Adult ADHD Self-Report Screening Scale for DSM-5 (AAS)

Version: 1.00; 03-30-21

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

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

Select the answer that best describes how you have felt and conducted yourself over the past 6 months.

	00-Never	01-Rarely	02-Sometimes	03-Often	04-Very Often
1. How often do you have difficulty concentrating on what people are saying to you even when they are speaking to you directly? *(AADFCCON)*	☐	☐	☐	☐	☐
2. How often do you leave your seat in meetings or other situations in which you are expected to remain seated? *(AALVSEAT)*	☐	☐	☐	☐	☐
3. How often do you have difficulty unwinding and relaxing when you have time to yourself? *(AADFCRLX)*	☐	☐	☐	☐	☐
4. When you're in a conversation, how often do you find yourself finishing the sentences of the people you are talking to before they can finish them themselves? *(AAINTRPT)*	☐	☐	☐	☐	☐
5. How often do you put things off until the last minute? *(AAPUTOFF)*	☐	☐	☐	☐	☐
6. How often do you depend on others to keep your life in order and attend to details? *(AAORDER)*	☐	☐	☐	☐	☐

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.(AASRAHLP)

Comments:*(AASCOMM)*

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:*(A1ALTETI)*
   - 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)*	*(A2_01DIN)*
b. *(A2_02DNM)*	*(A2_02DIN)*
c. *(A2_03DNM)*	*(A2_03DIN)*
d. *(A2_04DNM)*	*(A2_04DIN)*
e. *(A2_05DNM)*	*(A2_05DIN)*
f. *(A2_06DNM)*	*(A2_06DIN)*
g. *(A2_07DNM)*	*(A2_07DIN)*
h. *(A2_08DNM)*	*(A2_08DIN)*
i. *(A2_09DNM)*	*(A2_09DIN)*
j. *(A2_10DNM)*	*(A2_10DIN)*

4. Treatments for the event:*(A2SAETRT)* ☐ 00-No ☐ 01-Yes ☐ 97-Unknown

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

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)*	*(A2_1LBIN)*	*(A2_1LBDT)*
b. *(A2_2LBNM)*	*(A2_2LBIN)*	*(A2_2LBDT)*
c. *(A2_3LBNM)*	*(A2_3LBIN)*	*(A2_3LBDT)*
d. *(A2_4LBNM)*	*(A2_4LBIN)*	*(A2_4LBDT)*
e. *(A2_5LBNM)*	*(A2_5LBIN)*	*(A2_5LBDT)*

6. Follow-up:
   Include labs/test results as they become available, clinical changes, consultant diagnosis, etc.
   (A2FOLLUP)

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

   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 *(AESEQNO)* (key field):

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

Alcohol and Substance Use (ASU)

Version: 2.02; 08-13-21

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

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

Alcohol Use History

RA Instruction:

- *Definition of a standard drink: 1 12oz bottle of beer, 1 glass 5oz non-fortified wine, 1 mixed drink with 1.5oz liquor.*
- *If respondent needs a visual reference for the size of a drink, the flashcards from the Wave 1 National Epidemiologic Survey on Alcohol and Related Conditions (NESARC) study can be provided.*

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

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

b Think specifically about the past 30 days, from the date 30 days prior to the date of the interview, up to and including today. During the past 30 days, on how many days did you drink one or more drinks of an alcoholic beverage? *(AUALCDAY)* xx days **OR** ☐ 97-Don't know ☐ 98-Refused to answer

l On the days that you drank during the past 30 days, how many **drinks** did you usually have each day? *(AUALCEAC)*
Count as a drink a can or bottle of beer; a wine cooler or a glass of wine, champagne, or sherry; a shot of liquor or a mixed drink or cocktail. xx drinks **OR** ☐ 97-Don't know ☐ 98-Refused to answer

Substance Use History

Now I'd like to ask you about your experiences with medicines and other kinds of drugs that you may have used ON YOUR OWN-that is, either WITHOUT a doctor's prescription (PAUSE); in GREATER amounts, MORE OFTEN, or LONGER than prescribed (PAUSE); or for a reason other than a doctor said you should use them. People use these medicines and drugs ON THEIR OWN to feel more alert, to relax or quiet their nerves, to feel better, to enjoy themselves, to get high or just to see how they work.

Substance	Have you EVER used any of these medicines or drugs?	If "Yes", specify substance type(s)	How old were you when you FIRST used? *(years)*	How did you use _____? *(Note the usual or most recent route of administration. For more than one route, choose the most severe. The routes are listed from least severe to most severe)*	Have you used ____ in the past 12 months?	Think specifically about the past 30 days, from the date 30 days prior to the date of the interview up to and including today. During the past 30 days, on how many days did you use?		
						Number of Days	Don't Know	Refused
1 Sedatives: (e.g., sleeping pills, barbiturates, Seconal®, or Quaaludes)	☐ 0-No ☐ 1-Yes *(AUSEDLFT)*	*(AUSEDLSP)*	xx *(AUSEDAGE)*	(01) Oral (02) Nasal (03) Smoking (04) Non-IV injection (05) IV injection (96) Not applicable (97) Not answered *(AUSEDRTE)*	☐ 0-No ☐ 1-Yes *(AUSED12M)*	xx *(AUSED30D)*	☐ -97 *(AUSEDDKR)*	☐ -98 *(AUSEDDKR)*
2 Benzodiazepines: (e.g., Valium®, Librium®, or Xanax®)	☐ 0-No ☐ 1-Yes *(AUBZOLFT)*	*(AUBZOLSP)*	xx *(AUBZOAGE)*	(01) Oral (02) Nasal (03) Smoking (04) Non-IV injection (05) IV injection (96) Not applicable (97) Not answered *(AUBZORTE)*	☐ 0-No ☐ 1-Yes *(AUBZO12M)*	xx *(AUBZO30D)*	☐ -97 *(AUBZODKR)*	☐ -98 *(AUBZODKR)*
3 Opioid painkillers: (e.g., Codeine, Oxycontin®, Dilaudid®, Demerol®, methadone, Percocet®, or Vicodin®)	☐ 0-No ☐ 1-Yes *(AUPNKLFT)*	*(AUPNKLSP)*	xx *(AUPNKAGE)*	(01) Oral (02) Nasal (03) Smoking (04) Non-IV injection (05) IV injection (96) Not applicable (97) Not answered *(AUPNKRTE)*	☐ 0-No ☐ 1-Yes *(AUPNK12M)*	xx *(AUPNK30D)*	☐ -97 *(AUPNKDKR)*	☐ -98 *(AUPNKDKR)*

Substance	Have you EVER used any of these medicines or drugs?	If "Yes", specify substance type(s)	How old were you when you FIRST used? *(years)*	How did you use _____? *(Note the usual or most recent route of administration. For more than one route, choose the most severe. The routes are listed from least severe to most severe)*	Have you used ____ in the past 12 months?	Think specifically about the past 30 days, from the date 30 days prior to the date of the interview up to and including today. During the past 30 days, on how many days did you use?		
						Number of Days	Don't Know	Refused
4 Prescription stimulants: (e.g., Preludin®, Benzedrine®, amphetamine, Ritalin®, or uppers)	☐ 0-No ☐ 1-Yes *(AUSTMLFT)*	*(AUSTMLSP)*	xx *(AUSTMAGE)*	(01) Oral (02) Nasal (03) Smoking (04) Non-IV injection (05) IV injection (96) Not applicable (97) Not answered *(AUSTMRTE)*	☐ 0-No ☐ 1-Yes *(AUSTM12M)*	xx *(AUSTM30D)*	-97 *(AUSTMDKR)*	-98 *(AUSTMDKR)*
5 Methamphetamine:	☐ 0-No ☐ 1-Yes *(AUMETLFT)*	*(AUMETLSP)*	xx *(AUMETAGE)*	(01) Oral (02) Nasal (03) Smoking (04) Non-IV injection (05) IV injection (96) Not applicable (97) Not answered *(AUMETRTE)*	☐ 0-No ☐ 1-Yes *(AUMET12M)*	xx *(AUMET30D)*	-97 *(AUMETDKR)*	-98 *(AUMETDKR)*
6 Marijuana, cannabis, hash/hash oil, dabs, THC, or grass:	☐ 0-No ☐ 1-Yes *(AUTHCLFT)*	*(AUTHCLSP)*	xx *(AUTHCAGE)*	(01) Oral (02) Nasal (03) Smoking (04) Non-IV injection (05) IV injection (96) Not applicable (97) Not answered *(AUTHCRTE)*	☐ 0-No ☐ 1-Yes *(AUTHC12M)*	xx *(AUTHC30D)*	-97 *(AUTHCDKR)*	-98 *(AUTHCDKR)*
7 Cocaine or crack:	☐ 0-No ☐ 1-Yes *(AUCOCLFT)*	*(AUCOCLSP)*	xx *(AUCOCAGE)*	(01) Oral (02) Nasal (03) Smoking (04) Non-IV injection (05) IV injection (96) Not applicable (97) Not answered *(AUCOCRTE)*	☐ 0-No ☐ 1-Yes *(AUCOC12M)*	xx *(AUCOC30D)*	-97 *(AUCOCDKR)*	-98 *(AUCOCDKR)*
8 Hallucinogens: (e.g., Ecstasy/MDMA, LSD, mescaline, psilocybin, PCP, angel dust, or peyote)	☐ 0-No ☐ 1-Yes *(AUHALLFT)*	*(AUHALLSP)*	xx *(AUHALAGE)*	(01) Oral (02) Nasal (03) Smoking (04) Non-IV injection (05) IV injection (96) Not applicable (97) Not answered *(AUHALRTE)*	☐ 0-No ☐ 1-Yes *(AUHAL12M)*	xx *(AUHAL30D)*	-97 *(AUHALDKR)*	-98 *(AUHALDKR)*
9 Inhalants or solvents: (e.g., amyl nitrite, nitrous oxide, glue, toluene, or gasoline)	☐ 0-No ☐ 1-Yes *(AUINHLFT)*	*(AUINHLSP)*	xx *(AUINHAGE)*	(01) Oral (02) Nasal (03) Smoking (04) Non-IV injection (05) IV injection (96) Not applicable (97) Not answered *(AUINHRTE)*	☐ 0-No ☐ 1-Yes *(AUINH12M)*	xx *(AUINH30D)*	-97 *(AUINHDKR)*	-98 *(AUINHDKR)*
10 Heroin and/or fentanyl:	☐ 0-No ☐ 1-Yes *(AUHERLFT)*	*(AUHERLSP)*	xx *(AUHERAGE)*	(01) Oral (02) Nasal (03) Smoking (04) Non-IV injection (05) IV injection (96) Not applicable (97) Not answered *(AUHERRTE)*	☐ 0-No ☐ 1-Yes *(AUHER12M)*	xx *(AUHER30D)*	-97 *(AUHERDKR)*	-98 *(AUHERDKR)*
11 Any OTHER medicines, drugs, or substances: (e.g., Elavil®, anabolic steroids)	☐ 0-No ☐ 1-Yes *(AUOTHLFT)*	*(AUOTHLSP)*	xx *(AUOTHAGE)*	(01) Oral (02) Nasal (03) Smoking (04) Non-IV injection (05) IV injection (96) Not applicable (97) Not answered *(AUOTHRTE)*	☐ 0-No ☐ 1-Yes *(AUOTH12M)*	xx *(AUOTH30D)*	-97 *(AUOTHDKR)*	-98 *(AUOTHDKR)*

Comments: *(ASUCOMM)*

Critical Action Checklist (C97)

Version: 1.00; 01-22-21

Segment *(PROTSEG)*: C

Date of assessment:*(C97ASMDT)* _____ *(mm/dd/yyyy)*

This form is updated by the Research Assistant on a weekly basis throughout the induction phase and assesses the fidelity to clinical procedures and guidelines for each participant.
Complete the below checklist based on chart review.

	No-00	Yes-01	N/A-96
1. Urine toxicology obtained prior to XR-NTX injection. *(C9UTXINJ)*	☐	☐	☐
2. Urine pregnancy test done for females before or within 24 hours of admission. *(C9UPREGT)*	☐	☐	☐
3. COWS and vitals assessed daily. *(C9COWVDY)*	☐	☐	☐
4. Buprenorphine given for a minimum of 5 days. *(C9BUPFIV)*	☐	☐	☐
5. Washout (*no administration of opioid agonist*) period of at least 5 days. *(C9WASHPD)*	☐	☐	☐

Comments:*(C97COMM)*

Critical Action Checklist (C97)

Version: 1.00; 01-22-21

Segment *(PROTSEG)*: D

Date of assessment:*(C97ASMDT)* _____ *(mm/dd/yyyy)*

This form is updated by the Research Assistant on a weekly basis throughout the induction phase and assesses the fidelity to clinical procedures and guidelines for each participant.

Complete the below checklist based on chart review.

	No-00	Yes-01	N/A-96
1. Urine toxicology obtained before or within 24 hours of admission. *(C9UTXBAD)*	☐	☐	☐
2. Urine pregnancy test done for females before or within 24 hours of admission. *(C9UPREGT)*	☐	☐	☐
3. Daily individual counseling conducted and documented. *(C9CNCLDY)*	☐	☐	☐
4. COWS and vitals assessed at least 2 times a day starting at day of admission. *(C9COWVTW)*	☐	☐	☐
5. Documentation of one day of buprenorphine given at start of procedure (*max dose 10mg*). *(C9BUPST)*	☐	☐	☐
6. Daily standing and active order for clonidine at least three times a day from day one of admission. *(C9CLNDY)*	☐	☐	☐
7. Daily standing and active order for clonazepam at least three times a day from day one of admission. *(C9CNZPDY)*	☐	☐	☐
8. Oral naltrexone initiated at low dose (0.5 mg). *(C9ORNTX)*	☐	☐	☐
9. Offered second daily dose of naltrexone if no significant increase in COWS score following the first dose. *(C9ORLNTX)*	☐	☐	☐
10. Order for Long-acting injectable naltrexone 380 mg IM once, conditional if at least 6 mg dose is tolerated without increase in COWS on or before day 8 of admission. *(C9INJNTX)*	☐	☐	☐
11. Participant observed for at least 12 hours after administration of long-acting injectable naltrexone. *(C9PTPOBS)*	☐	☐	☐
12. If discharged home after XR-NTX injection, these medications prescribed at discharge:			
a. Zolpidem: *(C9PRZPDM)*	☐	☐	☐
b. Clonidine: *(C9PRSCLN)*	☐	☐	☐
c. Clonazepam: *(C9PCNZPM)*	☐	☐	☐
d. Instructions to use over the counter analgesics and antidiarrheals and to stay hydrated. *(C9OTCMED)*	☐	☐	☐

Comments:*(C97COMM)*

Clinical Opioid Withdrawal Scale (COW)

Version: 2.03; 05-07-21

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

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

Time of assessment:*(COASMTM)* _____ *(hh:mm) (24-hour time)*

For each item, choose the option that best describes the participant's signs or symptoms. Rate on just the apparent relationship to opiate withdrawal. For example, if heart rate is increased because the participant was jogging just prior to assessment, the increased pulse rate would not add to the score.

