (Abbreviation)	00-Negative	01-Positive	02-Invalid	97-Not Measured
Amphetamine (500 ng) (AMP):	(<i>UDAMP1</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Barbiturate (300 ng) (BAR):	(<i>UDBAR1</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Buprenorphine (10 ng) (BUP):	(<i>UDBUP1</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Benzodiazepines (300 ng) (BZO):	(<i>UDBZO1</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cocaine (150 ng) (COC):	(<i>UDCOC1</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ecstasy (500 ng) (MDMA):	(<i>UDMDA1</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Methamphetamine (500 ng) (MET):	(<i>UDMET1</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Methadone (300 ng) (MTD):	(<i>UDMTD1</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Opiates (300 ng) (OPI):	(<i>UDOPI31</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Oxycodone (100 ng) (OXY):	(<i>UDOXY1</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Phencyclidine (25 ng) (PCP):	(<i>UDPCP1</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Marijuana (50 ng) (THC):	(<i>UDTHC1</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Fentanyl (20 ng) (FEN):	(<i>UDFEN1</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments:(*CUTCOMM*)

Additional Selection Options for CUT

Sequence number (*SEQNUM2*) (key field):

01-1

02-2

03-3

04-4

05-5

06-6

07-7

08-8

09-9

10-10

Death Form (DTH)

Version: 1.00; 02-10-21

1. Date of Death:(*DTDTHDT*)

 (mm/dd/yyyy)

2. Date staff notified of death:(*DTNTFYDT*)

 (mm/dd/yyyy)

3. Date of last contact with participant:(*DTCNTCDT*)

 (mm/dd/yyyy)

4. Was there suspected or confirmed opioid overdose?(*DTOPIOD*)

 00-No 01-Yes 97-Unknown

a. If "Yes", date of suspected or confirmed opioid overdose?(*DTOPIDT*)

 (mm/dd/yyyy)

5. Primary and secondary causes of death:

This should be a "verbatim" extraction of the text from the source document.

a. Primary Cause of Death:(*DTPCOD*)

b. Secondary Cause of Death:(*DT2COD*)

6. Source for cause of death:(*DTSOURCE*)

01-Medical chart
02-Death certificate
03-Autopsy report
04-Treating physician
05-NDI
99-Other

a. If "Other", specify:(*DTSRCESP*)

7. Was an autopsy performed?(*DTAUTPSY*)

 00-No 01-Yes 97-Unknown

a. If "Yes", can a copy of the autopsy report be obtained?(*DTAUTCPY*)

 00-No 01-Yes 97-Unknown

8. Did death occur while the participant was hospitalized?(*DTHSPDTH*)

 00-No 01-Yes 97-Unknown

a. If "No", where did the death occur?(*DTDTHLOC*)

9. Was drug use a contributing factor in the death?(*DTDRUG*)

 00-No 01-Yes 97-Unknown

a. If "Yes", was the drug an opioid?(*DTOPIDRG*)

 00-No 01-Yes 97-Unknown

10. Was alcohol a contributing factor in the death?(*DTALCOHL*)

 00-No 01-Yes 97-Unknown

11. Short narrative about the circumstance surrounding the death of the participant:
(*DTNARRTV*)

Comments:(*DTHCOMM*)

If available, upload the autopsy, death report, discharge note, or any other supporting documentation.

0097E (ENR)

Version: 1.00; 01-29-21

Date of end of induction: (STARTDT)

 (mm/dd/yyyy)

Comments: (I97COMM)

End of Medication (Self-Reported) (EO2)

Version: 1.00; 03-30-21

Segment (PROTSEG): E

Visit Number (VISNO):

Date of assessment: (EO2ASMDT) (mm/dd/yyyy)

The following is a list of reasons why people sometimes stop their medication for opioid use disorder. Please indicate whether each of the following contributed to your stopping medication.

	0-No	1-Yes		0-No	1-Yes
1. I wanted to use opioids again. (E2RLUOPI)	<input type="checkbox"/>	<input type="checkbox"/>			
2. I relapsed to drug use. (E2RLUDRG)	<input type="checkbox"/>	<input type="checkbox"/>			
3. I wanted to use alcohol or other drugs and the medication was blocking the high. (E2RLMBLK)	<input type="checkbox"/>	<input type="checkbox"/>			
4. I didn't think it was okay to take the medication if I was also taking drugs. (E2RLMEDR)	<input type="checkbox"/>	<input type="checkbox"/>			
5. I stopped going to treatment because I relapsed. (E2RLTRTS)	<input type="checkbox"/>	<input type="checkbox"/>			
6. I wanted to do it on my own/without medication. (E2MATNOM)	<input type="checkbox"/>	<input type="checkbox"/>			
7. I felt cured. (E2MATCUR)	<input type="checkbox"/>	<input type="checkbox"/>			
8. I felt I no longer need medication to stay off of opioids. (E2MATOFF)	<input type="checkbox"/>	<input type="checkbox"/>			
9. I was no longer experiencing cravings to use opioids. (E2MATCRV)	<input type="checkbox"/>	<input type="checkbox"/>			
10. I believe I'm not truly in recovery if I'm taking this medication. (E2MATREC)	<input type="checkbox"/>	<input type="checkbox"/>			
11. I planned to stay on this medication for only a limited amount of time. (E2MATIME)	<input type="checkbox"/>	<input type="checkbox"/>			
12. I became pregnant. (E2LOPREG)	<input type="checkbox"/>	<input type="checkbox"/>			
13. I moved away. (E2LOMOVE)	<input type="checkbox"/>	<input type="checkbox"/>			
14. I had a family crisis. (E2LOFAML)	<input type="checkbox"/>	<input type="checkbox"/>			
15. I went to jail/prison. (E2LOPRSN)	<input type="checkbox"/>	<input type="checkbox"/>			
16. My insurance changed or stopped covering my treatment. (E2LOINSR)	<input type="checkbox"/>	<input type="checkbox"/>			
17. My provider stopped prescribing the medication. (E2LORXMD)	<input type="checkbox"/>	<input type="checkbox"/>			
			0-No	1-Yes	
18. Family or friends were pressuring me to get off the medicine. (E2EXFAML)			<input type="checkbox"/>	<input type="checkbox"/>	
19. I felt pressure from others in mutual help meetings (AA, NA, SMART Recovery) to get off medication. (E2EXMEET)			<input type="checkbox"/>	<input type="checkbox"/>	
20. I felt judged by others in mutual help meetings (AA, NA, SMART Recovery) because I was taking this medication. (E2EXJUDG)			<input type="checkbox"/>	<input type="checkbox"/>	
21. Taking this medication conflicts with my participation at work, school or sports. (E2EXPART)			<input type="checkbox"/>	<input type="checkbox"/>	
	0-No	1-Yes			
22. I was tired of getting the shots. (E2PETIRD)	<input type="checkbox"/>	<input type="checkbox"/>			
23. Side effects were bothering me. (E2PESIDE)	<input type="checkbox"/>	<input type="checkbox"/>			
24. I was interested in trying a different medication to support my recovery. (E2PEDIFF)	<input type="checkbox"/>	<input type="checkbox"/>			
25. I worried about long term effects of staying on this medication. (E2PELONG)	<input type="checkbox"/>	<input type="checkbox"/>			
			0-No	1-Yes	
26. I stopped due to COVID-19 illness (e.g., I became sick, a family member became sick, I needed to take care of someone who became sick, etc.). (E2CVILLN)			<input type="checkbox"/>	<input type="checkbox"/>	
27. I stopped due to COVID-19 public health measures (e.g., "Stay at home" order, social distancing mandates, clinic or offices closed, etc.). (E2CVPUBL)			<input type="checkbox"/>	<input type="checkbox"/>	
28. I stopped due to another reason related to COVID-19. (E2CVRELA)			<input type="checkbox"/>	<input type="checkbox"/>	
29. Other: (E2CVOTHE)			<input type="checkbox"/>	<input type="checkbox"/>	
a. If "Other", specify: (E2CVOTSP) <input type="text"/>					

Participant required research staff assistance in reading the questions in this assessment.
 Note: this includes if participant could not see well enough to read the questions or if the participant was unable to read well enough to read the questions. (EO2RAHLP)

Comments: (EO2COMM)

01-Yes

End of Medication (EOM)

Version: 1.00; 01-12-21

Segment (*PROTSEG*): E

Date of assessment:(*EOMASMDT*)

(mm/dd/yyyy)

1. Is the participant planning to discontinue XR-NTX injection early?
(*EODXRNTX*)

0-No 1-Yes

Comments:(*EOMCOMM*)

Generalized Anxiety Disorder (GA7)

Version: 1.00; 03-30-21

Segment (PROTSEG): C, D, E
 Visit Number (VISNO):

Date of assessment:(GA7ASMDT) (mm/dd/yyyy)

Over the **last 2 weeks**, how often have you been bothered by the following problems?

	00-Not at All	01-Several Days	02-Over Half the Days	03-Nearly Every Day
1. Feeling nervous, anxious, or on edge: (GANRVANX)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Not being able to stop or control worrying: (GAUSWOR)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Worrying too much about different things: (GAWORTM)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Trouble relaxing: (GATBRLX)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Being so restless that it's hard to sit still: (GAHDSIT)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Becoming easily annoyed or irritable: (GAEASAN)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Feeling afraid as if something awful might happen: (GAFLAFR)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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

- 00-Not difficult at all
- 01-Somewhat difficult
- 02-Very difficult
- 03-Extremely difficult

Participant required research staff assistance in reading the questions in this assessment.

01-Yes

Note: this includes if participant could not see well enough to read the questions or if the participant was unable to read well enough to read the questions. (GARAHL P)

Comments:(GA7COMM)

Source: Spitzer RL, Kroenke K, Williams JBW, Lowe B. A brief measure for assessing generalized anxiety disorder. Arch Intern Med. 2006;166:1092-1097.

Injection Site Abnormality (INA)

Version: 1.00; 02-01-21

Segment (PROTSEG): E

Injection number (INJNUM):

If abnormality results in a Serious Adverse Event (SAE), complete the Adverse Event forms as well.

Abnormal Event (If "Other", specify in comments)	Event Start Date	Severity	Treatment (If "Yes", specify in comments)	Event Resolution Date	Comments
1. (INTYP1) 01-Pain 02-Tenderness 03-Induration 04-Swelling 05-Erythema (redness) *Additional Options Listed Below	(INSDT1) <input type="text"/>	(INSVR1) 01-Mild 02-Moderate 03-Severe	(INTRT1) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(INRDT1) <input type="text"/>	(INCOM1) <input type="text"/>
		Meets criteria for SAE reporting (INSAE01) <input type="checkbox"/> 01-			
2. (INTYP2) 01-Pain 02-Tenderness 03-Induration 04-Swelling 05-Erythema (redness) *Additional Options Listed Below	(INSDT2) <input type="text"/>	(INSVR2) 01-Mild 02-Moderate 03-Severe	(INTRT2) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(INRDT2) <input type="text"/>	(INCOM2) <input type="text"/>
		Meets criteria for SAE reporting (INSAE02) <input type="checkbox"/> 01-			
3. (INTYP3) 01-Pain 02-Tenderness 03-Induration 04-Swelling 05-Erythema (redness) *Additional Options Listed Below	(INSDT3) <input type="text"/>	(INSVR3) 01-Mild 02-Moderate 03-Severe	(INTRT3) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(INRDT3) <input type="text"/>	(INCOM3) <input type="text"/>
		Meets criteria for SAE reporting (INSAE03) <input type="checkbox"/> 01-			
4. (INTYP4) 01-Pain 02-Tenderness 03-Induration 04-Swelling 05-Erythema (redness) *Additional Options Listed Below	(INSDT4) <input type="text"/>	(INSVR4) 01-Mild 02-Moderate 03-Severe	(INTRT4) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(INRDT4) <input type="text"/>	(INCOM4) <input type="text"/>
		Meets criteria for SAE reporting (INSAE04) <input type="checkbox"/> 01-			
5. (INTYP5) 01-Pain 02-Tenderness 03-Induration 04-Swelling 05-Erythema (redness) *Additional Options Listed Below	(INSDT5) <input type="text"/>	(INSVR5) 01-Mild 02-Moderate 03-Severe	(INTRT5) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(INRDT5) <input type="text"/>	(INCOM5) <input type="text"/>
		Meets criteria for SAE reporting (INSAE05) <input type="checkbox"/> 01-			

<p>6. (INTYP6)</p> <p>01-Pain 02-Tenderness 03-Induration 04-Swelling 05-Erythema (redness) *Additional Options Listed Below</p>	<p>(INSDT6)</p> <input type="text"/>	<p>(INSVR6)</p> <p>01-Mild 02-Moderate 03-Severe</p>	<p>(INTRT6)</p> <p><input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes</p>	<p>(INRDT6)</p> <input type="text"/>	<p>(INCOM6)</p> <input type="text"/>
		<p>Meets criteria for SAE reporting(<i>INSAE06</i>) <input type="checkbox"/> 01-</p>			
<p>7. (INTYP7)</p> <p>01-Pain 02-Tenderness 03-Induration 04-Swelling 05-Erythema (redness) *Additional Options Listed Below</p>	<p>(INSDT7)</p> <input type="text"/>	<p>(INSVR7)</p> <p>01-Mild 02-Moderate 03-Severe</p>	<p>(INTRT7)</p> <p><input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes</p>	<p>(INRDT7)</p> <input type="text"/>	<p>(INCOM7)</p> <input type="text"/>
		<p>Meets criteria for SAE reporting(<i>INSAE07</i>) <input type="checkbox"/> 01-</p>			
<p>8. (INTYP8)</p> <p>01-Pain 02-Tenderness 03-Induration 04-Swelling 05-Erythema (redness) *Additional Options Listed Below</p>	<p>(INSDT8)</p> <input type="text"/>	<p>(INSVR8)</p> <p>01-Mild 02-Moderate 03-Severe</p>	<p>(INTRT8)</p> <p><input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes</p>	<p>(INRDT8)</p> <input type="text"/>	<p>(INCOM8)</p> <input type="text"/>
		<p>Meets criteria for SAE reporting(<i>INSAE08</i>) <input type="checkbox"/> 01-</p>			
<p>9. (INTYP9)</p> <p>01-Pain 02-Tenderness 03-Induration 04-Swelling 05-Erythema (redness) *Additional Options Listed Below</p>	<p>(INSDT9)</p> <input type="text"/>	<p>(INSVR9)</p> <p>01-Mild 02-Moderate 03-Severe</p>	<p>(INTRT9)</p> <p><input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes</p>	<p>(INRDT9)</p> <input type="text"/>	<p>(INCOM9)</p> <input type="text"/>
		<p>Meets criteria for SAE reporting(<i>INSAE09</i>) <input type="checkbox"/> 01-</p>			
<p>10. (INTYP_10)</p> <p>01-Pain 02-Tenderness 03-Induration 04-Swelling 05-Erythema (redness) *Additional Options Listed Below</p>	<p>(INSDT_10)</p> <input type="text"/>	<p>(INSVR_10)</p> <p>01-Mild 02-Moderate 03-Severe</p>	<p>(INTRT_10)</p> <p><input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes</p>	<p>(INRDT_10)</p> <input type="text"/>	<p>(INCOM_10)</p> <input type="text"/>
		<p>Meets criteria for SAE reporting(<i>INSAE10</i>) <input type="checkbox"/> 01-</p>			

