

NIDA Clinical Trials Network

Buprenorphine Log (BLG)

Web Version: 1.0; 3.00; 11-16-18

Segment (PROTSEG): B

Visit number (VISNO):

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

Returned Films

1. Were any buprenorphine films returned at this visit?(BLRETURN)

0-No 1-Yes

If "Yes", which type:(BLRETTYP)

0-4mg
1-8mg
2-Both 4mg and 8mg

2. Date films returned:(BLRETFDT) (mm/dd/yyyy)

a. Indicate the number of 4 mg films returned and the corresponding lot information below.

Lot Number Returned	Lot Number Expiration Date	Number of 4 mg Films Returned from Lot
(BL4LNR1) <input type="text"/>	(BL4R1EDT) <input type="text"/> (mm/dd/yyyy)	(BL4NUMR1) <input type="text"/> (xxx.xx)
(BL4LNR2) <input type="text"/>	(BL4R2EDT) <input type="text"/> (mm/dd/yyyy)	(BL4NUMR2) <input type="text"/> (xxx.xx)
(BL4LNR3) <input type="text"/>	(BL4R3EDT) <input type="text"/> (mm/dd/yyyy)	(BL4NUMR3) <input type="text"/> (xxx.xx)

b. Indicate the number of 8 mg films returned and the corresponding lot information below.

Lot Number Returned	Lot Number Expiration Date	Number of 8 mg Films Returned from Lot
(BL8LNR1) <input type="text"/>	(BL8R1EDT) <input type="text"/> (mm/dd/yyyy)	(BL8NUMR1) <input type="text"/> (xxx.xx)
(BL8LNR2) <input type="text"/>	(BL8R2EDT) <input type="text"/> (mm/dd/yyyy)	(BL8NUMR2) <input type="text"/> (xxx.xx)
(BL8LNR3) <input type="text"/>	(BL8R3EDT) <input type="text"/> (mm/dd/yyyy)	(BL8NUMR3) <input type="text"/> (xxx.xx)

Dispensed Films (Current Visit)

3. Were any buprenorphine films dispensed at this visit?(BLDISPEN)

0-No 1-Yes

If "Yes", which type:(BLDSPTYP)

0-4mg
1-8mg
2-Both 4mg and 8mg

4. Date films dispensed:(BLDSPFDT) (mm/dd/yyyy)

5. Prescribed daily dose at current visit:(BLRXDOSE) (xx) mg

a. Indicate the number of 4 mg films dispensed and the corresponding lot information below.

Lot Number Dispensed	Lot Number Expiration Date	Number of 4 mg Films Dispensed from Lot
(BL4LND1) <input type="text"/>	(BL4D1EDT) <input type="text"/> (mm/dd/yyyy)	(BL4NUMD1) <input type="text"/> (xxx.xx)
(BL4LND2) <input type="text"/>	(BL4D2EDT) <input type="text"/> (mm/dd/yyyy)	(BL4NUMD2) <input type="text"/> (xxx.xx)
(BL4LND3) <input type="text"/>	(BL4D3EDT) <input type="text"/> (mm/dd/yyyy)	(BL4NUMD3) <input type="text"/> (xxx.xx)

b. Indicate the number of 8 mg films dispensed and the corresponding lot information below.

Lot Number Dispensed	Lot Number Expiration Date	Number of 8 mg Films Dispensed from Lot
(BL8LND1) <input type="text"/>	(BL8D1EDT) <input type="text"/> (mm/dd/yyyy)	(BL8NUMD1) <input type="text"/> (xxx.xx)
(BL8LND2) <input type="text"/>	(BL8D2EDT) <input type="text"/> (mm/dd/yyyy)	(BL8NUMD2) <input type="text"/> (xxx.xx)
(BL8LND3) <input type="text"/>	(BL8D3EDT) <input type="text"/> (mm/dd/yyyy)	(BL8NUMD3) <input type="text"/> (xxx.xx)

Dose Adjustment

6. If dose was adjusted, what was the reason for the adjustment?
(BLADJRSN)

7. Was the dose adjustment approved by the physician? (BLADJAPR)

0-No 1-Yes

Comments: (BLGCOMM)

Buprenorphine Visit Checklist (BVC)

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

Segment (PROTSEG): B
 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):	(BVVASPDPT) <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				
a. Current visit UDS positive for opioids/heroin:	(BVUDSDT) <input type="text"/> (mm/dd/yyyy)	(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:	(BVOIPIPOS) <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 any illicit benzodiazepine use since last visit 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) 0-No 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. Was a suicidality risk assessment required (SR1)?

