

NIDA Clinical Trials Network

Annual Family Income (AFI)

Web Version: 1.0; 1.01; 11-17-17

Segment (PROTSEG): A

Visit number (VISNO):

Date of assessment: (AFIASMDT)

 (mm/dd/yyyy)

The following questions are about your **total family** income during the last calendar year BEFORE TAXES.

1. What is your family size?

By family, we mean you plus all family members living in this household (including cohabitating partners and armed forces members living at home). (AFFAMSZE)

 (xx)

2. What is your best estimate of the total income of all family members from all sources, before taxes, during the last calendar year? (AFESTINC)

01-< \$12,060
02-\$12,060 - \$16,239
03-\$16,240 - \$20,419
04-\$20,420 - \$24,599
05-\$24,600 - \$28,779
*Additional Options Listed Below

Comments: (AFICOMM)

Additional Selection Options for AFI

What is your best estimate of the total income of all family members from all sources, before taxes, during the last calendar year?

- 06-\$28,780 - \$32,959
- 07-\$32,960 - \$37,139
- 08-\$37,140 - \$41,319
- 09-\$41,320 - \$45,499
- 10-\$45,500 - \$49,680
- 11->\$49,680
- 97-Don't know
- 98-Refused to answer

Alcohol and Substance Use History (ASU)

Segment (PROTSEG): A

Visit number (VISNO):

Date of assessment:(ASUASMDT)

 (mm/dd/yyyy)

Alcohol Use History

1. In your entire life, have you had at least 1 drink of any kind of alcohol, not counting small tastes or sips?(AUALCLFT)

 0-No 1-Yes

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

 (xx) years

2. 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) OR (AUALCDDK) 97-Don't know 98-Refused to answer

3. On the days that you drank during the past 30 days, how many **drinks** did you **usually** have each day? 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.(AUALCEAC)

 (xx) OR (AUALCEDK) 97-Don't know 98-Refused to answer

Substance Use History

@2Substance	@2Have you EVER used any of these medicines or drugs?	@2If "Yes", specify substance type(s)	@2 How old were you when you FIRST used? (years)	^3Think 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®, Quaaludes, or Chloral Hydrate)	(AUSEDLFT) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(AUSEDLSP) <input type="text"/>	(AUSEDAGE) <input type="text"/> (xx)	(AUSED30D) <input type="text"/> (xx)	(AUSEDDKR) <input type="checkbox"/>	<input type="checkbox"/>
2. Tranquilizers or anti-anxiety drugs: (e.g., Valium®, Librium®, muscle relaxants, or Xanax®)	(AUTNQLFT) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(AUTNQLSP) <input type="text"/>	(AUTRQAGE) <input type="text"/> (xx)	(AUTN30D) <input type="text"/> (xx)	(AUTNQDKR) <input type="checkbox"/>	<input type="checkbox"/>
3. Painkillers/Opioids: (e.g., Codeine, Darvon®, Percodan®, Oxycontin®, Dilaudid®, Demerol®, Celebrex® or Vioxx®)	(AUPNKLFT) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(AUPNKLSP) <input type="text"/>	(AUPNKAGE) <input type="text"/> (xx)	(AUPNK30D) <input type="text"/> (xx)	(AUPNKDKR) <input type="checkbox"/>	<input type="checkbox"/>
4. Stimulants: (e.g., Preludin®, Benzedrine®, Methedrine®, Ritalin®, uppers, or speed)	(AUSTMLFT) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(AUSTMLSP) <input type="text"/>	(AUSTMAGE) <input type="text"/> (xx)	(AUSTM30D) <input type="text"/> (xx)	(AUSTMDKR) <input type="checkbox"/>	<input type="checkbox"/>
5. Marijuana, hash, THC, grass, or cannabis:	(AUTHCLFT) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(AUTHCLSP) <input type="text"/>	(AUTHCAGE) <input type="text"/> (xx)	(AUTH30D) <input type="text"/> (xx)	(AUTHCDKR) <input type="checkbox"/>	<input type="checkbox"/>
6. @2Cocaine or crack:	(AUCOCLFT) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(AUCOCLSP) <input type="text"/>	(AUCOCAGE) <input type="text"/> (xx)	(AUCOC30D) <input type="text"/> (xx)	(AUCOCDKR) <input type="checkbox"/>	<input type="checkbox"/>
7. Hallucinogens: (e.g., Ecstasy/MDMA, LSD, mescaline, psilocybin, PCP, angel dust, or peyote)	(AUHALLFT) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(AUHALLSP) <input type="text"/>	(AUHALAGE) <input type="text"/> (xx)	(AUHAL30D) <input type="text"/> (xx)	(AUHALDKR) <input type="checkbox"/>	<input type="checkbox"/>
8. Inhalants or solvents: (e.g., amyl nitrite, nitrous oxide, glue, toluene, or gasoline)	(AUINHFT) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(AUINHLSP) <input type="text"/>	(AUINHAGE) <input type="text"/> (xx)	(AUINH30D) <input type="text"/> (xx)	(AUINHDKR) <input type="checkbox"/>	<input type="checkbox"/>
9. Heroin:			(AUHERAGE) <input type="text"/>	(AUHER30D) <input type="text"/>		

	<i>(AUHERLFT)</i> <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes		<input type="text"/> <i>(xx)</i>	<input type="text"/> <i>(xx)</i>	<i>(AUHERDKR)</i> <input type="checkbox"/>	<input type="checkbox"/>
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Comments: *(ASUCOMM)*

Buprenorphine Visit Checklist (BVC)

Web Version: 1.0; 3.03; 09-20-18

Segment (PROTSEG): A

Visit number (VISNO):

Research staff **must** complete all data collection for the visit before the pharmacist sees the participant in order to populate the summary report for this Buprenorphine Visit Checklist and to communicate with the pharmacist. In addition, the following forms **must** be entered in Advantage eClinical prior to completing the Buprenorphine Visit Checklist:

Research Staff Items

Tasks	Date of Assessment	Summary	Trigger (No/Yes)	Progress Notes/Comments
1. ^5Opioid withdrawal, per Clinical Opioid Withdrawal Scale (COWS)				
a. COWS score (current visit):	(BVCOWCDT) <input type="text"/> (mm/dd/yyyy)	(BVCOWCUR) <input type="text"/>		(BVCOWCNC) <input type="text"/>
b. COWS score (previous visit):	(BVCOWPDT) <input type="text"/> (mm/dd/yyyy)	(BVCOWPRV) <input type="text"/>		(BVCOWPNC) <input type="text"/>
c. Trigger:			(BVCOWTRG) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	
2. ^5Self-reported opioid craving, per Visual Analog Scale (VAS)				
a. VAS score (current visit):	(BVVASCDT) <input type="text"/> (mm/dd/yyyy)	(BVVASCUR) <input type="text"/>		(BVVASCNC) <input type="text"/>
b. VAS score (previous visit):	(BVVASPDT) <input type="text"/> (mm/dd/yyyy)	(BVVASPRV) <input type="text"/>		(BVVASPNC) <input type="text"/>
c. Trigger:			(BVVASTRG) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	
3. Urine drug testing				
	(BVUDSDT) <input type="text"/> (mm/dd/yyyy)			
a. Current visit UDS positive for opioids/heroin:		(BVUDSCUR) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes		(BVUDSCNC) <input type="text"/>
If "Yes", UDS was positive for the following opioids/heroin:		(BVOIPOS) <input type="text"/>		
b. Cumulative number of UDS positive for opioids/heroin:		(BVUDSCUM) <input type="text"/> (xx)		(BVUDCUNC) <input type="text"/>
c. Trigger:			(BVUDSTRG) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	
d. Was the current UDS positive for other drugs?		(BVUDSOTH) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes		(BVUDSONC) <input type="text"/>
If "Yes", UDS was positive for the following other substances:		(BVOTHPOS) <input type="text"/>		

4. Self-reported benzodiazepine use, per Timeline Followback (TLFB)

a. Was illicit benzodiazepine use reported?

(BVBZODT)

(mm/dd/yyyy)

(BVTFBZBO) 0-No 1-Yes

(BVBZONC)

b. Trigger:

(BVBZOTRG)
 0-No 1-Yes

5. Was the participant compliant with psychosocial intervention attendance, per the Psychosocial Counseling Attendance (PCA) form?

(BVPCADT)

(mm/dd/yyyy)

(BVPCACMP)
1-Yes
97-Does not remember
98-Does not report

(BVPCANC)

Trigger:

(BVPCATRG)
0-No 1-Yes

6. Did the participant report any substance use, financial, family, social, psychiatric, legal, or medical issues, per the Problem List (PLF) form?

(BVPLFDT)

(mm/dd/yyyy)

a. Alcohol/drug use:

(BVPLFSUB) 0-No 1-Yes

(BVPLFANC)

b. Employment/support status:

(BVPLFEMP) 0-No 1-Yes

(BVPLFENC)

c. Family relationships:

(BVPLFFAM) 0-No 1-Yes

(BVPLFFNC)

d. Social and recreational functioning:

(BVPLFSOC) 0-No 1-Yes

(BVPLFSNC)

e. Psychological status:

(BVPLFPSY) 0-No 1-Yes

(BVPLFPNC)

f. Legal status:

(BVPLFLGL) 0-No 1-Yes

(BVPLFLNC)

g. Medical status:

(BVPLFMED) 0-No 1-Yes

(BVPLFMNC)

h. Trigger:

(BVPLFTRG)
0-No 1-Yes

7. Suicidality (P4 suicidality screener) risk:

(BVS1DT)

(mm/dd/yyyy)

(BVS1SCR)
1-Lower
2-Higher

(BVS1SNC)

Trigger:

(BVS1TRG)
0-No 1-Yes

8. Were any prescriptions reported on the Concomitant Medications (CMD) form?

(BVCMDDT)

(mm/dd/yyyy)

(BVMEDNEW) 0-No 1-Yes

(BVMEDNC)

If "Yes", list names of prescribed

drugs in Progress
Notes/Comments field.

9. Were any treatments reported on the Non-Drug Therapy (TRT) form? (mm/dd/yyyy) (BVTRTNEW) 0-No 1-Yes

If "Yes", list names of non-drug therapies received in Progress Notes/Comments field.

10. Were any moderate or severe safety events or any hospitalizations, overdose events, Emergency Department (ED) visits, or deaths reported on the Safety Event Response Checklist (SEA)? (mm/dd/yyyy) (BVSEAMS) 0-No 1-Yes

If "Yes", provide pharmacist with a copy of the Safety Event Response Checklist.