11. (INTYP_11) <input type="text"/> 01-Pain 02-Tenderness 03-Induration 04-Swelling 05-Erythema (redness) *Additional Options Listed Below	(INSDT_11) <input type="text"/>	(INSVR_11) <input type="text"/> 01-Mild 02-Moderate 03-Severe	(INTRT_11) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(INRDT_11) <input type="text"/>	(INCOM_11) <input type="text"/>
		Meets criteria for SAE reporting(INSAE11) <input type="checkbox"/> 01-			
12. (INTYP_12) <input type="text"/> 01-Pain 02-Tenderness 03-Induration 04-Swelling 05-Erythema (redness) *Additional Options Listed Below	(INSDT_12) <input type="text"/>	(INSVR_12) <input type="text"/> 01-Mild 02-Moderate 03-Severe	(INTRT_12) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(INRDT_12) <input type="text"/>	(INCOM_12) <input type="text"/>
		Meets criteria for SAE reporting(INSAE12) <input type="checkbox"/> 01-			
13. (INTYP_13) <input type="text"/> 01-Pain 02-Tenderness 03-Induration 04-Swelling 05-Erythema (redness) *Additional Options Listed Below	(INSDT_13) <input type="text"/>	(INSVR_13) <input type="text"/> 01-Mild 02-Moderate 03-Severe	(INTRT_13) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(INRDT_13) <input type="text"/>	(INCOM_13) <input type="text"/>
		Meets criteria for SAE reporting(INSAE13) <input type="checkbox"/> 01-			
14. (INTYP_14) <input type="text"/> 01-Pain 02-Tenderness 03-Induration 04-Swelling 05-Erythema (redness) *Additional Options Listed Below	(INSDT_14) <input type="text"/>	(INSVR_14) <input type="text"/> 01-Mild 02-Moderate 03-Severe	(INTRT_14) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(INRDT_14) <input type="text"/>	(INCOM_14) <input type="text"/>
		Meets criteria for SAE reporting(INSAE14) <input type="checkbox"/> 01-			
15. (INTYP_15) <input type="text"/> 01-Pain 02-Tenderness 03-Induration 04-Swelling 05-Erythema (redness) *Additional Options Listed Below	(INSDT_15) <input type="text"/>	(INSVR_15) <input type="text"/> 01-Mild 02-Moderate 03-Severe	(INTRT_15) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(INRDT_15) <input type="text"/>	(INCOM_15) <input type="text"/>
		Meets criteria for SAE reporting(INSAE15) <input type="checkbox"/> 01-			

16. (INTYP_16) 01-Pain 02-Tenderness 03-Induration 04-Swelling 05-Erythema (redness) *Additional Options Listed Below	(INSDT_16)	(INSVR_16) 01-Mild 02-Moderate 03-Severe	(INTRT_16) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(INRDT_16)	(INCOM_16)
		Meets criteria for SAE reporting(INSAE16) <input type="checkbox"/> 01-			
17. (INTYP_17) 01-Pain 02-Tenderness 03-Induration 04-Swelling 05-Erythema (redness) *Additional Options Listed Below	(INSDT_17)	(INSVR_17) 01-Mild 02-Moderate 03-Severe	(INTRT_17) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(INRDT_17)	(INCOM_17)
		Meets criteria for SAE reporting(INSAE17) <input type="checkbox"/> 01-			
18. (INTYP_18) 01-Pain 02-Tenderness 03-Induration 04-Swelling 05-Erythema (redness) *Additional Options Listed Below	(INSDT_18)	(INSVR_18) 01-Mild 02-Moderate 03-Severe	(INTRT_18) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(INRDT_18)	(INCOM_18)
		Meets criteria for SAE reporting(INSAE18) <input type="checkbox"/> 01-			
19. (INTYP_19) 01-Pain 02-Tenderness 03-Induration 04-Swelling 05-Erythema (redness) *Additional Options Listed Below	(INSDT_19)	(INSVR_19) 01-Mild 02-Moderate 03-Severe	(INTRT_19) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(INRDT_19)	(INCOM_19)
		Meets criteria for SAE reporting(INSAE19) <input type="checkbox"/> 01-			
20. (INTYP_20) 01-Pain 02-Tenderness 03-Induration 04-Swelling 05-Erythema (redness) *Additional Options Listed Below	(INSDT_20)	(INSVR_20) 01-Mild 02-Moderate 03-Severe	(INTRT_20) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(INRDT_20)	(INCOM_20)
		Meets criteria for SAE reporting(INSAE20) <input type="checkbox"/> 01-			

Comments:(INACOMM)

Additional Selection Options for INA

Injection number (*INJNUM*) (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
16-16
17-17
18-18
19-19
20-20

Event 1 type

06-Bruising
07-Pruritus
08-Nodule
09-Hematoma
10-Abscess
11-Sterile abscess
12-Necrosis
13-Cellulitis
14-Warmth
99-Other

XR-NTX Administration (INN)

Version: 1.00; 07-02-21

Segment (PROTSEG): E

Visit Number (VISNO):

This form should capture study medication only.

Prior XR-NTX (380mg extended release Naltrexone) Injection

1. Is the prior site normal or abnormal?(INNABNST)

00-Normal 01-Abnormal 97-Not evaluated

An abnormal reaction is one that is a skin or tissue reaction more severe than expected (i.e. mild to moderate pain, tenderness, redness, or swelling that is not self-limited and resolving within a week).

a. If "Not evaluated", specify reason:(INNOEVAL)

01-Participant not present
98-Participant declined
02-Study staff error
92-COVID-19: Illness
93-COVID-19: Public health measures
94-COVID-19: Other

2. Date of prior injection:(INPRINDT)

(mm/dd/yyyy)

3. Location of prior injection:(INPRLOC)

01-Right buttock 02-Left buttock

If the injection site is "Abnormal", complete the Injection Site Abnormality Log, as necessary.

Current XR-NTX (380mg extended release Naltrexone) Injection

4. Was an injection administered during this study visit?(INADMINJ)

0-No 1-Yes

a. If "No", specify reason:(INNOINJ)

01-Missed visit
98-Declined injection
03-Temporary dose suspension due to AE/Safety
04-Injection not expected due to timing of previous injection
92-COVID-19: Illness
93-COVID-19: Public health measures
94-COVID-19: Other
99-Other

1. If "Other", specify:(INNOOTSP)

5. Date of injection:(ININJDT)

(mm/dd/yyyy)

6. Time of injection:(ININJTTM)

(hh:mm)

7. Location of injection:(ININJLOC)

01-Right buttock 02-Left buttock

Reminder: site rotation is recommended

Comments:(INNCOMM)

Timeline Followback Medications (M97)

Segment (PROTSEG): C, D, E

Version: 4.00; 01-11-22

TFB week start date (TFWKSTDT):

Day:	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Date	(TLMDATE1) <input type="text"/>	(TLMDATE2) <input type="text"/>	(TLMDATE3) <input type="text"/>	(TLMDATE4) <input type="text"/>	(TLMDATE5) <input type="text"/>	(TLMDATE6) <input type="text"/>	(TLMDATE7) <input type="text"/>
1. Has any medication for opioid use disorder been used during this assessment period?	(TLMSUD1) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLMSUD2) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLMSUD3) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLMSUD4) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLMSUD5) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLMSUD6) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLMSUD7) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes
2. Sublingual buprenorphine (suboxone equivalent):	(TLSBUP1) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLSBUP2) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLSBUP3) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLSBUP4) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLSBUP5) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLSBUP6) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLSBUP7) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes
Dose:	(TLSBPD1) <input type="text"/> (xx.x) mg	(TLSBPD2) <input type="text"/> (xx.x) mg	(TLSBPD3) <input type="text"/> (xx.x) mg	(TLSBPD4) <input type="text"/> (xx.x) mg	(TLSBPD5) <input type="text"/> (xx.x) mg	(TLSBPD6) <input type="text"/> (xx.x) mg	(TLSBPD7) <input type="text"/> (xx.x) mg
3. Participant received XR-NTX injection:	(TLRINJ1) <input type="checkbox"/> 00-None <input type="checkbox"/> 01-Study <input type="checkbox"/> 02-Clinic	(TLRINJ2) <input type="checkbox"/> 00-None <input type="checkbox"/> 01-Study <input type="checkbox"/> 02-Clinic	(TLRINJ3) <input type="checkbox"/> 00-None <input type="checkbox"/> 01-Study <input type="checkbox"/> 02-Clinic	(TLRINJ4) <input type="checkbox"/> 00-None <input type="checkbox"/> 01-Study <input type="checkbox"/> 02-Clinic	(TLRINJ5) <input type="checkbox"/> 00-None <input type="checkbox"/> 01-Study <input type="checkbox"/> 02-Clinic	(TLRINJ6) <input type="checkbox"/> 00-None <input type="checkbox"/> 01-Study <input type="checkbox"/> 02-Clinic	(TLRINJ7) <input type="checkbox"/> 00-None <input type="checkbox"/> 01-Study <input type="checkbox"/> 02-Clinic
4. Injectable buprenorphine:	(TLINBUP1) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLINBUP2) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLINBUP3) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLINBUP4) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLINBUP5) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLINBUP6) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLINBUP7) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes
Dose:	<input type="checkbox"/> 01-Weekly <input type="checkbox"/> 02-Monthly (TLINBPD1)	<input type="checkbox"/> 01-Weekly <input type="checkbox"/> 02-Monthly (TLINBPD2)	<input type="checkbox"/> 01-Weekly <input type="checkbox"/> 02-Monthly (TLINBPD3)	<input type="checkbox"/> 01-Weekly <input type="checkbox"/> 02-Monthly (TLINBPD4)	<input type="checkbox"/> 01-Weekly <input type="checkbox"/> 02-Monthly (TLINBPD5)	<input type="checkbox"/> 01-Weekly <input type="checkbox"/> 02-Monthly (TLINBPD6)	<input type="checkbox"/> 01-Weekly <input type="checkbox"/> 02-Monthly (TLINBPD7)
5. Oral naltrexone:	(TLONTX1) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLONTX2) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLONTX3) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLONTX4) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLONTX5) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLONTX6) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLONTX7) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes
Dose:	(TLONTXD1) <input type="text"/> (xxx.xx) mg	(TLONTXD2) <input type="text"/> (xxx.xx) mg	(TLONTXD3) <input type="text"/> (xxx.xx) mg	(TLONTXD4) <input type="text"/> (xxx.xx) mg	(TLONTXD5) <input type="text"/> (xxx.xx) mg	(TLONTXD6) <input type="text"/> (xxx.xx) mg	(TLONTXD7) <input type="text"/> (xxx.xx) mg
6. Implantable buprenorphine:	(TLIMBUP1) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLIMBUP2) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLIMBUP3) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLIMBUP4) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLIMBUP5) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLIMBUP6) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLIMBUP7) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes
Dose:	(TLIMBPD1) <input type="text"/> (xxx) mg	(TLIMBPD2) <input type="text"/> (xxx) mg	(TLIMBPD3) <input type="text"/> (xxx) mg	(TLIMBPD4) <input type="text"/> (xxx) mg	(TLIMBPD5) <input type="text"/> (xxx) mg	(TLIMBPD6) <input type="text"/> (xxx) mg	(TLIMBPD7) <input type="text"/> (xxx) mg
7. Methadone:	(TLMTD1) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLMTD2) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLMTD3) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLMTD4) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLMTD5) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLMTD6) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLMTD7) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes
Dose:	(TLMTDD1) <input type="text"/> (xxx) mg	(TLMTDD2) <input type="text"/> (xxx) mg	(TLMTDD3) <input type="text"/> (xxx) mg	(TLMTDD4) <input type="text"/> (xxx) mg	(TLMTDD5) <input type="text"/> (xxx) mg	(TLMTDD6) <input type="text"/> (xxx) mg	(TLMTDD7) <input type="text"/> (xxx) mg
8. Clonidine:	(TLCLODN1) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLCLODN2) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLCLODN3) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLCLODN4) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLCLODN5) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLCLODN6) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLCLODN7) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes
Dose:	(TLCLODD1) <input type="text"/> (x.xx) mg	(TLCLODD2) <input type="text"/> (x.xx) mg	(TLCLODD3) <input type="text"/> (x.xx) mg	(TLCLODD4) <input type="text"/> (x.xx) mg	(TLCLODD5) <input type="text"/> (x.xx) mg	(TLCLODD6) <input type="text"/> (x.xx) mg	(TLCLODD7) <input type="text"/> (x.xx) mg
9. Clonazepam:	(TLCLON1) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLCLON2) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLCLON3) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLCLON4) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLCLON5) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLCLON6) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLCLON7) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes
Dose:	(TLCLOND1) <input type="text"/> (xx.xx) mg	(TLCLOND2) <input type="text"/> (xx.xx) mg	(TLCLOND3) <input type="text"/> (xx.xx) mg	(TLCLOND4) <input type="text"/> (xx.xx) mg	(TLCLOND5) <input type="text"/> (xx.xx) mg	(TLCLOND6) <input type="text"/> (xx.xx) mg	(TLCLOND7) <input type="text"/> (xx.xx) mg

10. Zolpidem:	(TLZOLP1) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLZOLP2) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLZOLP3) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLZOLP4) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLZOLP5) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLZOLP6) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLZOLP7) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes
Dose:	(TLZOLPD1) <input type="text"/> (xx.x) mg	(TLZOLPD2) <input type="text"/> (xx.x) mg	(TLZOLPD3) <input type="text"/> (xx.x) mg	(TLZOLPD4) <input type="text"/> (xx.x) mg	(TLZOLPD5) <input type="text"/> (xx.x) mg	(TLZOLPD6) <input type="text"/> (xx.x) mg	(TLZOLPD7) <input type="text"/> (xx.x) mg
11. Trazodone	(TLTRAZ1) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLTRAZ2) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLTRAZ3) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLTRAZ4) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLTRAZ5) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLTRAZ6) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLTRAZ7) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes
Dose:	(TLTRAZD1) <input type="text"/> (xxx) mg	(TLTRAZD2) <input type="text"/> (xxx) mg	(TLTRAZD3) <input type="text"/> (xxx) mg	(TLTRAZD4) <input type="text"/> (xxx) mg	(TLTRAZD5) <input type="text"/> (xxx) mg	(TLTRAZD6) <input type="text"/> (xxx) mg	(TLTRAZD7) <input type="text"/> (xxx) mg
12. Other:	(TLOTH1) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLOTH2) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLOTH3) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLOTH4) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLOTH5) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLOTH6) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLOTH7) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes
Specify other:	(TLOTHSP1) <input type="text"/>	(TLOTHSP2) <input type="text"/>	(TLOTHSP3) <input type="text"/>	(TLOTHSP4) <input type="text"/>	(TLOTHSP5) <input type="text"/>	(TLOTHSP6) <input type="text"/>	(TLOTHSP7) <input type="text"/>
Dose:	(TLOTHSD1) <input type="text"/> (xxxx.xx) mg	(TLOTHSD2) <input type="text"/> (xxxx.xx) mg	(TLOTHSD3) <input type="text"/> (xxxx.xx) mg	(TLOTHSD4) <input type="text"/> (xxxx.xx) mg	(TLOTHSD5) <input type="text"/> (xxxx.xx) mg	(TLOTHSD6) <input type="text"/> (xxxx.xx) mg	(TLOTHSD7) <input type="text"/> (xxxx.xx) mg

Comments:(M97COMM)

Medical Management (MGT)

Version: 1.01; 07-30-21

Segment (PROTSEG): C, D, E

Visit Number (VISNO):

Date of assessment:(MGTASMDT) (mm/dd/yyyy)

List all visits with a provider during inpatient induction phase.
Reminder do not enter PHI/PII in this form.