Only required if indicated by Problem List Form or in case of Early Termination Visit.

(BVSR1CMP) 0-No 1-Yes

(BVSR1NC)

a. Suicidality (P4 suicidality screener) risk:

(BVSR1DT)

(mm/dd/yyyy)

(BVSR1SCR) 0-Minimal 1-Lower 2-Higher

(BVSR1SNC)

b. Trigger:

(BVSR1TRG)
0-No 1-Yes

8. Has the

(BVCMDDT)

(BVMEDNEW) 0-No 1-Yes

(BVMEDNC)

participant begun taking any new prescription drugs since the last visit?
 (mm/dd/yyyy)
 If "Yes", list names of newly prescribed drugs in Progress Notes/Comments field.

9. Were any new treatments reported on the Non-Drug Therapy (TRT) form?
 (BVTRTDT) (BVTRTNEW) 0-No 1-Yes
 (mm/dd/yyyy)
 If "Yes", list names of new non-drug therapies received in Progress Notes/Comments Field.

(BVTRTNC)

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)?
 (BVSEADT) (BVSEAMS) 0-No 1-Yes
 (mm/dd/yyyy)
 If "Yes", provide pharmacist with a copy of the Safety Event Response Checklist.

(BVSEANC)

Trigger:

(BVSEATRG)
 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>	(BVDBUPDT) <input type="text"/> (mm/dd/yyyy)	(BVDBUPFC) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(BVDBUPNC) <input type="text"/>
13. Was participant education (e.g., overdose prevention, other drug use, compliance with psychosocial treatment and medications, safety storage of medications) completed?	(BVDPEDDT) <input type="text"/> (mm/dd/yyyy)	(BVDPTEDC) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(BVDPEDNC) <input type="text"/>
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>	(BVDPDMDT) <input type="text"/> (mm/dd/yyyy)	(BVDPDMPC) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(BVDPDMNC) <input type="text"/>
a. Multiple buprenorphine prescriptions:		(BVDMUBUP) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(BVDMBUPC) <input type="text"/>
b. Other opiate prescriptions:		(BVDDMOPI) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(BVDDOPINC) <input type="text"/>
c. Unauthorized benzodiazepine prescriptions:		(BVDBZBO) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(BVDBZONC) <input type="text"/>
15. Was the Treatment Plan for Opioid Use Disorder completed? If "Yes", was the plan modified?	(BVDTPTD) <input type="text"/> (mm/dd/yyyy)	(BVDTTRPC) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes (BVDTMOD) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(BVDTPLNC) <input type="text"/> (BVDTMODC) <input type="text"/>
16. Is buprenorphine dose confirmed?	(BVDBUPD) <input type="text"/> (mm/dd/yyyy)	(BVDBUPDC) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(BVDBUPN) <input type="text"/>

17. Was buprenorphine prescribing completed?

(BVDBBUP)

(mm/dd/yyyy)

(BVDBUPRX) 0-No
 1-Yes

(BVDBUPRC)

18. Is a dose adjustment indicated?

(BVDADJDT)

(mm/dd/yyyy)

(BVDBUPAI) 0-No
1-Yes

(BVDBUPAC)