Trigger:

(BVSEATR) 0-No 1-Yes

Physician Items

11. Completed by: (BVDPHYID)

- 1-C. Erami
- 2-E. Morse
- 3-J. Battle
- 4-J. Finch
- 5-L. Bowlby
- *Additional Options Listed Below

Tasks	Date of Assessment	Summary	Progress Notes/Comments
12. Was medication reconciliation (buprenorphine film count) completed? <i>Unused Suboxone films from last visit prescription should be recounted.</i>	<input type="text" value="(BVDBUPDT)"/> (mm/dd/yyyy)	<input type="checkbox"/> (BVDBUPFC) 0-No <input type="checkbox"/> 1-Yes	<input type="text" value="(BVDBUPNC)"/>
13. Was participant education (e.g., overdose prevention, other drug use, compliance with psychosocial treatment and medications, safety storage of medications) completed?	<input type="text" value="(BVDPEDDT)"/> (mm/dd/yyyy)	<input type="checkbox"/> (BVDPTEDC) 0-No <input type="checkbox"/> 1-Yes	<input type="text" value="(BVDPEDNC)"/>
14. Was monitoring of the State Prescription Drug Monitoring Program (PDMP) completed? <i>If "Yes", indicate whether or not evidence of any of the following was found:</i>	<input type="text" value="(BVDPDMDT)"/> (mm/dd/yyyy)	<input type="checkbox"/> (BVDPDMP) 0-No <input type="checkbox"/> 1-Yes	<input type="text" value="(BVDPDMNC)"/>
a. Multiple buprenorphine prescriptions:		<input type="checkbox"/> (BVDMUBUP) 0-No <input type="checkbox"/> 1-Yes	<input type="text" value="(BVDMUBUPC)"/>
b. Other opiate prescriptions:		<input type="checkbox"/> (BVDDMOPI) 0-No <input type="checkbox"/> 1-Yes	<input type="text" value="(BVDDOPINC)"/>
c. Unauthorized benzodiazepine prescriptions:		<input type="checkbox"/> (BVDBUBZO) 0-No <input type="checkbox"/> 1-Yes	<input type="text" value="(BVDBBZONC)"/>
15. Was the Treatment Plan for Opioid Use Disorder completed? If "Yes", was the plan modified?	<input type="text" value="(BVDTPTDT)"/> (mm/dd/yyyy)	<input type="checkbox"/> (BVDTTRTPC) 0-No <input type="checkbox"/> 1-Yes	<input type="text" value="(BVDTPLNC)"/>
		<input type="checkbox"/> (BVDTMOD) 0-No <input type="checkbox"/> 1-Yes	<input type="text" value="(BVDTMODC)"/>
16. Is buprenorphine dose confirmed?	<input type="text" value="(BVDBUPD)"/> (mm/dd/yyyy)	<input type="checkbox"/> (BVDBUPDC) 0-No <input type="checkbox"/> 1-Yes	<input type="text" value="(BVDBUPN)"/>
17. Was buprenorphine prescribing completed?	<input type="text" value="(BVDBUP)"/> (mm/dd/yyyy)	<input type="checkbox"/> (BVDBUPRX) 0-No <input type="checkbox"/> 1-Yes	<input type="text" value="(BVDBUPRC)"/>
18. Is a dose adjustment indicated?	<input type="text" value="(BVDBADJDT)"/>	<input type="checkbox"/> (BVDBUPAI) 0-No <input type="checkbox"/>	<input type="text" value="(BVDBUPAC)"/>

(mm/dd/yyyy)

1-Yes

If "Yes", how was dose adjusted?
Clarify if dose remained the same or if any dose adjustments were made in the Progress Notes/Comments field.

(BVDBUPAJ)
0-Dose remained same
1-Dose increased
2-Dose reduced

Pharmacist Items

19. Completed by:(BVPRXID)

1-F. Joseph
2-J. Kim
3-J. Pippin
4-N. Griffin
5-S. Adkins
*Additional Options Listed Below

Tasks	Date of Assessment	Summary	Progress Notes/Comments
20. Was medication reconciliation (buprenorphine film count) completed?	(BVPBUPDT) <input type="text"/> (mm/dd/yyyy)	(BVPBUPFC) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(BVPBUPNC) <input type="text"/>
21. Was participant education (e.g., overdose prevention, other drug use, compliance with psychosocial treatment and medications, safety storage of medications) completed?	(BVPPEDDT) <input type="text"/> (mm/dd/yyyy)	(BVPPTEDC) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(BVPPE DNC) <input type="text"/>
22. Was monitoring of the State Prescription Drug Monitoring Program (PDMP) completed? <i>If "Yes", indicate whether or not evidence of any of the following was found:</i>	(BVPMDT) <input type="text"/> (mm/dd/yyyy)	(BVPDMP) <input type="checkbox"/> 0-No <input type="checkbox"/> 1- Yes	(BVPDMNC) <input type="text"/>
a. Multiple buprenorphine prescriptions:		(BVMUBUP) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(BVMUBUPC) <input type="text"/>
b. Other opiate prescriptions:		(BVPDMOPI) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(BVPPOPINC) <input type="text"/>
c. Unauthorized benzodiazepine prescriptions:		(BVPUBZO) <input type="checkbox"/> 0-No <input type="checkbox"/> 1- Yes	(BVPBZONC) <input type="text"/>
23. Were the Electronic Medical Records (EHR) accessed?	(BVP EHRDT) <input type="text"/> (mm/dd/yyyy)	(BVP AEHR) <input type="checkbox"/> 0-No <input type="checkbox"/> 1- Yes <input type="checkbox"/> 96-N/A (unable to access EHR)	(BVP EHRNC) <input type="text"/>
24. Did the participant provide a negative urine pregnancy test prior to buprenorphine dispensing?	(BVP PRGDT) <input type="text"/> (mm/dd/yyyy)	(BVP BUPNG) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(BVP PRGNC) <input type="text"/>
25. Was buprenorphine dispensing completed?	(BVP BUPD) <input type="text"/> (mm/dd/yyyy)	(BVP BUPDS) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(BVP BUPDC) <input type="text"/>
26. Date of next appointment:	(BVP APTDT) <input type="text"/> (mm/dd/yyyy)		(BVP APTNC) <input type="text"/>

Comments:(BVCCOMM)

Upload File Name

Please ensure that the upload file is a PDF and follows the naming convention: [Participant ID]_[Visit Number]_[Upload Date (yyyymmdd)].pdf

For example: 0211400750099_01_20171127.pdf

Additional Selection Options for BVC

Completed by:
6-L. Greenblatt

Completed by:
6-W. Jones

Concomitant Medications (CMD)

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

Date of assessment: (CMDASMDT)

 (mm/dd/yyyy)

Indicate which of the following medications the participant is currently taking.

Higher Risk Combination

- 1. Atazanavir: (CMATAZAN) 0-No 1-Yes 97-Unknown
- 2. Azelastine (Nasal): (CMAZELAS) 0-No 1-Yes 97-Unknown
- 3. Conivaptan: (CMCONIVA) 0-No 1-Yes 97-Unknown
- 4. Eluxadoline: (CMELUXAD) 0-No 1-Yes 97-Unknown
- 5. Fusidic Acid (Systemic): (CMFUSIDI) 0-No 1-Yes 97-Unknown
- 6. Idelalisib: (CMIDELAL) 0-No 1-Yes 97-Unknown
- 7. MAO Inhibitors: (CMMAOINH) 0-No 1-Yes 97-Unknown
- 8. Methylalntrexone: (CMMETHYL) 0-No 1-Yes 97-Unknown
- 9. Naldemedine: (CMNALDEM) 0-No 1-Yes 97-Unknown
- 10. Naloxegol: (CMNALOXE) 0-No 1-Yes 97-Unknown
- 11. Orphenadrine: (CMORPHEN) 0-No 1-Yes 97-Unknown
- 12. Oxememazine: (CMOXOMEM) 0-No 1-Yes 97-Unknown
- 13. Paraldehyde: (CMPARALD) 0-No 1-Yes 97-Unknown
- 14. Thalidomide: (CMTHALID) 0-No 1-Yes 97-Unknown

Consider Therapy Modification

- 15. Alvimopan: (CMALVIMO) 0-No 1-Yes 97-Unknown
- 16. Blonanserin: (CMBLONAN) 0-No 1-Yes 97-Unknown
- 17. Dabrafenib: (CMDABRAF) 0-No 1-Yes 97-Unknown
- 18. Droperidol: (CMDROPER) 0-No 1-Yes 97-Unknown
- 19. Enzalutamide: (CMENZALU) 0-No 1-Yes 97-Unknown
- 20. Methotrimeprazine: (CMMETHOT) 0-No 1-Yes 97-Unknown
- 21. Mifeprestone: (CMMIFEPR) 0-No 1-Yes 97-Unknown
- 22. Mitotane: (CMMITOTA) 0-No 1-Yes 97-Unknown
- 23. Perampanel: (CMPERAMP) 0-No 1-Yes 97-Unknown
- 24. Sodium Oxybate: (CMSODIUM) 0-No 1-Yes 97-Unknown
- 25. St. John's Wort: (CMSTJOHN) 0-No 1-Yes 97-Unknown
- 26. Stiripentol: (CMSTIRIP) 0-No 1-Yes 97-Unknown
- 27. Suvorexant: (CMSUVORE) 0-No 1-Yes 97-Unknown
- 28. Tapentadol: (CMTAPENT) 0-No 1-Yes 97-Unknown
- 29. Zolpidem: (CMZOLPID) 0-No 1-Yes 97-Unknown

Monitor Therapy

- 30. Ammonium Chloride: (CMAMMONI) 0-No 1-Yes 97-Unknown
- 31. Amphetamines: (CMAMPHET) 0-No 1-Yes 97-Unknown
- 32. Anticholinergic Agents: (CMANTICH) 0-No 1-Yes 97-Unknown
- 33. Aprepitant: (CMAPREPI) 0-No 1-Yes 97-Unknown
- 34. Boceprevir:

- (CMBOCEPR) 0-No 1-Yes 97-Unknown
35. Bosentan: (CMBOSENT) 0-No 1-Yes 97-Unknown
36. Brimonidine (Topical): (CMBRIMON) 0-No 1-Yes 97-Unknown
37. Ceritinib: (CMCERITI) 0-No 1-Yes 97-Unknown
38. Chlorphenesin Carbamate: (CMCHLORP) 0-No 1-Yes 97-Unknown
39. Cobicistat: (CMCOBICI) 0-No 1-Yes 97-Unknown
40. Daclatasvir: (CMDACLVR) 0-No 1-Yes 97-Unknown
41. Dasatinib: (CMDASATI) 0-No 1-Yes 97-Unknown
42. Deferasirox: (CMDEFERA) 0-No 1-Yes 97-Unknown
43. Dimethindene (Topical): (CMDIMETH) 0-No 1-Yes 97-Unknown
44. Diuretics: (CMDIURET) 0-No 1-Yes 97-Unknown
45. Doxylamine: (CMDOXYLA) 0-No 1-Yes 97-Unknown
46. Dronabinol: (CMDRONAB) 0-No 1-Yes 97-Unknown
47. Efavirenz: (CMEFAVIR) 0-No 1-Yes 97-Unknown
48. Etravirine: (CMETRAVI) 0-No 1-Yes 97-Unknown
49. Fosaprepitant: (CMFOSAPR) 0-No 1-Yes 97-Unknown
50. Gastrointestinal Agents (Prokinetic): (CMGASTAG) 0-No 1-Yes 97-Unknown
51. Hydroxyzine: (CMHYDROX) 0-No 1-Yes 97-Unknown
52. Kava Kava: (CMKAVA) 0-No 1-Yes 97-Unknown
53. Lofexidine: (CMLOFEXI) 0-No 1-Yes 97-Unknown
54. Magnesium Sulfate: (CMMAGNES) 0-No 1-Yes 97-Unknown
55. Metyrosine: (CMMETYRO) 0-No 1-Yes 97-Unknown
56. Minocycline: (CMMINOCY) 0-No 1-Yes 97-Unknown
57. Mirtazapine: (CMMIRTAZ) 0-No 1-Yes 97-Unknown
58. Nabilone: (CMNABILO) 0-No 1-Yes 97-Unknown
59. Netupitant: (CMNETUPI) 0-No 1-Yes 97-Unknown
60. Octreotide: (CMOCTREO) 0-No 1-Yes 97-Unknown
61. Ombitasvir, Paritaprevir, Ritonavir, and Dasabuvir: (CMOMPRDS) 0-No 1-Yes 97-Unknown
62. Oprelvekin: (CMOPRELV) 0-No 1-Yes 97-Unknown
63. Palbociclib: (CMPALBOC) 0-No 1-Yes 97-Unknown
64. Pegvisomant: (CMPEGVIS) 0-No 1-Yes 97-Unknown
65. Piribedil: (CMPIRIBE) 0-No 1-Yes 97-Unknown
66. Pramipexole: (CMPRAMIP) 0-No 1-Yes 97-Unknown
67. Ramosetron: (CMRAMOSE) 0-No 1-Yes 97-Unknown
68. Ropinirole: (CMROPINI) 0-No 1-Yes 97-Unknown
69. Rufinamide: (CMRUFINA) 0-No 1-Yes 97-Unknown
70. Sarilumab: (CMSARILU) 0-No 1-Yes 97-Unknown
71. Selective Serotonin Reuptake Inhibitors: (CMSERINH) 0-No 1-Yes 97-Unknown
72. Serotonin Modulators: (CMSERMOD) 0-No 1-Yes 97-Unknown
73. Siltuximab: (CMSILTUX) 0-No 1-Yes 97-Unknown
74. Simeprevir: (CMSIMEPR) 0-No 1-Yes 97-Unknown
75. Succinylcholine: (CMSUCCIN) 0-No 1-Yes 97-Unknown
76. Tocilizumab: (CMTOCILI) 0-No 1-Yes 97-Unknown
77. Trimeprazine: (CMTRIMEP) 0-No 1-Yes 97-Unknown

Comments:(CMDCOMM)

Clinical Opiate Withdrawal Scale (COW)

Web Version: 1.0; 1.00; 09-20-17

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

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

1. Time of assessment:(COASMTM) (hh:mm)

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.

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

- 0-Pulse rate of 80 or below
- 1-Pulse rate of 81-100
- 2-Pulse rate of 101-120
- 4-Pulse rate greater than 120

3. Sweating (Over past 1/2 hour not accounted for by room temperature or participant activity): (COSWTSCR)

- 0-No report of chills or flushing
- 1-Subjective report of chills or flushing
- 2-Flushed or observable moistness on face
- 3-Beads of sweat on brow or face
- 4-Sweat streaming off face

4. Restlessness (Observation during assessment):(CORSLSCR)

- 0-Able to sit still
- 1-Reports difficulty sitting still, but is able to do so
- 3-Frequent shifting or extraneous movements of legs/arms
- 5-Unable to sit still for more than a few seconds

5. Pupil size:(COPPLSCR)

- 0-Pupils pinned or normal size for room light
- 1-Pupils possibly larger than normal for room light
- 2-Pupils moderately dilated
- 5-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):(COBJASCR)

- 0-Not present
- 1-Mild diffuse discomfort
- 2-Patient reports severe diffuse aching of joints/muscles
- 4-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):(CORNTSCR)

- 0-Not present
- 1-Nasal stuffiness or unusually moist eyes
- 2-Nose running or tearing
- 4-Nose constantly running or tears streaming down cheeks

8. GI upset (Over last 1/2 hour):(COGIUSCR)

- 0-No GI symptoms
- 1-Stomach cramps
- 2-Nausea or loose stool
- 3-Vomiting or diarrhea
- 5-Multiple episodes of diarrhea or vomiting

9. Tremor (Observation of outstretched hands):(COTRMSCR)

- 0-No tremor
- 1-Tremor can be felt, but not observed
- 2-Slight tremor observable
- 4-Gross tremor or muscle twitching

10. Yawning (Observation during assessment):(COYWNSCR)

- 0-No yawning
- 1-Yawning once or twice during assessment
- 2-Yawning three or more times during assesment
- 4-Yawning several times/minute

11. Anxiety or irritability:(COANXSCR)

- 0-None
- 1-Patient reports increasing irritability or anxiousness
- 2-Patient obviously irritable or anxious
- 4-Patient so irritable or anxious that participation in the assessment is difficult

12. Gooseflesh skin:(COGSFSCR)

- 0-Skin is smooth
- 3-Piloerection of skin can be felt or hairs standing up on arms
- 5-Prominent piloerection

13. Total score (Sum of all 11 items):(COTOTSCR)

14. Opiate withdrawal rating:(COWDRAT)

- 0-0-4 No withdrawal
- 1-5-12 Mild
- 2-13-24 Moderate
- 3-25-36 Moderately severe
- 4->36 Severe withdrawal

Comments:(COWCOMM)

NIDA Clinical Trials Network

Demographics (DEM)

Web Version: 1.0; 4.06; 12-04-17

1. Date of birth: (DEBRTHDT)

Text input field for date of birth (mm/dd/yyyy)

2. Sex: (DESEX)

Radio buttons for 1-Male, 2-Female, 97-Don't know, 98-Refused to answer

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

Radio buttons for 0-No, 1-Yes, 97-Don't know, 98-Refused to answer

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

Dropdown menu for Hispanic origin or ancestry with options: 1-Puerto Rican, 2-Dominican (Republic), 3-Mexican/Mexican American, 5-Chicano, 6-Cuban/Cuban American, *Additional Options Listed Below

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

American Indian or Alaska Native: (DEAMEIND)

Radio button for 1-

Asian: (DEASIAN)

Radio button for 1-

Asian Indian: (DEASAIND)

Radio button for 1-

Chinese: (DECHINA)

Radio button for 1-

Filipino: (DEFILIPN)

Radio button for 1-

Japanese: (DEJAPAN)

Radio button for 1-

Korean: (DEKOREA)

Radio button for 1-

Vietnamese: (DEVIETNM)

Radio button for 1-

Specify other Asian: (DEASIAOT)

Text input field for specifying other Asian

Black or African American: (DEBLACK)

Radio button for 1-

Native Hawaiian or Pacific Islander: (DEHAWAII)

Radio button for 1-

Native Hawaiian: (DENATHAW)

Radio button for 1-

Guamanian or Chamorro: (DEGUAM)

Radio button for 1-

Samoa: (DESAMOAN)

Radio button for 1-

Specify other Pacific Islander: (DEPACISO)

Text input field for specifying other Pacific Islander

White: (DEWHITE)

Radio button for 1-

Some other race: (DERACEOT)

Radio button for 1- Specify: (DERACESP)

Text input field for specifying other race

-or-

Don't know: (DERACEDK)

Radio button for 1-

Refused: (DERACERF)

Radio button for 1-

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

Dropdown menu for school grade/level with options: 00-Never attended / kindergarten only, 01-1st grade, 02-2nd grade, 03-3rd grade, 04-4th grade, *Additional Options Listed Below

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

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

If "Other", specify: (DEJOBSP)

Text input field for specifying other job status

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

Dropdown menu for marital status with options: 01-Married, 02-Widowed, 03-Divorced, 04-Separated, 05-Never married, *Additional Options Listed Below

Comments: (DEMCOMM)

Text input field for comments

Additional Selection Options for DEM

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

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

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

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

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

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

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

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

NIDA Clinical Trials Network

DSM-5 - Opioids (DSO)

Web Version: 1.0; 2.01; 05-04-18

Segment (PROTSEG): A

Visit number (VISNO):

Date of assessment:(DSOASMDT)

 (mm/dd/yyyy)

1. Have you used opioids in the past 12 months?(DSOPI12M)

- 0-No 1-Yes

Note: Opioids include heroin.

Answer the following questions about your use of [xx] in the past 12 months.