Date MM Occurred	In Person or Remote Encounter	Comments
1. (MGMMDT01) <input type="text"/> (mm/dd/yyyy) (MGNRT01) <input type="checkbox"/> 01-In-Person <input type="checkbox"/> 02-Remote (MGCOMM01)		<input type="text"/>
2. (MGMMDT02) <input type="text"/> (mm/dd/yyyy) (MGNRT02) <input type="checkbox"/> 01-In-Person <input type="checkbox"/> 02-Remote (MGCOMM02)		<input type="text"/>
3. (MGMMDT03) <input type="text"/> (mm/dd/yyyy) (MGNRT03) <input type="checkbox"/> 01-In-Person <input type="checkbox"/> 02-Remote (MGCOMM03)		<input type="text"/>
4. (MGMMDT04) <input type="text"/> (mm/dd/yyyy) (MGNRT04) <input type="checkbox"/> 01-In-Person <input type="checkbox"/> 02-Remote (MGCOMM04)		<input type="text"/>
5. (MGMMDT05) <input type="text"/> (mm/dd/yyyy) (MGNRT05) <input type="checkbox"/> 01-In-Person <input type="checkbox"/> 02-Remote (MGCOMM05)		<input type="text"/>
6. (MGMMDT06) <input type="text"/> (mm/dd/yyyy) (MGNRT06) <input type="checkbox"/> 01-In-Person <input type="checkbox"/> 02-Remote (MGCOMM06)		<input type="text"/>
7. (MGMMDT07) <input type="text"/> (mm/dd/yyyy) (MGNRT07) <input type="checkbox"/> 01-In-Person <input type="checkbox"/> 02-Remote (MGCOMM07)		<input type="text"/>
8. (MGMMDT08) <input type="text"/> (mm/dd/yyyy) (MGNRT08) <input type="checkbox"/> 01-In-Person <input type="checkbox"/> 02-Remote (MGCOMM08)		<input type="text"/>
9. (MGMMDT09) <input type="text"/> (mm/dd/yyyy) (MGNRT09) <input type="checkbox"/> 01-In-Person <input type="checkbox"/> 02-Remote (MGCOMM09)		<input type="text"/>
10. (MGMMDT10) <input type="text"/> (mm/dd/yyyy) (MGNRT10) <input type="checkbox"/> 01-In-Person <input type="checkbox"/> 02-Remote (MGCOMM10)		<input type="text"/>
11. (MGMMDT11) <input type="text"/> (mm/dd/yyyy) (MGNRT11) <input type="checkbox"/> 01-In-Person <input type="checkbox"/> 02-Remote (MGCOMM11)		<input type="text"/>
12. (MGMMDT12) <input type="text"/> (mm/dd/yyyy) (MGNRT12) <input type="checkbox"/> 01-In-Person <input type="checkbox"/> 02-Remote (MGCOMM12)		<input type="text"/>
13. (MGMMDT13) <input type="text"/> (mm/dd/yyyy) (MGNRT13) <input type="checkbox"/> 01-In-Person <input type="checkbox"/> 02-Remote (MGCOMM13)		<input type="text"/>
14. (MGMMDT14) <input type="text"/> (mm/dd/yyyy) (MGNRT14) <input type="checkbox"/> 01-In-Person <input type="checkbox"/> 02-Remote (MGCOMM14)		<input type="text"/>
15. (MGMMDT15) <input type="text"/> (mm/dd/yyyy) (MGNRT15) <input type="checkbox"/> 01-In-Person <input type="checkbox"/> 02-Remote (MGCOMM15)		<input type="text"/>
16. (MGMMDT16) <input type="text"/> (mm/dd/yyyy) (MGNRT16) <input type="checkbox"/> 01-In-Person <input type="checkbox"/> 02-Remote (MGCOMM16)		<input type="text"/>
17. (MGMMDT17) <input type="text"/> (mm/dd/yyyy) (MGNRT17) <input type="checkbox"/> 01-In-Person <input type="checkbox"/> 02-Remote (MGCOMM17)		<input type="text"/>

18. (MGMMDT18) (mm/dd/yyyy) (MGPVRT18) 01-In-Person 02-Remote (MGCOMM18)
19. (MGMMDT19) (mm/dd/yyyy) (MGPVRT19) 01-In-Person 02-Remote (MGCOMM19)
20. (MGMMDT20) (mm/dd/yyyy) (MGPVRT20) 01-In-Person 02-Remote (MGCOMM20)
21. (MGMMDT21) (mm/dd/yyyy) (MGPVRT21) 01-In-Person 02-Remote (MGCOMM21)
22. (MGMMDT22) (mm/dd/yyyy) (MGPVRT22) 01-In-Person 02-Remote (MGCOMM22)
23. (MGMMDT23) (mm/dd/yyyy) (MGPVRT23) 01-In-Person 02-Remote (MGCOMM23)
24. (MGMMDT24) (mm/dd/yyyy) (MGPVRT24) 01-In-Person 02-Remote (MGCOMM24)
25. (MGMMDT25) (mm/dd/yyyy) (MGPVRT25) 01-In-Person 02-Remote (MGCOMM25)
26. (MGMMDT26) (mm/dd/yyyy) (MGPVRT26) 01-In-Person 02-Remote (MGCOMM26)
27. (MGMMDT27) (mm/dd/yyyy) (MGPVRT27) 01-In-Person 02-Remote (MGCOMM27)
28. (MGMMDT28) (mm/dd/yyyy) (MGPVRT28) 01-In-Person 02-Remote (MGCOMM28)
29. (MGMMDT29) (mm/dd/yyyy) (MGPVRT29) 01-In-Person 02-Remote (MGCOMM29)
30. (MGMMDT30) (mm/dd/yyyy) (MGPVRT30) 01-In-Person 02-Remote (MGCOMM30)
31. (MGMMDT31) (mm/dd/yyyy) (MGPVRT31) 01-In-Person 02-Remote (MGCOMM31)
32. (MGMMDT32) (mm/dd/yyyy) (MGPVRT32) 01-In-Person 02-Remote (MGCOMM32)
33. (MGMMDT33) (mm/dd/yyyy) (MGPVRT33) 01-In-Person 02-Remote (MGCOMM33)
34. (MGMMDT34) (mm/dd/yyyy) (MGPVRT34) 01-In-Person 02-Remote (MGCOMM34)
35. (MGMMDT35) (mm/dd/yyyy) (MGPVRT35) 01-In-Person 02-Remote (MGCOMM35)
36. (MGMMDT36) (mm/dd/yyyy) (MGPVRT36) 01-In-Person 02-Remote (MGCOMM36)
37. (MGMMDT37) (mm/dd/yyyy) (MGPVRT37) 01-In-Person 02-Remote (MGCOMM37)
38. (MGMMDT38) (mm/dd/yyyy) (MGPVRT38) 01-In-Person 02-Remote (MGCOMM38)
39. (MGMMDT39) (mm/dd/yyyy) (MGPVRT39) 01-In-Person 02-Remote (MGCOMM39)

- 40. (MGMMDT40) (mm/dd/yyyy) (MGPVRT40) 01-In-Person 02-Remote (MGCOMM40)
- 41. (MGMMDT41) (mm/dd/yyyy) (MGPVRT41) 01-In-Person 02-Remote (MGCOMM41)
- 42. (MGMMDT42) (mm/dd/yyyy) (MGPVRT42) 01-In-Person 02-Remote (MGCOMM42)
- 43. (MGMMDT43) (mm/dd/yyyy) (MGPVRT43) 01-In-Person 02-Remote (MGCOMM43)
- 44. (MGMMDT44) (mm/dd/yyyy) (MGPVRT44) 01-In-Person 02-Remote (MGCOMM44)
- 45. (MGMMDT45) (mm/dd/yyyy) (MGPVRT45) 01-In-Person 02-Remote (MGCOMM45)
- 46. (MGMMDT46) (mm/dd/yyyy) (MGPVRT46) 01-In-Person 02-Remote (MGCOMM46)
- 47. (MGMMDT47) (mm/dd/yyyy) (MGPVRT47) 01-In-Person 02-Remote (MGCOMM47)
- 48. (MGMMDT48) (mm/dd/yyyy) (MGPVRT48) 01-In-Person 02-Remote (MGCOMM48)
- 49. (MGMMDT49) (mm/dd/yyyy) (MGPVRT49) 01-In-Person 02-Remote (MGCOMM49)
- 50. (MGMMDT50) (mm/dd/yyyy) (MGPVRT50) 01-In-Person 02-Remote (MGCOMM50)

Comments:(MGTCOMM)

Mental Health Follow-up Assessment (MHA)

Version: 4.02; 12-06-21

Segment (PROTSEG): C, D, E
Visit Number (VISNO):

Date of assessment:(MHAASMDT) (mm/dd/yyyy)

This form must be completed for every participant who indicates a risk for suicidality/homicidality from a mental health assessment CRF. Please answer the following questions to document the actions taken.

1. In what setting were the participant's responses collected?(MHSETTNG) 01-In person 02-Remotely

2. Was the responsible clinician notified? 0-No 1-Yes

If "No", submit a PD if required by the protocol.(MHNOTIFY)

a. If "Yes", date of clinician notification:(MHNOTIDT) (mm/dd/yyyy)

3. Was the participant provided with either national or local mental health resource referral/contact information (e.g., National/local suicide hotlines, 911, other emergency response resources)? 0-No 1-Yes

If "No", submit a PD if required by the protocol.(MHRRESOR)

a. If "Yes", date referral provided:(MHRRESDT) (mm/dd/yyyy)

Comments:(MHACOMM)



Segment (PROTSEG): C, D
 Visit Number (VISNO):

Non-Medical and Other Services - Page 2 (NM2)
 Baseline

Version: 2.01; 12-06-21

Date of assessment:(NM2ASMDT)

 (mm/dd/yyyy)

When did the participant last complete this form?(NMLSTCDT)

 (mm/dd/yyyy)

Now 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. If the response should be "none" or "not applicable", enter "0" for the respective question below.

1. **During the past 28 days**, how many days were you involved in any activities that might get you into trouble or be against the law besides drug use?

 (xx) days

During the past 28 days, how many times have you...

a. ...been in possession of small amounts of drugs? (drug possession)(NMDRGPOS)

 (xx) times

b. ...been drunk or high in public? (drunkenness or other liquor law violations)(NMDRUNK)

 (xx) times

c. ...driven a vehicle while under the influence of alcohol or illegal drugs? (driving under the influence or while intoxicated)(NMDUIDWI)

 (xx) times

d. ...sold, distributed or helped to make illegal drugs? (possession, dealing, distribution or sale of drugs)(NMDRUGS)

 (xx) times

e. ...purposely damaged or destroyed property that did not belong to you? (vandalism or property destruction)(NMVANDES)

 (xx) times

f. ...bought, received, possessed or sold any stolen goods? (receiving, possessing or selling stolen goods)(NMSTLNGD)

 (xx) times

g. ...passed bad checks, forged or altered a prescription, or took money illegally from an employer? (forgery, fraud or embezzlement)(NMFRAUD)

 (xx) times

h. ...taken something from a store without paying for it? (shoplifting)(NMSHPLFT)

 (xx) times

i. ...other than from a store, taken money or property that didn't belong to you? (larceny or theft)(NMLRCTHF)

 (xx) times

j. ...broken into a house or building to steal something or just to look around? (burglary or breaking and entering)(NMBRGLBE)

 (xx) times

k. ...taken a car from someone who was in it? (carjacking)(NMCARJCK)

 (xx) times

l. ...taken a car without people in it that didn't belong to you? (motor vehicle theft)(NMMVTHFT)

 (xx) times

m. ...hit someone or gotten into a physical fight? (simple assault or battery)(NMASLBAT)

 (xx) times

n. ...used a weapon, force, or strong-arm methods to get money or things from a person? (robbery)(NMROBBRY)

 (xx) times

o. ...hurt someone badly enough they needed bandages or a doctor? (aggravated assault or battery)(NMAGRAB)

 (xx) times

p. ...made someone have sex with you by force when they did not want to have sex? (forcible rape)(NMRAP)

 (xx) times

q. ...been involved in the death or murder of another person, including accidents? (murder, homicide or non-negligent manslaughter)(NMHMCDS)

 (xx) times

r. ...intentionally set a building, car or other property on fire? (arson)(NMARSON)

 (xx) times

s. ...traded sex for food, drugs or money? (prostitution, pimping or commercialized sex)(NMPRSPMP)