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) (mm/dd/yyyy)	(BVPBUPFC) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(BVPBUPNC)
21. Was participant education (e.g., overdose prevention, other drug use, compliance with psychosocial treatment and medications, safety storage of medications) completed?	(BVPPEDDT) (mm/dd/yyyy)	(BVPPTEDC) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(BVPPE DNC)
22. Was monitoring of the State Prescription Drug Monitoring Program (PDMP) completed? If "Yes", indicate whether or not evidence of any of the following was found:	(BVPPMDT) (mm/dd/yyyy)	(BVPPDMP) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(BVPPDMNC)
a. Multiple buprenorphine prescriptions:		(BVPMBUP) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(BVPMBUPC)
b. Other opiate prescriptions:		(BVPDMOPI) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(BVPPOPINC)
c. Unauthorized benzodiazepine prescriptions:		(BVPUBZO) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(BVPBZONC)
23. Were the Electronic Medical Records (EHR) accessed?	(BVPEHRDT) (mm/dd/yyyy)	(BVPAEHR) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes <input type="checkbox"/> 96-N/A (unable to access EHR)	(BVPEHRNC)
24. Did the participant provide a negative urine pregnancy test prior to buprenorphine dispensing?	(BVPPRGDT) (mm/dd/yyyy)	(BVPBUPNG) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(BVPPRGNC)
25. Was buprenorphine dispensing completed?	(BVPBUPD) (mm/dd/yyyy)	(BVPBUPDS) <input type="checkbox"/> 0-No <input type="checkbox"/> 1-Yes	(BVPBUPDC)
26. Date of next appointment:	(BVPAPTDT) (mm/dd/yyyy)		(BVPAPTNC)

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

NIDA Clinical Trials Network

Buprenorphine Visit Monitor (BVM)

Web Version: 1.0; 4.01; 01-04-19

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

1. Date of supervision (date form completed):(BMSUPDT) (mm/dd/yyyy)

2. Date of visit being monitored:(BMVSTDT) (mm/dd/yyyy)

3. Completed by:(BMCOMPID)
 01-C. Erami
 02-E. Morse
 03-J. Battle
 04-J. Finch
 05-L. Bowlby
 *Additional Options Listed Below

Research Staff Items

Tasks	Summary	Progress Notes/Comments
4. Opioid withdrawal, per Clinical Opioid Withdrawal Scale (COWS):	(BMCOWCMP) <input type="checkbox"/> 0-Incomplete <input type="checkbox"/> 1-Complete <input type="checkbox"/> 96-N/A	(BMCOWNC) <input type="text"/>
5. Self-reported opioid craving, per Visual Analog Craving Scale (VAS):	(BMVASCMP) <input type="checkbox"/> 0-Incomplete <input type="checkbox"/> 1-Complete <input type="checkbox"/> 96-N/A	(BMVASNC) <input type="text"/>
6. Urine Drug Screening (UDS):	(BMUDSCMP) <input type="checkbox"/> 0-Incomplete <input type="checkbox"/> 1-Complete <input type="checkbox"/> 96-N/A	(BMUDSNC) <input type="text"/>
7. Self-reported benzodiazepine use, per Timeline Followback (TLFB):	(BMTFBCMP) <input type="checkbox"/> 0-Incomplete <input type="checkbox"/> 1-Complete <input type="checkbox"/> 96-N/A	(BMTLFBNC) <input type="text"/>
8. Participant compliance with psychosocial intervention attendance, per the Psychosocial Intervention/Counseling Attendance (PCA) form:	(BMPCACMP) <input type="checkbox"/> 0-Incomplete <input type="checkbox"/> 1-Complete <input type="checkbox"/> 96-N/A	(BMPCANC) <input type="text"/>
9. Participant report of any substance use, financial, family, social, psychiatric, legal, or medical issues, per the Problem List (PLF) form:	(BMPLFCMP) <input type="checkbox"/> 0-Incomplete <input type="checkbox"/> 1-Complete <input type="checkbox"/> 96-N/A	(BMPLFNC) <input type="text"/>
10. Suicidality (P4 Suicidality Screener):	(BMSR1CMP) <input type="checkbox"/> 0-Incomplete <input type="checkbox"/> 1-Complete <input type="checkbox"/> 96-N/A	(BMSR1NC) <input type="text"/>
11. Concomitant Medications:	(BMCMDCMP) <input type="checkbox"/> 0-Incomplete <input type="checkbox"/> 1-Complete <input type="checkbox"/> 96-N/A	(BMCMDNC) <input type="text"/>
12. Non-Drug Therapy Log (TRT) form:	(BMTRTCMP) <input type="checkbox"/> 0-Incomplete <input type="checkbox"/> 1-Complete <input type="checkbox"/> 96-N/A	(BMTRTNC) <input type="text"/>
13. Safety Event Response Checklist - Part A (SEA):	(BMSEACMP) <input type="checkbox"/> 0-Incomplete <input type="checkbox"/> 1-Complete <input type="checkbox"/> 96-N/A	(BMSEANC) <input type="text"/>