1. If this assessment was retrieved retrospectively by chart review, is information for all the elements of the assessment available?*(CORTCHRT)* ☐ 00-No ☐ 01-Yes ☐ 96-N/A

2. Resting pulse rate:
   Measured after participant is sitting or lying for one minute(COPULSE)

   00-Pulse rate of 80 or below
   01-Pulse rate of 81-100
   02-Pulse rate of 101-120
   04-Pulse rate greater than 120

   beats/minute

3. Sweating:*(COSWEAT)*

   00-No report of chills or flushing
   01-Subjective report of chills or flushing
   02-Flushed or observable moistness on face
   03-Beads of sweat on brow or face
   04-Sweat streaming off face

4. Restlessness:
   Observation during assessment(CORESTLS)

   00-Able to sit still
   01-Reports difficulty sitting still, but is able to do so
   03-Frequent shifting or extraneous movements of legs/arms
   05-Unable to sit still for more than a few seconds

5. Pupil size:*(COPUPIL)*

   00-Pupils pinned or normal size for room light
   01-Pupils possibly larger than normal for room light
   02-Pupils moderately dilated
   05-Pupil so dilated that only the rim of the iris is visible

6. Bone or joint aches:
   If participant was having pain previously, only the additional component attributed to opiates withdrawal is scored.(COBONJNT)

   00-Not present
   01-Mild diffuse discomfort
   02-Patient reports severe diffuse aching of joints/muscles
   04-Patient is rubbing joints or muscles and is unable to sit still because of discomfort

7. Runny nose or tearing:
   Not accounted for by cold symptoms or allergies(CONOSEYE)

   00-Not present
   01-Nasal stuffiness or unusually moist eyes
   02-Nose running or tearing
   04-Nose constantly running or tears streaming down cheeks

8. GI upset:*(COGIUPST)*

   00-No GI symptoms
   01-Stomach cramps
   02-Nausea or loose stool
   03-Vomiting or diarrhea
   05-Multiple episodes of diarrhea or vomiting

9. Tremor:
   Observation of outstretched hands(COTREMOR)

   00-No tremor
   01-Tremor can be felt, but not observed
   02-Slight tremor observable
   04-Gross tremor or muscle twitching

10. Yawning:
Observation during assessment(COYAWN)

00-No yawning
01-Yawning once or twice during assessment
02-Yawning three or more times during assessment
04-Yawning several times/minute

11. Anxiety or irritability:*(COANXITY)*

00-None
01-Patient reports increasing irritability or anxiousness
02-Patient obviously irritable or anxious
04-Patient so irritable or anxious that participation in the assessment is difficult

12. Gooseflesh skin:*(COGOOSKN)*

00-Skin is smooth
03-Piloerection of skin can be felt or hairs standing up on arms
05-Prominent piloerection

Save form to generate score.

Total score:
Sum of all 11 items(COCOWSCR)

(xx)

Total score:*(COWSCRRT)*

(xx)

Opiate withdrawal rating:*(COWRATE)*

00-0-4 No withdrawal
01-5-12 Mild
02-13-24 Moderate
03-25-36 Moderately severe
04->36 Severe withdrawal

Comments:*(COWCOMM)*

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)*

2. Date urine specimen collected:*(UDCOLDT)* *(mm/dd/yyyy)*
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):	*(UDAMP1)* ☐	☐	☐	☐
Barbiturate (300 ng) (BAR):	*(UDBAR1)* ☐	☐	☐	☐
Buprenorphine (10 ng) (BUP):	*(UDBUP1)* ☐	☐	☐	☐
Benzodiazepines (300 ng) (BZO):	*(UDBZO1)* ☐	☐	☐	☐
Cocaine (150 ng) (COC):	*(UDCOC1)* ☐	☐	☐	☐
Ecstasy (500 ng) (MDMA):	*(UDMDA1)* ☐	☐	☐	☐
Methamphetamine (500 ng) (MET):	*(UDMET1)* ☐	☐	☐	☐
Methadone (300 ng) (MTD):	*(UDMTD1)* ☐	☐	☐	☐
Opiates (300 ng) (OPI):	*(UDOPI31)* ☐	☐	☐	☐
Oxycodone (100 ng) (OXY):	*(UDOXY1)* ☐	☐	☐	☐
Phencyclidine (25 ng) (PCP):	*(UDPCP1)* ☐	☐	☐	☐
Marijuana (50 ng) (THC):	*(UDTHC1)* ☐	☐	☐	☐
Fentanyl (20 ng) (FEN):	*(UDFEN1)* ☐	☐	☐	☐

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

COVID-19 Impact Assessment (CVD)

Version: 1.01; 03-30-21

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

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

Mental Health and Health Care Impact

*Please answer the following questions regarding your mental state and health care treatment access **after the COVID-19 outbreak in your country/region.***

1. In general, I feel more stressed:*(CVSTRESS)*
   - 00-Strongly agree
   - 01-Somewhat agree
   - 02-Neutral
   - 03-Somewhat disagree
   - 04-Strongly disagree
2. In general, I feel that I have more anxiety:*(CVANXITY)*
   - 00-Strongly agree
   - 01-Somewhat agree
   - 02-Neutral
   - 03-Somewhat disagree
   - 04-Strongly disagree
3. In general, I feel that I am more sad:*(CVSAD)*
   - 00-Strongly agree
   - 01-Somewhat agree
   - 02-Neutral
   - 03-Somewhat disagree
   - 04-Strongly disagree
4. How has the quality of your sleep changed since COVID-19?*(CVSLEEP)*
   - 00-Improved
   - 01-Worsened
   - 02-Stayed the same
   - 03-I have not noticed
5. Prior to admission, were you currently receiving treatment for substance use, including alcohol?*(CVTRTSUS)* ☐ 00-No ☐ 01-Yes ☐ 97-Unsure or don't know ☐ 98-Refuse to answer
6. Prior to admission, were you currently participating in a 12-step program like AA, NA, CA?*(CV12STEP)* ☐ 00-No ☐ 01-Yes ☐ 97-Unsure or don't know ☐ 98-Refuse to answer
7. Since the COVID-19 outbreak, have you experienced difficulty obtaining other medical and psychiatric care or prescriptions?*(CVMEDCOB)* ☐ 00-No ☐ 01-Yes ☐ 97-Unsure or don't know

   If "Yes":

   a. Does this include psychiatric care?*(CVPSYCOB)* ☐ 00-No ☐ 01-Yes ☐ 97-Unsure or don't know
   b. Does this include prescriptions?*(CVRXOB)* ☐ 00-No ☐ 01-Yes ☐ 97-Unsure or don't know
   c. Did you experience other difficulties related to obtaining medical care or prescriptions?*(CVDFOB)* ☐ 0-No ☐ 1-Yes
      1. If "Yes", specify other difficulties:*(CVDFOBSP)* _____
8. How much is/did the COVID-19 pandemic impact your day-to-day life?*(CVIMPDAY)*
   - 00-Not at all
   - 01-A little
   - 02-Much
   - 03-Very much
   - 04-Extremely

Optional: Employment/economic impact and housing stability

1. Are you currently employed?*(CVEMPLOY)*
   - 00-No, I am not employed nor am I working
   - 01-I work but I do not have a regular job
   - 02-I was furloughed or laid off from employment
   - 03-Yes, I am employed but with a significant change in hours I work
   - 04-Yes, I am employed full time

If "Yes", how has the COVID-19 outbreak affected you in the past two weeks for the following:

	0-No	1-Yes
a. Worked remotely or from home more than you usually do: *(CVWKREMO)*	☐	☐
b. Worked more hours than usual: *(CVWKMHRS)*	☐	☐
c. Worked reduced hours: *(CVWKLHRS)*	☐	☐
d. Was not able to work or lost job: *(CVUNEMP)*	☐	☐
e. Had difficulty arranging for childcare: *(CVDFCHDC)*	☐	☐
f. Incurred increased costs for childcare expenses: *(CVICCCST)*	☐	☐
g. Income or pay has been reduced: *(CVINCRED)*	☐	☐
h. Not paid at all: *(CVNOINCM)*	☐	☐
i. Had serious financial problems: *(CVSFINPB)*	☐	☐

In the past two weeks have you experienced the following as a result of COVID-19?

	0-No	1-Yes
2. Not enough money to pay rent: *(CVNORENT)*	☐	☐
3. Not enough money to pay for gas: *(CVNOGAS)*	☐	☐
4. Not enough money to pay for food: *(CVNOFOOD)*	☐	☐
5. Did not have a regular place to sleep or stay: *(CVNOSTAY)*	☐	☐

6. Which of the following has had the biggest impact on your access to food in the past month?*(CVIMFOOD)*

00-I have not had enough money to buy food
01-I have had to ration my food so I do not run out (e.g., skipped meals, eaten less than I want to)
02-I have not been able to find foods I need in the store
03-My access to food has not been impacted
98-Decline to answer

7. Are you an essential worker?
Essential workers are exempt from stay at home and shelter in place orders, and must report to their place of work. Essential workers include but are not limited to those working in public health/health care, law enforcement, public safety, first responders, food and agriculture, energy and electricity, petroleum, water and wastewater, transportation, public works, communications and IT, and others.(CVESSNTL)

00-Yes, I am an essential worker
01-No, I am not an essential worker
97-Unsure or don't know

8. To what degree are you concerned about the stability of your living situation? *(CVCONSTB)*

00-Not at all
01-Slight
02-Moderately
03-Very
04-Extremely

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.(CVDRAHLP)

☐ 01-Yes

Comments:*(CVDCOMM)*

Items adapted from C3PNO COVID-19 Survey (Gorbach, 2020).

Study Demographics (RA Administered) (D97)

Version: 1.00; 11-09-20

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

Date of assessment:*(D97ASMDT)* _____ *(mm/dd/yyyy)*

1. Are you under criminal justice supervision, for example parole, probation or drug court? *(D97CRMJS)*
   ☐ 00-No ☐ 01-Yes ☐ 97-Not answered
2. Choose living arrangements most representative of the past 3 years. *If there is an even split in time between these living arrangements, choose the most recent arrangement.(D97LVWTH)*
   - 01-With sexual partner and children
   - 02-With sexual partner alone
   - 03-With children alone
   - 04-With parents
   - 05-With family
   - *Additional Options Listed Below
3. Do you live with anyone who:
   a. Has a current alcohol problem?*(D97ALCPR)*
   ☐ 00-No ☐ 01-Yes ☐ 97-Not answered
   b. Uses non-prescribed drugs?*(D97NPPRB)*
   ☐ 00-No ☐ 01-Yes ☐ 97-Not answered
   c. Uses non-prescribed opioids?*(D97NPOPI)*
   ☐ 00-No ☐ 01-Yes ☐ 97-Not answered
4. Do you spend time with friends and/or family members who use heroin or other illicit drugs?*(D97FFUSE)*
   ☐ 0-No ☐ 1-Yes
5. Do you have regular access to a smartphone?*(D97SMPHO)*
   ☐ 0-No ☐ 1-Yes
   a. If "Yes", what plan do you have?*(D97SPLAN)*
   - 01-Limited data plan
   - 02-Unlimited data plan
   - 03-No data plan but regular access to WiFi
   - 04-No data plan and no regular access to WiFi
   - 97-I'm not sure

Comments:*(D97COMM)* _____

Additional Selection Options for D97

Choose living arrangements most representative of the past 3 years.
If there is an even split in time between these living arrangements, choose the most recent arrangement.
06-With friends
07-Alone
08-Controlled environment
09-No stable arrangements
97-Not answered

Daily Medication Administration Log (DMA)

Version: 3.01; 08-30-21

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

This form captures anticipated side-effects/symptoms, relevant detoxification medications and other concomitant medications.
Date of 24-hour assessment period:*(DMAMDDT)* _____ *(mm/dd/yyyy)*

Section A:

1. Were anticipated side-effects/symptoms assessed during this 24-hour period? *(DMEFF24H)* ☐ 0-No ☐ 1-Yes

Anticipated side-effects/symptoms:	00-None	01-Mild	02-Moderate	03-Severe	97-Not Assessed
a. Do you feel drowsy? *(DMDROWSY)*	☐	☐	☐	☐	☐
b. Do you feel dizzy? *(DMDIZZY)*	☐	☐	☐	☐	☐
c. Did you have trouble sleeping last night? *(DMSLEEP)*	☐	☐	☐	☐	☐

Section B:

2. Was blood pressure collected during this 24-hour period?*(DMBP24HR)* ☐ 0-No ☐ 1-Yes

Blood Pressure Log

	Systolic	Diastolic	Pulse	Time Collected	Position
a.	*(DMBPSYS1)* *(xxx)*	*(DMBPDIA1)* *(xxx)*	*(DMPULSE1)* *(xxx)*	*(DMBPTIM1)* *(hh:mm)*	*(DMBPOSN1)* 01-Sitting 02-Standing 99-Unknown/Other
b.	*(DMBPSYS2)* *(xxx)*	*(DMBPDIA2)* *(xxx)*	*(DMPULSE2)* *(xxx)*	*(DMBPTIM2)* *(hh:mm)*	*(DMBPOSN2)* 01-Sitting 02-Standing 99-Unknown/Other
c.	*(DMBPSYS3)* *(xxx)*	*(DMBPDIA3)* *(xxx)*	*(DMPULSE3)* *(xxx)*	*(DMBPTIM3)* *(hh:mm)*	*(DMBPOSN3)* 01-Sitting 02-Standing 99-Unknown/Other
d.	*(DMBPSYS4)* *(xxx)*	*(DMBPDIA4)* *(xxx)*	*(DMPULSE4)* *(xxx)*	*(DMBPTIM4)* *(hh:mm)*	*(DMBPOSN4)* 01-Sitting 02-Standing 99-Unknown/Other
e.	*(DMBPSYS5)* *(xxx)*	*(DMBPDIA5)* *(xxx)*	*(DMPULSE5)* *(xxx)*	*(DMBPTIM5)* *(hh:mm)*	*(DMBPOSN5)* 01-Sitting 02-Standing 99-Unknown/Other
f.	*(DMBPSYS6)* *(xxx)*	*(DMBPDIA6)* *(xxx)*	*(DMPULSE6)* *(xxx)*	*(DMBPTIM6)* *(hh:mm)*	*(DMBPOSN6)* 01-Sitting 02-Standing 99-Unknown/Other
g.	*(DMBPSYS7)* *(xxx)*	*(DMBPDIA7)* *(xxx)*	*(DMPULSE7)* *(xxx)*	*(DMBPTIM7)* *(hh:mm)*	*(DMBPOSN7)* 01-Sitting 02-Standing 99-Unknown/Other
h.	*(DMBPSYS8)* *(xxx)*	*(DMBPDIA8)* *(xxx)*	*(DMPULSE8)* *(xxx)*	*(DMBPTIM8)* *(hh:mm)*	*(DMBPOSN8)* 01-Sitting 02-Standing 99-Unknown/Other
i.	*(DMBPSYS9)* *(xxx)*	*(DMBPDIA9)* *(xxx)*	*(DMPULSE9)* *(xxx)*	*(DMBPTIM9)* *(hh:mm)*	*(DMBPOSN9)* 01-Sitting 02-Standing 99-Unknown/Other
j.	*(DMBPSY10)* *(xxx)*	*(DMBPDI10)* *(xxx)*	*(DMPULS10)* *(xxx)*	*(DMBPTI10)* *(hh:mm)*	*(DMBPOS10)* 01-Sitting 02-Standing 99-Unknown/Other
k.	*(DMBPSY11)* *(xxx)*	*(DMBPDI11)* *(xxx)*	*(DMPULS11)* *(xxx)*	*(DMBPTI11)* *(hh:mm)*	*(DMBPOS11)* 01-Sitting 02-Standing 99-Unknown/Other
l.	*(DMBPSY12)* *(xxx)*	*(DMBPDI12)* *(xxx)*	*(DMPULS12)* *(xxx)*	*(DMBPTI12)* *(hh:mm)*	*(DMBPOS12)* 01-Sitting 02-Standing 99-Unknown/Other
m.	*(DMBPSY13)* *(xxx)*	*(DMBPDI13)* *(xxx)*	*(DMPULS13)* *(xxx)*	*(DMBPTI13)* *(hh:mm)*	*(DMBPOS13)* 01-Sitting 02-Standing 99-Unknown/Other

Section C:

For medications 1-4, indicate if a medication was administered and if "Yes", list each dose and time given.
For medications 5-15, select only one option from the dropdown list of medications, indicate if a medication was administered and if "Yes", include the total daily dose. If there is more than one, you can add this as an "Other" medication.
For medications 16-20, indicate if a medication was administered and if "Yes", include the total daily dose.
For medications 21-30, indicate all other medications and include the total daily dose.