 (xx) times

t. ...done something else that would have gotten you into trouble with the police if they had known about it? (carrying a weapon, gang involvement, domestic violence, trespass, gambling, disturbing the peace, disorderly conduct, paraphernalia, runaway, curfew, truancy)(NMCROMTH)

 (xx) times

1. Please describe:(NMCROMSP)

2. **During the past 28 days**, how many times were you arrested?(NMARREST)

 (xx) times

3. **During the past 28 days**, how many times were you charged?(NMCHARGE)

 (xx) times

	Number of Arrests		Number of Charges
a. For drug possession:	(NMDRGPOA) <input type="text"/> (xx)	(NMDRGPOC) <input type="text"/> (xx)	
b. For drunkenness or other liquor law violations:	(NMDRUNKA) <input type="text"/> (xx)	(NMDRUNKC) <input type="text"/> (xx)	
c. For driving under the influence or while intoxicated:	(NMDUDWIA) <input type="text"/> (xx)	(NMDUDWIC) <input type="text"/> (xx)	
d. For possession, dealing, distribution or sale of drugs:	(NMDRUGSA) <input type="text"/> (xx)	(NMDRUGSC) <input type="text"/> (xx)	
e. For vandalism or property destruction:	(NMVANDEA) <input type="text"/> (xx)	(NMVANDEC) <input type="text"/> (xx)	
f. For receiving, possessing or selling stolen goods:	(NMSTLGDA) <input type="text"/> (xx)	(NMSTLGDC) <input type="text"/> (xx)	
g. For forgery, fraud or embezzlement:	(NMFRAUDA) <input type="text"/> (xx)	(NMFRAUDC) <input type="text"/> (xx)	
h. For shoplifting:	(NMSHPLFA) <input type="text"/> (xx)	(NMSHPLFC) <input type="text"/> (xx)	
i. For larceny or theft:	(NMLRCTHA) <input type="text"/> (xx)	(NMLRCTHC) <input type="text"/> (xx)	

Number of Arrests

Number of Charges

j. For burglary or breaking and entering:

(NMBRGLA) (xx) (NMBRGLC) (xx)

k. For motor vehicle theft:

(NMMVTHFA) (xx) (NMMVTHFC) (xx)

l. For car jacking:

(NMCARJCA) (xx) (NMCARJCC) (xx)

m. For simple assault or battery:

(NMASLBTA) (xx) (NMASLBTC) (xx)

n. For robbery:

(NMROBRYA) (xx) (NMROBRYC) (xx)

o. For aggravated assault or battery:

(NMAGRVA) (xx) (NMAGRVC) (xx)

p. For forcible rape:

(NMRAPEA) (xx) (NMRAPEC) (xx)

q. For murder, homicide or non-negligent manslaughter:

(NMHMCMSA) (xx) (NMHMCMSC) (xx)

r. For arson:

(NMARSONA) (xx) (NMARSONC) (xx)

s. For prostitution, pimping or commercialized sex:

(NMPRSPMA) (xx) (NMPRSPMC) (xx)

t. For other charges (carrying a weapon, gang involvement, domestic violence, trespass, gambling, disturbing the peace, disorderly conduct, paraphernalia, runaway, curfew, truancy) :

(NMCRMOTA) (xx) (NMCRMOTC) (xx)

4. During the past 28 days, how many days have you been...

a. ...on electric monitoring?(NMEMTRDY)

(xx) days

b. ...on house arrest?(NMHSARDY)

(xx) days

c. ...in jail?(NMJAILYR)

(xx) days

d. ...in prison?(NMPRSNDY)

(xx) days

5. Are you currently in jail or prison? (can mark if obvious)(NMJLPRSN)

00-No 01-Yes 98-Refused to answer

a. How long have you been in jail or prison? (just this episode)(NMJLPRDY)

(xx) days

6. During the past 28 days, how many days have you...

a. ...been on parole?(NMPARLDY)

(xx) days

b. ...been on probation?(NMPRBTDY)

(xx) days

c. ...been on any other kind of community supervision?(NMCMSUDY)

(xx) days

d. ...met with your probation or parole officer?(NMPOMTDY)

(xx) days

e. ...been in trouble with your probation or parole officer?(NMPOTRDY)

(xx) days

7. During your lifetime...

a. How many times in your life have you been arrested including as a juvenile? (NMLTARST)

(xx) times

b. How old were you the first time you were arrested? (NMFAAGE)

(xx) years old

c. How much total time have you spent in detention, jail or prison during your lifetime?(NMJAILYR)

(xx) years(NMJAILYR) (xx.xx) months

d. How many times have you been found guilty and sentenced (including adjudications as a youth or convictions as an adult)? (NMGUILTM)

(xx) times

e. How old were you the first time you were adjudicated or convicted?(NMCONAGE)

(xx) years old

Comments:(NM2COMM)

Non-Medical and Other Services (NMS)

Baseline

Version: 3.00; 09-20-21

Segment (PROTSEG): C, D
 Visit Number (VISNO): B00

Date of assessment: (NMSASMDT) (mm/dd/yyyy)

We'd like you to answer these questions for the medical services you've received and other relevant resources you have utilized. If the response should be "none" or "not applicable", enter "0" for the respective question below.

During the past 28 days, how many...

1. ...times have you had to go to an emergency room without being admitted to the hospital? (NMERNADM) (xx) times
2. ...nights were you in a hospital detoxification program for your alcohol and other drug use? (across all episodes) (NMHSPDTX) (xx) nights
3. ...nights were you in a hospital for any other reason than detoxification? (NMHSPOTH) (xx) nights
4. ...nights were you in a non-hospital or social detoxification program from alcohol or other drugs? (also called residential detox) (NMRESDTX) (xx) nights
5. ...nights were you in a residential treatment program for alcohol or drug use? (NMRTALDU) (xx) nights
6. ...nights were you in a residential treatment program for mental health? (NMRTMTHL) (xx) nights
7. ...nights were you in a residential, nursing home or other rehabilitation facility for your physical health? (NMREHAB) (xx) nights
8. ...times have you visited a primary care provider (physician, nurse, nurse practitioner, or physician's assistant)? (NMVSTPCP) (xx) times
 - How many of these times...
 - a. ...did you participate on-line (phone, computer or tablet)? (NMPCPONL) (xx) times
 - b. ...did you see a doctor? (NMPCPDO) (xx) times

Other than times you already mentioned above, during the past 28 days, how many...

9. ...days did you participate in any other outpatient treatment program specializing in alcohol or substance use? (Other than questions 1-8) (NMOPPRGM) (xx) days
 - How many of these days...
 - a. ...did you participate on-line (e.g., smart phone, computer or tablet)? (NMOPONL) (xx) days
 - b. ...did you see a doctor? (NMOPDOC) (xx) days
 - c. ...did you only participate in individual or group therapy? (NMOPTHRP) (xx) days
 - d. ...were for medication management only (e.g., medication adjustment or refills)? (NMOPMEDM) (xx) days
10. ...times have you seen a psychiatrist (MD) or psychologist (Ph.D., PsyD.) (Other than questions 1-9)? (NMNUMPSY) (xx) times
 - How many of these times...
 - a. ...did you participate on-line (phone, computer or tablet)? (NMPSYONL) (xx) times
 - b. ...were for medication management only (e.g., medication adjustment or refills)? (NMPSYMDM) (xx) times
11. ...times have you seen any other kind of counselor or social worker? (Other than questions 1-10)? (NMNUMCSW) (xx) times
 - How many of these times...
 - a. ...did you participate on-line (phone, computer or tablet)? (NMSCWONL) (xx) times
 - b. ...were for medication management only (e.g., medication adjustment or refills)? (NMSCWMDM) (xx) times

12. Have you **ever** been prescribed and taken medication to treat opioid use disorder? [Illicit use should be excluded.](*NMOUDRX*) 0-No 1-Yes

Medication	Months/Day
a. Buprenorphine-naloxone or buprenorphine daily sublingual (e.g., Suboxone® film or tablet, generic films or tablets, or Subutex tablets):	
i. Lifetime months:	(<i>NMBPSLLT</i>) <input type="text"/> (xxx.xx) Months
b. Buprenorphine injection (SUBLOCADE®):	
i. Lifetime months:	(<i>NMBPIJLT</i>) <input type="text"/> (xxx.xx) Months
c. Buprenorphine weekly injection (BRIXADI®):	
i. Lifetime months:	(<i>NMBPWJL</i>) <input type="text"/> (xxx.xx) Months
d. Buprenorphine monthly injection (BRIXADI®):	
i. Lifetime months:	(<i>NMBPMILT</i>) <input type="text"/> (xxx.xx) Months
e. Buprenorphine 6-month implant (Probuphine®):	
i. Lifetime months:	(<i>NMBPIMPL</i>) <input type="text"/> (xxx.xx) Months
f. Naltrexone daily (oral):	
i. Lifetime months:	(<i>NMNXORLT</i>) <input type="text"/> (xxx.xx) Months
g. Naltrexone monthly injection (Vivitrol®):	
i. Lifetime months:	(<i>NMVIMILT</i>) <input type="text"/> (xxx.xx) Months
h. Methadone daily:	
i. Lifetime months:	(<i>NMMTDLT</i>) <input type="text"/> (xxx.xx) Months
i. Other (specify): (<i>NMOTHSP</i>) <input type="text"/>	
i. Lifetime months:	(<i>NMOTRXLT</i>) <input type="text"/> (xxx.xx) Months

13. Have you **ever** been prescribed and taken medication to treat alcohol use disorder? [Illicit use should be excluded.](*NMAUDRX*) 0-No 1-Yes

Medication	Alcohol Use Disorder Dose/Day <i>(the dose taken most often 'usual dose')</i>	Months/Days
Disulfiram (e.g., Antabuse®):		
i. Lifetime months:	N/A	(<i>NMDSLFLT</i>) <input type="text"/> (xxx) Months
ii. Past 28 days:	(<i>NMDSYMG</i>) <input type="text"/> (xxxx) mg	(<i>NMDS28DY</i>) <input type="text"/> (xx) Days
Naltrexone injection (e.g., Vivitrol®):		
i. Lifetime months:	N/A	(<i>NMALVILT</i>) <input type="text"/> (xxx) Months
ii. Past 28 days:	380 mg/month	(<i>NMAVI28D</i>) <input type="text"/> (xx) Days
Naltrexone daily (oral):		
i. Lifetime months:	N/A	(<i>NMANXOLT</i>) <input type="text"/> (xxx) Months
ii. Past 28 days:	(<i>NMANODMG</i>) <input type="text"/> (xxxx) mg	(<i>NMANO28D</i>) <input type="text"/> (xx) Days
Acamprosate (e.g., Campral®):		
i. Lifetime months:	N/A	(<i>NMACPRLT</i>) <input type="text"/> (xxx) Months
ii. Past 28 days:	(<i>NMACDYMG</i>) <input type="text"/> (xxxx.x) mg	(<i>NMAC28DY</i>) <input type="text"/> (xx) Days

14. During the past 28 days, how much of your own money have you spent on healthcare (e.g., copayments, prescriptions)?(NMOOPHC) \$ (xxxxx)

15. During the past 28 days, how many days were you uninsured?(NMDUNINS) (xx) days

16. Are you currently covered by health insurance or some other kind of health care plan?(NMCURRH) 0-No 1-Yes

What kind of health insurance or health care coverage do you have?

- Include those that pay for only one type of service (such as nursing home care, accidents, or dental care).
- Exclude private plans that only provide extra cash while hospitalized.
- If you had more than one kind of health insurance, tell me all plans that you had.
- Public insurance: Includes Medical Assistance/MA, the Children's Health Insurance Program/CHIP, or any kind of state or government-sponsored assistance plan based on income or disability.

a. Medicaid:(NMDCAID) 0-No 1-Yes

b. Medicare:
For people over 65 or with certain disabilities.(NMMDCARE) 0-No 1-Yes

c. Private health insurance:
Insurance provided through a current or former employer or union, including COBRA coverage, or purchased directly from an insurance company by you or another family member, includes coverage purchased through an exchange or marketplace such as HealthCare.gov.(NMPRIVHI) 0-No 1-Yes

d. Military Health Care (Tricare/VA/CHAMP-VA):(NMTRICR) 0-No 1-Yes

e. Medigap:(NMDGAP) 0-No 1-Yes

f. SCHIP (CHIP/Children's Health Insurance Program):(NMSCHIP) 0-No 1-Yes

g. Indian Health Service:(NMIHS) 0-No 1-Yes

h. State-Sponsored Health Plan:(NMSTPLN) 0-No 1-Yes

i. Other government program:(NMGVPL) 0-No 1-Yes

j. Single service plan (e.g., dental, vision, prescriptions):(NMSSPL) 0-No 1-Yes

k. Don't know:(NMHIDK) 01- Yes

17. Where did you spend the night before you came to the unit?(NMSPNLN)

- 01-Own apartment, room or house - subsidized, for example Section 8 or living in public housing
- 02-Own apartment, room or house - not subsidized
- 03-Someone else's apartment, room or house
- 04-Hotel, SRO, or boarding home
- 05-Halfway house, residential treatment program (focus: establishing sobriety)
- 06-Transitional housing (focus: movement into permanent housing)
- 07-Institution (hospital, nursing home, etc.)
- 08-Homeless shelter
- 09-Outdoors/street, abandoned/public building, vehicle, or other place not meant for human habitation
- 10-Detox
- 11-Other - homeless
- 12-Other - stable housing
- 99-Other
- 98-Refused

a. Specify if "Other":(NMSLNSP)

The next few questions are about your HOUSEHOLD in the past 28 days. Your household includes people you live with, and with whom you share your income and expenses - husband, wife, children, relatives, and others.