2. Have you often found that when you started using [xx], you ended up taking more than you intended to? For example, you planned to have a small amount of [xx] but you ended up having much more; or using for a longer period than intended?(DSOPIDOS) 0-No 1-Yes
3. Have you wanted to stop or cut down using or control your use of [xx]?(DSOPICUT) 0-No 1-Yes
4. Have you spent a lot of time getting or using [xx]? Has it taken a lot of time for you to get over the effect?(DSOPITIM) 0-No 1-Yes
5. Have you had a strong desire or urge to use [XX] in between those times when you were using? (Has there been a time when you had such strong urges to use that you had trouble thinking about anything else?(DSOPICRA) 0-No 1-Yes
6. Have you missed work or school or often arrived late because you were intoxicated, high, or recovering from the night before? How about not taking care of things at home because of your use?(DSOPIOBL) 0-No 1-Yes
7. Has your use of [xx] caused problems with other people such as with family members, friends, or people at work? Do you get into arguments about your use or fights when you are using? Do you keep on using anyway?(DSOPISOC) 0-No 1-Yes
8. Have you had to give up or spend less time working, enjoying hobbies, or being with others because of your drug use?(DSOPIACT) 0-No 1-Yes
9. Have you ever gotten high before doing something that requires coordination or concentration like driving, boating, climbing a ladder, or operating heavy machinery? Would you say that your use affected your coordination or concentration so that it was more likely that you or someone else could have been hurt?(DSOPIHAZ) 0-No 1-Yes
10. Have you continued to use even though you knew that [xx] caused you problems like making you depressed, anxious, agitated or irritable? Has your use ever caused physical problems like heart palpitations, trouble breathing or constipation?(DSOPICON) 0-No 1-Yes
11. Have you found you needed to use much more [xx] to get the same effect that you did when you first started taking it?(DSOPI/TOL) 0-No 1-Yes
12. When you reduced or stopped using [xx], did you have withdrawal symptoms or felt sick when you cut down or stopped using? (aches, shaking, fever, weakness, diarrhea, nausea, sweating, heart pounding, difficulty sleeping, or feel agitated, anxious, irritable, or depressed)? Did you use again to keep yourself from getting sick?(DSOPIWIT) 0-No 1-Yes

Meets criteria for Opioid Use Disorder:(DSOPI/SCO)

- 1-Severe
 2-Moderate
 3-Mild
 4-None

Comments:(DSOCOMM)

NIDA Clinical Trials Network

0075A (ENR)

Web Version: 1.0; 1.00; 01-15-18

1. Date informed consent signed:(STARTDT)

 (mm/dd/yyyy)

Comments:(S8COMM)

Main Study Consent

Original main consent

IRB approval date of ICF:(S8IRBDT)

 (mm/dd/yyyy)

Main study re-consent

IRB approval date of ICF:(S8IRB2DT)

 (mm/dd/yyyy)

Date informed consent signed:(S8CST2DT)

 (mm/dd/yyyy)

Main study re-consent

IRB approval date of ICF:(S8IRB3DT)

 (mm/dd/yyyy)

Date of informed consent signed:(S8CST3DT)

 (mm/dd/yyyy)

Main study re-consent

IRB approval date of ICF:(S8IRB4DT)

 (mm/dd/yyyy)

Date of informed consent signed:(S8CST4DT)

 (mm/dd/yyyy)

Other Consents

Other consent 1

Type of consent:(S8CST5TY)

3-HIPAA
4-Medical Release
99-Other

If "Other", specify:(S8CST5SP)

IRB approval date of ICF:(S8IRB5DT)

 (mm/dd/yyyy)

Date informed consent signed:(S8CST5DT)

 (mm/dd/yyyy)

Other 1 re-consent

IRB approval of ICF:(S8IRB6DT)

 (mm/dd/yyyy)

Date informed consent signed:(S8CST6DT)

 (mm/dd/yyyy)

Other consent 2

Type of consent:(S8CST7TY)

3-HIPAA
4-Medical Release
99-Other

If "Other", specify:(S8CST7SP)

IRB approval date of ICF:(S8IRB7DT)

 (mm/dd/yyyy)

Date informed consent signed:(S8CST7DT)

 (mm/dd/yyyy)

Other 2 re-consent

IRB approval date of ICF:(S8IRB8DT)

 (mm/dd/yyyy)

Date informed consent signed:(S8CST8DT)

 (mm/dd/yyyy)

Self-Report of HIV Testing (HIV)

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

Date of assessment: (HIVASMDT)

 (mm/dd/yyyy)

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

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

0-No
1-Yes
97-Don't know
98-Refuse to answer

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

 (xx) month (HITESTYR)/ (xxxx) year

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

0-Negative
1-Positive
4-Indeterminate
3-Never obtained results
98-Refused to answer
*Additional Options Listed Below

4. Which of these best describes the most important reason you have not been tested for HIV in the past 12 months? (HINORES1)

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

Comments: (HIVCOMM)

Additional Selection Options for HIV

What was the result of your most recent HIV test?

97-Don't know

NIDA Clinical Trials Network

Clinical Laboratory Tests (LAB)

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

Segment (PROTSEG): A

Visit number (VISNO):

□

LFTs	Result	Date of Collection	Abstracted from Medical Records
1. Aspartate Aminotransferase (AST/SGOT):	(LAAST) <input type="text"/> (xxxx.x) IU/L	(LAASTDT) <input type="text"/> (mm/dd/yyyy)	(LAASTMR) <input type="checkbox"/> 1-Yes
2. Alanine Aminotransferase (ALT/SGPT):	(LAALT) <input type="text"/> (xxxx.x) IU/L	(LAALTD) <input type="text"/> (mm/dd/yyyy)	(LAALTM) <input type="checkbox"/> 1-Yes

Comments:(LABCOMM)

Medical and Psychiatric History (MHX)

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

Segment (PROTSEG): A

Visit number (VISNO):

Date of assessment: (MHXASMDT)

 (mm/dd/yyyy)

Medical and Psychiatric History

Medical Condition	History of the Condition	If "Yes", specify:	Condition Present Currently
1. Eye disorders:	(MHEYEH) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(MHEYESP) <input type="text"/>	(MHEYEC) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes
2. Ear disorders:	(MHEARH) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(MHEARSP) <input type="text"/>	(MHEARC) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes
3. Respiratory and throat disorders:	(MHRESPH) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(MHRESPPSP) <input type="text"/>	(MHRESPC) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes
4. Cardiovascular disorders:	(MHCARDH) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(MHCARDSP) <input type="text"/>	(MHCARDC) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes
5. Liver and gallbladder disorders:	(MHLIVRH) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(MHLIVRSP) <input type="text"/>	(MHLIVRC) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes
6. Other gastrointestinal disorders:	(MHGIH) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(MHGISP) <input type="text"/>	(MHGIC) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes
7. Skin disorders:	(MHSKINH) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(MHSKINSP) <input type="text"/>	(MHSKINC) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes
8. Musculoskeletal disorders:	(MHMUSCH) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(MHMUSCSP) <input type="text"/>	(MHMUSCC) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes
9. Metabolic disorders:	(MHMETAH) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(MHMETASP) <input type="text"/>	(MHMETAC) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes
10. Endocrine disorders:	(MHENDOH) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(MHENDOSP) <input type="text"/>	(MHENDOC) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes
11. Renal and urinary tract disorders:	(MHRENLH) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(MHRENLSP) <input type="text"/>	(MHRENLC) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes
12. Reproductive system and breast disorders:	(MHREPOH) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(MHREPOSP) <input type="text"/>	(MHREPOC) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes
13. Epilepsy or seizure disorder:	(MHELPYH) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(MHELPYSP) <input type="text"/>	(MHELPYC) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes
14. Clinically significant neurological damage:	(MHNEURH) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(MHNEURSP) <input type="text"/>	(MHNEURC) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes
15. Other nervous system disorders:	(MHNERVH) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(MHNERVSP) <input type="text"/>	(MHNERVC) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes
Psychiatric Condition	History of the Condition	If "Yes", specify:	Condition Present Currently
16. Anxiety or panic disorder:	(MHANXH) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(MHANXSP) <input type="text"/>	(MHANXC) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes
17. Attention Deficit Hyperactivity Disorder:	(MHADHDH) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(MHADHDSP) <input type="text"/>	(MHADHDC) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes
18. Bipolar Disorder:	(MHBPLRH) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(MHBPLRSP) <input type="text"/>	(MHBPLRC) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes
19. Eating Disorder:	(MHEATH) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(MHEATSP) <input type="text"/>	(MHEATC) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes
20. Major Depressive Disorder:	(MHMDDH) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(MHMDDSP) <input type="text"/>	(MHMDDC) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes
21. Schizophrenia:	(MHSCHZH) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(MHSCHZSP) <input type="text"/>	(MHSCHZC) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes

22. Suicidal ideation:	(MHSIDH) <input type="checkbox"/> 0-No <input type="checkbox"/> 1- Yes	(MHSIDSP)	(MHSIDC) <input type="checkbox"/> 0-No <input type="checkbox"/> 1- Yes
23. Suicidal behavior:	(MHSBEHH) <input type="checkbox"/> 0-No <input type="checkbox"/> 1- Yes	(MHSBEHSP)	(MHSBEHC) <input type="checkbox"/> 0-No <input type="checkbox"/> 1- Yes
24. Homicidal ideation:	(MHHIDH) <input type="checkbox"/> 0-No <input type="checkbox"/> 1- Yes	(MHHIDSP)	(MHHIDC) <input type="checkbox"/> 0-No <input type="checkbox"/> 1- Yes
25. Homicidal behavior:	(MHHBEHH) <input type="checkbox"/> 0-No <input type="checkbox"/> 1- Yes	(MHHBEHSP)	(MHHBEHC) <input type="checkbox"/> 0-No <input type="checkbox"/> 1- Yes
26. Violent behavior:	(MHVBEHH) <input type="checkbox"/> 0-No <input type="checkbox"/> 1- Yes	(MHVBEHSP)	(MHVBEHC) <input type="checkbox"/> 0-No <input type="checkbox"/> 1- Yes
27. Psychotic episodes not specified above:	(MHPSYEH) <input type="checkbox"/> 0-No <input type="checkbox"/> 1- Yes	(MHPSYESP)	(MHPSYEC) <input type="checkbox"/> 0-No <input type="checkbox"/> 1- Yes
28. Other psychiatric disorder:	(MHPSYOH) <input type="checkbox"/> 0-No <input type="checkbox"/> 1- Yes	(MHPSYOSP)	(MHPSYOC) <input type="checkbox"/> 0-No <input type="checkbox"/> 1- Yes

Other Conditions Not Listed Above	Specific Details	Condition Present Currently
29. (MHOTHR1)	(MHOTH1SP)	(MHOTHR1C) <input type="checkbox"/> 0-No <input type="checkbox"/> 1- Yes
30. (MHOTHR2)	(MHOTH2SP)	(MHOTHR2C) <input type="checkbox"/> 0-No <input type="checkbox"/> 1- Yes
31. (MHOTHR3)	(MHOTH3SP)	(MHOTHR3C) <input type="checkbox"/> 0-No <input type="checkbox"/> 1- Yes

Surgical/Medical Procedure History

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

If the participant has had major surgery, provide most important/significant surgical event data below, including date of surgery.