Medication	Medication Given During this 24 Hour Period?	Dose 1 (mg)	Dose 2 (mg)	Dose 3 (mg)	Dose 4 (mg)	Dose 5 (mg)	Dose 6 (mg)	Total Daily Dose (mg)
1. Buprenorphine:	*(DMBUP24)* ☐ 0-No ☐ 1-Yes	*(DMBUPD01)* *(xx.xx)*	*(DMBUPD02)* *(xx.xx)*	*(DMBUPD03)* *(xx.xx)*	*(DMBUPD04)* *(xx.xx)*	*(DMBUPD05)* *(xx.xx)*	*(DMBUPD06)* *(xx.xx)*	*(DMBUPDTL)* *(xxx.xx)*
	Time administered (24-hour clock):	*(DMBUPT01)* *(hh:mm)*	*(DMBUPT02)* *(hh:mm)*	*(DMBUPT03)* *(hh:mm)*	*(DMBUPT04)* *(hh:mm)*	*(DMBUPT05)* *(hh:mm)*	*(DMBUPT06)* *(hh:mm)*	
2. Oral Naltrexone:	*(DMVIV24)* ☐ 0-No ☐ 1-Yes	*(DMVIVD01)* *(xxx.xx)*	*(DMVIVD02)* *(xxx.xx)*	*(DMVIVD03)* *(xxx.xx)*	*(DMVIVD04)* *(xxx.xx)*	*(DMVIVD05)* *(xxx.xx)*	*(DMVIVD06)* *(xxx.xx)*	*(DMVIVDTL)* *(xxxx.xx)*
	Time administered (24-hour clock):	*(DMVIVT01)* *(hh:mm)*	*(DMVIVT02)* *(hh:mm)*	*(DMVIVT03)* *(hh:mm)*	*(DMVIVT04)* *(hh:mm)*	*(DMVIVT05)* *(hh:mm)*	*(DMVIVT06)* *(hh:mm)*	
3. Clonidine (PO):	*(DMCLD24)* ☐ 0-No ☐ 1-Yes	*(DMCLDD01)* *(xx.xx)*	*(DMCLDD02)* *(xx.xx)*	*(DMCLDD03)* *(xx.xx)*	*(DMCLDD04)* *(xx.xx)*	*(DMCLDD05)* *(xx.xx)*	*(DMCLDD06)* *(xx.xx)*	*(DMCLDDTL)* *(xx.xx)*
	Time administered (24-hour clock):	*(DMCLDT01)* *(hh:mm)*	*(DMCLDT02)* *(hh:mm)*	*(DMCLDT03)* *(hh:mm)*	*(DMCLDT04)* *(hh:mm)*	*(DMCLDT05)* *(hh:mm)*	*(DMCLDT06)* *(hh:mm)*	
4. Clonazepam (PO):	*(DMCZP24)* ☐ 0-No ☐ 1-Yes	*(DMCZPD01)* *(xxx.xx)*	*(DMCZPD02)* *(xxx.xx)*	*(DMCZPD03)* *(xxx.xx)*	*(DMCZPD04)* *(xxx.xx)*	*(DMCZPD05)* *(xxx.xx)*	*(DMCZPD06)* *(xxx.xx)*	*(DMCZPDTL)* *(xxx.xx)*
	Time administered (24-hour clock):	*(DMCZPT01)* *(hh:mm)*	*(DMCZPT02)* *(hh:mm)*	*(DMCZPT03)* *(hh:mm)*	*(DMCZPT04)* *(hh:mm)*	*(DMCZPT05)* *(hh:mm)*	*(DMCZPT06)* *(hh:mm)*	

Medication		Medication Given During this 24 Hour Period?	Total Daily Dose (mg)
5. Other Benzodiazepines:*(DMOTBZO)*	01-Diazepam 02-Chlordiazepoxide 03-Lorazepam 04-Alprazolam 05-Temazepam 06-Oxazepam 99-Other	*(DMBZO24)* ☐ 0-No ☐ 1-Yes	*(DMBZODTL)* _____ *(xxxxx.xx)*
If "Other", specify:*(DMBZOSP)*			
6. Antiemetic:*(DMANTIME)*	01-Prochlorperazine 02-Promethazine 03-Meclizine 04-Ondansetron 99-Other	*(DMANTM24)* ☐ 0-No ☐ 1-Yes	*(DMANTMTL)* _____ *(xxxxx.xx)*
If "Other", specify:*(DMANTMSP)*			
7. Antidiarrheal:*(DMANTIDA)*	01-Loperamide 02-Diphenoxylate/atropine (Lomotil) 03-Octreotide 99-Other	*(DMANTD24)* ☐ 0-No ☐ 1-Yes	*(DMANTDTL)* _____ *(xxxxx.xx)*
If "Other", specify:*(DMANTDSP)*			
8. Sleep agent:*(DMSLPAGT)*	01-Trazodone 02-Zolpidem 03-Mirtazapine 04-Doxepin 05-Melatonin 06-Suvorexant 07-Eszopiclone 08-Ramelteon 99-Other	*(DMSLP24)* ☐ 0-No ☐ 1-Yes	*(DMSLPTL)* _____ *(xxxxx.xx)*
If "Other", specify:*(DMSLPSP)*			
9. Non-steroidal anti-inflammatory agent:*(DMNSAID)*	01-Ibuprofen 02-Aspirin 03-Naproxen 04-Ketorolac 99-Other	*(DMNSID24)* ☐ 0-No ☐ 1-Yes	*(DMNSIDTL)* _____ *(xxxxx.xx)*
If "Other", specify:*(DMNSIDSP)*			
10. Nicotine replacement therapy:*(DMNICTRP)*	01-Nicotine patch 02-Nicotine patch plus other 03-Nicotine gum 04-Nicotine lozenge 99-Other	*(DMNICT24)* ☐ 0-No ☐ 1-Yes	*(DMNICTTL)* _____ *(xxxxx.xx)*
If "Other", specify:*(DMNICTSP)*			
11. Alpha 2 agonists:*(DMALPHAA)*	01-Lofexidine 02-Tizanidine 03-Clonidine patch 04-Guanfacine 99-Other	*(DMALPH24)* ☐ 0-No ☐ 1-Yes	*(DMALPHTL)* _____ *(xxxxx.xx)*
If "Other", specify:*(DMALPHSP)*			

Medication		Medication Given During this 24 Hour Period?	Total Daily Dose (mg)
12. Anxiety/Antihistamine agents:*(DMANXHIS)*	01-Hydroxyzine 02-Diphenhydramine 03-Promethazine 99-Other	*(DMANXH24)* ☐ 0-No ☐ 1-Yes	*(DMANXHTL)* ☐ *(xxxxx.xx)*
If "Other", specify:*(DMANXHSP)*			
13. GABA agents/Muscle relaxants:*(DMGABAAG)*	01-Gabapentin 02-Pregabalin 03-Baclofen 04-Cyclobenzaprine 99-Other	*(DMGABA24)* ☐ 0-No ☐ 1-Yes	*(DMGABATL)* ☐ *(xxxxx.xx)*
If "Other", specify:*(DMGABASP)*			
14. Antacids:*(DMANTACD)*	01-Calcium carbonate 02-Simethicone 03-Sodium bicarbonate 99-Other	*(DMANTA24)* ☐ 0-No ☐ 1-Yes	*(DMANTATL)* ☐ *(xxxxxx.xx)*
If "Other", specify:*(DMANTASP)*			
15. Neuroleptics:*(DMNUERLP)*	01-Quetiapine 02-Olanzapine 03-Risperidone 04-Haloperidol 05-Chlorpromazine 99-Other	*(DMNUER24)* ☐ 0-No ☐ 1-Yes	*(DMNUERTL)* ☐ *(xxxxx.xx)*
If "Other", specify:*(DMNUERSP)*			
16. Naloxone:		*(DMNAL24)* ☐ 0-No ☐ 1-Yes	*(DMNALDTL)* ☐ *(xxxxx.xx)*
17. Benzodiazepines (IM), specify:*(DMBZOISP)* ☐		*(DMBZOI24)* ☐ 0-No ☐ 1-Yes	*(DMBZIDTL)* ☐ *(xxxxx.xx)*
18. Clonidine patch:		*(DMCLN24)* ☐ 0-No ☐ 1-Yes	*(DMCLNDTL)* ☐ *(xxxxx.xx)*
19. Buprenorphine patch:		*(DMBZOP24)* ☐ 0-No ☐ 1-Yes	*(DMBZPDTL)* ☐ *(xxxxx.xx)*
20. Methadone:		*(DMMTD24)* ☐ 0-No ☐ 1-Yes	*(DMMTDDTL)* ☐ *(xxxxx.xx)*
21. Other medication 1:*(DMOTMD01)* ☐		*(DMOM2401)* ☐ 0-No ☐ 1-Yes	*(DMOMTL01)* ☐ *(xxxxx.xx)*
22. Other medication 2:*(DMOTMD02)* ☐		*(DMOM2402)* ☐ 0-No ☐ 1-Yes	*(DMOMTL02)* ☐ *(xxxxx.xx)*
23. Other medication 3:*(DMOTMD03)* ☐		*(DMOM2403)* ☐ 0-No ☐ 1-Yes	*(DMOMTL03)* ☐ *(xxxxx.xx)*
24. Other medication 4:*(DMOTMD04)* ☐		*(DMOM2404)* ☐ 0-No ☐ 1-Yes	*(DMOMTL04)* ☐ *(xxxxx.xx)*
25. Other medication 5:*(DMOTMD05)* ☐		*(DMOM2405)* ☐ 0-No ☐ 1-Yes	*(DMOMTL05)* ☐ *(xxxxx.xx)*
26. Other medication 6:*(DMOTMD06)* ☐		*(DMOM2406)* ☐ 0-No ☐ 1-Yes	*(DMOMTL06)* ☐ *(xxxxx.xx)*
27. Other medication 7:*(DMOTMD07)* ☐		*(DMOM2407)* ☐ 0-No ☐ 1-Yes	*(DMOMTL07)* ☐ *(xxxxx.xx)*
28. Other medication 8:*(DMOTMD08)* ☐		*(DMOM2408)* ☐ 0-No ☐ 1-Yes	*(DMOMTL08)* ☐ *(xxxxx.xx)*
29. Other medication 9:*(DMOTMD09)* ☐		*(DMOM2409)* ☐ 0-No ☐ 1-Yes	*(DMOMTL09)* ☐ *(xxxxx.xx)*
30. Other medication 10:*(DMOTMD10)* ☐		*(DMOM2410)* ☐ 0-No ☐ 1-Yes	*(DMOMTL10)* ☐ *(xxxxx.xx)*

Comments:*(DMACOMM)* ☐

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.

0097C (ENR)

Version: 1.01; 12-06-21

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

Time of assessment:*(E97ASMTM)* *(hh:mm)* *(24-hour format)*

Date of admission:*(E97ADMDT)* *(mm/dd/yyyy)*

Time of admission:*(E97ADMTM)* *(hh:mm)* *(24-hour format)*

Inclusion Criteria

In order to meet eligibility ALL Inclusion answers must be "Yes" or "Not Applicable".

1. Is the participant 18 years of age or older?*(E97PTAGE)* ☐ 00-No ☐ 01-Yes ☐ 97-Not assessed
2. Does the participant meet current DSM-5 criteria for opioid use disorder?*(E97DSM5)* ☐ 00-No ☐ 01-Yes ☐ 97-Not assessed
3. Is the participant seeking treatment for opioid use disorder, willing to accept treatment with XR-NTX and, in the judgement of the treating physician, a good candidate for naltrexone-based treatment?*(E97STOUD)* ☐ 00-No ☐ 01-Yes ☐ 97-Not assessed
4. Is the participant willing and able to provide written informed consent?*(E97CNSNT)* ☐ 00-No ☐ 01-Yes ☐ 97-Not assessed
5. Is the participant able to speak English sufficiently to understand the study procedures and provide written informed consent to participate in the study?*(E97ENGLS)* ☐ 00-No ☐ 01-Yes ☐ 97-Not assessed
6. If the participant is of childbearing potential, is the participant willing to practice an effective method of birth control for the duration of participation in the study? *(E97BCUSE)* ☐ 00-No ☐ 01-Yes ☐ 97-Unknown ☐ 96-Not applicable

Exclusion Criteria

In order to meet eligibility ALL Exclusion answers must be "No" or "Not applicable".

7. Does the participant have a serious medical, psychiatric or substance use disorder that, in the opinion of the study physician, would make a detoxification and naltrexone initiation, or maintenance treatment with XR-NTX, hazardous (relative contra-indications)? Examples include:*(E97PSYCH)* ☐ 00-No ☐ 01-Yes ☐ 97-Not assessed
   a. Disabling or terminal medical illness (e.g., uncompensated heart failure, severe acute hepatitis, cirrhosis or end-stage liver disease) as assessed by medical history and/or review of systems.
   b. Severe, untreated or inadequately treated mental disorder (e.g., active psychosis, uncontrolled manic-depressive illness) as assessed by history and/or clinical interview.
   c. Current severe alcohol, benzodiazepine, or other depressant or sedative hypnotic use likely to require a complicated medical detoxification (routine alcohol and sedative detoxifications may be included).
   d. Suicidal or homicidal ideation that requires immediate attention.
8. Does the participant have a known allergy or sensitivity to buprenorphine, naloxone, naltrexone, polylactide-co-glycolide, carboxymethylcellulose, or other components of the Vivitrol® diluent?*(E97ALRGY)* ☐ 00-No ☐ 01-Yes ☐ 97-Not assessed
9. Is the participant on maintenance treatment with methadone?*(E97MTDDP)* ☐ 00-No ☐ 01-Yes ☐ 97-Not assessed
10. Is the participant on maintenance treatment with buprenorphine unless the patient is determined to have a poor treatment response (in the form of buprenorphine non-adherence with or without the use of illicit opioids), warranting change to XR-NTX treatment.*(E97BUPDP)* ☐ 00-No ☐ 01-Yes ☐ 97-Not assessed
11. Is the participant experiencing the presence of pain of sufficient severity as to require ongoing pain management with opioids?*(E97OPIDP)* ☐ 00-No ☐ 01-Yes ☐ 97-Not assessed
12. Is the participant experiencing circumstances (legal, personal, occupational) that would threaten the feasibility of XR-NTX treatment or make another treatment (e.g. buprenorphine or methadone) a better choice?*(E97CRCMS)* ☐ 00-No ☐ 01-Yes ☐ 97-Not assessed
13. Is the participant currently in jail, prison or other overnight facility as required by court of law or have pending legal action that could prevent participation in study activities? *(E97PRISN)* ☐ 00-No ☐ 01-Yes ☐ 97-Not assessed
14. If the participant is female, is the participant currently pregnant or breastfeeding, or planning on conception?*(E97PREG)* ☐ 00-No ☐ 01-Yes ☐ 97-Unknown ☐ 96-Not applicable
15. Does the participant have a body habitus that, in the judgment of the study physician, precludes safe intramuscular injection of XR-NTX (e.g., BMI>40, excess fat tissue over the buttocks, emaciation)?*(E97BHEXC)* ☐ 00-No ☐ 01-Yes ☐ 97-Not assessed
16. Was the participant admitted to the inpatient detoxification or residential rehabilitation unit more than 3 days prior to consent?*(E973DAYS)* ☐ 00-No ☐ 01-Yes ☐ 97-Not assessed
17. Was the participant admitted to the inpatient detoxification or residential rehabilitation unit more than 4 calendar days prior to the enrollment assessment date?*(E973DAYS)* ☐ 00-No ☐ 01-Yes ☐ 97-Not assessed

Eligibility for Enrollment

18. Is the participant eligible for enrollment into the study?*(E97ELGST)* ☐ 0-No ☐ 1-Yes
19. If the participant is eligible, will they be enrolled in the study?*(E97ELENR)* ☐ 0-No ☐ 1-Yes

0097D (ENR)

Version: 1.01; 12-06-21

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

Time of assessment:*(E97ASMTM)* *(hh:mm)* *(24-hour format)*

Date of admission:*(E97ADMDT)* *(mm/dd/yyyy)*

Time of admission:*(E97ADMTM)* *(hh:mm)* *(24-hour format)*

Inclusion Criteria

In order to meet eligibility ALL Inclusion answers must be "Yes" or "Not Applicable".