Physician Items

Tasks	Summary	Progress Notes/Comments
14. Monitoring of the State Prescription Drug Monitoring Program (PDMP):	(BMDDPMP) <input type="checkbox"/> 0-Incomplete <input type="checkbox"/> 1-Complete <input type="checkbox"/> <input type="checkbox"/> 96-N/A	(BMDDPMNC) <input type="text"/>

15. Treatment Plan for Opioid Use Disorder:

(BMDTRTPC) 0-Incomplete 1-Complete
 96-N/A

(BMDTPLNC)

16. Buprenorphine prescribing:

(BMDBUPRX) 0-Incomplete 1-Complete
 96-N/A

(BMDBUPRC)

Pharmacist Items

Tasks

Summary

Progress Notes/Comments

17. Medication reconciliation (buprenorphine film count):

(BMPBUPFC) 0-Incomplete 1-Complete
Complete 96-N/A

(BMPBUPNC)

18. Participant education (e.g., overdose prevention, other drug use, compliance with psychosocial treatment and medications, safety storage of medications):

(BMPPTEDC) 0-Incomplete 1-Complete
Complete 96-N/A

(BMPPEDNC)

19. Monitoring of the State Prescription Drug Monitoring Program (PDMP):

(BMPPDMP) 0-Incomplete 1-Complete
Complete 96-N/A

(BMPPDMNC)

20. Was buprenorphine dispensing completed?

(BMPBUPDS) 0-Incomplete 1-Complete
Complete 96-N/A

(BMPBUPDC)

21. Total number of items "Incomplete"/"No":(BMNUMINN)

 (xx)

22. Total number of items "Complete"/"Yes":(BMNUMCOY)

 (xx)

23. Total number of items "N/A":(BMNUMNA)

 (xx)

Comments:(BVMCOMM)

Additional Selection Options for BVM

Completed by:
06-L. Greenblatt
07-P. Mannelli

Clinical Opiate Withdrawal Scale (COW)

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

Segment (PROTSEG): B
 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)

 (mm/dd/yyyy)

2. Sex:(DESEX)

 1-Male 2-Female 97-Don't know 98-Refused to answer

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

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

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

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

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

American Indian or Alaska Native:(DEAMEIND)

 1-

Asian:(DEASIAN)

 1-

Asian Indian:(DEASAIND)

 1-

Chinese:(DECHINA)

 1-

Filipino:(DEFILIPN)

 1-

Japanese:(DEJAPAN)

 1-

Korean:(DEKOREA)

 1-

Vietnamese:(DEVIETNM)

 1-

Specify other Asian:(DEASIAOT)

Black or African American:(DEBLACK)

 1-

Native Hawaiian or Pacific Islander:(DEHAWAII)

 1-

Native Hawaiian:(DENATHAW)

 1-

Guamanian or Chamorro:(DEGUAM)

 1-

Samoa:(DESAMOAN)

 1-

Specify other Pacific Islander:(DEPACISO)

White:(DEWHITE)

 1-

Some other race:(DERACEOT)

 1- Specify:(DERACESP)

-or-

Don't know:(DERACEDK)

 1-

Refused:(DERACERF)

 1-

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

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

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

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

If "Other", specify:(DEJOBSP)

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

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

Comments:(DEMCOMM)

Additional Selection Options for DEM

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

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

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

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

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

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

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

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

End of Medication (EOM)