18. How many people, including yourself, are there in your household?(NMHOUSE) (xx) People

a. How many of the people in your household are under the age of 18?(NMCHILD) (xx) People

19. These questions are about the income of everyone in your household together. We do not need an exact number. You can give your answer to the nearest hundreds or thousands of dollars if that is easier.

a. During the past 28 days, what was the total income of everyone in your household together that provided you with support?(NMINCOME) \$ (xxxxxx)

b. During the past 12 months, which of the following is the category that your total household income from legal sources would be in?(NMINCCAT)

- 01-Less than \$12,500
- 02-\$12,500 - \$20,000
- 03-\$20,001 - \$30,000
- 04-\$30,001 - \$40,000
- 05-\$40,001 - \$50,000
- 06-\$50,001 - \$100,000
- 07-More than \$100,000

c. **During the past 12 months**, did your household receive any public assistance like unemployment, food stamps/TANF, subsidized housing, or supplemental security income?(*NMRCVPA*) 00-No 01-Yes 98-Refused to answer

d. **During the past 28 days**, approximately how much money has your household all together received from public assistance sources like unemployment, food stamps (TANF), subsidized housing, supplemental security income?(*NMPAINCM*) \$ (xxxxxx)

e. **During the past 28 days**, did your household receive any other non-employment income sources like retirement, pension, alimony, child support, or interest? (*NMROTINM*) 00-No 01-Yes 98-Refused to answer

f. **During the past 28 days**, approximately how much money has your household all together received from other non-employment sources like retirement, pension, alimony, child support, interest?(*NMOTINTL*) \$ (xxxxxx)

g. **During the past 28 days**, outside of employment described above, did you receive any other income from activities that might get you into trouble or be against the law, like dealing, gambling, theft for fencing?(*NMRILLIN*) 00-No 01-Yes 98-Refused to answer

h. **During the past 28 days**, outside of employment described above, how much money did you earn from activities that might get you into trouble or be against the law, like dealing, gambling?(*NMILLINC*) \$ (xxxxxx)

20. Which one of the following statements best describes your work or school situation **during the past 28 days**?(*NMWRKSL*)

- 01-Working full-time, 35 hours or more a week
- 02-Working part-time, less than 35 hours a week
- 03-Have a job where you are paid one day at a time (day labor)
- 04-Have a job, not at work because of treatment, extended illness, maternity leave, furlough or strike
- 05-Have a job but not at work because it is seasonal work
- 06-Unemployed or laid off and looking for work
- 07-Unemployed or laid off and not looking for work
- 08-Full-time homemaker (keeping house)
- 09-In school or training
- 10-In school or training, but not currently going to classes
- 11-Retired
- 12-In jail, prison or detention
- 13-Too disabled for work
- 14-In the military
- 15-Doing volunteer work
- 99-Some other work situation

a. If "Some other work situation", specify:(*NMOTHWSP*)

21. **During the past 28 days**, on how many days have you worked?(*NMWORKED*) (xx) days

a. How many days per week did you typically work?(*NMDYSWRK*)

- 01-1 day a week
- 02-2 days a week
- 03-3 days a week
- 04-4 days a week
- 05-5 days a week
- 06-6 days a week
- 07-7 days a week

b. How many hours per day did you typically work?(*NMHRSWRK*) (xx) hours

c. Approximately how much did you make per hour?(*NMHRWAGE*) \$ (xxxxxx) per hour

d. Did any of the places that you work offer you the following benefits?

- 1. Health insurance:(*NMHIBEN*) 01-Yes 00-No 97-Don't know
- 2. Paid time off:(*NMPTOBEN*) 01-Yes 00-No 97-Don't know
- 3. Defined benefit plan or pension:(*NMPENBEN*) 01-Yes 00-No 97-Don't know
- 4. An arrangement such as a 401(k) or 403(b) plan, under which your employer contributes money towards your retirement every pay period:(*NMRETBEN*) 01-Yes 00-No 97-Don't know

22. What is your occupation?(*NMJOB*)

23. **During the past 28 days**, how many hours have you spent on **your** healthcare (including time with providers, travelling to appointments, picking up prescriptions, etc.)? (*NMHOURS*) (xxx) hours

a. How many of those hours involved missing work?(*NMWRKHRS*) (xxx) hours

b. How many of those hours involved missing school?(*NMSCLHRS*) (xxx) hours

c. How many **additional** hours of work have you missed because of **problems with your** physical or mental health?(*NMWKHLT*) (xxx) hours

d. How many **additional** hours of school have you missed because of **problems with your** physical or mental health?(*NMSCHHLT*) (xxx) hours

24. **During the past 28 days**, how many miles do you **usually** travel to your clinic appointments?(*NMTVLMLS*)

(xxx) miles

a. How many minutes does it usually take you?(*NMTVLMIN*)

(xxx) minutes

b. What mode of transportation do you usually use?(*NMTRANS*)

01-I drive myself
02-Someone else drives me
03-Clinic van
04-Bus
05-Subway
06-Walk
99-Other

1. If "Other", specify:(*NMOTTRSP*)

25. **During the past 28 days**, how many hours have you required the use of a caregiver for your healthcare needs (e.g., babysitter or someone to travel with you to appointments)? (*NMCARHRS*)

(xxx) hours

Comments:(*NMSCOMM*)

Opioid Craving Scale (OCI)

Baseline

Version: 1.00; 03-30-21

Segment (PROTSEG): C, D

Visit Number (VISNO):

Date of assessment:(OCIASMDT)

(mm/dd/yyyy)

Please answer the following questions.

1. Think about your craving for opioids. How intense is it right now?(OCOPICRA)

(xxx)

Click on the circle on the line below and drag it to the spot that indicates the intensity of your craving. 0 means you do not crave opioids at all. 100 means you have the most intense craving possible. You can leave your circle anywhere on the line to show how intense your craving is.

2. Think about your desire to use opioids in the past 24 hours. How intense was your strongest desire to use?(OCOPID24)

(xxx)

Click on the circle on the line below and drag it to the spot that indicates the intensity of your strongest desire to use from the past week. 0 means you had no desire to use opioids at all. 100 means you had the most intense desire to use possible. You can leave your circle anywhere on the line to show how intense your desire was.

Participant required research staff assistance in reading the questions in this assessment:

01-Yes

Note: this includes if participant could not see well enough to read the questions or if the participant was unable to read well enough to read the questions.(OCIRAHLP)

Comments:(OCICOMM)

Opioid Effect Scale (OES)

Version: 2.00; 05-19-21

Segment (PROTSEG): E

Visit Number (VISNO):

Date of assessment:(OESASMDT)

 (mm/dd/yyyy)

Please answer the following questions.

1. Have you used opioids within the last week?(OEOPIUWK)

 0-No 1-Yes

If no, STOP

2. The last time you used opioids, did you get high?(OEOPIHGH)

 00-No high 01-Not certain 03-Some high 04-Full high

3. The last time you used opioids, how high did you feel?(OEOPIHGF)

 (xxx)

Click on the circle on the line below and drag it to the spot that indicates the intensity of your craving. 0 means you do not crave opioids at all. 100 means you have the most intense craving possible. You can leave your circle anywhere on the line to show how intense your craving is.

4. The last time you used opioids, how much did you use?(OEOPIAMT)

\$ (xxx)

5. The last time you used opioids, what was the primary route?(OEOPIROU)

- 01-Oral
- 02-Nasal
- 03-Smoking
- 04-Non-IV Injection
- 05-IV Injection

6. The last time you used opioids, what was the primary reason for using?(OEOPIREA)

- 01-Test blockade
- 02-Override blockade
- 99-Other

a. If "Other", specify:(OEOPIRSP)

Participant required research staff assistance in reading the questions in this assessment:

 01-Yes

Note: this includes if participant could not see well enough to read the questions or if the participant was unable to read well enough to read the questions.(OESRAHLP)

Comments:(OESCOMM)

Pregnancy and Birth Control Assessment (PBC)

Version: 1.00; 01-19-21

Segment (PROTSEG): B, C, D, E
Visit Number (VISNO):

Complete this form only for biologically female participants.
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

- 4. Was a pregnancy test performed?(PBPRGTST) 0-No 1-Yes
- a. Date of pregnancy test:(PBPTSTDY) (mm/dd/yyyy)
- b. Result of pregnancy test:(PBRESULT) 00-Negative 01-Positive

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

Comments:(PBCCOMM)

Protocol Deviation (PDV)

Version: 2.02; 02-24-22

Date of deviation (PDDATE):

Protocol deviation number (PDSEQNO):

1. Is this deviation related to one or more participants?(PDPPTREL)

a. If "Yes", how many participants?(PDPRELNO)

0-No 1-Yes

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

Select related participants:

Participant ID 1:(PDPPT01)

99999999999999999999-DUMMYPARTICIPANTID

Participant ID 2:(PDPPT02)

99999999999999999999-DUMMYPARTICIPANTID

Participant ID 3:(PDPPT03)

99999999999999999999-DUMMYPARTICIPANTID

Participant ID 4:(PDPPT04)

99999999999999999999-DUMMYPARTICIPANTID

Participant ID 5:(PDPPT05)

99999999999999999999-DUMMYPARTICIPANTID

Participant ID 6:(PDPPT06)

99999999999999999999-DUMMYPARTICIPANTID

Participant ID 7:(PDPPT07)

99999999999999999999-DUMMYPARTICIPANTID

Participant ID 8:(PDPPT08)

99999999999999999999-DUMMYPARTICIPANTID

Participant ID 9:(PDPPT09)

99999999999999999999-DUMMYPARTICIPANTID

Participant ID 10:(PDPPT10)

99999999999999999999-DUMMYPARTICIPANTID

Participant ID 11:(PDPPT11)

99999999999999999999-DUMMYPARTICIPANTID

Participant ID 12:(PDPPT12)

99999999999999999999-DUMMYPARTICIPANTID

Participant ID 13:(PDPPT13)

99999999999999999999-DUMMYPARTICIPANTID

Participant ID 14:(PDPPT14)

99999999999999999999-DUMMYPARTICIPANTID

Participant ID 15:(PDPPT15)

99999999999999999999-DUMMYPARTICIPANTID

Participant ID 16:(PDPPT16)

99999999999999999999-DUMMYPARTICIPANTID

Participant ID 17:(PDPPT17)

99999999999999999999-DUMMYPARTICIPANTID

Participant ID 18:(PDPPT18)

99999999999999999999-DUMMYPARTICIPANTID

Participant ID 19:(PDPPT19)

99999999999999999999-DUMMYPARTICIPANTID

Participant ID 20:(PDPPT20)

999999999999999999999999-DUMMYPARTICIPANTID

2. Date deviation identified:(PDVDATE)

(mm/dd/yyyy)

3. Deviation type:(PDTYPE)

010-INFORMED CONSENT/ASSENT PROCEDURES
01A--- No consent/assent obtained
01B--- Unauthorized assessments and/or procedures conducted prior to obtaining informed consent/assent
01C--- Non IRB approved/outdated/obsolete informed consent/assent documents used
01Y--- Other major informed consent/assent procedures issues (specify)
*Additional Options Listed Below

a. If "Other", specify:(PDYSP)

4. Reason for Protocol Deviation: (select all that apply)

a. Research staff error:(PDRSSTFF)

0-No 1-Yes

b. Hospital error:(PDRSHSP)

0-No 1-Yes

c. Laboratory error:(PDRSLAB)

0-No 1-Yes

d. Pharmacy error:(PDRSPHRM)

0-No 1-Yes

e. Equipment/supply failure:(PDRSEQSP)

0-No 1-Yes

f. Issue with Advantage eClinical (e.g., system down, system glitch):(PDRSEDC)

0-No 1-Yes

g. Participant unable to comply:(PDRSPTNC)

0-No 1-Yes

h. Participant refusal:(PDRSPTRF)

0-No 1-Yes

i. Investigator/study decision:(PDRSINDC)

0-No 1-Yes

j. Other:(PDRSOTHR)

0-No 1-Yes

1. If "Other", specify:(PDRSOTSP)

5. Is this deviation related to COVID-19?(PDCVD19)

0-No 1-Yes

6. Brief description of what occurred:(PDESCPT)

7. Was/will there be corrective action for this event?(PDCORNY)

0-No 1-Yes

a. If "No", describe why corrective action was not or will not be taken:(PDNOCRSP)

b. If "Yes", which of the following corrective actions were/will be taken: (select all that apply)

1. Participant consent/reconsent was/will be obtained:(PDCACNST)

0-No 1-Yes

2. Research staff corrected/will correct error(s) and/or completed/will complete document(s):(PDCASTCR)

0-No 1-Yes

3. Participant corrected/will correct error(s) and/or completed/will complete document(s):(PDCAPTCR)

0-No 1-Yes

4. Document(s) was/will be moved to correct file location(s):(PDCADCMV)

0-No 1-Yes

5. Participant was/will be withdrawn from study:(PDCAPTWD)

0-No 1-Yes

6. Study drug administration was/will be halted:(PDCADGSP)

0-No 1-Yes

7. Study assessment was/will be performed or repeated:(PDCAASAD)

0-No 1-Yes

8. Other:(PDCAOTHR)

0-No 1-Yes

1. If "Other", specify:(PDCAOTSP)

c. As needed or requested, provide additional details about the corrective action plan:(PDCAPSP)

8. Brief description of the plan to prevent recurrence: (select all that apply)

a. Complete local retraining:(PDPLPTRN)

0-No 1-Yes

1. If "Complete local retraining", specify:(PDPLPSP)

b. Revise local SOP(s):(PDPLPRV)

0-No 1-Yes

c. Recalibrate/fix or replace faulty equipment/supplies:(PDPLPEQ)

0-No 1-Yes

d. Remove and/or replace incorrect/outdated document(s) from file(s):(PDPLPDOC)

0-No 1-Yes

e. No site action needed:(PDPLPNAN)

0-No 1-Yes

f. Other:(PDPLPOTH)

0-No 1-Yes

1. If "Other", specify:(PDPLPOSP)

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

0-No 1-Yes

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

0-No 1-Yes

b. If "Yes", date of planned submission:(*PDIRBPDT*)

(*mm/dd/yyyy*)

c. 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:

- 010--- INFORMED CONSENT/ASSENT PROCEDURES
- 01A--- No consent/assent obtained
- 01B--- Unauthorized assessments and/or procedures conducted prior to obtaining informed consent/assent
- 01C--- Non IRB approved/outdated/obsolete informed consent/assent documents used
- 01Y--- Other major informed consent/assent procedures issues (specify)
- 020-INCLUSION/EXCLUSIONCRITERIA
- 02A--- Ineligible participant enrolled/inclusion/exclusion criteria not met or eligibility not fully assessed prior to enrollment
- 02Z--- Other inclusion/exclusion criteria issues (specify)
- 040-LABORATORY ASSESSMENTS
- 04Y--- Other laboratory assessment issues - Minor (specify)
- 04Z--- Other laboratory assessments issues - Major (specify)
- 050-STUDY PROCEDURES/ASSESSMENTS
- 05A--- Study assessment/procedures not followed in accordance with study protocol
- 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 not dispensed/administered in accordance with the study protocol
- 08B--- Participant use of protocol prohibited medication
- 08Z--- Other study medication management issues (specify)
- 990-OTHER SIGNIFICANT DEVIATIONS
- 99A--- Destruction of study materials without prior authorization from sponsor
- 99B--- Breach of Confidentiality
- 99Y--- Other significant deviations issues - Minor (specify)
- 99Z--- Other significant deviations issues - Major (specify)

Patient Health Questionnaire (PHQ-9) (PHQ)

Version: 1.00; 03-30-21

Segment (PROTSEG): C, D, E

Visit Number (VISNO):

Date of assessment:(PHQASMDT)

 (mm/dd/yyyy)

Time of assessment:(PHQASMTM)

 (hh:mm) (24-hour format)

Please answer the following to the best of your ability.