1. Is the participant 18 years of age or older?*(E97PTAGE)* ☐ 00-No ☐ 01-Yes ☐ 97-Not assessed
2. Does the participant meet current DSM-5 criteria for opioid use disorder?*(E97DSM5)* ☐ 00-No ☐ 01-Yes ☐ 97-Not assessed
3. Is the participant seeking treatment for opioid use disorder, willing to accept treatment with XR-NTX and, in the judgement of the treating physician, a good candidate for naltrexone-based treatment?*(E97STOUD)* ☐ 00-No ☐ 01-Yes ☐ 97-Not assessed
4. Is the participant willing and able to provide written informed consent?*(E97CNSNT)* ☐ 00-No ☐ 01-Yes ☐ 97-Not assessed
5. Is the participant able to speak English sufficiently to understand the study procedures and provide written informed consent to participate in the study?*(E97ENGLS)* ☐ 00-No ☐ 01-Yes ☐ 97-Not assessed
6. If the participant is of childbearing potential, is the participant willing to practice an effective method of birth control for the duration of participation in the study? *(E97BCUSE)* ☐ 00-No ☐ 01-Yes ☐ 97-Unknown ☐ 96-Not applicable

Exclusion Criteria

In order to meet eligibility ALL Exclusion answers must be "No" or "Not applicable".

7. Does the participant have a serious medical, psychiatric or substance use disorder that, in the opinion of the study physician, would make a detoxification and naltrexone initiation, or maintenance treatment with XR-NTX, hazardous (relative contra-indications)? Examples include:*(E97PSYCH)* ☐ 00-No ☐ 01-Yes ☐ 97-Not assessed
   a. Disabling or terminal medical illness (e.g., uncompensated heart failure, severe acute hepatitis, cirrhosis or end-stage liver disease) as assessed by medical history and/or review of systems.
   b. Severe, untreated or inadequately treated mental disorder (e.g., active psychosis, uncontrolled manic-depressive illness) as assessed by history and/or clinical interview.
   c. Current severe alcohol, benzodiazepine, or other depressant or sedative hypnotic use likely to require a complicated medical detoxification (routine alcohol and sedative detoxifications may be included).
   d. Suicidal or homicidal ideation that requires immediate attention.
8. Does the participant have a known allergy or sensitivity to buprenorphine, naloxone, naltrexone, polylactide-co-glycolide, carboxymethylcellulose, or other components of the Vivitrol® diluent?*(E97ALRGY)* ☐ 00-No ☐ 01-Yes ☐ 97-Not assessed
9. Is the participant on maintenance treatment with methadone?*(E97MTDDP)* ☐ 00-No ☐ 01-Yes ☐ 97-Not assessed
10. Is the participant on maintenance treatment with buprenorphine unless the patient is determined to have a poor treatment response (in the form of buprenorphine non-adherence with or without the use of illicit opioids), warranting change to XR-NTX treatment.*(E97BUPDP)* ☐ 00-No ☐ 01-Yes ☐ 97-Not assessed
11. Is the participant experiencing the presence of pain of sufficient severity as to require ongoing pain management with opioids?*(E97OPIDP)* ☐ 00-No ☐ 01-Yes ☐ 97-Not assessed
12. Is the participant experiencing circumstances (legal, personal, occupational) that would threaten the feasibility of XR-NTX treatment or make another treatment (e.g. buprenorphine or methadone) a better choice?*(E97CRCMS)* ☐ 00-No ☐ 01-Yes ☐ 97-Not assessed
13. Is the participant currently in jail, prison or other overnight facility as required by court of law or have pending legal action that could prevent participation in study activities? *(E97PRISN)* ☐ 00-No ☐ 01-Yes ☐ 97-Not assessed
14. If the participant is female, is the participant currently pregnant or breastfeeding, or planning on conception?*(E97PREG)* ☐ 00-No ☐ 01-Yes ☐ 97-Unknown ☐ 96-Not applicable
15. Does the participant have a body habitus that, in the judgment of the study physician, precludes safe intramuscular injection of XR-NTX (e.g., BMI>40, excess fat tissue over the buttocks, emaciation)?*(E97BHEXC)* ☐ 00-No ☐ 01-Yes ☐ 97-Not assessed
16. Was the participant admitted to the inpatient detoxification or residential rehabilitation unit more than 3 days prior to consent?*(E973DAYS)* ☐ 00-No ☐ 01-Yes ☐ 97-Not assessed
17. Was the participant admitted to the inpatient detoxification or residential rehabilitation unit more than 4 calendar days prior to the enrollment assessment date?*(E973DAYS)* ☐ 00-No ☐ 01-Yes ☐ 97-Not assessed

Eligibility for Enrollment

18. Is the participant eligible for enrollment into the study?*(E97ELGST)* ☐ 0-No ☐ 1-Yes
19. If the participant is eligible, will they be enrolled in the study?*(E97ELENR)* ☐ 0-No ☐ 1-Yes

a. If "No", specify: *(E97NORSP)*

- 00-No longer interested in participating in the study
- 02-Judgment of site/research staff
- 05-Time commitment
- 07-Left prior to completion
- 92-COVID-19: Illness
- 93-COVID-19: Public health measures
- 94-COVID-19: Other
- 99-Other

1. If "Other", specify: *(E97OTHSP)*

Comments: *(E97COMM)*

a. If "No", specify: *(E97NORSP)*

- 00-No longer interested in participating in the study
- 02-Judgment of site/research staff
- 05-Time commitment
- 07-Left prior to completion
- 92-COVID-19: Illness
- 93-COVID-19: Public health measures
- 94-COVID-19: Other
- 99-Other

1. If "Other", specify: *(E97OTHSP)*

Comments: *(E97COMM)*

End of Induction Survey (EIP)

Version: 1.01; 03-30-21

Segment *(PROTSEG)*: C, D

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

1. Staff provided adequate information and education about medications for opioid use disorder **before** you entered the study.

	01-Strongly Disagree	02-Disagree	03-Not Sure	04-Agree	05-Strongly Agree
(EISTFEDU)	☐	☐	☐	☐	☐

2. Staff were available and supportive throughout your time on the detoxification unit.

	01-Strongly Disagree	02-Disagree	03-Not Sure	04-Agree	05-Strongly Agree
(EISTFAVL)	☐	☐	☐	☐	☐

3. In general, you were satisfied with the process toward starting on XR-NTX (Vivitrol) on the unit.

	01-Strongly Disagree	02-Disagree	03-Not Sure	04-Agree	05-Strongly Agree
(EISATVIV)	☐	☐	☐	☐	☐

4. The medications you received adequately managed your opioid withdrawal symptoms.

	01-Strongly Disagree	02-Disagree	03-Not Sure	04-Agree	05-Strongly Agree
(EIOPMANG)	☐	☐	☐	☐	☐

5. Compared to previous experiences on detoxification units, this taper process and experience was:

	01-Much Worse	02-Worse	03-The Same	04-Better	05-Much Better	96-Not Applicable
(EIDTXEXP)	☐	☐	☐	☐	☐	☐

6. How would you describe the length of time to receive your first XR-NTX (Vivitrol) naltrexone shot?

	01-Too Short	02-Short	03-About Right	04-Long	05-Too Long	96-Not Applicable
(EIVIVTME)	☐	☐	☐	☐	☐	☐

7. At this time, how motivated are you to continue treatment for opioid use disorder?

	Not Motivated at All									Very Motivated
	1	2	3	4	5	6	7	8	9	10
	01-	02-	03-	04-	05-	06-	07-	08-	09-	10-
(EITRTMOT)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Participant requires 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. (EIPRAHLP)
☐ 01-Yes

Comments:*(EIPCOMM)*

End of Induction (EOI)

Version: 1.01; 05-19-21

Segment *(PROTSEG)*: C, D

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

Inpatient admission date:*(EOIADMDT)* *(mm/dd/yyyy)*

Transferred to residential:*(EIRESTRN)* ☐ 0-No ☐ 1-Yes Date:*(EITRNSDT)* *(mm/dd/yyyy)*

This survey is administered by the Research Assistant at the end of induction/receipt of 1st XR-NTX OR if the participant terminates the induction phase of study treatment early for any reason. If the participant is not available in-person to complete this, the Research Assistant should attempt to complete this assessment over the phone with the participant.

1. Did the participant receive extended-release naltrexone during the induction phase of study treatment?*(EINTXIND)* ☐ 0-No ☐ 1-Yes
   a. If "Yes", specify the following:
      1. Date of injection:*(EOIINJDT)* *(mm/dd/yyyy)*
      2. Time of injection:*(EOIINJTM)* *(hh:mm) (24-hour clock)*
      3. Location of injection:*(EIINJLOC)* ☐ 01-Right buttock ☐ 02-Left buttock
   b. If "No", date participant terminated induction protocol:*(EITERMDT)* *(mm/dd/yyyy)*
   c. If "No", reason(s) why:
      Check all that apply.
      1. Prefers other medication (buprenorphine or methadone):*(EIPREFMD)* ☐ 01-
      2. Prefers to not be on medication for opioid use disorder:*(EINOMOUD)* ☐ 01-
      3. Does not want naltrexone since it blocks opioids and prevents high:*(EIPREVHI)* ☐ 01-
      4. Fear of precipitated withdrawal from naltrexone shot:*(EIFEARWD)* ☐ 01-
      5. Withdrawal symptoms were too uncomfortable:*(EIWITHDR)* ☐ 01-
      6. Left detox unit early:*(EILEFTDX)* ☐ 01-
      7. Medical contraindication (including pregnancy, COVID-19 infection):*(EIMEDCON)* ☐ 01-
      8. Psychiatric contraindication:*(EIPSYCON)* ☐ 01-
      9. Other:*(EINTXOTH)* ☐ 01-
         1. If "Other", specify:*(EINTXRSP)*
2. Did the participant leave the unit prior to completing induction?*(EIDETOX)* ☐ 0-No ☐ 1-Yes
   a. If "Yes", date participant left unit:*(EILEFTDT)* *(mm/dd/yyyy)*
   b. If "Yes", reason(s) why:
      Check all that apply.
      1. Withdrawal symptoms were too uncomfortable:*(EIDTXWTD)* ☐ 01-
      2. Insurance would not cover stay:*(EIINSUR)* ☐ 01-
      3. Employment obligation:*(EIEMPLOY)* ☐ 01-
      4. Legal obligation/issue:*(EILEGAL)* ☐ 01-
      5. Family obligation:*(EIFAMILY)* ☐ 01-
      6. Concerned about contracting COVID-19:*(EICOVID)* ☐ 01-
      7. Disliked or argued with staff:*(EIDISLIK)* ☐ 01-
      8. Disliked or argued with peers:*(EIPEERS)* ☐ 01-
      9. Admitted for medical issue:*(EIMEDISS)* ☐ 01-
      10. Admitted for psychiatric issue:*(EIPSYISS)* ☐ 01-
      11. Other:*(EILEVOTH)* ☐ 01-
         1. If "Other", specify:*(EILVRSP)*
3. Is there a plan for the participant to continue on medication for opioid use disorder? *(EICMOUD)* ☐ 0-No ☐ 1-Yes
   a. If "Yes" which one?*(EIWMOUD)*
      01-Buprenorphine
      02-Injectable buprenorphine
      03-Methadone
      04-Injectable naltrexone
      05-Oral naltrexone
   b. If "No", reason(s) why:
      Check all that apply.
      1. Participant declined, did not specify why:*(EIDECLIN)* ☐ 01-
      2. Participant preferred to reduce opioid use or become abstinent without medication: *(EIABSTIN)* ☐ 01-

3. Participant believed he/she was cured and did not need further treatment: *(EICURED)* ☐ 01-
4. Participant felt judged or criticized by others for being on medication: *(EISTIGMA)* ☐ 01-
5. Other: *(EICONOTH)* ☐ 01-
   1. If "Other", specify: *(EIMOUDSP)*

Comments: *(EOICOMM)*

Family Origin (FAM)

Version: 2.00; 04-25-22

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

Date of assessment:*(FAMASMDT)* ☐ *(mm/dd/yyyy)*

1. **Participant**
   a. Place of birth: (country, state, or region; not city) *(FAPTPOB)*
   b. Ancestry: (country, state, or region; not city) *(FAPTANCS)*
2. **Biological Mother**
   a. Race:
      1. American Indian or Alaska Native:*(FABMINDN)* ☐ 0-No ☐ 1-Yes
      2. Asian:*(FABMASAN)* ☐ 0-No ☐ 1-Yes
      3. Black or African American:*(FABMBLCK)* ☐ 0-No ☐ 1-Yes
      4. Native Hawaiian or Pacific Islander:*(FABMISLN)* ☐ 0-No ☐ 1-Yes
      5. White:*(FABMWHTE)* ☐ 0-No ☐ 1-Yes
      6. Unknown:*(FABMRUK)* ☐ 01-
      7. Participant chooses not to provide information:*(FABMRREF)* ☐ 01-
   b. Ethnicity:*(FABMETHN)*

      1-Hispanic or Latino
      2-Not Hispanic or Latino
      97-Unknown
      98-Participant chooses not to answer

   c.Place of birth: (country, state, or region; not city) *(FABMPOB)*
   d.Ancestry: (country, state, or region; not city) *(FABMANCS)*
3. **Biological Father**
   a. Race:
      1. American Indian or Alaska Native:*(FABFINDN)* ☐ 0-No ☐ 1-Yes
      2.Asian:*(FABFASAN)* ☐ 0-No ☐ 1-Yes
      3.Black or African American:*(FABFBLCK)* ☐ 0-No ☐ 1-Yes
      4.Native Hawaiian or Pacific Islander:*(FABFISLN)* ☐ 0-No ☐ 1-Yes
      5.White:*(FABFWHTE)* ☐ 0-No ☐ 1-Yes
      6. Unknown:*(FABFRUK)* ☐ 01-
      7. Participant chooses not to provide information: *(FABFRREF)* ☐ 01-
      b. Ethnicity:*(FABFETHN)*