If the participant remembers only the year, then record "06" for the month and "15" for the day. If the participant remembers only the month and year, then record "15" for the day.

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

Comments: (MHXCOMM)

Pregnancy and Birth Control Assessment (PBC)

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

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

Complete this form only for females.

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

1. Is the participant of childbearing potential? (PBCHILD)

0-No 1-Yes

a. Why is the participant not of childbearing potential? (PBCHDRSN)

- 1-Participant reports a documented congenital or acquired disorder that is incompatible with pregnancy ▲
- 2-Participant reports having had a hysterectomy or bilateral oophorectomy
- 3-Participant is older than 55
- 4-Participant is at least 50 years of age and reports not menstruating for at least 12 months
- 5-Participant is at least 50 years of age and reports a documented FSH level of greater than 40 mIU/ml
- *Additional Options Listed Below ▼

2. Is the participant breastfeeding? (PBBSTFED)

0-No 1-Yes

3. Does the participant agree to use an acceptable method of birth control? (PBUSEBC)

0-No 1-Yes

If "Yes", select all that apply:

a. Oral contraceptives: (PBORALCN)

0-No 1-Yes

b. Contraceptive patch: (PBPATCH)

0-No 1-Yes

c. Barrier (diaphragm or condom): (PBBARRIR)

0-No 1-Yes

d. Levonorgestrel implant: (PBLEVIMP)

0-No 1-Yes

e. Medroxyprogesterone acetate injection: (PBMEDINJ)

0-No 1-Yes

f. Complete abstinence from sexual intercourse: (PBABSTIN)

0-No 1-Yes

g. Hormonal vaginal contraceptive ring: (PBRING)

0-No 1-Yes

h. Surgical sterilization: (PBSURGSZ)

0-No 1-Yes

i. Intrauterine contraceptive device (IUD): (PBINTDEV)

0-No 1-Yes

j. Other: (PBBCOTH)

0-No 1-Yes

If "Other", specify: (PBBCOSP)

4. Date of the first day of the participant's last menstrual period: (PBPRDDT)

(mm/dd/yyyy)

5. How many days did the participant's last menstrual period last? (PBMNTDUR)

days

6. Was a urine pregnancy test performed? (PBPRGTST)

0-No 1-Yes

a. Date of pregnancy test: (PBPTSTDY)

(mm/dd/yyyy)

b. Result of pregnancy test: (PBRESULT)

0-Negative 1-Positive

Comments: (PBCCOMM)

Additional Selection Options for PBC

Why is the participant not of childbearing potential?

6-Participant is at least 45 years of age and reports not menstruating for at least 18 months

7-Participant is at least 45 years of age and reports a documented FSH level of greater than 40 mIU/ml

Psychosocial Intervention/Counseling Attendance (PCA)

Web Version: 1.0; 1.00; 02-28-18

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

Psychosocial intervention may include cognitive-behavioral therapy, contingency management, motivational enhancement therapy, 12-step facilitation therapy, or any other individual or group therapy.

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

1. Is the participant receiving psychosocial treatment as planned?(PCCONTPT)

0-No
 1-Yes
 97-Does not remember
 98-Does not report

2. In the past 90 days, what treatment has the participant attended:

@2	@2Number of sessions planned	^2Did you attend planned sessions:		@2Number of sessions attended
	No	Yes		
a. Individual counseling:	(PCICPLN) (xxx)	(PCINCNSL)		(PCICATN) (xxx)
b. Group therapy:	(PCGTPLN) (xxx)	(PCGRPTHR)		(PCGTATN) (xxx)
c. Self-help groups:	(PCSHPLN) (xxx)	(PCSHGRP)		(PCSHATN) (xxx)
d. Other, specify:(PCATNSP)	(PCOTHPLN) (xxx)	(PCATNOTH)		(PCOTHATN) (xxx)

If participant does not remember or report psychosocial treatment attendance, the research staff should contact sponsor/counselor and/or family/significant other to collect the following information before the next visit:

3. Confirmed by sponsor/counselor:(PCCONSC) 0-No 1-Yes
 4. Confirmed by family/significant other:(PCCONFSO) 0-No 1-Yes
 Comments:(PCACOMM)

Protocol Deviation (PDV)

Date of deviation (PDDATE):

Protocol deviation number (PDSEQNO):

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

If "Yes", how many participants?(PDPRELN)

0-No 1-Yes

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

Select related participants:

Participant ID 1:(PDPPT01)

9999999999999999-DUMMYPARTICIPANTID ▲
▼

Participant ID 2:(PDPPT02)

9999999999999999-DUMMYPARTICIPANTID ▲
▼

Participant ID 3:(PDPPT03)

9999999999999999-DUMMYPARTICIPANTID ▲
▼

Participant ID 4:(PDPPT04)

9999999999999999-DUMMYPARTICIPANTID ▲
▼

Participant ID 5:(PDPPT05)

9999999999999999-DUMMYPARTICIPANTID ▲
▼

Participant ID 6:(PDPPT06)

9999999999999999-DUMMYPARTICIPANTID ▲
▼

Participant ID 7:(PDPPT07)

9999999999999999-DUMMYPARTICIPANTID ▲
▼

Participant ID 8:(PDPPT08)

9999999999999999-DUMMYPARTICIPANTID ▲
▼

Participant ID 9:(PDPPT09)

9999999999999999-DUMMYPARTICIPANTID ▲
▼

Participant ID 10:(PDPPT10)

9999999999999999-DUMMYPARTICIPANTID ▲
▼

Participant ID 11:(PDPPT11)

9999999999999999-DUMMYPARTICIPANTID ▲
▼

Participant ID 12:(PDPPT12)

9999999999999999-DUMMYPARTICIPANTID ▲
▼

Participant ID 13:(PDPPT13)

9999999999999999-DUMMYPARTICIPANTID ▲
▼

Participant ID 14:(PDPPT14)

9999999999999999-DUMMYPARTICIPANTID ▲
▼

Participant ID 15:(PDPPT15)

9999999999999999-DUMMYPARTICIPANTID ▲
▼

Participant ID 16:(PDPPT16)

9999999999999999-DUMMYPARTICIPANTID ▲
▼

Participant ID 17:(PDPPT17)

9999999999999999-DUMMYPARTICIPANTID ▲
▼

Participant ID 18:(PDPPT18)

9999999999999999-DUMMYPARTICIPANTID ▲
▼

Participant ID 19:(PDPPT19)

9999999999999999-DUMMYPARTICIPANTID ▲
▼

Participant ID 20:(PDPPT20)

9999999999999999-DUMMYPARTICIPANTID ▲
▼

2. Date deviation identified:(PDVDATE)

(mm/dd/yyyy)

3. Deviation type:(PDTYPE)

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

If "Other", specify:(PDYSP)

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

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

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

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

0-No 1-Yes

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

0-No 1-Yes

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

(*mm/dd/yyyy*)

If "No", date of actual submission:(*PDIRBADT*)

(*mm/dd/yyyy*)

Comments:(*PDVCOMM*)

Additional Selection Options for PDV

Protocol deviation number (PSEQNO) (key field):

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

If "Yes", how many participants?

06-6
07-7
08-8
09-9
10-10
11-11
12-12
13-13
14-14
15-15
16-16
17-17
18-18
19-19
20-20

Deviation type:

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

Physical Examination (PEX)

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

Date of assessment: (PEXASMDT)

(mm/dd/yyyy)

Comments

- | | | |
|----------------------------------|---|------------|
| 1. General appearance: | <div style="border: 1px solid gray; padding: 2px;"> 1-Normal
 2-Abnormal, not clinically significant
 3-Abnormal, clinically significant
 97-Not assessed </div> (PEGASP) | (PEGASP) |
| 2. Skin, hair, and nails: | <div style="border: 1px solid gray; padding: 2px;"> 1-Normal
 2-Abnormal, not clinically significant
 3-Abnormal, clinically significant
 97-Not assessed </div> (PESKHRNA) | (PESHNSP) |
| 3. Head and neck: | <div style="border: 1px solid gray; padding: 2px;"> 1-Normal
 2-Abnormal, not clinically significant
 3-Abnormal, clinically significant
 97-Not assessed </div> (PEHDNK) | (PEHDNKSP) |
| 4. Ears, eyes, nose, and throat: | <div style="border: 1px solid gray; padding: 2px;"> 1-Normal
 2-Abnormal, not clinically significant
 3-Abnormal, clinically significant
 97-Not assessed </div> (PEEENT) | (PEENTSP) |
| 5. Cardiovascular: | <div style="border: 1px solid gray; padding: 2px;"> 1-Normal
 2-Abnormal, not clinically significant
 3-Abnormal, clinically significant
 97-Not assessed </div> (PECARD) | (PECARDSP) |
| 6. Respiratory: | <div style="border: 1px solid gray; padding: 2px;"> 1-Normal
 2-Abnormal, not clinically significant
 3-Abnormal, clinically significant
 97-Not assessed </div> (PERESP) | (PERESPSP) |
| 7. Gastrointestinal: | <div style="border: 1px solid gray; padding: 2px;"> 1-Normal
 2-Abnormal, not clinically significant
 3-Abnormal, clinically significant
 97-Not assessed </div> (PEGAST) | (PEGASTSP) |
| 8. Extremities: | <div style="border: 1px solid gray; padding: 2px;"> 1-Normal
 2-Abnormal, not clinically significant
 3-Abnormal, clinically significant
 97-Not assessed </div> (PEEXTR) | (PEEXTRSP) |
| 9. Lymph nodes: | <div style="border: 1px solid gray; padding: 2px;"> 1-Normal
 2-Abnormal, not clinically significant
 3-Abnormal, clinically significant
 97-Not assessed </div> (PELYMP) | (PELYMPSP) |
| 10. Musculoskeletal: | <div style="border: 1px solid gray; padding: 2px;"> 1-Normal
 2-Abnormal, not clinically significant
 3-Abnormal, clinically significant
 97-Not assessed </div> (PEMUSC) | (PEMUSCSP) |
| 11. Neurological: | <div style="border: 1px solid gray; padding: 2px;"> 1-Normal
 2-Abnormal, not clinically significant
 3-Abnormal, clinically significant
 97-Not assessed </div> (PENEUR) | (PENEURSP) |
| 12. Other: (specify in comments) | | |

(PEOTHER)

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

 (PEOTHESP)

Comments: (PEXCOMM)

Patient Health Questionnaire (PHQ-9) (PHQ)

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

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

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

Please answer the following to the best of your ability.