Over the last 2 weeks, how often have you been bothered by any of the following problems?	00-Not At All	01-Several Days	02-More Than Half The Days	03-Nearly Every Day
1. Little interest or pleasure in doing things (PHINTPLE)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Feeling down, depressed, or hopeless (PHDEPRES)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Trouble falling or staying asleep, or sleeping too much (PH2SLEEP)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Feeling tired or having little energy (PH2TIRED)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Poor appetite or overeating (PHAPPEAT)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Feeling bad about yourself - or that you are a failure or have let yourself or your family down (PHFAILUR)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Trouble concentrating on things, such as reading the newspaper or watching television (PH2CONC)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Thoughts that you would be better off dead, or of hurting yourself in some way (PHDEADHU)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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

- 00-Not difficult at all
- 01-Somewhat difficult
- 02-Very difficult
- 03-Extremely difficult

Participant required research staff assistance in reading the questions in this assessment:

 01-Yes

Note: this includes if participant could not see well enough to read the questions or if the participant was unable to read well enough to read the questions.(PHQRAHLP)

Comments:(PHQCOMM)

Pregnancy Outcome 1 (PO1)

Version: 1.00; 01-19-21

Pregnancy number (PGSEQNUM):

Newborn Information

1. Gender:(PO1GENDR)

01-Male 02-Female 97-Unknown

2. Gestational age at delivery:(PO1GESWK)

(xx) weeks (PO1GESDY) (x) days (PO1GESUN) **OR** 97-Unknown

3. Weight at delivery:(PO1WTLBS)

(xx) lbs (PO1WTOZ) (xx) oz (PO1WTUNK) **OR** 97-Unknown

4. Apgar score at 1 minute:(PO1APG1M)

(xx) (PO11APUK) **OR** 97-Unknown

5. Apgar score at 5 minutes:(PO1APG5M)

(xx) (PO15APUK) **OR** 97-Unknown

6. Normal infant?(PO1NORML)

0-No 1-Yes

a. If "No", is there a congenital anomaly?(PO1CONAN)

00-No 01-Yes 97-Unknown

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

Comments:(PO1COMM)

Additional Selection Options for PO1

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

01-1

02-2

03-3

04-4

Pregnancy Outcome 2 (PO2)

Version: 1.00; 01-29-21

Pregnancy number (PGSEQNUM):

Newborn Information

1. Gender:(PO2GENDR)

01-Male 02-Female 97-Unknown

2. Gestational age at delivery:(PO2GESWK)

(xx) weeks (PO2GESDY) (x) days (PO2GESUN) **OR** 97-Unknown

3. Weight at delivery:(PO2WTLBS)

(xx) lbs (PO2WTOZ) (xx) oz (PO2WTUNK) **OR** 97-Unknown

4. Apgar score at 1 minute:(PO2APG1M)

(xx) (PO21APUK) **OR** 97-Unknown

5. Apgar score at 5 minutes:(PO2APG5M)

(xx) (PO25APUK) **OR** 97-Unknown

6. Normal infant?(PO2NORML)

0-No 1-Yes

a. If "No", is there a congenital anomaly?(PO2CONAN)

00-No 01-Yes 97-Unknown

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

Comments:(PO2COMM)

Additional Selection Options for PO2

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

01-1

02-2

03-3

04-4

Pregnancy Outcome 3 (PO3)

Version: 1.00; 01-19-21

Pregnancy number (PGSEQNUM):

Newborn Information

1. Gender:(PO3GENDR)

01-Male 02-Female 97-Unknown

2. Gestational age at delivery:(PO3GESWK)

(xx) weeks (PO3GESDY) (x) days (PO3GESUN) OR 97-Unknown

3. Weight at delivery:(PO3WTLBS)

(xx) lbs (PO3WTOZ) (xx) oz (PO3WTUNK) OR 97-Unknown

4. Apgar score at 1 minute:(PO3APG1M)

(xx) (PO31APUK) OR 97-Unknown

5. Apgar score at 5 minutes:(PO3APG5M)

(xx) (PO35APUK) OR 97-Unknown

6. Normal infant?(PO3NORML)

0-No 1-Yes

a. If "No", is there a congenital anomaly?(PO3CONAN)

00-No 01-Yes 97-Unknown

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

Comments:(PO3COMM)

Additional Selection Options for PO3

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

01-1

02-2

03-3

04-4

Pregnancy Outcome 4 (PO4)

Version: 1.00; 01-19-21

Pregnancy number (PGSEQNUM):

Newborn Information

1. Gender:(PO4GENDR)

01-Male 02-Female 97-Unknown

2. Gestational age at delivery:(PO4GESWK)

(xx) weeks (PO4GESDY) (x) days (PO4GESUN) OR 97-Unknown

3. Weight at delivery:(PO4WTLBS)

(xx) lbs (PO4WTOZ) (xx) oz (PO4WTUNK) OR 97-Unknown

4. Apgar score at 1 minute:(PO4APG1M)

(xx) (PO41APUK) OR 97-Unknown

5. Apgar score at 5 minutes:(PO4APG5M)

(xx) (PO45APUK) OR 97-Unknown

6. Normal infant?(PO4NORML)

0-No 1-Yes

a. If "No", is there a congenital anomaly?(PO4CONAN)

00-No 01-Yes 97-Unknown

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

Comments:(PO4COMM)

Additional Selection Options for PO4

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

01-1

02-2

03-3

04-4

Confirmed Pregnancy and Outcome (PRG)

Version: 1.00; 12-07-20

Pregnancy number (PGSEQNUM) (keyfield): 01-1 02-2 03-3 04-4

Information About Pregnancy

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

 (mm/dd/yyyy)

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

a. Urine pregnancy test result:(PRURICNF)

 0-No 1-Yes

b. Serum pregnancy test result:(PRSERCNF)

 0-No 1-Yes

c. Ultrasound result:(PRULTCNF)

 0-No 1-Yes

d. Other:(PROTHCNF)

 0-No 1-Yes

1. If "Other", specify:(PROTCNSP)

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

 (mm/dd/yyyy)

4. Action taken with study medication:(PRACTIND)

00-None
01-Dose reduced
02-Temporarily stopped medication
03-Permanently stopped medication

5. Approximate due date:(PRAPXDDT)

 (mm/dd/yyyy) (PRDDTUNK) OR 97-Unknown

6. Outcome of pregnancy:(PROUTCME)

01-Vaginal delivery
02-Cesarean delivery
03-Miscarriage
04-Termination
99-Other
97-Unknown

a. If "Other", specify:(PROTCMSP)

7. Date of pregnancy outcome:(PROTCMDT)

 (mm/dd/yyyy)

8. Number of live births:(PRNMLIVB)

00-0
01-1
02-2
03-3
04-4
99-Other
97-Unknown

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

Comments:(PRGCOMM)

PROMIS (PRO)

Version: 1.02; 03-30-21

Segment (PROTSEG): C, D, E

Visit Number (VISNO):

Date of assessment:(PROASMDT)

 (mm/dd/yyyy)

Please respond to each question or statement by marking one box per row.

Physical Function

		05-	04-	03-	02-	01-
		Without any Difficulty	With a Little Difficulty	With Some Difficulty	With Much Difficulty	Unable to Do
1. Are you able to do chores such as vacuuming or yard work?	(PRCHORES)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Are you able to go up and down stairs at a normal pace?	(PRSTAIRS)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Are you able to go for a walk of at least 15 minutes?	(PRWALK)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Are you able to run errands and shop?	(PRERRAND)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Anxiety

In the past 7 days...

		01-	02-	03-	04-	05-
		Never	Rarely	Sometimes	Often	Always
5. I felt fearful.	(PRFEAR)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. I found it hard to focus on anything other than my anxiety.	(PRDIFFOC)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. My worries overwhelmed me.	(PRWORRY)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. I felt uneasy.	(PRUNEASY)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Depression

In the past 7 days...

		01-	02-	03-	04-	05-
		Never	Rarely	Sometimes	Often	Always
9. I felt worthless.	(PRWORLES)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. I felt helpless.	(PRHLPLES)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. I felt depressed.	(PRDEPRES)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. I felt hopeless.	(PRHOPLES)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Fatigue

During the past 7 days...

		01-	02-	03-	04-	05-
		Not at All	A Little Bit	Somewhat	Quite a Bit	Very Much
13. I feel fatigued.	(PRFTGNOW)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. I have trouble starting things because I am tired.	(PRTIRED)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. How run-down did you feel on average?	(PRRUNDOW)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. How fatigued were you on average?	(PRFTGAVG)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Sleep Disturbance

In the past 7 days...

		05-	04-	03-	02-	01-
		Very Poor	Poor	Fair	Good	Very Good
17. My sleep quality was...	(PRSLPQUA)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

In the past 7 days...

		05-	04-	03-	02-	01-
		Not at All	A Little Bit	Somewhat	Quite a Bit	Very Much
18. My sleep was refreshing.	(PRSLPREF)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. I had a problem with my sleep.	(PRSLPPRB)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20. I had difficulty falling asleep.	(PRSLPDIF)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Ability to Participate in Social Roles and Activities

		05-	04-	03-	02-	01-
		Never	Rarely	Sometimes	Usually	Always
21. I have trouble doing all of my regular leisure activities with others.	(PRLEISUR)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22. I have trouble doing all of the family activities that I want to do.	(PRFAMILY)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23. I have trouble doing all of my usual work (include work at home).	(PRUSUWRK)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
24. I have trouble doing all of the activities with friends that I want to do.	(PRFRDACT)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Pain Interference

In the past 7 days...

		01-	02-	03-	04-	05-
		Not at All	A Little Bit	Somewhat	Quite a Bit	Very Much
25. How much did pain interfere with your day to day activities?	(PRPNDAY)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
26. How much did pain interfere with work around the home?	(PRPNHOME)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
27. How much did pain interfere with your ability to participate in social activities?	(PRPNSOCI)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
28. How much did pain interfere with your household chores?	(PRPNCHOR)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Cognitive Function Abilities

In the past 7 days...

		01-	02-	03-	04-	05-
		Not at All	A Little Bit	Somewhat	Quite a Bit	Very Much
29. I have been able to concentrate.	(PRCONCEN)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
30. I have been able to remember to do things, like take medicine or buy something I needed.	(PRREMEMB)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Pain Intensity

In the past 7 days...

		0	1	2	3	4	5	6	7	8	9	10	
		00-	01-	02-	03-	04-	05-	06-	07-	08-	09-	10-	
31. How would you rate your pain on average?	(PRPNRATE)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
		No Pain						Worst Pain Imaginable					

Participant required research staff assistance in reading the questions in this assessment:

01-Yes

Note: this includes if participant could not see well enough to read the questions or if the participant was unable to read well enough to read the questions.(PRORAHLP)

Comments:(PROCOMM)

Prisoner Status Assessment (PSA)

Version: 2.01; 09-20-21

Segment (PROTSEG): B, E

Visit Number (VISNO):

Date of assessment(PSAASMDT)

 (mm/dd/yyyy)

A response of "Yes" to any question indicates that the participant meets the OHRP definition of prisoner; do not enroll participant into study.

1. Are you currently being made to stay in an institution (such as a substance use treatment program), by sentence of a court, due to a criminal or civil proceeding? (PSINST)

 0-No 1-Yes

a. If "Yes", please describe the situation:(PSINSTSP)

2. Are you currently being detained while awaiting trial, arraignment, or sentencing? (PSTRIAL)

 0-No 1-Yes

3. Are you currently being detained as an alternative to criminal prosecution or incarceration in a jail or prison?(PSALTPRS)

 0-No 1-Yes

4. Are you currently under house arrest, such that you are escorted to treatment or, upon discharge from treatment, you will be escorted to jail, prison, or any inpatient overnight facility as required by law?(PSPROBHA)

 0-No 1-Yes

5. Does the participant meet the definition of "prisoner" by any local or state regulations? (PSPRISON)

 0-No 1-Yes

Comments:(PSACOMM)



Psychosocial Treatment (PST)

Follow up

Version: 3.01; 02-15-22

Segment (PROTSEG): E
Visit Number (VISNO):

Date of assessment:(PSTASMDT) (mm/dd/yyyy)

1. Since your last visit, did you engage in any treatment other than medication?(PSTXNOMD)

00-No
01-Yes
97-Unknown

If "Yes", what treatment did you engage in? (Check all that apply)

Sessions

- a. Individual counseling/therapy: (PSINDCNS) 01- (PSINDNUM) (xx)
 - b. Group counseling/therapy: (PSGRPCNS) 01- (PSGRPNUM) (xxx)
 - c. Intensive outpatient/partial hospital program: (PSOUTPAT) 01- (PSOUTNUM) (xx)
 - d. Alcoholics Anonymous (AA), or Narcotics Anonymous (NA): (PSTXAA) 01- (PSAANUM) (xx)
 - e. Other self-help group (e.g., SMART Recovery): (PSOTHLPG) 01- (PSHLPNUM) (xx)
 - f. Recovery coach: (PSCOACH) 01- (PSCOANUM) (xx)
 - g. Other: (PSTRTOT) 01- (PSOTHNUM) (xx)
- If "Other", specify: (PSOTHSP)

2. Since the last visit, did you use a smartphone app to support your recovery?(PSUSEAPP)

00-No
01-Yes
97-Unknown

If "Yes", specify:

- a. reSET or reSET-O:(PSRESET) 0-No 1-Yes
- b. Connections:(PSCONNECT) 0-No 1-Yes
- c. Other:(PSAPPOT) 0-No 1-Yes

1. If "Other", specify name of app:(PSAPOTSP)

Participant required researchstaff assistance in reading thequestions in this assessment. 01-Yes
Note: this includes if participantcould not see well enough toread the questions or if the participant was unable to readwell enough to read thequestions.(PSTRAHLP)

Comments:(PSTCOMM)

The Subjective Opiate Withdrawal Scale (SBW)

Version: 1.00; 03-30-21

Segment (PROTSEG): C, D, E

Visit Number (VISNO):

Date of assessment:(SBWASMDT)

 (mm/dd/yyyy)

Time of assessment:(SBASMTM)

 (hh:mm) 24-hour format

Please score each of the 16 items below according to how you feel now.