      1-Hispanic or Latino
      2-Not Hispanic or Latino
      97-Unknown
      98-Participant chooses not to answer

   c. Place of birth: (country, state, or region; not city) *(FABFPOB)*
   d. Ancestry: (country, state, or region; not city) *(FABFANCS)*
4. **Maternal Grandmother *(your biological mom's mom)***
   a. Race:
      1. American Indian or Alaska Native:*(FAMMINDN)* ☐ 0-No ☐ 1-Yes
      2. Asian:*(FAMMASAN)* ☐ 0-No ☐ 1-Yes
      3. Black or African American:*(FAMMBLCK)* ☐ 0-No ☐ 1-Yes
      4. Native Hawaiian or Pacific Islander:*(FAMMISLN)* ☐ 0-No ☐ 1-Yes
      5. White:*(FAMMWHTE)* ☐ 0-No ☐ 1-Yes
      6. Unknown:*(FAMMRUK)* ☐ 01-
      7. Participant chooses not to provide information: *(FAMMRREF)* ☐ 01-

b. Ethnicity:*(FAMMETHN)*

1-Hispanic or Latino
2-Not Hispanic or Latino
97-Unknown
98-Participant chooses not to answer

c. Place of birth: (country, state, or region; not city) *(FAMMPOB)*

d. Ancestry: (country, state, or region; not city) *(FAMMANCS)*

5. **Maternal Grandfather *(your biological mom's dad)***

a. Race:

1. American Indian or Alaska Native:*(FAMFINDN)* ☐ 0-No ☐ 1-Yes
2. Asian:*(FAMFASAN)* ☐ 0-No ☐ 1-Yes
3. Black or African American:*(FAMFBLCK)* ☐ 0-No ☐ 1-Yes
4. Native Hawaiian or Pacific Islander:*(FAMFISLN)* ☐ 0-No ☐ 1-Yes
5. White:*(FAMFWHTE)* ☐ 0-No ☐ 1-Yes
6. Unknown:*(FAMFRUK)* ☐ 01-
7. Participant chooses not to provide information: *(FAMFRREF)* ☐ 01-

b. Ethnicity:*(FAMFETHN)*

1-Hispanic or Latino
2-Not Hispanic or Latino
97-Unknown
98-Participant chooses not to answer

c. Place of birth: (country, state, or region; not city) *(FAMFPOB)*

d. Ancestry: (country, state, or region; not city) *(FAMFANCS)*

6. **Paternal Grandmother *(your biological dad's mom)***

a. Race:

1. American Indian or Alaska Native:*(FAPMINDN)* ☐ 0-No ☐ 1-Yes
2. Asian:*(FAPMASAN)* ☐ 0-No ☐ 1-Yes
3. Black or African American:*(FAPMBLCK)* ☐ 0-No ☐ 1-Yes
4. Native Hawaiian or Pacific Islander:*(FAPMISLN)* ☐ 0-No ☐ 1-Yes
5. White:*(FAPMWHTE)* ☐ 0-No ☐ 1-Yes
6. Unknown:*(FAPMRUK)* ☐ 01-
7 Participant chooses not to provide information:*(FAPMRREF)* ☐ 01-

b. Ethnicity:*(FAPMETHN)*

1-Hispanic or Latino
2-Not Hispanic or Latino
97-Unknown
98-Participant chooses not to answer

c. Place of birth: (country, state, or region; not city) *(FAPMPOB)*

d. Ancestry: (country, state, or region; not city) *(FAPMANCS)*

7. P**aternal Grandfather *(your biological dad's dad)***

a. Race:

1. American Indian or Alaska Native:*(FAPFINDN)* ☐ 0-No ☐ 1-Yes
2. Asian:*(FAPFASAN)* ☐ 0-No ☐ 1-Yes
3. Black or African American:*(FAPFBLCK)* ☐ 0-No ☐ 1-Yes
4. Native Hawaiian or Pacific Islander:*(FAPFISLN)* ☐ 0-No ☐ 1-Yes
5. White:*(FAPFWHTE)* ☐ 0-No ☐ 1-Yes
6. Unknown:*(FAPFRUK)* ☐ 01-
7. Participant chooses not to provide information: *(FAPFRREF)* ☐ 01-

b. Ethnicity:*(FAPFETHN)*

1-Hispanic or Latino
2-Not Hispanic or Latino
97-Unknown
98-Participant chooses not to answer

c. Place of birth: (country, state, or region; not city)
(FAPFPOB)

d. Ancestry: (country, state, or region; not city)
(FAPFANCS)

Comments:*(FAMCOMM)*

Fagerstrom Test for Nicotine Dependence (FND)

Version: 1.02; 04-26-21

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

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

Do you currently smoke cigarettes?*(FNSMOKE)* ☐ 0-No ☐ 1-Yes

If "Yes", read each of the following questions. For each question enter the answer choice which best describes your responses.

1. How soon after you wake up do you smoke your first cigarette?*(FNFIRST)*
   - 03-Within 5 minutes
   - 02-6 - 30 minutes
   - 01-31 - 60 minutes
   - 00-After 60 minutes
2. Do you find it difficult to refrain from smoking in places where it is forbidden (e.g., in church, at the library, in cinema)?*(FNFORBDN)* ☐ 0-No ☐ 1-Yes
3. Which cigarette would you hate most to give up?*(FNGIVEUP)* ☐ 01-The first one in the morning ☐ 00-All others
4. How many cigarettes a day do you smoke?*(FNNODAY)*
   - 00-10 or less
   - 01-11-20
   - 02-21-30
   - 03-31 or more
5. Do you smoke more frequently during the first hours after waking than during the rest of the day?*(FNFREQ)* ☐ 0-No ☐ 1-Yes
6. Do you smoke if you are so ill that you are in bed most of the day?*(FNSICK)* ☐ 0-No ☐ 1-Yes

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.(FNDRAHLP)

Comments:*(FNDCOMM)* _____

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

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)*	☐	☐	☐	☐
2. Not being able to stop or control worrying: *(GAUSWOR)*	☐	☐	☐	☐
3. Worrying too much about different things: *(GAWORTM)*	☐	☐	☐	☐
4. Trouble relaxing: *(GATBRLX)*	☐	☐	☐	☐
5. Being so restless that it's hard to sit still: *(GAHDSIT)*	☐	☐	☐	☐
6. Becoming easily annoyed or irritable: *(GAEASAN)*	☐	☐	☐	☐
7. Feeling afraid as if something awful might happen: *(GAFLAFR)*	☐	☐	☐	☐

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.
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. (GARAHLP)

☐ 01-Yes

Comments:*(GA7COMM)*

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

Genetics (GEN)

Version: 1.01; 07-30-21

Segment *(PROTSEG)*: C, D

1. Was a saliva sample collected?*(GESMPSAL)* ☐ 0-No ☐ 1-Yes
   a. If "Yes", date sample collected:*(GETAKNDT)* _____ *(mm/dd/yyyy)*
   b. RUCDR subject code:*(GESITEID)* _____ - *(GEPARTID)* _____
   c. Alternate ID:*(GEALTID)* _____
   d. If "Yes", date sample shipped:*(GESHIPDT)* _____ *(mm/dd/yyyy)*
   e. If "No", reason sample was not collected:*(GENORSN)*

- 01-Phlebotomist unable to draw sample
- 02-Phlebotomist not available to draw sample
- 03-Withdrew consent
- 05-Participant ate/drank/smoked/chewed gum <30 minutes prior to sample collection
- 06-Participant could not provide enough saliva (e.g., dry mouth)
- 07-Participant lost to follow-up before sample collected
- 08-Sample collected under a different CTN protocol
- 92-COVID-19: Illness
- 93-COVID-19: Public health measures
- 94-COVID-19: Other
- 98-Participant refused to provide sample

2. Was genetic sample consent withdrawn?*(GECNSWTH)* ☐ 0-No ☐ 1-Yes
   a. If "Yes", date withdrawn:*(GECWTHDT)* _____ *(mm/dd/yyyy)*

Comments:*(GENCOMM)*

Self-Report of Hepatitis Testing and Treatment (HEP)

Version: 1.00; 03-30-21

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

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

1. Have you ever been tested for Hepatitis C?*(HEHCVTST)*

00-No
01-Yes
97-Don't know
98-Refused to answer

2. What was the result of your most recent Hepatitis C test?*(HEHCVRES)*

00-Negative
01-Positive
97-Don't know
98-Refused to answer

a. If "Positive", have you ever been treated for Hepatitis C?*(HEHCVTRT)*

00-No
01-Yes
97-Don't know
98-Refused to answer

1. If "Yes", are you still in treatment for Hepatitis C?*(HEHCVCT)*

00-No
01-Yes
97-Don't know
98-Refused to answer

3. Have you ever been tested for Hepatitis B?*(HEHBVTST)*

00-No
01-Yes
97-Don't know
98-Refused to answer

4. What was the result of your most recent Hepatitis B test?*(HEHBVRES)*

00-Negative
01-Positive
97-Don't know
98-Refused to answer

Participant required research staff assistance in reading the question 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.(HEPRAHLP)

☐ 01-Yes

Comments:*(HEPCOMM)*

Self-Report of HIV Testing (HIV)

Version: 2.00; 07-30-21

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

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

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

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

- 00-No
- 01-Yes
- 97-Don't know
- 98-Refused to answer

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

(HIVTSTMO) _____ *(xx)* month *(HIVTSTYR)* _____ *(xxxx)* year

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

- 00-Negative
- 01-Positive
- 03-Never obtained results
- 04-Indeterminate
- 97-Don't know
- 98-Refused to answer

a. Have you ever been treated for HIV?*(HIVTREAT)*

☐ 00-No ☐ 01-Yes ☐ 97-Don't know ☐ 98-Refused to answer

1. Are you still in treatment for HIV?*(HIVINTRE)*

☐ 00-No ☐ 01-Yes ☐ 97-Don't know ☐ 98-Refused to answer

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

- 01-You think you are at a low risk for HIV infection
- 02-You were afraid of finding out that you had HIV
- 03-You didn't have time
- 04-Some other reason
- 05-No particular reason
- 97-Don't know
- 98-Refused to answer

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.(HIVRAHLP)

☐ 01-Yes

Comments:*(HIVCOMM)*

Low Dose Naltrexone Titration (LDN)

Version: 2.00; 12-28-21

Segment *(PROTSEG)*: D
Visit Number *(VISNO)*:

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

Section A

1. Did a low dose naltrexone titration occur on this day?*(LDTITDY)* ☐ 0-No ☐ 1-Yes

   If "No", please explain here why not *(select all that apply)*:

   a. Patient declined:*(LDPTDECL)* ☐ 01-
   b. Clinician's concern:*(LDCLCONC)* ☐ 01-
   c. Not indicated by the Rapid Procedure:*(LDNTIRP)* ☐ 01-
   d. Other:*(LDNTDOTH)* ☐ 01-
      1. If "Other", specify:*(LDNTDOSP)*

   Comments:*(LDNCOMM)*

Timeline Followback Medications (M97)

Version: 4.00; 01-11-22

Segment *(PROTSEG)*: C, D, E
, **TFB week start date *(TFWKSTDT)*:**

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

10. Zolpidem:	*(TLZOLP1)* ☐ 0-No ☐ 1-Yes	*(TLZOLP2)* ☐ 0-No ☐ 1-Yes	*(TLZOLP3)* ☐ 0-No ☐ 1-Yes	*(TLZOLP4)* ☐ 0-No ☐ 1-Yes	*(TLZOLP5)* ☐ 0-No ☐ 1-Yes	*(TLZOLP6)* ☐ 0-No ☐ 1-Yes	*(TLZOLP7)* ☐ 0-No ☐ 1-Yes
Dose:	*(TLZOLPD1)* *(xx.x)* mg	*(TLZOLPD2)* *(xx.x)* mg	*(TLZOLPD3)* *(xx.x)* mg	*(TLZOLPD4)* *(xx.x)* mg	*(TLZOLPD5)* *(xx.x)* mg	*(TLZOLPD6)* *(xx.x)* mg	*(TLZOLPD7)* *(xx.x)* mg
11. Trazodone	*(TLTRAZ1)* ☐ 0-No ☐ 1-Yes	*(TLTRAZ2)* ☐ 0-No ☐ 1-Yes	*(TLTRAZ3)* ☐ 0-No ☐ 1-Yes	*(TLTRAZ4)* ☐ 0-No ☐ 1-Yes	*(TLTRAZ5)* ☐ 0-No ☐ 1-Yes	*(TLTRAZ6)* ☐ 0-No ☐ 1-Yes	*(TLTRAZ7)* ☐ 0-No ☐ 1-Yes
Dose:	*(TLTRAZD1)* *(xxxx)* mg	*(TLTRAZD2)* *(xxxx)* mg	*(TLTRAZD3)* *(xxxx)* mg	*(TLTRAZD4)* *(xxxx)* mg	*(TLTRAZD5)* *(xxxx)* mg	*(TLTRAZD6)* *(xxxx)* mg	*(TLTRAZD7)* *(xxxx)* mg
12. Other:	*(TLOTH1)* ☐ 0-No ☐ 1-Yes	*(TLOTH2)* ☐ 0-No ☐ 1-Yes	*(TLOTH3)* ☐ 0-No ☐ 1-Yes	*(TLOTH4)* ☐ 0-No ☐ 1-Yes	*(TLOTH5)* ☐ 0-No ☐ 1-Yes	*(TLOTH6)* ☐ 0-No ☐ 1-Yes	*(TLOTH7)* ☐ 0-No ☐ 1-Yes
Specify other:	*(TLOTHSP1)*	*(TLOTHSP2)*	*(TLOTHSP3)*	*(TLOTHSP4)*	*(TLOTHSP5)*	*(TLOTHSP6)*	*(TLOTHSP7)*
Dose:	*(TLOTHSD1)* *(xxxx.xx)* mg	*(TLOTHSD2)* *(xxxx.xx)* mg	*(TLOTHSD3)* *(xxxx.xx)* mg	*(TLOTHSD4)* *(xxxx.xx)* mg	*(TLOTHSD5)* *(xxxx.xx)* mg	*(TLOTHSD6)* *(xxxx.xx)* mg	*(TLOTHSD7)* *(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)*	*(mm/dd/yyyy)*	*(MGPNRT01)* ☐ 01-In-Person ☐ 02-Remote	*(MGCOMM01)*
2. *(MGMMDT02)*	*(mm/dd/yyyy)*	*(MGPNRT02)* ☐ 01-In-Person ☐ 02-Remote	*(MGCOMM02)*
3. *(MGMMDT03)*	*(mm/dd/yyyy)*	*(MGPNRT03)* ☐ 01-In-Person ☐ 02-Remote	*(MGCOMM03)*
4. *(MGMMDT04)*	*(mm/dd/yyyy)*	*(MGPNRT04)* ☐ 01-In-Person ☐ 02-Remote	*(MGCOMM04)*
5. *(MGMMDT05)*	*(mm/dd/yyyy)*	*(MGPNRT05)* ☐ 01-In-Person ☐ 02-Remote	*(MGCOMM05)*
6. *(MGMMDT06)*	*(mm/dd/yyyy)*	*(MGPNRT06)* ☐ 01-In-Person ☐ 02-Remote	*(MGCOMM06)*
7. *(MGMMDT07)*	*(mm/dd/yyyy)*	*(MGPNRT07)* ☐ 01-In-Person ☐ 02-Remote	*(MGCOMM07)*
8. *(MGMMDT08)*	*(mm/dd/yyyy)*	*(MGPNRT08)* ☐ 01-In-Person ☐ 02-Remote	*(MGCOMM08)*
9. *(MGMMDT09)*	*(mm/dd/yyyy)*	*(MGPNRT09)* ☐ 01-In-Person ☐ 02-Remote	*(MGCOMM09)*
10. *(MGMMDT10)*	*(mm/dd/yyyy)*	*(MGPNRT10)* ☐ 01-In-Person ☐ 02-Remote	*(MGCOMM10)*
11. *(MGMMDT11)*	*(mm/dd/yyyy)*	*(MGPNRT11)* ☐ 01-In-Person ☐ 02-Remote	*(MGCOMM11)*
12. *(MGMMDT12)*	*(mm/dd/yyyy)*	*(MGPNRT12)* ☐ 01-In-Person ☐ 02-Remote	*(MGCOMM12)*
13. *(MGMMDT13)*	*(mm/dd/yyyy)*	*(MGPNRT13)* ☐ 01-In-Person ☐ 02-Remote	*(MGCOMM13)*
14. *(MGMMDT14)*	*(mm/dd/yyyy)*	*(MGPNRT14)* ☐ 01-In-Person ☐ 02-Remote	*(MGCOMM14)*
15. *(MGMMDT15)*	*(mm/dd/yyyy)*	*(MGPNRT15)* ☐ 01-In-Person ☐ 02-Remote	*(MGCOMM15)*
16. *(MGMMDT16)*	*(mm/dd/yyyy)*	*(MGPNRT16)* ☐ 01-In-Person ☐ 02-Remote	*(MGCOMM16)*
17. *(MGMMDT17)*	*(mm/dd/yyyy)*	*(MGPNRT17)* ☐ 01-In-Person ☐ 02-Remote	*(MGCOMM17)*