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

Not At All Several Days More Than Half The Days Nearly Every Day

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

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

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

Comments:(PHQCOMM)

Problem List (PLF)

Web Version: 1.0; 1.00; 10-09-17

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

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

1. Alcohol/Drug Use

In the past 12 months, have you had any concern or problem related to your use of alcohol or drugs (including overdose on drugs)? 0-No 1-Yes
Drugs include opioid pain relievers (e.g. fentanyl), heroin, marijuana, antidepressants, medications for anxiety or sleeping, cocaine, methamphetamine (meth, ice), amphetamines (e.g. medications for ADHD), hallucinogens, ecstasy/MDMA (molly), inhalants, or synthetic drugs.(PLADPROB)

- a. How bothered have you been by these alcohol/drug use problems? (PLADBTHR) Not at all Slightly Moderately Considerably Extremely
- b. How important to you now is treatment for these alcohol/drug use problems in addition to the treatment you are already receiving? (PLADTRT)
- Alcohol/drug use comments:(PLADCOMM)

2. Employment/Support Status

In the past 12 months, have you experienced any employment problems (including unemployment)? 0-No 1-Yes
A problem may include an employment condition that affects your family income or support for your family.(PLESPROB)

- a. How bothered have you been by these employment problems? (PLESBTHR) Not at all Slightly Moderately Considerably Extremely
- b. How important to you now is counseling for these employment problems? (PLESCNSL)
- Employment/support status comments:(PLESCOMM)

3. Family Relationships

In the past 12 months, have you had any problems/conflicts with family members or significant others? 0-No 1-Yes
A problem may include: having a significant period in which you have experienced serious problems getting along with one or more family member or significant other, or living with a family member or significant other who has had a significant drinking, drug use, or psychological problem that requires treatment.(PLFRPROB)

- a. How bothered have you been by these problems/conflicts with family members or significant others? (PLFRBTHR) Not at all Slightly Moderately Considerably Extremely
- b. How important to you now is counseling for these problems/conflicts with family members or significant others? (PLFRCNSL)
- Family relationships comments:(PLFRCOMM)

4. Social and Recreational Functioning

In the past 12 months, have you had any problem or conflict with one or more non-family individuals (outside the family) that interferes with your social or recreational functioning? 0-No 1-Yes
A problem may include having a significant period in which you have experienced serious problems getting along with one or more non-family members.(PLSRPROB)

- a. How bothered have you been by these problems or conflicts with one or more non-family individuals? (PLSRBTHR) Not at all Slightly Moderately Considerably Extremely
- b. How important to you now is counseling for these problems/conflicts with one or more non-family individuals? (PLSRCNSL)
- Social and recreational functioning comments:(PLSRCOMM)

5. Psychological Status

In the past 12 months, have you had any psychological or emotional problems? 0-No 1-Yes
A problem may include the receipt of treatment services for any psychological or emotional problems in a hospital or inpatient setting or as an outpatient or private patient.(PLPSPROB)

- a. How bothered have you been by these psychological or emotional problems? (PLPSBTHR) Not at all Slightly Moderately Considerably Extremely
- b. How important to you now is counseling/treatment for these psychological or emotional problems? (PLPSCNSL)
- Psychological status comments:(PLPSCOMM)

6. Legal Status

In the past 12 months, have you had any legal problems?

A legal problem includes any arrest or charge for breaking a law by the criminal justice system (judge, probation/parole officer, etc.), such as driving while intoxicated.(PLLSPROB)

0-No 1-Yes

Not at all

Slightly Somewhat Considerably Extremely

a. How bothered have you been by these legal problems? (PLLSBTHR)

b. How important to you now is counseling for these legal problems? (PLLSCNSL)

Legal status comments:(PLLSCOMM)

7. Medical Status

In the past 12 months, have you experienced any medical problems?

A medical problem includes a hospitalization, an emergency department visit, the receipt of any prescribed medication on a regular basis for a medical problem, or a chronic medical condition that continues to interfere with your life.(PLMSPROB)

0-No 1-Yes

Not at all

Slightly Somewhat Considerably Extremely

a. How bothered have you been by these medical problems? (PLMSBTHR)

b. How important to you now is treatment for these medical problems? (PLMSTRT)

Medical status comments:(PLMSCOMM)

Confirmed Pregnancy and Outcome (PRG)

Web Version: 1.0; 1.01; 04-26-19

Pregnancy number (PGSEQNUM):

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

If "Other", specify:(PROTCNSP)

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

(mm/dd/yyyy)

4. Action taken with study medication:(PRACTIND)

0-None
 1-Dose reduced
 2-Temporarily stopped medication
 3-Permanently stopped medication

5. Approximate due date:(PRAPXDDT)

(mm/dd/yyyy) (PRDDTUNK)OR

97-Unknown

6. Outcome of pregnancy:(PROUTCME)

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

If "Other", specify:(PROTCMSP)

7. Date of pregnancy outcome:(PROTCMDT)

(mm/dd/yyyy)

8. Number of live births:(PRNMLIVB)

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

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

Comments:(PRGCOMM)

Additional Selection Options for PRG

Pregnancy number (PGSEQNUM) (key field):

1-1
2-2
3-3
4-4

Outcome of pregnancy:

97-Unknown

Number of live births:

99-Other
97-Unknown

Quality of Life (QLP)

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

Date of assessment: (QLPASMDT)

(mm/dd/yyyy)

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

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

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

(xx) days

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

(xx) days

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

(xx) days

Comments: (QLPCOMM)

Pre-screen Recruitment (RCT)

Web Version: 1.0; 1.00; 09-29-17

Recruitment date (RCTDATE):

- Approached: (RCAPPRCH)
- 1. Declined pre-screening: (RCDECLNE)
- 2. Pre-screened: (RCSCREEN)
- a. Ineligible - language: (RCLANG)
- b. Ineligible - age: (RCAGE)
- c. Ineligible - medical or psychiatric: (RCMEDPSY)
- d. Ineligible - buprenorphine induction: (RCBUPIND)
- e. Ineligible - buprenorphine maintenance: (RCBUPMT)
- f. Ineligible - short term treatment for OUD: (RCSTTOUD)
- g. Ineligible - not patient with OUD: (RCNOTPT)
- h. Ineligible - can't consent: (RCCONSNT)
- i. Ineligible - other: (RCINELOT) If "Other", specify:(RCINELSP)
- j. Eligible and declined - not interested: (RCNOTINT)
- k. Eligible and declined - refuses transfer: (RCRFTRAN)
- l. Eligible and declined - no time: (RCNOTIME)
- m. Eligible and declined - other: (RCDCLNOT) If "Other", specify:(RCDCLNSP)
- n. Eligible and enrolled: (RCENROLL)

Comments:

(RCTCOMM)

Safety Event Response Checklist - Part A (Self-Report) (SEA)

Segment (PROTSEG): A

Visit number (VISNO):

PART A

To be completed at the beginning of each visit.

Date of assessment:(SEAASMDT)

(mm/dd/yyyy)

Note if the participant has experienced any of the following since the last study visit (or since the time of informed consent, if Visit 1).

For items 1 through 13, use the Medical Events Severity Rating Scale to assess the severity of any reported events.

For item 14, use the Overdose Events Severity Rating Scale to assess the severity of any reported overdoses.

Event	Response	If "Yes", Severity/Grade	Comments
1. Headache:	(SEHDACHE) 0-No 1-Yes	(SEHDSVR) 1-Mild 2-Moderate 3-Severe	(SEHDCOMM)
2. Nausea:	(SENAUSEA) 0-No 1-Yes	(SENASVR) 1-Mild 2-Moderate 3-Severe	(SENAComm)
3. Vomiting:	(SEVOMIT) 0-No 1-Yes	(SEVOMSVR) 1-Mild 2-Moderate 3-Severe	(SEVOCOMM)
4. Constipation:	(SECONSTP) 0-No 1-Yes	(SECONSVR) 1-Mild 2-Moderate 3-Severe	(SECOCOMM)
5. Insomnia:	(SEINSOM) 0-No 1-Yes	(SEINSVR) 1-Mild 2-Moderate 3-Severe	(SEINCOMM)
6. Excessive sweating:	(SEEXCSWT) 0-No 1-Yes	(SESWTSVR) 1-Mild 2-Moderate 3-Severe	(SEESCOMM)
7. Increased sensitivity in the mouth:	(SEINSMTH) 0-No 1-Yes	(SEMTHSVR) 1-Mild 2-Moderate 3-Severe	(SEISCOMM)
8. Burning sensation in the mouth:	(SEBRNMTH) 0-No 1-Yes	(SEBRNSVR) 1-Mild 2-Moderate 3-Severe	(SEBSCOMM)
9. Sores in the mouth:	(SESORES) 0-No 1-Yes	(SESORSVR) 1-Mild 2-Moderate 3-Severe	(SESMCOMM)
10. Pain: If "Yes", specify location:(SEPNLOC)	a. (SEPAIN) 0-No 1-Yes	(SEPNSVR) 1-Mild 2-Moderate 3-Severe	(SEPNCOMM)
11. Swelling: If "Yes", specify location:(SESWLOC)	(SESWELL) 0-No 1-Yes	(SESWLSVR) 1-Mild 2-Moderate 3-Severe	(SESWCOMM)

12. Emergency Department Visit: <i>If "Yes", answer additional questions below.</i>	(SEEDVST) Yes	0-No	1-	(SEEDSVR) 1-Mild 2-Moderate 3-Severe	(SEEDCOMM)
13. Hospitalization: <i>If "Yes", answer additional questions below.</i>	(SEHOSPT) Yes	0-No	1-	(SEHOSSVR) 1-Mild 2-Moderate 3-Severe	(SEHPCOMM)
14. Overdose: <i>If "Yes", answer additional question below.</i>	(SEOD) Yes	0-No	1-Yes	(SEODSVR) 1-Mild 2-Moderate 3-Severe	(SEODCOMM)
15. Death: <i>If "Yes", answer additional questions below.</i>	(SEDEATH) Yes	0-No	1-		(SEDTCOMM)

Emergency Department Visit Follow-up Questions

If "Emergency Department Visit" is answered "Yes" above, respond to the following questions.