Symptom		00- Not at All	01- A Little	02- Moderately	03- Quite a Bit	04- Extremely
1. I feel anxious:	(SBANXIUS)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. I feel like yawning:	(SBYAWN)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. I am perspiring:	(SBSWEAT)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. My eyes are teary:	(SBTEARY)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. My nose is running:	(SBNOSRUN)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. I have goosebumps:	(SBGMBMPS)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. I am shaking:	(SBSHAKE)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. I have hot flushes:	(SBHTFLSH)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. I have cold flushes:	(SBCDFLSH)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. My bones and muscles ache:	(SBMSACHE)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. I feel restless:	(SBRSTLS)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. I feel nauseous:	(SBNAUS)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. I feel like vomiting:	(SBVOMIT)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. My muscles twitch:	(SBMSCLTW)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. I have stomach cramps:	(SBCRAMPS)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. I feel like using now:	(SBUSENOW)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Participant required research staff assistance in reading the questions in this assessment.

 01-Yes

Note: this includes if participant could not see well enough to read the questions or if the participant was unable to read well enough to read the questions.(SBWRAHLP)

Comments:(SBWCOMM)

Study Completion (STC)

Version: 3.04; 09-20-21

Segment (*PROTSEG*): E

1. Did the participant complete the final post-induction follow-up visit (Week8)? (*STCOMPLT*)

0-No 1-Yes

a. If "No", select the primary reason for study termination: (*STEARLY*)

01-Participant failed to return to clinic and unable to contact
02-Participant stopped participation due to practical problems (e.g., no childcare or transportation)
03-Participant moved from area
47-Participant incarcerated and unable to complete assessments
05-Participant terminated due to AE/SAE
*Additional Options Listed Below

1. If "Participant terminated for other clinical reasons", "Participant terminated for administrative issues", "Participant terminated due to COVID-19: Other", or "Participant terminated for other reason", specify: (*STCMPOSP*)

2. Date of study completion or last attended study visit: (*STCOMPDT*)

(mm/dd/yyyy)

3. Date of discharge to community: (*STDCCMDT*)

(mm/dd/yyyy)

4. Did the participant consent and enroll into RDD? (*STENRRDD*)

0-No 1-Yes

a. If "Yes", date of enrollment: (*STENRDDT*)

(mm/dd/yyyy)

Comments: (*STCCOMM*)

Investigator's Signature

With this act of signing, I confirm that all data collected for this participant was under my guidance and the data submitted to Advantage eClinical are complete and accurate to the best of my knowledge.

Principal Investigator: (*STPISIGN*)

Date: (*STPISGDT*)

(mm/dd/yyyy)

Additional Selection Options for STC

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

- 06-Participant terminated for other clinical reasons
- 48-Participant no longer wishes to complete assessments due to time involved and inconvenience
- 49-Participant withdrew consent/assent for other reasons
- 09-Participant deceased
- 10-Participant terminated for administrative issues
- 50-Participant in hospital, in-patient or residential treatment and not available for assessment
- 15-Site closed
- 17-Participant uncomfortable answering questions
- 18-Research staff unable to complete interview (unrelated to participant)
- 19-Technical difficulties (unrelated to participant)
- 34-Participant was ineligible and should not have been enrolled in study
- 41-Unable to contact participant
- 92-Participant terminated due to COVID-19: Illness
- 93-Participant terminated due to COVID-19: Public health measures
- 94-Participant terminated due to COVID-19: Other
- 99-Participant terminated for other reason

Timeline Followback (T97)

Segment (PROTSEG): C, D, E

TFB week start date (TFWKSTDT):

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. Was the participant in a controlled setting?	(TLCTSET1) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLCTSET2) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLCTSET3) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLCTSET4) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLCTSET5) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLCTSET6) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLCTSET7) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes
2. Have you used heroin, another opioid or any other substances during the assessment period (for example, alcohol, marijuana/cannabis, methamphetamine, or cocaine)?	(TLSUBAL1) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLSUBAL2) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLSUBAL3) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLSUBAL4) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLSUBAL5) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLSUBAL6) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLSUBAL7) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes
3. Alcohol (Number of standard drinks per day):	(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"/>
4. Cannabinoids/Marijuana (includes medical and non-medical):	(TLTHCR1) 00-00-No use 01-01-Oral 02-02-Nasal 03-03-Smoking 04-04-Non-IV Injection 05-05-IV Injection 99-99-Other	(TLTHCR2) 00-00-No use 01-01-Oral 02-02-Nasal 03-03-Smoking 04-04-Non-IV Injection 05-05-IV Injection 99-99-Other	(TLTHCR3) 00-00-No use 01-01-Oral 02-02-Nasal 03-03-Smoking 04-04-Non-IV Injection 05-05-IV Injection 99-99-Other	(TLTHCR4) 00-00-No use 01-01-Oral 02-02-Nasal 03-03-Smoking 04-04-Non-IV Injection 05-05-IV Injection 99-99-Other	(TLTHCR5) 00-00-No use 01-01-Oral 02-02-Nasal 03-03-Smoking 04-04-Non-IV Injection 05-05-IV Injection 99-99-Other	(TLTHCR6) 00-00-No use 01-01-Oral 02-02-Nasal 03-03-Smoking 04-04-Non-IV Injection 05-05-IV Injection 99-99-Other	(TLTHCR7) 00-00-No use 01-01-Oral 02-02-Nasal 03-03-Smoking 04-04-Non-IV Injection 05-05-IV Injection 99-99-Other
5. Cocaine/crack:	(TLCOCR1) 00-00-No use 01-01-Oral 02-02-Nasal 03-03-Smoking 04-04-Non-IV Injection 05-05-IV Injection 99-99-Other	(TLCOCR2) 00-00-No use 01-01-Oral 02-02-Nasal 03-03-Smoking 04-04-Non-IV Injection 05-05-IV Injection 99-99-Other	(TLCOCR3) 00-00-No use 01-01-Oral 02-02-Nasal 03-03-Smoking 04-04-Non-IV Injection 05-05-IV Injection 99-99-Other	(TLCOCR4) 00-00-No use 01-01-Oral 02-02-Nasal 03-03-Smoking 04-04-Non-IV Injection 05-05-IV Injection 99-99-Other	(TLCOCR5) 00-00-No use 01-01-Oral 02-02-Nasal 03-03-Smoking 04-04-Non-IV Injection 05-05-IV Injection 99-99-Other	(TLCOCR6) 00-00-No use 01-01-Oral 02-02-Nasal 03-03-Smoking 04-04-Non-IV Injection 05-05-IV Injection 99-99-Other	(TLCOCR7) 00-00-No use 01-01-Oral 02-02-Nasal 03-03-Smoking 04-04-Non-IV Injection 05-05-IV Injection 99-99-Other
6. Methamphetamine:	(TLMETR1) 00-00-No use 01-01-Oral 02-02-Nasal 03-03-Smoking 04-04-Non-IV Injection 05-05-IV Injection 99-99-Other	(TLMETR2) 00-00-No use 01-01-Oral 02-02-Nasal 03-03-Smoking 04-04-Non-IV Injection 05-05-IV Injection 99-99-Other	(TLMETR3) 00-00-No use 01-01-Oral 02-02-Nasal 03-03-Smoking 04-04-Non-IV Injection 05-05-IV Injection 99-99-Other	(TLMETR4) 00-00-No use 01-01-Oral 02-02-Nasal 03-03-Smoking 04-04-Non-IV Injection 05-05-IV Injection 99-99-Other	(TLMETR5) 00-00-No use 01-01-Oral 02-02-Nasal 03-03-Smoking 04-04-Non-IV Injection 05-05-IV Injection 99-99-Other	(TLMETR6) 00-00-No use 01-01-Oral 02-02-Nasal 03-03-Smoking 04-04-Non-IV Injection 05-05-IV Injection 99-99-Other	(TLMETR7) 00-00-No use 01-01-Oral 02-02-Nasal 03-03-Smoking 04-04-Non-IV Injection 05-05-IV Injection 99-99-Other
7. Other amphetamine-type stimulants:	(TLOAMPR1) 00-00-No use 01-01-Oral 02-02-Nasal 03-03-Smoking 04-04-Non-IV Injection 05-05-IV Injection 99-99-Other	(TLOAMPR2) 00-00-No use 01-01-Oral 02-02-Nasal 03-03-Smoking 04-04-Non-IV Injection 05-05-IV Injection 99-99-Other	(TLOAMPR3) 00-00-No use 01-01-Oral 02-02-Nasal 03-03-Smoking 04-04-Non-IV Injection 05-05-IV Injection 99-99-Other	(TLOAMPR4) 00-00-No use 01-01-Oral 02-02-Nasal 03-03-Smoking 04-04-Non-IV Injection 05-05-IV Injection 99-99-Other	(TLOAMPR5) 00-00-No use 01-01-Oral 02-02-Nasal 03-03-Smoking 04-04-Non-IV Injection 05-05-IV Injection 99-99-Other	(TLOAMPR6) 00-00-No use 01-01-Oral 02-02-Nasal 03-03-Smoking 04-04-Non-IV Injection 05-05-IV Injection 99-99-Other	(TLOAMPR7) 00-00-No use 01-01-Oral 02-02-Nasal 03-03-Smoking 04-04-Non-IV Injection 05-05-IV Injection 99-99-Other

8. Heroin/Fentanyl:	(TLHERR1) 00-00-No use 01-01-Oral 02-02-Nasal 03-03-Smoking 04-04-Non-IV Injection 05-05-IV Injection 99-99-Other	(TLHERR2) 00-00-No use 01-01-Oral 02-02-Nasal 03-03-Smoking 04-04-Non-IV Injection 05-05-IV Injection 99-99-Other	(TLHERR3) 00-00-No use 01-01-Oral 02-02-Nasal 03-03-Smoking 04-04-Non-IV Injection 05-05-IV Injection 99-99-Other	(TLHERR4) 00-00-No use 01-01-Oral 02-02-Nasal 03-03-Smoking 04-04-Non-IV Injection 05-05-IV Injection 99-99-Other	(TLHERR5) 00-00-No use 01-01-Oral 02-02-Nasal 03-03-Smoking 04-04-Non-IV Injection 05-05-IV Injection 99-99-Other	(TLHERR6) 00-00-No use 01-01-Oral 02-02-Nasal 03-03-Smoking 04-04-Non-IV Injection 05-05-IV Injection 99-99-Other	(TLHERR7) 00-00-No use 01-01-Oral 02-02-Nasal 03-03-Smoking 04-04-Non-IV Injection 05-05-IV Injection 99-99-Other
Daily dollar value:	(TLDVHER1) \$ <input type="text"/> (xxx.xx)	(TLDVHER2) \$ <input type="text"/> (xxx.xx)	(TLDVHER3) \$ <input type="text"/> (xxx.xx)	(TLDVHER4) \$ <input type="text"/> (xxx.xx)	(TLDVHER5) \$ <input type="text"/> (xxx.xx)	(TLDVHER6) \$ <input type="text"/> (xxx.xx)	(TLDVHER7) \$ <input type="text"/> (xxx.xx)
Number of times per day:	(TLPDHER1) <input type="text"/> (xx)	(TLPDHER2) <input type="text"/> (xx)	(TLPDHER3) <input type="text"/> (xx)	(TLPDHER4) <input type="text"/> (xx)	(TLPDHER5) <input type="text"/> (xx)	(TLPDHER6) <input type="text"/> (xx)	(TLPDHER7) <input type="text"/> (xx)
9. Opioid analgesics:	(TLOPIR1) 00-00-No use 01-01-Oral 02-02-Nasal 03-03-Smoking 04-04-Non-IV Injection 05-05-IV Injection 99-99-Other	(TLOPIR2) 00-00-No use 01-01-Oral 02-02-Nasal 03-03-Smoking 04-04-Non-IV Injection 05-05-IV Injection 99-99-Other	(TLOPIR3) 00-00-No use 01-01-Oral 02-02-Nasal 03-03-Smoking 04-04-Non-IV Injection 05-05-IV Injection 99-99-Other	(TLOPIR4) 00-00-No use 01-01-Oral 02-02-Nasal 03-03-Smoking 04-04-Non-IV Injection 05-05-IV Injection 99-99-Other	(TLOPIR5) 00-00-No use 01-01-Oral 02-02-Nasal 03-03-Smoking 04-04-Non-IV Injection 05-05-IV Injection 99-99-Other	(TLOPIR6) 00-00-No use 01-01-Oral 02-02-Nasal 03-03-Smoking 04-04-Non-IV Injection 05-05-IV Injection 99-99-Other	(TLOPIR7) 00-00-No use 01-01-Oral 02-02-Nasal 03-03-Smoking 04-04-Non-IV Injection 05-05-IV Injection 99-99-Other
Daily dollar value:	(TLDVOPI1) \$ <input type="text"/> (xxx.xx)	(TLDVOPI2) \$ <input type="text"/> (xxx.xx)	(TLDVOPI3) \$ <input type="text"/> (xxx.xx)	(TLDVOPI4) \$ <input type="text"/> (xxx.xx)	(TLDVOPI5) \$ <input type="text"/> (xxx.xx)	(TLDVOPI6) \$ <input type="text"/> (xxx.xx)	(TLDVOPI7) \$ <input type="text"/> (xxx.xx)
Number of times per day:	(TLPDOPI1) <input type="text"/> (xx)	(TLPDOPI2) <input type="text"/> (xx)	(TLPDOPI3) <input type="text"/> (xx)	(TLPDOPI4) <input type="text"/> (xx)	(TLPDOPI5) <input type="text"/> (xx)	(TLPDOPI6) <input type="text"/> (xx)	(TLPDOPI7) <input type="text"/> (xx)
10. Methadone (illicit):	(TLMTDR1) 00-00-No use 01-01-Oral 02-02-Nasal 03-03-Smoking 04-04-Non-IV Injection 05-05-IV Injection 99-99-Other	(TLMTDR2) 00-00-No use 01-01-Oral 02-02-Nasal 03-03-Smoking 04-04-Non-IV Injection 05-05-IV Injection 99-99-Other	(TLMTDR3) 00-00-No use 01-01-Oral 02-02-Nasal 03-03-Smoking 04-04-Non-IV Injection 05-05-IV Injection 99-99-Other	(TLMTDR4) 00-00-No use 01-01-Oral 02-02-Nasal 03-03-Smoking 04-04-Non-IV Injection 05-05-IV Injection 99-99-Other	(TLMTDR5) 00-00-No use 01-01-Oral 02-02-Nasal 03-03-Smoking 04-04-Non-IV Injection 05-05-IV Injection 99-99-Other	(TLMTDR6) 00-00-No use 01-01-Oral 02-02-Nasal 03-03-Smoking 04-04-Non-IV Injection 05-05-IV Injection 99-99-Other	(TLMTDR7) 00-00-No use 01-01-Oral 02-02-Nasal 03-03-Smoking 04-04-Non-IV Injection 05-05-IV Injection 99-99-Other
Total daily dose:	(TLPDMTD1) <input type="text"/> (xxx)	(TLPDMTD2) <input type="text"/> (xxx)	(TLPDMTD3) <input type="text"/> (xxx)	(TLPDMTD4) <input type="text"/> (xxx)	(TLPDMTD5) <input type="text"/> (xxx)	(TLPDMTD6) <input type="text"/> (xxx)	(TLPDMTD7) <input type="text"/> (xxx)
11. Buprenorphine (illicit):	(TLBUPR1) 00-00-No use 01-01-Oral 02-02-Nasal 03-03-Smoking 04-04-Non-IV Injection 05-05-IV Injection 99-99-Other	(TLBUPR2) 00-00-No use 01-01-Oral 02-02-Nasal 03-03-Smoking 04-04-Non-IV Injection 05-05-IV Injection 99-99-Other	(TLBUPR3) 00-00-No use 01-01-Oral 02-02-Nasal 03-03-Smoking 04-04-Non-IV Injection 05-05-IV Injection 99-99-Other	(TLBUPR4) 00-00-No use 01-01-Oral 02-02-Nasal 03-03-Smoking 04-04-Non-IV Injection 05-05-IV Injection 99-99-Other	(TLBUPR5) 00-00-No use 01-01-Oral 02-02-Nasal 03-03-Smoking 04-04-Non-IV Injection 05-05-IV Injection 99-99-Other	(TLBUPR6) 00-00-No use 01-01-Oral 02-02-Nasal 03-03-Smoking 04-04-Non-IV Injection 05-05-IV Injection 99-99-Other	(TLBUPR7) 00-00-No use 01-01-Oral 02-02-Nasal 03-03-Smoking 04-04-Non-IV Injection 05-05-IV Injection 99-99-Other
Total daily dose:	(TLPDBUP1) <input type="text"/> (xxx)	(TLPDBUP2) <input type="text"/> (xxx)	(TLPDBUP3) <input type="text"/> (xxx)	(TLPDBUP4) <input type="text"/> (xxx)	(TLPDBUP5) <input type="text"/> (xxx)	(TLPDBUP6) <input type="text"/> (xxx)	(TLPDBUP7) <input type="text"/> (xxx)