18. *(MGMMDT18)* *(mm/dd/yyyy)* *(MGPNRT18)* ☐ 01-In-Person ☐ 02-Remote *(MGCOMM18)*

19. *(MGMMDT19)* *(mm/dd/yyyy)* *(MGPNRT19)* ☐ 01-In-Person ☐ 02-Remote *(MGCOMM19)*

20. *(MGMMDT20)* *(mm/dd/yyyy)* *(MGPNRT20)* ☐ 01-In-Person ☐ 02-Remote *(MGCOMM20)*

21. *(MGMMDT21)* *(mm/dd/yyyy)* *(MGPNRT21)* ☐ 01-In-Person ☐ 02-Remote *(MGCOMM21)*

22. *(MGMMDT22)* *(mm/dd/yyyy)* *(MGPNRT22)* ☐ 01-In-Person ☐ 02-Remote *(MGCOMM22)*

23. *(MGMMDT23)* *(mm/dd/yyyy)* *(MGPNRT23)* ☐ 01-In-Person ☐ 02-Remote *(MGCOMM23)*

24. *(MGMMDT24)* *(mm/dd/yyyy)* *(MGPNRT24)* ☐ 01-In-Person ☐ 02-Remote *(MGCOMM24)*

25. *(MGMMDT25)* *(mm/dd/yyyy)* *(MGPNRT25)* ☐ 01-In-Person ☐ 02-Remote *(MGCOMM25)*

26. *(MGMMDT26)* *(mm/dd/yyyy)* *(MGPNRT26)* ☐ 01-In-Person ☐ 02-Remote *(MGCOMM26)*

27. *(MGMMDT27)* *(mm/dd/yyyy)* *(MGPNRT27)* ☐ 01-In-Person ☐ 02-Remote *(MGCOMM27)*

28. *(MGMMDT28)* *(mm/dd/yyyy)* *(MGPNRT28)* ☐ 01-In-Person ☐ 02-Remote *(MGCOMM28)*

29. *(MGMMDT29)* *(mm/dd/yyyy)* *(MGPNRT29)* ☐ 01-In-Person ☐ 02-Remote *(MGCOMM29)*

30. *(MGMMDT30)* *(mm/dd/yyyy)* *(MGPNRT30)* ☐ 01-In-Person ☐ 02-Remote *(MGCOMM30)*

31. *(MGMMDT31)* *(mm/dd/yyyy)* *(MGPNRT31)* ☐ 01-In-Person ☐ 02-Remote *(MGCOMM31)*

32. *(MGMMDT32)* *(mm/dd/yyyy)* *(MGPNRT32)* ☐ 01-In-Person ☐ 02-Remote *(MGCOMM32)*

33. *(MGMMDT33)* *(mm/dd/yyyy)* *(MGPNRT33)* ☐ 01-In-Person ☐ 02-Remote *(MGCOMM33)*

34. *(MGMMDT34)* *(mm/dd/yyyy)* *(MGPNRT34)* ☐ 01-In-Person ☐ 02-Remote *(MGCOMM34)*

35. *(MGMMDT35)* *(mm/dd/yyyy)* *(MGPNRT35)* ☐ 01-In-Person ☐ 02-Remote *(MGCOMM35)*

36. *(MGMMDT36)* *(mm/dd/yyyy)* *(MGPNRT36)* ☐ 01-In-Person ☐ 02-Remote *(MGCOMM36)*

37. *(MGMMDT37)* *(mm/dd/yyyy)* *(MGPNRT37)* ☐ 01-In-Person ☐ 02-Remote *(MGCOMM37)*

38. *(MGMMDT38)* *(mm/dd/yyyy)* *(MGPNRT38)* ☐ 01-In-Person ☐ 02-Remote *(MGCOMM38)*

39. *(MGMMDT39)* *(mm/dd/yyyy)* *(MGPNRT39)* ☐ 01-In-Person ☐ 02-Remote *(MGCOMM39)*

40. *(MGMMDT40)* *(mm/dd/yyyy)* *(MGPNRT40)* ☐ 01-In-Person ☐ 02-Remote *(MGCOMM40)*

41. *(MGMMDT41)* *(mm/dd/yyyy)* *(MGPNRT41)* ☐ 01-In-Person ☐ 02-Remote *(MGCOMM41)*

42. *(MGMMDT42)* *(mm/dd/yyyy)* *(MGPNRT42)* ☐ 01-In-Person ☐ 02-Remote *(MGCOMM42)*

43. *(MGMMDT43)* *(mm/dd/yyyy)* *(MGPNRT43)* ☐ 01-In-Person ☐ 02-Remote *(MGCOMM43)*

44. *(MGMMDT44)* *(mm/dd/yyyy)* *(MGPNRT44)* ☐ 01-In-Person ☐ 02-Remote *(MGCOMM44)*

45. *(MGMMDT45)* *(mm/dd/yyyy)* *(MGPNRT45)* ☐ 01-In-Person ☐ 02-Remote *(MGCOMM45)*

46. *(MGMMDT46)* *(mm/dd/yyyy)* *(MGPNRT46)* ☐ 01-In-Person ☐ 02-Remote *(MGCOMM46)*

47. *(MGMMDT47)* *(mm/dd/yyyy)* *(MGPNRT47)* ☐ 01-In-Person ☐ 02-Remote *(MGCOMM47)*

48. *(MGMMDT48)* *(mm/dd/yyyy)* *(MGPNRT48)* ☐ 01-In-Person ☐ 02-Remote *(MGCOMM48)*

49. *(MGMMDT49)* *(mm/dd/yyyy)* *(MGPNRT49)* ☐ 01-In-Person ☐ 02-Remote *(MGCOMM49)*

50. *(MGMMDT50)* *(mm/dd/yyyy)* *(MGPNRT50)* ☐ 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)*

Cannabis Use Assessment (MJA)

Version: 1.02; 03-30-21

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

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

When we use the term 'marijuana/cannabis' we are referring to marijuana, cannabis concentrates, edibles, tinctures and other inhaled or consumed products made with marijuana or cannabis. We are not referring to lotions, ointment, and CBD-only (e.g., hemp) products.

1. How often in the past 12 months have you used marijuana/cannabis? *(MJYRFREQ)*

04-Daily or Almost Daily	03-Weekly	02-Monthly	01-Less Than Monthly	00-Never
☐	☐	☐	☐	☐

2. When you used marijuana/cannabis during the past 12 months, was it: *(MJREASON)*

01-For medical reasons
02-For non-medical reasons
03-For both medical and non-medical reasons

3. During the past 12 months, have you used marijuana/cannabis to help you manage any of the following:

		0-No	1-Yes
a. Pain:	*(MJPAIN)*	☐	☐
b. Muscle spasm:	*(MJMSPASM)*	☐	☐
c. Seizures:	*(MJSEIZUR)*	☐	☐
d. Nausea or vomiting:	*(MJNAUSEA)*	☐	☐
e. Sleep:	*(MJSLEEP)*	☐	☐
f. Stress:	*(MJSTRESS)*	☐	☐
g. Appetite:	*(MJAPPETI)*	☐	☐
h. Worry or anxiety:	*(MJANXTY)*	☐	☐
i. Depression or sadness:	*(MJDEPRES)*	☐	☐
j. Focus or concentration:	*(MJFOCUS)*	☐	☐
k. Other symptoms (please specify):*(MJMOTHS2)*	*(MJUSOTH2)*		☐ **01-Yes**
l. None of the above:	*(MJNONE)*		☐ **01-Yes**

4. During the past 12 months, did you use marijuana/cannabis to *replace, reduce* or *stop* use of opioids (such as oxycodone, heroin, fentanyl, codeine, Vicodin, OxyContin or methadone)?*(MJSTOPI)* ☐ 0-No ☐ 1-Yes

5. During the past 12 months, how did you use marijuana/cannabis? *Please select all that apply.*
   a. Smoked it (for example, in a joint, bong, blunt, spliff or pipe):*(MJSMOKE)* ☐ 01-Yes
   b. Vaporized it (for example, hash oil in an e-cigarette-like vaporizer, vape pen or another vaporizing device):*(MJVAPE)* ☐ 01-Yes
   c. Ate it (for example, in brownies, cakes, cookies or candy):*(MJATE)* ☐ 01-Yes
   d. Used it some other way:*(MJUOTHER)* ☐ 01- Yes
   1. If "Used it some other way", please specify:*(MJUOTHSP)*

These next questions ask you to consider all the ways you typically use marijuana/cannabis.

6. How many days per week do you typically use marijuana/cannabis?*(MJWKFREQ)*

00-Less than 1
01-1
02-2
03-3
04-4
05-5
06-6
07-7

7. On a typical day that you use any marijuana/cannabis, how many times per day do you use it?*(MJDYFREQ)*

01-Less than 1
02-1
03-2
04-3-4
05-5-9
06-10 or more

8. How do you feel marijuana/cannabis use affects your life?*(MJLIFE)*

(xxxx)

9. Do you have a certificate or card for medical marijuana?*(MJCARD)*

☐ 0-No ☐ 1-Yes

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.(MJARAHLP)

☐ 01-Yes

Comments:*(MJACOMM)*

Motivation Scale (MTV)

Version: 1.00; 03-30-21

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

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

1.How motivated are you to complete detox and start injectable naltrexone for relapse prevention? *(MTMOTIVE)*

Not Motivated at All										Very Motivated
0	1	2	3	4	5	6	7	8	9	10
00-	01-	02-	03-	04-	05-	06-	07-	08-	09-	10-
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

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. (MTVRAHLP)

☐ 01-Yes

Comments:*(MTVCOMM)*

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

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

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)*(NMAGRVAB)* *(xx)* times
p. ...made someone have sex with you by force when they did not want to have sex? (forcible rape)*(NMRAPE)* *(xx)* times
q. ...been involved in the death or murder of another person, including accidents? (murder, homicide or non-negligent manslaughter)*(NMHMCDMS)* *(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)*(NMCRMOTH)* *(xx)* times
   1. Please describe:*(NMCRMOSP)*

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)*	*(xx)*	*(NMDRGPOC)*	*(xx)*
b. For drunkenness or other liquor law violations:	*(NMDRUNKA)*	*(xx)*	*(NMDRUNKC)*	*(xx)*
c. For driving under the influence or while intoxicated:	*(NMDUDWIA)*	*(xx)*	*(NMDUDWIC)*	*(xx)*
d. For possession, dealing, distribution or sale of drugs:	*(NMDRUGSA)*	*(xx)*	*(NMDRUGSC)*	*(xx)*
e. For vandalism or property destruction:	*(NMVANDEA)*	*(xx)*	*(NMVANDEC)*	*(xx)*
f. For receiving, possessing or selling stolen goods:	*(NMSTLGDA)*	*(xx)*	*(NMSTLGDC)*	*(xx)*
g. For forgery, fraud or embezzlement:	*(NMFRAUDA)*	*(xx)*	*(NMFRAUDC)*	*(xx)*
h. For shoplifting:	*(NMSHPLFA)*	*(xx)*	*(NMSHPLFC)*	*(xx)*
i. For larceny or theft:	*(NMLRCTHA)*	*(xx)*	*(NMLRCTHC)*	*(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:	*(NMAGRVBA)* *(xx)*	*(NMAGRVBC)* *(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? *(NMJAILDY)* *(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 *(NMJAILMO)* *(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?*(NMPCPDOC)* _____ *(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:	*(NMBPSLLT)* ☐ *(xxx.xx)* Months
b. Buprenorphine injection (SUBLOCADE©):	
i. Lifetime months:	*(NMBPIJLT)* ☐ *(xxx.xx)* Months
c. Buprenorphine **weekly** injection (BRIXADI©):	
i. Lifetime months:	*(NMBPWIJL)* ☐ *(xxx.xx)* Months
d. Buprenorphine **monthly** injection (BRIXADI©):	
i. Lifetime months:	*(NMBPMILT)* ☐ *(xxx.xx)* Months
e. Buprenorphine 6-month implant (Probuphine©):	
i. Lifetime months:	*(NMBPIMPL)* ☐ *(xxx.xx)* Months
f. Naltrexone daily (oral):	
i. Lifetime months:	*(NMNXORLT)* ☐ *(xxx.xx)* Months
g. Naltrexone monthly injection (Vivitrol©):	
i. Lifetime months:	*(NMVIMILT)* ☐ *(xxx.xx)* Months
h. Methadone daily:	
i. Lifetime months:	*(NMMTDLT)* ☐ *(xxx.xx)* Months
i. Other (specify): *(NMOTHSP)* ☐	
i. Lifetime months:	*(NMOTRXLT)* ☐ *(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 *(the dose taken most often 'usual dose')*	Months/Days
Disulfiram (e.g., Antabuse©):		
i. Lifetime months:	N/A	*(NMDSLFLT)* ☐ *(xxx)* Months
ii. Past 28 days:	*(NMDSDYMG)* ☐ *(xxxx)* mg	*(NMDS28DY)* ☐ *(xx)* Days
Naltrexone injection (e.g., Vivitrol©):		
i. Lifetime months:	N/A	*(NMALVILT)* ☐ *(xxx)* Months
ii. Past 28 days:	380 mg/month	*(NMAVI28D)* ☐ *(xx)* Days
Naltrexone daily (oral):		
i. Lifetime months:	N/A	*(NMANXOLT)* ☐ *(xxx)* Months
ii. Past 28 days:	*(NMANODMG)* ☐ *(xxxx)* mg	*(NMANO28D)* ☐ *(xx)* Days
Acamprosate (e.g., Campral©):		
i. Lifetime months:	N/A	*(NMACPRLT)* ☐ *(xxx)* Months
ii. Past 28 days:	*(NMACDYMG)* ☐ *(xxxx.x)* mg	*(NMAC28DY)* ☐ *(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?*(NMCURRHI)* ☐ 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:*(NMMDCAID)* ☐ 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:*(NMMDGAP)* ☐ 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:*(NMGOVPL)* ☐ 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 <u>total household income from legal sources</u> 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**?*(NMWRKSCL)*

- 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?*(NMWKHHLT)* ☐ *(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:
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)

☐ 01-Yes

Comments:*(OCICOMM)*

Overdose Questionnaire (ODQ)

Baseline

Version: 1.00; 03-30-21

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

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

*When we use the term **overdose**, we mean when a toxic amount of a drug or drugs overwhelms the body such that a person is no longer able to respond to others or breathe adequately, resulting in Narcan/naloxone rescue and/or emergency medical care. An overdose can occur with prescription or recreational drugs, or a combination of both, and can be deliberate or accidental.*

1. Have you ever overdosed on opioids? *(OQODOPI)* ☐ 0-No ☐ 1-Yes

2. How may times have you overdosed on opioids in your life? *(OQODNUM)* _____ *(xx)*

3. When was the most recent time that you overdosed on opioids? *(OQRCNTOD)*

01-Less than 1 month ago
02-1 to 6 months ago
03-7 to 12 months ago
04-1 to 2 years ago
05-3 to 4 years ago
06-5 to 10 years ago
07-More than 10 years ago