1. Diagnosis:(SEEDDX)
2. Substance use related:(SEEDSBUS) 0-No 1-Yes

Hospitalization Follow-up Questions

If "Hospitalization" is answered "Yes" above, respond to the following questions.

1. Diagnosis:(SEHOSPDX)
2. Substance use related:(SEHSBUSE) 0-No 1-Yes

Overdose Follow-up Question

If "Overdose" is answered "Yes" above, respond to the following question.

- Overdose treatment received:(SEODTRT) 0-No 1-Yes

Death Follow-up Questions

If "Death" is answered "Yes" above, respond to the following questions.

1. Date of death:(SETHDT) (mm/dd/yyyy)
2. Cause of death:(SETHCS)

Comments:(SEACOMM)

Upload File Name

Please ensure that the upload file is a PDF and follows the naming convention: **[Participant ID]_[Visit Number]_[Upload Date (yyyymmdd)].pdf**

For example: 0211400750099_01_20180301.pdf

Safety Event Response Checklist - Part B (SEB)

PART B

To be completed within 48 hours of study visit.

Date of assessment:(SEBASMDT)

(mm/dd/yyyy)

A moderate or severe event, or an overdose, hospitalization, ED visit or death, was reported on the Safety Event Response Checklist - Part A (Self-Report).

Notification of the pharmacist and physician is indicated. Complete the questions below.

Notification should occur as soon as possible, but no later than 48 hours after becoming aware of an event.

Method of Reporting to Pharmacist	Date	Time (24-hour format)	Method of Reporting to Physician	Date	Time (24-hour format)
1. (SERPR1MT) 01-Advantage eClinical 02-In-person 03-Phone 04-Email 05-Fax 06-Paper source document 07-Electronic file sharing 99-Other	(SERPR1DT)	(SERPR1TM)	2. (SERPY1MT) 01-Advantage eClinical 02-In-person 03-Phone 04-Email 05-Fax 06-Paper source document 07-Electronic file sharing 99-Other	(SERPY1DT)	(SERPY1TM)
	(mm/dd/yyyy)	(hh:mm)		(mm/dd/yyyy)	(hh:mm)
^3 If "Other", specify:(SERPR1OT)			^3 If "Other", specify:(SERPY1OT)		
3. (SERPR2MT) 01-Advantage eClinical 02-In-person 03-Phone 04-Email 05-Fax 06-Paper source document 07-Electronic file sharing 99-Other	(SERPR2DT)	(SERPR2TM)	4. (SERPY2MT) 01-Advantage eClinical 02-In-person 03-Phone 04-Email 05-Fax 06-Paper source document 07-Electronic file sharing 99-Other	(SERPY2DT)	(SERPY2TM)
	(mm/dd/yyyy)	(hh:mm)		(mm/dd/yyyy)	(hh:mm)
^3 If "Other", specify:(SERPR2OT)			^3 If "Other", specify:(SERPY2OT)		
5. (SERPR3MT) 01-Advantage eClinical 02-In-person 03-Phone 04-Email 05-Fax 06-Paper source document 07-Electronic file sharing 99-Other	(SERPR3DT)	(SERPR3TM)	6. (SERPY3MT) 01-Advantage eClinical 02-In-person 03-Phone 04-Email 05-Fax 06-Paper source document 07-Electronic file sharing 99-Other	(SERPY3DT)	(SERPY3TM)
	(mm/dd/yyyy)	(hh:mm)		(mm/dd/yyyy)	(hh:mm)
^3 If "Other", specify:(SERPR3OT)			^3 If "Other", specify:(SERPY3OT)		

Comments:(SEBCOMM)

Suicide Risk Screener - Part 1 (SR1)

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

Date of assessment: (SR1ASMDT) (mm/dd/yyyy)

Have you had thoughts of actually hurting yourself? (SRTHOGHT) 0-No 1-Yes

1. Have you ever attempted to harm yourself in the past? (SRATTMPT) 0-No 1-Yes

2. Have you thought about how you might actually hurt yourself? (SRHOWHRT) 0-No 1-Yes

How? (SRHOWSP)

3. There's a big difference between having a thought and acting on a thought. How likely do you think it is that you will act on these thoughts about hurting yourself or ending your life some time over the next month? (SRACTON)

0-Not at all likely
1-Somewhat likely
2-Very likely

4. Is there anything that would prevent or keep you from harming yourself? (SRPREVNT) 0-No 1-Yes

What? (SRPRVTSP)

Risk category: (SRRISK)

0-Minimal
1-Lower
2-Higher

Comments: (SR1COMM)

Suicide Risk Screener - Part 2 (SR2)

Web Version: 1.0; 1.00; 10-09-17

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

Date of assessment: (SR2ASMDT) (mm/dd/yyyy)

1. Do you live alone? (SRLIVALN) 0-No 1-Yes

2. Have you thought about taking an overdose of medication, driving your car off the road, using a gun, or doing something else serious like this? (SRSETHHT)
What is it? (SRSESP) 0-No 1-Yes

3. Do you own a gun? (SRGUN) 0-No 1-Yes

4. Have you been stockpiling (saving up) medication? (SRSAVMED) 0-No 1-Yes

5. Do you feel hopeless about the future? (SRHOPLES) 0-No 1-A little 2-Somewhat 3-Very

6. Do you feel you can resist your impulses to harm yourself? (SRRESIST) 0-No 1-Yes

7. Right now, how strong is your wish to die? (SRWHDIE) 0-No wish 1-Weak 2-Strong

Comments: (SR2COMM)

Suicidal Risk (SUR)

Web Version: 1.0; 1.00; 03-18-19

Segment (PROTSEG): A

Visit number (VISNO):

The participant's score on a mental health assessment given at this visit indicates they should have seen a clinician in order to receive an in-person assessment for suicide risk before leaving the clinic.

Date of assessment:(SURASMDT)

(mm/dd/yyyy)

Was an assessment of suicidal risk performed?(SUASSESS)

0-No

1-Yes

If "Yes", document the actions taken and the outcome of local SOP activation:
(SUSOPACT)

NIDA Clinical Trials Network

Timeline Followback (T75)

Web Version: 1.0; 1.00; 10-05-17

TFB week start date (TFWKSTD):

Day	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Date	(TLDATE1) <input type="text"/>	(TLDATE2) <input type="text"/>	(TLDATE3) <input type="text"/>	(TLDATE4) <input type="text"/>	(TLDATE5) <input type="text"/>	(TLDATE6) <input type="text"/>	(TLDATE7) <input type="text"/>
1. Have any cigarettes or e-cigarettes, alcohol, marijuana or any other illicit substances been used during this assessment period?	(TLSUBAL1) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLSUBAL2) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLSUBAL3) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLSUBAL4) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLSUBAL5) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLSUBAL6) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLSUBAL7) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes
2. Number of cigarettes (xx):	(TLNMCIG1) <input type="text"/>	(TLNMCIG2) <input type="text"/>	(TLNMCIG3) <input type="text"/>	(TLNMCIG4) <input type="text"/>	(TLNMCIG5) <input type="text"/>	(TLNMCIG6) <input type="text"/>	(TLNMCIG7) <input type="text"/>
3. E-cigarettes:	(TLECI1) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLECI2) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLECI3) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLECI4) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLECI5) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLECI6) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(TLECI7) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes
4. Number of standard alcoholic drinks (xx):	(TLALCHL1) <input type="text"/>	(TLALCHL2) <input type="text"/>	(TLALCHL3) <input type="text"/>	(TLALCHL4) <input type="text"/>	(TLALCHL5) <input type="text"/>	(TLALCHL6) <input type="text"/>	(TLALCHL7) <input type="text"/>
5. Cannabinoids/ Marijuana:	(TLTHCR1) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLTHCR2) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLTHCR3) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLTHCR4) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLTHCR5) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLTHCR6) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLTHCR7) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below
6. Cocaine:	(TLCOCR1) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLCOCR2) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLCOCR3) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLCOCR4) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLCOCR5) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLCOCR6) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLCOCR7) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below
7. Crack:	(TL CRAK1) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TL CRAK2) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TL CRAK3) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TL CRAK4) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TL CRAK5) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TL CRAK6) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TL CRAK7) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below
8. Amphetamine-type stimulants, including methamphetamine:	(TLAMPR1) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLAMPR2) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLAMPR3) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLAMPR4) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLAMPR5) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLAMPR6) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLAMPR7) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below
9. Opioid analgesics, including methadone and fentanyl:	(TLMTDR1) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLMTDR2) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLMTDR3) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLMTDR4) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLMTDR5) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLMTDR6) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLMTDR7) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below
10. Heroin:	(TLHERR1) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLHERR2) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLHERR3) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLHERR4) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLHERR5) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLHERR6) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLHERR7) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below
11. Hallucinogens, including MDMA/ecstasy(molly):	(TLM DAR1) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLM DAR2) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLM DAR3) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLM DAR4) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLM DAR5) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLM DAR6) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLM DAR7) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below
12. Sedatives and hypnotics, excluding Benzodiazepines:	(TLBARR1) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLBARR2) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLBARR3) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLBARR4) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLBARR5) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLBARR6) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLBARR7) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below
13. Benzodiazepines:	(TLBZOR1) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLBZOR2) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLBZOR3) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLBZOR4) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLBZOR5) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLBZOR6) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLBZOR7) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below

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

Comments: (TFBCOMM)

Additional Selection Options for T75

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

TLFB Assessment Period (TAP)

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

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

Date of assessment: (*TAPASMDT*)

(*mm/dd/yyyy*)

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

From: (*mm/dd/yyyy*)

To: (*mm/dd/yyyy*)

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

0-No

1-Yes

Comments: (*TAPCOMM*)

Non-Drug Therapy Log (TRT)

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

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

Non-drug therapy may include, but not be limited to: physical therapy, acupuncture, massage, relaxation therapy, aromatherapy, music therapy, light box therapy, mindfulness-based intervention, or meditation therapy.