TLFB Assessment Period (TAP)

Baseline

Version: 4.01; 12-28-21

Segment (*PROTSEG*): C, D

Visit Number (*VISNO*):

Date of assessment:(*TAPASMDT*)

(mm/dd/yyyy)

1. Assessment period:

(*TATFSTDT*) From: (mm/dd/yyyy)

(*TATFENDT*) To: (mm/dd/yyyy)

2. Have you used heroin, another opioid or any other substances during the assessment period (for example, alcohol, marijuana/cannabis, methamphetamine, or cocaine)?(*TASUBALC*)

0-No 1-Yes

3. Has any medication for opioid use disorder been used during this assessment period?(*TAMSUD*)

0-No 1-Yes

4. During this assessment period, did the participant spend **any** time in a controlled setting (by controlled setting, we mean an environment where access to drugs and alcohol is limited, e.g., jail, hospital, detox, residential program)?(*TACTRLST*)

0-No 1-Yes

a. During this assessment period, did the participant spend **≥ 48** consecutive hours in a controlled setting?(*TA48CTRL*)

0-No 1-Yes

5. Did the participant use opioids in the past 31 days up to and including day of admission?(*TAOPI31D*)

0-No 1-Yes

a. What is the date and time of the participant's last opioid use up to and including date of admission? (*TALSTODT*)

Date: (mm/dd/yyyy)

(*TALSTOTM*) Time: (hh:mm) (24-hour time)

Comments:(*TAPCOMM*)

Treatment Satisfaction Survey (TS5)

Version: 2.01; 12-06-21

Segment (PROTSEG): E
 Visit Number (VISNO):

Date of assessment: (TS5ASMDT)

 (mm/dd/yyyy)

1. This is how many shots of injectable naltrexone you have received: (TSVIVINJ)

 (x)

2. Are you planning on continuing to receive XR-NTX (Vivitrol) shots? (TSVIVSCT)

 0-No 1-Yes

a. If "No", reason(s) why: [Check all that apply]

- 1. Injectable naltrexone is not available: (TSVIVINU) 01-
- 2. Prefer other medication (buprenorphine or methadone): (TSPROTMD) 01-
- 3. Do not want XR-NTX (Vivitrol) since it blocks opioids and prevents high: (TSDNTVIV) 01-
- 4. Do not like getting shots: (TSDNTINJ) 01-
- 5. Do not like the side effects of long acting naltrexone: (TSSEVIV) 01-
- 6. Prefer to not be on medication for opioid use disorder: (TSPRFNMD) 01-
- 7. Medical contraindication: (TSMEDCON) 01-
- 8. Psychiatric contraindication: (TSPSYCON) 01-
- 9. Other: (TSVIVOTH) 01-

1. If "Other", specify: (TSVIVOSP)

3. Are you currently on other medication for opioid use disorder? (TSOUDMDO)

 0-No 1-Yes

a. If "Yes", which one? (TSMEDOUD)

- 01-Buprenorphine
- 02-Injectable buprenorphine
- 03-Methadone
- 04-Injectable naltrexone
- 05-Oral naltrexone

b. If "No", reason(s) why: [Check all that apply]

- 1. Prefer to not be on medication for opioid use disorder: (TSPRFNMO) 01-
- 2. Prefer to reduce opioid use or become abstinent without medication: (TSPRFABS) 01-
- 3. Unable to establish care with provider: (TSUNESCR) 01-
- 4. I feel cured and did not need further treatment: (TSCURED) 01-
- 5. I feel shamed or criticized by others for being on medication: (TSSTIGMA) 01-
- 6. Other: (TSOTMDOT) 01-

1. If "Other", specify: (TSOTMDSP)

4. In your community, are there barriers to being maintained on medication for opioid use disorder? (TSOUDMBR) 0-No 1-Yes

a. If "Yes", what barrier(s)? [Check all that apply]

- 1. Insurance coverage: (TSINSCVR) 01-
- 2. Cost: (TS5COST) 01-
- 3. Availability of providers: (TSAVLPRO) 01-
- 4. Wait-time to enroll a program: (TSWTTMPG) 01-
- 5. I feel shamed or criticized by others for being on medication: (TSSTGMAB) 01-
- 6. Other: (TSOTHBAR) 01-

1. If "Other", specify: (TSOTBASP)

5. How likely are you to continue medication for opioid use disorder in the community?

	01-Very Unlikely 1	02- Unlikely 2	03- Undecided 3	04- Likely 4	05-Very Likely 5
(TSLKCONT)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

6. Overall, how satisfied are you with the care you received?

	01-Very Unsatisfied 1	02- Unsatisfied 2	03- Neutral 3	04- Satisfied 4	05-Very Satisfied 5
(TSCAREST)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

7. Any additional comments?(TSADCMMT)

Participant required research staff assistance in reading the questions in this assessment:

Note: this includes if participant could not see well enough to read the questions or if the participant was unable to read well enough to read the questions.(TS5RAHLP)

Comments:(TS5COMM)

01-Yes

Targeted Safety Event (TSE)

Version: 1.00; 01-19-21

Segment (*PROTSEG*): B, C, D, E

TSE date (*TSDATE*):

TSE sequence number (*TSEQNO*):

1. Event type: (*TSEVNTYP*)

01-Fall event (likely related to medical/psychiatric condition such as dizziness, confusion with head
02-Acute change in mental status (i.e., disorientation, amnesia, cerebrovascular accident, coma)
03-Acute medical complication likely exacerbated by the stress of withdrawal (i.e., hypertensive crisis
04-Acute psychiatric symptoms (i.e., psychosis, hypomania, severe agitation, violence)

2. Specify details of event: (*TSEDETLSP*)

3. Is this event related to study regimen (including all medications): (*TSRELSR*)

0-No 1-Yes

4. Date site became aware of event: (*TSAWARDT*)

(mm/dd/yyyy)

5. Severity: (*TSSEVERE*)

01-Mild
02-Moderate
03-Severe

6. Is this event a serious adverse event as defined by the protocol? (*TSSAE*)

0-No 1-Yes

If "Yes", SAE onset date: (*TSSAEDT*)

(mm/dd/yyyy)

If "Yes", please also complete an SAE form.

Comments: (*TSECOMM*)

Additional Selection Options for TSE

TSE sequence number (*TSSEQNO*) (key field):

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

Urine Drug Screen (UDS)

Version: 3.01; 07-30-21

Segment (*PROTSEG*): B, C, D, E
 Visit Number (*VISNO*):

Date of assessment:(*UDSASMDT*)

 (mm/dd/yyyy)

- 1. Was a urine drug screen performed?(*UDTEST1*)
 - a. If "No", reason:(*UDNORSN1*)

 0-No 1-Yes

- 01-Participant reported being unable to provide sample
- 02-Participant refused to provide sample
- 04-Study staff error
- 92-COVID-19: Illness
- 93-COVID-19: Public health measures
- 94-COVID-19: Other
- 99-Other

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

First Urine Drug Screen

- 2. Date 1st urine specimen collected:(*UDCOLDT1*)
- 3. Time 1st urine specimen collected:(*UDCOLTM1*)
- 4. Was the 1st urine specimen temperature within the range? (90-100 °F)(*UDTEMP1*)
- 5. Was the 1st urine specimen determined to be adulterated?(*UDADULT1*)
- 6. 1st Urine Drug Screen Results:

 (mm/dd/yyyy)

 (hh:mm)

 0-No 1-Yes

 0-No 1-Yes

Drug Name (Abbreviation)	00-Negative	01-Positive	02-Invalid
Amphetamine (500 ng) (AMP):	(<i>UDAMP1</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Barbiturate (300 ng) (BAR):	(<i>UDBAR1</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Buprenorphine (10 ng) (BUP):	(<i>UDBUP1</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Benzodiazepines (300 ng) (BZO):	(<i>UDBZO1</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cocaine (150 ng) (COC):	(<i>UDCOC1</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ecstasy (500 ng) (MDMA):	(<i>UDMDA1</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Methamphetamine (500 ng) (MET):	(<i>UDMET1</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Methadone (300 ng) (MTD):	(<i>UDMTD1</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Turn urine dip card over</i>			
Opiates (300 ng) (OPI):	(<i>UDOPI31</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Oxycodone (100 ng) (OXY):	(<i>UDOXY1</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Phencyclidine (25 ng) (PCP):	(<i>UDPCP1</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Marijuana (50 ng) (THC):	(<i>UDTHC1</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Single Dipstick</i>			
Fentanyl (20 ng) (FEN):	(<i>UDFEN1</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Second Urine Drug Screen

- 7. If the 1st urine specimen was determined to be adulterated, was a second specimen collected?(*UDTEST2*)
 - a. If "No", reason:(*UDNORSN2*)

 0-No 1-Yes

- 01-Participant reported being unable to provide sample
- 02-Participant refused to provide sample
- 04-Study staff error
- 92-COVID-19: Illness
- 93-COVID-19: Public health measures
- 94-COVID-19: Other
- 99-Other

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

8. Time 2nd urine specimen collected:(UDCOLTM2)

(hh:mm)

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

0-No 1-Yes

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

0-No 1-Yes

Second Urine Drug Screen Results:

Drug Name (Abbreviation)	00-Negative	01-Positive	02-Invalid
Amphetamine (500 ng) (AMP):	(UDAMP2) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Barbiturate (300 ng) (BAR):	(UDBAR2) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Buprenorphine (10 ng) (BUP):	(UDBUP2) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Benzodiazepines (300 ng) (BZO):	(UDBZO2) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cocaine (150 ng) (COC):	(UDCOC2) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ecstasy (500 ng) (MDMA):	(UDMDA2) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Methamphetamine (500 ng) (MET):	(UDMET2) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Methadone (300 ng) (MTD):	(UDMTD2) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Turn urine dip card over</i>			
Opiates (300 ng) (OPI):	(UDOPI32) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Oxycodone (100 ng) (OXY):	(UDOXY2) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Phencyclidine (25 ng) (PCP):	(UDPCP2) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Marijuana (50 ng) (THC):	(UDTHC2) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>Single Dipstick</i>			
Fentanyl (20 ng) (FEN):	(UDFEN2) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments:(UDSCOMM)

Missed Visit and Visit Documentation (V97)

Version: 1.00; 02-08-21

Segment (PROTSEG): E

Visit Number (VISNO):

1. Did the visit occur?(VFATTEND)

0-No 1-Yes

Reason for Missed Visit

Select the one option that best describes the reason for the missed visit.

2. If visit did not occur, indicate why:(VFNOATND)

01-Participant on vacation
02-Participant illness
03-Participant in hospital, in-patient, or residential treatment
04-Participant moved from area
05-Participant incarcerated
*Additional Options Listed Below

a. If "Other", specify:(VFOTHSP)

Visit Attendance Information

3. Where did the visit occur: (select all that apply)

a. In clinic:(VFINCLIN)

b. Telehealth:(VFTELHLT)

01-

01-

0-No 1-Yes

4. Was any assessment at this visit completed outside of the expected window?
(VFVISWIN)

a. If "Yes", was it outside of the window due to COVID-19?(VFWINCVD)

0-No 1-Yes

1. If "Yes", which of the following was the reason?(VFCVDRSN)

92-COVID-19: Illness
93-COVID-19: Public health measures
94-COVID-19: Other

Comments:(VMFCOMM)

Additional Selection Options for V97

If visit did not occur, indicate why:

06-Site closed

07-Participant withdrew consent

08-Participant deceased

09-Participant unable to attend visit due to logistical barriers

10-Participant failed to return to site and unable to contact

11-Visit was not scheduled

12-Unable to contact

13-Site decision/error

92-COVID-19: Illness

93-COVID-19: Public health measures

94-COVID-19: Other

99-Other