4. Were you hospitalized for your most recent opioid overdose event?*(OQODHOSP)* ☐ 0-No ☐ 1-Yes

5. Did you receive Narcan at home during your most recent opioid overdose event? *(OQODNAR)* ☐ 0-No ☐ 1-Yes

6. Which of the following substances did you use during your most recent opioid overdose event?

Check all that apply.

a. Heroin - injected:	*(OQRUHERI)*	☐ 01-Yes
b. Heroin - other route of administration such as snorting, smoking etc.:	*(OQRUHERO)*	☐ 01-Yes
c. Oxycodone or Oxycontin or Percocet:	*(OQRUOXY)*	☐ 01-Yes
d. Hydrocodone or Vicodin:	*(OQRUVIC)*	☐ 01-Yes
e. Methadone:	*(OQRUMTD)*	☐ 01-Yes
f. Other opioid analgesic pills:	*(OQRUOPIA)*	☐ 01-Yes
g. Fentanyl:	*(OQRUFEN)*	☐ 01-Yes
h. Liquid morphine:	*(OQRULQMR)*	☐ 01-Yes
i. Kratom:	*(OQRUKRAT)*	☐ 01-Yes
j. Alcohol:	*(OQRUALC)*	☐ 01-Yes
k. Benzodiazepines (such as Ativan, Klonopin, Xanax, Valium):	*(OQRUBZO)*	☐ 01-Yes
l. Cocaine:	*(OQRUCOC)*	☐ 01-Yes
m. Methamphetamine:	*(OQRUMET)*	☐ 01-Yes
n. Ambien or other sleeping pill:	*(OQRUSLEP)*	☐ 01-Yes
o. I don't know what I took:	*(OQRUDK)*	☐ 01-Yes
p. Other:	*(OQRUOTH)*	☐ 01-Yes
1. If "Other", specify:	*(OQRUOTSP)*	_____

7. Just before your most recent opioid overdose, how likely did you think it was that you would overdose?

	No Chance										Extremely Likely
	0	1	2	3	4	5	6	7	8	9	10
	00-	01-	02-	03-	04-	05-	06-	07-	08-	09-	10-
(OQTHNKOD)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

8. Just before your most recent opioid overdose, how strongly did you want to die?

	I Did Not Want to Die										I Definitely Wanted to Die
	0	1	2	3	4	5	6	7	8	9	10
	00-	01-	02-	03-	04-	05-	06-	07-	08-	09-	10-
(OQWANTDH)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

9. At the time of your most recent opioid overdose, were you trying to kill yourself?

	Not at All										Definitely
	0	1	2	3	4	5	6	7	8	9	10
	00-	01-	02-	03-	04-	05-	06-	07-	08-	09-	10-
(OQSUICID)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

10. If you learned that a particular batch of opioids in the area had resulted in several fatal overdoses, how likely would you be to seek that out?

	Not at All										Definitely
	0	1	2	3	4	5	6	7	8	9	10
	00-	01-	02-	03-	04-	05-	06-	07-	08-	09-	10-
(OQSKFOPI)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

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.(ODQRAHLP)

☐ 01-Yes

Comments:*(ODQCOMM)*

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

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

4. Was a pregnancy test performed?*(PBPRGTST)* ☐ 0-No ☐ 1-Yes

a. Date of pregnancy test:*(PBPTSTDT)* _____ *(mm/dd/yyyy)*
b. Result of pregnancy test:*(PBRESULT)* ☐ 00-Negative ☐ 01-Positive

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

Comments:*(PBCCOMM)*

PTSD Checklist for DSM-5 (PCL)

Version: 1.00; 03-30-21

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

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

Sometimes things happen to people that are unusually or especially frightening, horrible, or traumatic. It could be something that happened to you directly, something you witnessed, or something you learned happened to a close family member or close friend. Some examples are a serious accident; fire; disaster such as a hurricane, tornado, or earthquake; physical or sexual attack or abuse; war; homicide; or suicide.

Have you ever experienced this kind of event?*(PCLEVENT)* ☐ 0-No ☐ 1-Yes

If no, please stop here.

Instructions: *Below is a list of problems that people sometimes have in response to a very stressful experience. Please read each problem carefully and then select the appropriate response to indicate how much you have been bothered by that problem in the past month.*

In the past month, how much were you bothered by:		00-Not at All	01-A Little Bit	02-Moderately	03-Quite a Bit	04-Extremely
1. Repeated, disturbing, and unwanted memories of the stressful experience?	*(PCMEMORY)*	☐	☐	☐	☐	☐
2. Repeated, disturbing dreams of the stressful experience?	*(PCDREAMS)*	☐	☐	☐	☐	☐
3. Suddenly feeling or acting as if the stressful experience were actually happening again (as if you were actually back there reliving it)?	*(PCRELIVE)*	☐	☐	☐	☐	☐
4. Feeling very upset when something reminded you of the stressful experience?	*(PCUPSET)*	☐	☐	☐	☐	☐
5. Having strong physical reactions when something reminded you of the stressful experience (for example, heart pounding, trouble breathing, sweating)?	*(PCPHYSCL)*	☐	☐	☐	☐	☐
6. Avoiding memories, thoughts, or feelings related to the stressful experience?	*(PCINTAVD)*	☐	☐	☐	☐	☐
7. Avoiding external reminders of the stressful experience (for example, people, places, conversations, activities, objects, or situations)?	*(PCEXTAVD)*	☐	☐	☐	☐	☐
8. Trouble remembering important parts of the stressful experience?	*(PCMEMTRB)*	☐	☐	☐	☐	☐
9. Having strong negative beliefs about yourself, other people, or the world (for example, having thoughts such as: I am bad, there is something seriously wrong with me, no one can be trusted, the world is completely dangerous)?	*(PCNEGATV)*	☐	☐	☐	☐	☐
10. Blaming yourself or someone else for the stressful experience or what happened after it?	*(PCBLAME)*	☐	☐	☐	☐	☐
11. Having strong negative feelings such as fear, horror, anger, guilt, or shame?	*(PCNGFEEL)*	☐	☐	☐	☐	☐
12. Loss of interest in activities that you used to enjoy?	*(PCINTRST)*	☐	☐	☐	☐	☐
13. Feeling distant or cut off from other people?	*(PCDISTNT)*	☐	☐	☐	☐	☐
14. Trouble experiencing positive feelings (for example, being unable to feel happiness or have loving feelings for people close to you)?	*(PCPSFEEL)*	☐	☐	☐	☐	☐
15. Irritable behavior, angry outbursts, or acting aggressively?	*(PCIRRTBL)*	☐	☐	☐	☐	☐
16. Taking too many risks or doing things that could cause you harm?	*(PCRISKS)*	☐	☐	☐	☐	☐
17. Being "superalert" or watchful or on guard?	*(PCONGRD)*	☐	☐	☐	☐	☐
18. Feeling jumpy or easily startled?	*(PCJUMPY)*	☐	☐	☐	☐	☐
19. Having difficulty concentrating?	*(PCCNCTRT)*	☐	☐	☐	☐	☐
20. Trouble falling or staying asleep?	*(PCSLEEP)*	☐	☐	☐	☐	☐

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.(PCLRAHLP)
Comments:*(PCLCOMM)*

Panic Disorder Assessment (PDA)

Version: 1.00; 03-30-21

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

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

Questions about anxiety.

1. **In the last 4 weeks**, have you had an anxiety attack - suddenly feeling fear or panic? *(PDANXATK)* ☐ 0-No ☐ 1-Yes
2. Has this ever happened before?*(PDANXBFR)* ☐ 0-No ☐ 1-Yes
3. Do some of these attacks come suddenly out of the blue - that is, in situations where you don't expect to be nervous or uncomfortable?*(PDANXUEX)* ☐ 0-No ☐ 1-Yes
4. Do these attacks bother you a lot or are you worried about having another attack? *(PDANXBTR)* ☐ 0-No ☐ 1-Yes

Think about your last bad anxiety attack.

1. Were you short of breath?*(PDANXSBR)* ☐ 0-No ☐ 1-Yes
2. Did your heart race, pound, or skip?*(PDANXHTP)* ☐ 0-No ☐ 1-Yes
3. Did you have chest pain or pressure?*(PDANXCPN)* ☐ 0-No ☐ 1-Yes
4. Did you sweat?*(PDANXSWT)* ☐ 0-No ☐ 1-Yes
5. Did you feel as if you were choking?*(PDANXCHK)* ☐ 0-No ☐ 1-Yes
6. Did you have hot flashes or chills?*(PDANXHTF)* ☐ 0-No ☐ 1-Yes
7. Did you have nausea or an upset stomach, or the feeling that you were going to have diarrhea?*(PDANXNAU)* ☐ 0-No ☐ 1-Yes
8. Did you feel dizzy, unsteady, or faint?*(PDANXDZY)* ☐ 0-No ☐ 1-Yes
9. Did you have tingling or numbness in parts of your body?*(PDANXTGL)* ☐ 0-No ☐ 1-Yes
10. Did you tremble or shake?*(PDANXSHK)* ☐ 0-No ☐ 1-Yes
11. Were you afraid you were dying?*(PDANXAFD)* ☐ 0-No ☐ 1-Yes

Participant required research staff assistance in reading the questions in this assessment: ☐ 01-
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.(PDARAHLP)

Comments:*(PDACOMM)*

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)* ☐ 0-No ☐ 1-Yes
   a. If "Yes", how many participants?*(PDPRELNO)*

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

Select related participants:

Participant ID 1:*(PDPPT01)*	999999999999999-DUMMYPARTICIPANTID
Participant ID 2:*(PDPPT02)*	999999999999999-DUMMYPARTICIPANTID
Participant ID 3:*(PDPPT03)*	999999999999999-DUMMYPARTICIPANTID
Participant ID 4:*(PDPPT04)*	999999999999999-DUMMYPARTICIPANTID
Participant ID 5:*(PDPPT05)*	999999999999999-DUMMYPARTICIPANTID
Participant ID 6:*(PDPPT06)*	999999999999999-DUMMYPARTICIPANTID
Participant ID 7:*(PDPPT07)*	999999999999999-DUMMYPARTICIPANTID
Participant ID 8:*(PDPPT08)*	999999999999999-DUMMYPARTICIPANTID
Participant ID 9:*(PDPPT09)*	999999999999999-DUMMYPARTICIPANTID
Participant ID 10:*(PDPPT10)*	999999999999999-DUMMYPARTICIPANTID
Participant ID 11:*(PDPPT11)*	999999999999999-DUMMYPARTICIPANTID
Participant ID 12:*(PDPPT12)*	999999999999999-DUMMYPARTICIPANTID
Participant ID 13:*(PDPPT13)*	999999999999999-DUMMYPARTICIPANTID
Participant ID 14:*(PDPPT14)*	999999999999999-DUMMYPARTICIPANTID
Participant ID 15:*(PDPPT15)*	999999999999999-DUMMYPARTICIPANTID
Participant ID 16:*(PDPPT16)*	999999999999999-DUMMYPARTICIPANTID
Participant ID 17:*(PDPPT17)*	999999999999999-DUMMYPARTICIPANTID
Participant ID 18:*(PDPPT18)*	999999999999999-DUMMYPARTICIPANTID
Participant ID 19:*(PDPPT19)*	999999999999999-DUMMYPARTICIPANTID

Participant ID 20:*(PDPPT20)*

999999999999999-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:*(PDTYPSP)*

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:*(PDDESCPT)*

7. Was/will there be corrective action for this event?*(PDCORRNY)* ☐ 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)*	☐	☐	☐	☐
2. Feeling down, depressed, or hopeless *(PHDEPRES)*	☐	☐	☐	☐
3. Trouble falling or staying asleep, or sleeping too much *(PH2SLEEP)*	☐	☐	☐	☐
4. Feeling tired or having little energy *(PH2TIRED)*	☐	☐	☐	☐
5. Poor appetite or overeating *(PHAPPEAT)*	☐	☐	☐	☐
6. Feeling bad about yourself - or that you are a failure or have let yourself or your family down *(PHFAILUR)*	☐	☐	☐	☐
7. Trouble concentrating on things, such as reading the newspaper or watching television *(PH2CONC)*	☐	☐	☐	☐
8. Moving or speaking so slowly that other people could have noticed. Or the opposite - being so fidgety or restless that you have been moving around a lot more than usual *(PHMOVSPK)*	☐	☐	☐	☐
9. Thoughts that you would be better off dead, or of hurting yourself in some way *(PHDEADHU)*	☐	☐	☐	☐

10. If you checked off *any* problems, how *difficult* have 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:
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)
☐ 01-Yes

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

Anxiety

In the past 7 days...

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

Depression

In the past 7 days...

		01- Never	02- Rarely	03- Sometimes	04- Often	05- Always
9. I felt worthless.	*(PRWORLES)*	☐	☐	☐	☐	☐
10. I felt helpless.	*(PRHLPLES)*	☐	☐	☐	☐	☐
11. I felt depressed.	*(PRDEPRES)*	☐	☐	☐	☐	☐
12. I felt hopeless.	*(PRHOPLES)*	☐	☐	☐	☐	☐

Fatigue

During the past 7 days...

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

Sleep Disturbance

In the past 7 days...

		05- Very Poor	04- Poor	03- Fair	02- Good	01- Very Good
17. My sleep quality was...	*(PRSLPQUA)*	☐	☐	☐	☐	☐

In the past 7 days...

		05- Not at All	04- A Little Bit	03- Somewhat	02- Quite a Bit	01- Very Much
18. My sleep was refreshing.	*(PRSLPREF)*	☐	☐	☐	☐	☐
19. I had a problem with my sleep.	*(PRSLPPRB)*	☐	☐	☐	☐	☐
20. I had difficulty falling asleep.	*(PRSLPDIF)*	☐	☐	☐	☐	☐

Ability to Participate in Social Roles and Activities

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

Pain Interference

In the past 7 days...

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

Cognitive Function Abilities

In the past 7 days...

		01-Not at All	02-A Little Bit	03-Somewhat	04-Quite a Bit	05-Very Much
29.	I have been able to concentrate. *(PRCONCEN)*	☐	☐	☐	☐	☐
30.	I have been able to remember to do things, like take medicine or buy something I needed. *(PREMEMB)*	☐	☐	☐	☐	☐

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)*	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

No Pain — Worst Pain Imaginable

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.(PRORAHLP)

☐ 01-Yes

Comments:*(PROCOMM)*

Psychosocial Treatment (PST)

Baseline

Version: 3.01; 02-15-22

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

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

1. Is there group counseling/therapy available on the unit?*(PSGRPTHP)*
   - 00-No
   - 01-Yes
   - 97-Unknown

   a. About how many group therapy sessions did you engage in since the last visit? *(PSGRPSES)*
      - 00-0 (none)
      - 01-1 to 3 sessions
      - 02-4 to 6 sessions
      - 03-Over 6 sessions

2. Is there individual counseling/therapy available on the unit?*(PSINDTHP)*
   - 00-No
   - 01-Yes
   - 97-Unknown

   a. About how many individual sessions did you engage in since the last visit? *(PSINDSES)*
      - 00-0 (none)
      - 01-1 to 3 sessions
      - 02-4 to 6 sessions
      - 03-Over 6 sessions

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.(PSTRAHLP)
- 01-Yes

Comments:*(PSTCOMM)*

Quality of Life (QLP)

Version: 1.00; 03-30-21

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

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

Instruction: Ask the following questions within 30 days prior to admission.