Segment (PROTSEG): B

1. Did the participant discontinue study buprenorphine early? 0-No 1-Yes

(EOOEARLY)

a. If "Yes", primary reason for not continuing with study buprenorphine:(EOOSTOP)

- 1-Participant failed to return to site and unable to contact
- 2-Participant stopped participation due to practical problems (e.g., no childcare or transportation)
- 3-Participant moved from area
- 4-Participant incarcerated
- 5-Participant had a significant psychiatric risk (e.g., suicidal, homicidal, psychotic)
- *Additional Options Listed Below

If "Other", specify:(EOOSTPSP)

b. Date of last study buprenorphine dose taken:
(EOORALDT)

(mm/dd/yyyy)

Comments:(EOMCOMM)

Additional Selection Options for EOM

If "Yes", primary reason for not continuing with study buprenorphine:

- 6-Participant deceased
- 7-Participant became pregnant
- 8-Participant withdrew consent/assent
- 9-Participant reports intolerable symptoms or side effects
- 10-Participant feels treatment no longer necessary, cured
- 11-Participant feels treatment no longer necessary, not working
- 12-Participant in hospital, in-patient, or residential treatment (not for substance use treatment)
- 13-Participant is in detox, residential, or intensive outpatient treatment for substance use treatment
- 14-Participant met criteria for prisoner status
- 15-Participant was ineligible and should not have been enrolled in study
- 16-Participant interested in seeking alternate treatment
- 17-Participant refused, non-specific
- 18-Physical illness or condition that precludes taking study medication
- 19-Contraindicated concomitant medication
- 20-Clinical deterioration: New onset of psychiatric or medical condition
- 21-Clinical deterioration: Worsening of pre-existing psychiatric or medical condition
- 22-Clinical deterioration: Worsening of substance use disorder
- 23-Clinical deterioration: Overdose
- 24-Administrative or technical issues
- 25-Protocol deviation
- 26-Site closed
- 99-Other

0075B (ENR)

Web Version: 1.0; 1.03; 04-27-18

Date of assessment:(*STARTDT*)

 (mm/dd/yyyy)

Date of last stabilization visit:(*R8STVSDT*)

 (mm/dd/yyyy)

Inclusion Criteria

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

1. Participant is 18 years of age or older:(*R8PTAGE*) 0-No 1-Yes
2. Participant uses adequate birth control methods:(*R8BCUSE*) 0-No 1-Yes 97-Unknown 96-Not applicable
3. Participant meets DSM-5 criteria for past-year opioid use disorder:(*R8PYOUD*) 0-No 1-Yes 97-Unknown
4. Participant has completed buprenorphine induction for opioid use disorder:(*R8BIOUD*) 0-No 1-Yes 97-Unknown
5. Participant has expressed the intention to receive maintenance (>=6 months) buprenorphine treatment:(*R8BUPMNT*) 0-No 1-Yes 97-Unknown
6. Participant is willing to receive pharmacist administered buprenorphine maintenance treatment:(*R8PHRBUP*) 0-No 1-Yes 97-Unknown
7. Participant is willing and able to provide written informed consent and HIPAA authorization:(*R8CHIPA*) 0-No 1-Yes
8. Participant is able to read and communicate in English:(*R8COMENG*) 0-No 1-Yes 97-Unknown
9. Participant is able to comply with buprenorphine treatment policies:(*R8BUPPOL*) 0-No 1-Yes 97-Unknown

Exclusion Criteria

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

1. Participant has a serious medical, psychiatric, or substance use disorder that, in the opinion of the study physician, would make study participation hazardous to the participant, compromise study findings, or prevent the participant from completing the study:(*R8MPSD/S*) 0-No 1-Yes 97-Unknown

Examples Include:

- A disabling or terminal medical illness (e.g., heart failure, cirrhosis or end-stage liver disease, acute hepatitis or moderate to severe renal impairment) as assessed by medical history, review of systems, physical exam, and/or laboratory assessments.
- A current severe, untreated or inadequately treated mental health disorder (e.g., active psychosis, uncontrolled manic-depressive illness) as assessed by mental health history and/or clinical interview.
- A current severe benzodiazepine or other substance use requiring medical detoxification.
- Suicidal or homicidal ideations requiring immediate action.