	No	Yes	If "Yes", how many times since your last visit?	Date Stopped	Ongoing at Termination	1-Yes	Progress Notes or Comments
1. Did you receive any of the following non-drug therapies since your last visit? (TRTHPVST)					0-No	1-Yes	
a. Physical therapy:	(TRPHYTHP)	(TRPHYVST)	(TRPHYVST)	(TRPHYDT)	(TRPHYTRM)	(TRPHCOMM)	
		(xx)		(mm/dd/yyyy)	1-Yes		
b. Acupuncture:	(TRACUPUN)	(TRACUVST)	(TRACUVST)	(TRACUDT)	(TRACUTRM)	(TRACCOMM)	
		(xx)		(mm/dd/yyyy)	1-Yes		
c. Massage:	(TRMASSGE)	(TRMSGVST)	(TRMSGVST)	(TRMSGDT)	(TRMSGTRM)	(TRMSCOMM)	
		(xx)		(mm/dd/yyyy)	1-Yes		
d. Relaxation therapy:	(TRLAXTHP)	(TRLAXVST)	(TRLAXVST)	(TRLAXDT)	(TRLAXTRM)	(TRLACOMM)	
		(xx)		(mm/dd/yyyy)	1-Yes		
e. Aromatherapy:	(TRAROTHP)	(TRAROVST)	(TRAROVST)	(TRARODT)	(TRAROTRM)	(TRARCOMM)	
		(xx)		(mm/dd/yyyy)	1-Yes		
f. Music therapy:	(TRMSCTHP)	(TRMSCVST)	(TRMSCVST)	(TRMSCDT)	(TRMSCTRM)	(TRMCCOMM)	
		(xx)		(mm/dd/yyyy)	1-Yes		
g. Light box therapy:	(TRLGTTHP)	(TRLGTVST)	(TRLGTVST)	(TRLGTDI)	(TRLGTTRM)	(TRLGCOMM)	
		(xx)		(mm/dd/yyyy)	1-Yes		
h. Mindfulness-based intervention:	(TRMNDTHP)	(TRMNDVST)	(TRMNDVST)	(TRMNDI)	(TRMNDTRM)	(TRMNCOMM)	
		(xx)		(mm/dd/yyyy)	1-Yes		
i. Meditation therapy:	(TRMDTTHP)	(TRMDTVST)	(TRMDTVST)	(TRMDTDI)	(TRMDTTRM)	(TRMDCOMM)	
		(xx)		(mm/dd/yyyy)	1-Yes		
j. If "Other", specify: (TROTHESP)	(TROTHSP)	(TROTHVST)	(TROTHVST)	(TROTHDI)	(TROTHTRM)	(TROTHCOMM)	
		(xx)		(mm/dd/yyyy)	1-Yes		

Comments: (TRTCOMM)

Treatment Satisfaction (TS2)

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

Date of assessment:(TS2ASMDT) (mm/dd/yyyy)

Think about your study experience since 03/28/2018.
 Think about your study experience since 04/02/2018.

Very Satisfied Satisfied Neither Satisfied nor Dissatisfied Dissatisfied Very Dissatisfied

- 1. Overall, how satisfied are you with your experience in this study? (T2SATEXP)
- 2. Overall, how satisfied are you with the quality of treatment offered in this study? (T2SATTRT)

- 3. How difficult do you think it made it for the treatment to be transferred from the physician's office to the pharmacy?(T2TRTPTP)
 - 0-Not difficult at all
 - 1-Somewhat difficult
 - 2-Very difficult
 - 3-Extremely difficult

- 4. How useful/convenient do you think it is to hold buprenorphine visits in the same place the medication is dispensed?(T2CONVBT)
 - 0-Not at all useful/convenient
 - 1-Somewhat useful/convenient
 - 2-Moderately useful/convenient
 - 3-Very useful/convenient
 - 4-Extremely useful/convenient

5. Indicate whether you found the following aspects of study treatment to be less effective, equally effective, or more effective when compared to receiving regular office based buprenorphine treatment:

Less Effective No Difference in Effectiveness More Effective

- a. Having more than one health professional figure involved: (T2ASMOP)
- b. Time spent in each visit: (T2ASTVST)
- c. Time to release buprenorphine prescription: (T2ASTBRX)
- d. Efficiency of treatment delivery: (T2ASDELV)
- e. Other, specify:(T2SASPSP) (T2SASPOT)

- 6. If you had to do it all over again, would you still choose to participate in the study? (T2DOOVER)
 - 4-Definitely participate
 - 3-Probably participate
 - 2-Probably not participate
 - 1-Definitely not participate

7. Indicate whether each of the following would influence your decision to participate again:

- a. I like the compensation:(T2YPACMP) 0-No 1-Yes
- b. My participation may help to improve and expand treatment delivery/options: (T2YPAEXP) 0-No 1-Yes
- c. Pharmacy is the right location for this type of treatment:(T2YPAPHR) 0-No 1-Yes
- d. The treatment offered was of better quality than the usual treatment:(T2YPAQUL) 0-No 1-Yes
- e. It was easy to understand/distinguish patient, physician, and pharmacist roles: (T2YPAROL) 0-No 1-Yes
- f. Other:(T2YPAOT) 0-No 1-Yes
 - 1. If "Other", specify:(T2YPASP)

8. Indicate whether each of the following would influence your decision not to participate again:

- a. I would rather be part of the usual treatment process:(T2NPAUST) 0-No 1-Yes
- b. It was difficult to find time to be part of this treatment process (time consuming): (T2NPATC) 0-No 1-Yes
- c. Pharmacy is inconvenient for confidentiality purpose:(T2NPACON) 0-No 1-Yes
- d. There are too many procedures/visits are too long:(T2NPAPRV) 0-No 1-Yes
- e. It was difficult to understand/distinguish patient, physician, and pharmacist roles: (T2NPADRL) 0-No 1-Yes
- f. Other:(T2NPAOT) 0-No 1-Yes
 - 1. If "Other", specify:(T2NPASP)

Comments:(TS2COMM)

Tobacco Use History (TUH)

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

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

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

- 1. Have you smoked at least 100 cigarettes in your entire life?(TUSMK100)
- 2. Do you now smoke cigarettes every day, some days, or not at all?(TUSMFREQ)

0-No	1-Yes	97-Don't know/refused
<div style="border: 1px solid gray; padding: 2px;"> 1-Every day 2-Some days 3-Not at all 97-Don't know/refused </div>		

- 3. Have you EVER smoked cigarettes EVERY DAY for at least 6 months?(TUEVERY)
- 4. How old were you when you first started smoking cigarettes FAIRLY REGULARLY? (TUSTRTRG)

0-No	1-Yes	97-Don't know/refused
	(xx) years old (TUSTRGDR)	97-Don't know/refused

Section A: Every-Day Smokers

- 5. On the average, about how many cigarettes do you now smoke each day?(TUNUMDY)
- 6. How old were you when you first started smoking cigarettes every day?(TUSTRTAG)

(xx) cigarettes per day (TUNMDYDR)	97-Don't know/refused
(xx) years old (TUSTAGDR)	97-Don't know/refused

Section B: Some-Day Smokers

- 7. On how many of the past 30 days did you smoke cigarettes?(TU30DAYS)
- 8. On the average, on those days, how many cigarettes did you usually smoke each day? (TU30AVG)

(xx) days (TU30DDR)	97-Don't know/refused
(xx) cigarettes per day (TU30ADR)	97-Don't know/refused

Section C: Former Smokers

- 9. When you last smoked every day, on average how many cigarettes did you smoke each day?(TUNUMEDY)
- 10. When you last smoked fairly regularly, on average how many cigarettes did you smoke each day?(TUNUMRDY)

(xx) cigarettes per day (TUNMEDDR)	97-Don't know/refused
(xx) cigarettes per day (TUNMRDDR)	97-Don't know/refused

Comments:(TUHCOMM)

Urine Drug Screen (UDS)

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

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

0-No 1-Yes

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

If "Other", specify:(UDNOSP1)

1st Urine Drug Screen

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

(mm/dd/yyyy)

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

0-No 1-Yes

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

0-No 1-Yes

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

Drug Name (Abbreviation)	Negative	Positive	Invalid
Benzodiazepines (BZO):	(UDBZO1)		
Amphetamine (AMP):	(UDAMP1)		
Marijuana (THC):	(UDTHC1)		
Methamphetamine (MET):	(UDMET1)		
Opiates (2000 ng) (OPI):	(UDOPI1)		
Cocaine (COC):	(UDCOC1)		
Ecstasy (MDMA):	(UDMDA1)		
Oxycodone (OXY):	(UDOXY1)		
Methadone (MTD):	(UDMTD1)		
Barbiturate (BAR):	(UDBAR1)		
Opiates (300 ng) (OPI):	(UDOPI31)		
Buprenorphine (10 ng) (BUP):	(UDBUP1)		

2nd Urine Drug Screen

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

0-No 1-Yes

If "No", reason:(UDNORSN2)

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

If "Other", specify:(UDNOSP2)

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

0-No 1-Yes

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

0-No 1-Yes

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

Drug Name (Abbreviation)	Negative	Positive	Invalid
Benzodiazepines (BZO):	(UDBZO2)		
Amphetamine (AMP):	(UDAMP2)		
Marijuana (THC):	(UDTHC2)		
Methamphetamine (MET):	(UDMET2)		
Opiates (2000 ng) (OPI):	(UDOPI2)		

Cocaine (COC): (UDCOC2)

Ecstasy (MDMA): (UDMDA2)

Oxycodone (OXY): (UDOXY2)

Methadone (MTD): (UDMTD2)

Barbiturate (BAR): (UDBAR2)

Opiates (300 ng) (OPI): (UDOPI32)

Buprenorphine (10 ng) (BUP): (UDBUP2)

Comments:(UDSCOMM)

Visual Analog Craving Scale (VAS)

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

Segment (PROTSEG): A

Visit number (VISNO):

Date of assessment:(VASASMDT)

(mm/dd/yyyy)

Think about your current cravings.

How intense is your worst craving?

Click on the line below or click and drag the blue circle to the spot that indicates the intensity of the worst craving you are currently having for each of the substances.

You can leave your circle anywhere on the line to show how intense your craving is.

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

(xxx)

Comments:(VASCOMM)

Vital Signs (VIT)

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

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

Date of assessment: (VITASMDT)

(mm/dd/yyyy)

1. Standing height: (VIHGTIN)

(xx.x) in (VIHGTCM)

(xxx.x) cm

Body Mass Index

2. Measured weight: (VIWTLBS)

(xxx.x) lbs (VIWTKGS)

(xxx.x) kgs

3. BMI: (VIBMI)

Vital Signs

4. Temperature: (VITMPF)

(xxx.x) °F

5. Respiration: (VIRESP)

(xx) breaths per minute

6. Heart rate/pulse: (VIPULS)

(xxx) beats per minute

7. Systolic/diastolic blood pressure: (VIBPSY)

(xxx) / (VIBPDI)

(xxx) mmHg

Comments: (VITCOMM)