1. Would you say that in general your health is:*(QLHEALTH)*
   - 01-Excellent
   - 02-Very good
   - 03-Good
   - 04-Fair
   - 05-Poor
   - 97-Don't know/Not sure
   - 98-Refused
2. Now thinking about your physical health, which includes physical illness and injury, for how many days during the past 30 days was your physical health not good?*(QLPHYNGD)* ☐ *(xx)* days
3. Now thinking about your mental health, which includes stress, depression, and problems with emotions, for how many days during the past 30 days was your mental health not good?*(QLMTLNG)* ☐ *(xx)* days
4. During the past 30 days, for about how many days did poor physical or mental health keep you from doing your usual activities, such as self-care, work, or recreation? *(QLACT)* ☐ *(xx)* days

Suicide History

1. In your lifetime, have you had a significant period of time in which you have:
   a. Experienced serious thoughts of suicide?*(QLSUICID)* ☐ 00-No ☐ 01-Yes ☐ 97-Not answered
   b. Attempted suicide?*(QLATTEMP)* ☐ 00-No ☐ 01-Yes ☐ 97-Not answered

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.(QLPRAHLP)

Comments:*(QLPCOMM)*

Additional Demographics (S97)

Version: 1.00; 03-30-21

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

Date of assessment:*(S97ASMDT)* *(mm/dd/yyyy)*

1. Would you describe yourself as:*(S7GENDER)*
   - 01-Male
   - 02-Female
   - 03-Transgender male
   - 04-Transgender female
   - 05-Non-binary
   - 06-Not listed

   a. If "Not listed", describe:*(S7GENDSP)*

2. Do you consider yourself to be:*(S7SEXORT)*
   - 01-Heterosexual or straight
   - 02-Gay or lesbian
   - 03-Bisexual
   - 04-Queer
   - 05-Not sure
   - 06-Something else

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.(S97RAHLP)
☐ 01-Yes

Comments:*(S7COMM)*

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)*	☐	☐	☐	☐	☐
2. I feel like yawning:	*(SBYAWN)*	☐	☐	☐	☐	☐
3. I am perspiring:	*(SBSWEAT)*	☐	☐	☐	☐	☐
4. My eyes are teary:	*(SBTEARY)*	☐	☐	☐	☐	☐
5. My nose is running:	*(SBNOSRUN)*	☐	☐	☐	☐	☐
6. I have goosebumps:	*(SBGSBMPS)*	☐	☐	☐	☐	☐
7. I am shaking:	*(SBSHAKE)*	☐	☐	☐	☐	☐
8. I have hot flushes:	*(SBHTFLSH)*	☐	☐	☐	☐	☐
9. I have cold flushes:	*(SBCDFLSH)*	☐	☐	☐	☐	☐
10. My bones and muscles ache:	*(SBMSACHE)*	☐	☐	☐	☐	☐
11. I feel restless:	*(SBRSTLS)*	☐	☐	☐	☐	☐
12. I feel nauseous:	*(SBNAUS)*	☐	☐	☐	☐	☐
13. I feel like vomiting:	*(SBVOMIT)*	☐	☐	☐	☐	☐
14. My muscles twitch:	*(SBMSCLTW)*	☐	☐	☐	☐	☐
15. I have stomach cramps:	*(SBCRAMPS)*	☐	☐	☐	☐	☐
16. I feel like using now:	*(SBUSENOW)*	☐	☐	☐	☐	☐

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)*

Timeline Followback (T97)

Version: 1.00; 01-29-21

Segment *(PROTSEG)*: C, D, E
TFB week start date *(TFWKSTDT)*:

Day	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Date	*(TLDATE1)*	*(TLDATE2)*	*(TLDATE3)*	*(TLDATE4)*	*(TLDATE5)*	*(TLDATE6)*	*(TLDATE7)*
1. Was the participant in a controlled setting?	*(TLCTSET1)* ☐ 0-No ☐ 1-Yes	*(TLCTSET2)* ☐ 0-No ☐ 1-Yes	*(TLCTSET3)* ☐ 0-No ☐ 1-Yes	*(TLCTSET4)* ☐ 0-No ☐ 1-Yes	*(TLCTSET5)* ☐ 0-No ☐ 1-Yes	*(TLCTSET6)* ☐ 0-No ☐ 1-Yes	*(TLCTSET7)* ☐ 0-No ☐ 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)* ☐ 0-No ☐ 1-Yes	*(TLSUBAL2)* ☐ 0-No ☐ 1-Yes	*(TLSUBAL3)* ☐ 0-No ☐ 1-Yes	*(TLSUBAL4)* ☐ 0-No ☐ 1-Yes	*(TLSUBAL5)* ☐ 0-No ☐ 1-Yes	*(TLSUBAL6)* ☐ 0-No ☐ 1-Yes	*(TLSUBAL7)* ☐ 0-No ☐ 1-Yes
3. Alcohol (Number of standard drinks per day):	*(TLALCHL1)*	*(TLALCHL2)*	*(TLALCHL3)*	*(TLALCHL4)*	*(TLALCHL5)*	*(TLALCHL6)*	*(TLALCHL7)*
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:	*(TLCOCRK1)* 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	*(TLCOCRK2)* 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	*(TLCOCRK3)* 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	*(TLCOCRK4)* 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	*(TLCOCRK5)* 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	*(TLCOCRK6)* 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	*(TLCOCRK7)* 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)* $ *(xxx.xx)*	*(TLDVHER2)* $ *(xxx.xx)*	*(TLDVHER3)* $ *(xxx.xx)*	*(TLDVHER4)* $ *(xxx.xx)*	*(TLDVHER5)* $ *(xxx.xx)*	*(TLDVHER6)* $ *(xxx.xx)*	*(TLDVHER7)* $ *(xxx.xx)*
Number of times per day:	*(TLPDHER1)* *(xx)*	*(TLPDHER2)* *(xx)*	*(TLPDHER3)* *(xx)*	*(TLPDHER4)* *(xx)*	*(TLPDHER5)* *(xx)*	*(TLPDHER6)* *(xx)*	*(TLPDHER7)* *(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)* $ *(xxx.xx)*	*(TLDVOPI2)* $ *(xxx.xx)*	*(TLDVOPI3)* $ *(xxx.xx)*	*(TLDVOPI4)* $ *(xxx.xx)*	*(TLDVOPI5)* $ *(xxx.xx)*	*(TLDVOPI6)* $ *(xxx.xx)*	*(TLDVOPI7)* $ *(xxx.xx)*
Number of times per day:	*(TLPDOPI1)* *(xx)*	*(TLPDOPI2)* *(xx)*	*(TLPDOPI3)* *(xx)*	*(TLPDOPI4)* *(xx)*	*(TLPDOPI5)* *(xx)*	*(TLPDOPI6)* *(xx)*	*(TLPDOPI7)* *(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)* *(xxx)*	*(TLPDMTD2)* *(xxx)*	*(TLPDMTD3)* *(xxx)*	*(TLPDMTD4)* *(xxx)*	*(TLPDMTD5)* *(xxx)*	*(TLPDMTD6)* *(xxx)*	*(TLPDMTD7)* *(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)* *(xxx)*	*(TLPDBUP2)* *(xxx)*	*(TLPDBUP3)* *(xxx)*	*(TLPDBUP4)* *(xxx)*	*(TLPDBUP5)* *(xxx)*	*(TLPDBUP6)* *(xxx)*	*(TLPDBUP7)* *(xxx)*

12. Hallucinogens, including MDMA/ecstasy:	*(TLMDAR1)* 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	*(TLMDAR2)* 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	*(TLMDAR3)* 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	*(TLMDAR4)* 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	*(TLMDAR5)* 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	*(TLMDAR6)* 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	*(TLMDAR7)* 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
13. Sedatives and hypnotics, non-benzodiazepines (illicit):	*(TLBARR1)* 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	*(TLBARR2)* 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	*(TLBARR3)* 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	*(TLBARR4)* 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	*(TLBARR5)* 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	*(TLBARR6)* 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	*(TLBARR7)* 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
14. Benzodiazepines (illicit):	*(TLBZOR1)* 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	*(TLBZOR2)* 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	*(TLBZOR3)* 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	*(TLBZOR4)* 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	*(TLBZOR5)* 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	*(TLBZOR6)* 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	*(TLBZOR7)* 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
15. Inhalants:	*(TLINHR1)* 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	*(TLINHR2)* 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	*(TLINHR3)* 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	*(TLINHR4)* 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	*(TLINHR5)* 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	*(TLINHR6)* 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	*(TLINHR7)* 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
Other Drugs							
16. Other drug 1 use:	*(TLOT1R1)* 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	*(TLOT1R2)* 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	*(TLOT1R3)* 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	*(TLOT1R4)* 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	*(TLOT1R5)* 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	*(TLOT1R6)* 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	*(TLOT1R7)* 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
Specify other drug 1:	*(TLOTSP11)*	*(TLOTSP12)*	*(TLOTSP13)*	*(TLOTSP14)*	*(TLOTSP15)*	*(TLOTSP16)*	*(TLOTSP17)*
17. Other drug 2 use:	*(TLOT2R1)* 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	*(TLOT2R2)* 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	*(TLOT2R3)* 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	*(TLOT2R4)* 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	*(TLOT2R5)* 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	*(TLOT2R6)* 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	*(TLOT2R7)* 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
Specify other drug 2:	*(TLOTSP21)*	*(TLOTSP22)*	*(TLOTSP23)*	*(TLOTSP24)*	*(TLOTSP25)*	*(TLOTSP26)*	*(TLOTSP27)*

Comments:*(TFBCOMM)*

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)*

Targeted Safety Event (TSE)

Version: 1.00; 01-19-21

Segment *(PROTSEG)*: B, C, D, E
TSE date *(TSDATE)*:
TSE sequence number *(TSSEQNO)*:

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:*(TSDETLSP)*

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 compete 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

Tobacco Use History (TUH)

Version: 1.01; 03-30-21

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

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

1. Have you ever smoked a cigarette, even one or two puffs?*(TUSMKPFF)* ☐ 00-No ☐ 01-Yes ☐ 97-Don't know ☐ 98-Refused

2. Do you now smoke cigarettes?*(TUNSMFRQ)*
   - 01-Every day
   - 02-Some days
   - 03-Not at all
   - 97-Don't know
   - 98-Refused

3. How many cigarettes have you smoked in your entire life? A pack usually has 20 cigarettes in it.*(TUSMKLIF)*
   - 01-1 or more puffs but never a whole cigarette
   - 02-1 to 10 cigarettes (about 1/2 pack total)
   - 03-11 to 20 cigarettes (about 1/2 pack to 1 pack)
   - 04-21 to 50 cigarettes (more than 1 pack but less than 3 packs)
   - 05-51 to 99 cigarettes (more than 2 1/2 packs but less than 5 packs)
   - 06-100 or more cigarettes (5 packs or more)
   - 97-Don't know
   - 98-Refused

4. Around this time 12 months ago, were you smoking cigarettes every day, some days, or not at all?*(TUYSMFRQ)*
   - 01-Every day
   - 02-Some days
   - 03-Not at all
   - 97-Don't know
   - 98-Refused

Section A: Every-Day Smokers

5. On the average, about how many cigarettes do you now smoke each day?*(TUNUMDY)* _____ *(xx)* cigarettes per day *(TUNMDYDR)* ☐ 97-Don't know ☐ 98-Refused

6. How old were you when you first started smoking cigarettes each day?*(TUEDAGON)* _____ *(xx)*

Section B: Some-Day Smokers

7. On how many of the past 30 days did you smoke cigarettes?*(TU30DAYS)* _____ *(xx)* days *(TU30DDR)* ☐ 97-Don't know ☐ 98-Refused

8. How old were you when you first started smoking cigarettes FAIRLY REGULARLY? *(TUSDAGON)* _____ *(xx)*

9. Would you say you smoked on AT LEAST 12 DAYS in the past 30 days?*(TU12OF30)* ☐ 00-No ☐ 01-Yes ☐ 97-Don't know ☐ 98-Refused

10. On average, on those days, how many cigarettes did you usually smoke each day?*(TUCIGSSD)* _____ *(xx)* cigarettes per day *(TUCDSDR)* ☐ 97-Don't know ☐ 98-Refused

Section C: Former Smokers

11. About how long has it been since you COMPLETELY quit smoking cigarettes? *(TUQTNUMB)* _____ *(xx)* *(TUQTUNIT)* ☐ 01-days ☐ 02-weeks ☐ 03-months ☐ 04-years

12. Have you EVER smoked cigarettes EVERY DAY for at least 6 months?*(TUEVERY)* ☐ 00-No ☐ 01-Yes ☐ 97-Don't know ☐ 98-Refused

13. When you last smoked every day, on average how many cigarettes did you smoke each day?*(TUNUMEDY)* _____ *(xx)* cigarettes per day *(TUNMEDDR)* ☐ 97-Don't know ☐ 98-Refused

Section D: e-Cigarettes/Vaping

The next questions are about electronic cigarettes or nicotine vaping devices, often called e-cigarettes. E-cigarettes are battery-powered and produce vapor instead of smoke.

14. Have you ever used an e-cigarette or nicotine vaping device (even one or two times)? *(TUVAPUSE)* ☐ 0-No ☐ 1-Yes

15. Do you now use e-cigarettes or a nicotine vaping device?*(TUVAPFRQ)*

- 01-Every day
- 02-Some days
- 03-Not at all
- 97-Don't know
- 98-Refused

16. On how many days of the past 30 days did you use an e-cigarette or nicotine vaping device?*(TU30DVAP)*

_____ *(xx)* days *(TU30DVDR)* ☐ 97-Don't know ☐ 98-Refused

Click next to proceed

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.(TUHRAHLP)

☐ 01-Yes

Comments:*(TUHCOMM)*

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)* ☐ 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)* _____

First Urine Drug Screen

2. Date 1st urine specimen collected:*(UDCOLDT1)* _____ *(mm/dd/yyyy)*
3. Time 1st urine specimen collected:*(UDCOLTM1)* _____ *(hh:mm)*
4. Was the 1st urine specimen temperature within the range? (90-100 °F)*(UDTEMP1)* ☐ 0-No ☐ 1-Yes
5. Was the 1st urine specimen determined to be adulterated?*(UDADULT1)* ☐ 0-No ☐ 1-Yes
6. 1st Urine Drug Screen Results:

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

Second Urine Drug Screen

7. If the 1st urine specimen was determined to be adulterated, was a second specimen collected?*(UDTEST2)* ☐ 0-No ☐ 1-Yes
   a. If "No", reason:*(UDNORSN2)*

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)* ☐	☐	☐
Barbiturate (300 ng) (BAR):	*(UDBAR2)* ☐	☐	☐
Buprenorphine (10 ng) (BUP):	*(UDBUP2)* ☐	☐	☐
Benzodiazepines (300 ng) (BZO):	*(UDBZO2)* ☐	☐	☐
Cocaine (150 ng) (COC):	*(UDCOC2)* ☐	☐	☐
Ecstasy (500 ng) (MDMA):	*(UDMDA2)* ☐	☐	☐
Methamphetamine (500 ng) (MET):	*(UDMET2)* ☐	☐	☐
Methadone (300 ng) (MTD):	*(UDMTD2)* ☐	☐	☐
Turn urine dip card over			
Opiates (300 ng) (OPI):	*(UDOPI32)* ☐	☐	☐
Oxycodone (100 ng) (OXY):	*(UDOXY2)* ☐	☐	☐
Phencyclidine (25 ng) (PCP):	*(UDPCP2)* ☐	☐	☐
Marijuana (50 ng) (THC):	*(UDTHC2)* ☐	☐	☐
Single Dipstick			
Fentanyl (20 ng) (FEN):	*(UDFEN2)* ☐	☐	☐

Comments:*(UDSCOMM)*