2. Participant has a known allergy or hypersensitivity to buprenorphine, naloxone, or other components of the buprenorphine/naloxone formulation:(*R8BUPALG*) 0-No 1-Yes 97-Unknown
3. Participant has aspartate aminotransferase (AST) or alanine aminotransferase (ALT) liver enzymes greater than 5 times the upper limit of normal on screening phlebotomy performed within 60 days prior to the date of the last stabilization visit:(*R8ASTALT*) 0-No 1-Yes 97-Unknown
4. Participant has chronic pain requiring ongoing pain management with opioid analgesics:(*R8PAIN*) 0-No 1-Yes 97-Unknown
5. Participant is currently in jail, prison or any overnight facility as required by court of law or pending legal action that could prevent participation in study activities (i.e., unable to complete 6 months of pharmacy-based OUD management):(*R8LGLOTH*) 0-No 1-Yes 97-Unknown
6. Participant is pregnant or breastfeeding at the time of screening:(*R8PREGBF*) 0-No 1-Yes 97-Unknown 96-Not applicable

Eligibility for Study Enrollment

1. Is the participant eligible for the study?(*R8ELGSTY*) 0-No 1-Yes
2. Will the participant be enrolled?(*R8ELGRND*) 0-No 1-Yes

If "No", specify:(*R8NORAND*)

If "Judgement of site/research staff" or "Other", specify:(*R8NORDSP*)

Comments:(*R8COMM*)

NIDA Clinical Trials Network

Missed Visit (MVF)

Web Version: 1.0; 1.01; 07-10-17

Segment (PROTSEG): B

Visit number (VISNO):

Reason for missed visit:(MVREASON)

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

If "Other", specify:(MVOTHRSP)

Comments:(MVFCOMM)

Additional Selection Options for MVF

Reason for missed visit:

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

Pregnancy and Birth Control Assessment (PBC)

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

Complete this form only for females.

Date of assessment:(PBCASMDT)

 (mm/dd/yyyy)

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

 0-No 1-Yes

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

 (mm/dd/yyyy)

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

 days

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

 0-No 1-Yes

Urine pregnancy test must be performed before buprenorphine is dispensed.

a. Date of pregnancy test:(PBPTSTD)

 (mm/dd/yyyy)

b. Result of pregnancy test:(PBRESULT)

 0-Negative 1-Positive

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

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): B
 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 continuing to receive psychosocial treatment as planned? (PCCONTPT)

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

2. Since the last visit, 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)	(PCGRPTH)	(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?(PDPRELN0)

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:
(*PDACTION*)

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

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

0-No 1-Yes

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

0-No 1-Yes

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

(*mm/dd/yyyy*)

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

(*mm/dd/yyyy*)

Comments:(*PDVCOMM*)

Additional Selection Options for PDV

Protocol deviation number (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)

Patient Health Questionnaire (PHQ-9) (PHQ)

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

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

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

1. Alcohol/Drug Use

Since your last visit, 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

Since your last visit, 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

Since your last visit, 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

Since your last visit, 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

Since your last visit, 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

Since your last visit, 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

Since your last visit, 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)

Pregnancy Outcome 1 (PO1)

Web Version: 1.0; 1.00; 04-26-19

Pregnancy number (PGSEQNUM):

Newborn Information

- | | | | | | |
|---|-----------------------|---------------------|------------|--|------------|
| 1. Gender:(PO1GENDR) | 1-Male | 2-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 | | | |
| If "No", is there a congenital anomaly?(PO1CONAN) | 0-No | 1-Yes | | | 97-Unknown |
| If "Yes", specify abnormality and contributing factors:(PO1ABNSP) | | | | | |

Comments:(PO1COMM)

Additional Selection Options for PO1

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

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

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

Prisoner Status Assessment (PSA)

Web Version: 1.0; 1.01; 06-08-18

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

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

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

1. Are you currently being detained or made to stay in an institution (such as a substance use treatment program) due to a criminal or civil proceeding or parole and is your ability to leave the institution restricted? (PSINST) 0-No 1-Yes

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

2. Are you currently being detained while awaiting trial, arraignment, or sentencing? (PSTRIAL) 0-No 1-Yes

3. Are you currently on probation or under house arrest, such that you are escorted to treatment or, upon discharge from treatment, you will be escorted to jail, prison, or any inpatient overnight facility as required by law? (PSPROBHA) 0-No 1-Yes

4. Does the participant meet the definition of "prisoner" by any local or state regulations? (PSPRISON) 0-No 1-Yes

Comments: (PSACOMM)

Quality of Life (QLP)

Segment (PROTSEG): B
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)

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

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

PART A

To be completed at the beginning of each visit.

Date of assessment:(SEASMDT) (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:(SEDTHTD) (mm/dd/yyyy)
2. Cause of death:(SEDTHCS)

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): B
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): B
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? (SRSERTHT)
What is it? (SRSERSP) 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)

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)

1-Weak
2-Strong

Comments: (SR2COMM)

Study Completion (STC)

Web Version: 1.0; 8.00; 03-15-19

Segment (PROTSEG): B

1. Did the participant complete the 6 month visit?(STCOMPLT)

If "No", select the primary reason for not completing the 6 month visit:(STERLY75)

0-No 1-Yes

- 1-Participant failed to return to site and unable to contact
- 2-Participant stopped participation due to practical problems (e.g., no childcare or transportation)
- 3-Participant moved from area
- 4-Participant incarcerated
- 5-Participant terminated due to AE/SAE
- *Additional Options Listed Below

If "Participant terminated for administrative issues" or "Participant terminated for other reason", specify:(STCM75SP)

2. Date of last data collection or date of withdrawn consent:(STCOMPDT)

(mm/dd/yyyy)

Comments:(STCCOMM)

Investigator's Signature

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

Principal Investigator:(STPISIGN)

Date:(STPISGDT)

(mm/dd/yyyy)

Additional Selection Options for STC

If "No", select the primary reason for not completing the 6 month visit:

- 6-Participant terminated for other clinical reasons
- 7-Participant had a significant psychiatric risk (e.g., suicidal, homicidal, psychotic)
- 8-Participant withdrew consent/assent
- 9-Participant deceased
- 10-Participant terminated for administrative issues
- 11-Participant terminated due to pressure or advice from outsiders
- 12-Participant feels treatment no longer necessary, cured
- 13-Participant feels treatment no longer necessary, not working
- 14-Participant in hospital, in-patient, or residential treatment (not for substance use treatment)
- 16-Participant terminated due to protocol deviation
- 17-Participant uncomfortable answering questions
- 20-Participant became pregnant
- 21-Participant reports intolerable symptoms or side effects
- 22-Participant reports use of medication that could adversely interact with study medication
- 23-Clinical deterioration: New onset of psychiatric or medical condition
- 24-Clinical deterioration: Worsening of pre-existing psychiatric or medical condition
- 25-Clinical deterioration: Worsening of substance use disorder
- 38-Clinical deterioration: Overdose - Opioid or heroin use
- 39-Clinical deterioration: Overdose - Other prescription or illicit drug use
- 27-Participant interested in seeking alternate treatment
- 28-Participant is in detox, residential, or intensive outpatient treatment for substance use treatment
- 34-Participant was ineligible and should not have been enrolled in study
- 99-Participant terminated for other reason

Suicidal Risk (SUR)

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

Segment (PROTSEG): B

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)

Timeline Followback (T75)

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*): B

Visit number (*VISNO*):

Date of assessment: (*TAPASMDT*)

(*mm/dd/yyyy*)

1. Assessment period: (*TATFSTD*)

From:

(*mm/dd/yyyy*)

(*TATFEND*)

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): B
 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.

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

Comments: (TRTCOMM)

Treatment Satisfaction (TS2)

Segment (PROTSEG): B
 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?(T2TRTP)
 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): B
 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): B
 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): B

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)