NIDA Clinical Trials Network

Engagement in Treatment: Patient (ETP)

Web Version: 1.0; 3.00; 06-14-18

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

*The next questions ask about the medical care you have received for an opioid use disorder on **[insert 30day Target Date]**.*

1. On **[insert 30day Target Date]** are/were you receiving treatment for opioid use disorder?*(ETMEDTRT)* ☐ No ☐ Yes

		Program/Provider #1	Program/Provider #2	Program/Provider #3
a. **Where are/were you receiving this treatment?**				
	Program/provider name:	*(ETPRLC01)*	*(ETPRLC02)*	*(ETPRLC03)*
b. **What type(s)of treatmentare/were youreceiving?** *Only include formal treatment (e.g., do not include NA, AA, or faith-based).*	Methadone:	*(ETMETH1)* ☐ No ☐ Yes	*(ETMETH2)* ☐ No ☐ Yes	*(ETMETH3)* ☐ No ☐ Yes
	Buprenorphine:	*(ETBUP1)* ☐ No ☐ Yes	*(ETBUP2)* ☐ No ☐ Yes	*(ETBUP3)* ☐ No ☐ Yes
	SL-Buprenorphine:	*(ETSLBUP1)* ☐ No ☐ Yes	*(ETSLBUP2)* ☐ No ☐ Yes	*(ETSLBUP3)* ☐ No ☐ Yes
	XR-Buprenorphine 7 day:	*(ETX7BP1)* ☐ No ☐ Yes	*(ETX7BP2)* ☐ No ☐ Yes	*(ETX7BP3)* ☐ No ☐ Yes
	XR-Buprenorphine 30 day:	*(ETX30BP1)* ☐ No ☐ Yes	*(ETX30BP2)* ☐ No ☐ Yes	*(ETX30BP3)* ☐ No ☐ Yes
	Naltrexone:	*(ETNALTR1)* ☐ No ☐ Yes	*(ETNALTR2)* ☐ No ☐ Yes	*(ETNALTR3)* ☐ No ☐ Yes
	Short-term detoxification:	*(ETDETOX1)* ☐ No ☐ Yes	*(ETDETOX2)* ☐ No ☐ Yes	*(ETDETOX3)* ☐ No ☐ Yes
	Inpatient/residential:	*(ETINPAT1)* ☐ No ☐ Yes	*(ETINPAT2)* ☐ No ☐ Yes	*(ETINPAT3)* ☐ No ☐ Yes
	Counseling:	*(ETOTPAT1)* ☐ No ☐ Yes	*(ETOTPAT2)* ☐ No ☐ Yes	*(ETOTPAT3)* ☐ No ☐ Yes
	Outpatient medication:	*(ETOTMED1)* ☐ No ☐ Yes	*(ETOTMED2)* ☐ No ☐ Yes	*(ETOTMED3)* ☐ No ☐ Yes
	Other:	*(ETOTHER1)* ☐ No ☐ Yes	*(ETOTHER2)* ☐ No ☐ Yes	*(ETOTHER3)* ☐ No ☐ Yes
	If "Other", specify:	*(ETOTHSP1)*	*(ETOTHSP2)*	*(ETOTHSP3)*
c. **Who is/wasyour counselor/clinician?**		*(ETCOCLI1)*	*(ETCOCLI2)*	*(ETCOCLI3)*
d. **Is/was this service covered by:**		*(ETCOVRD1)* 1-Insurance; 2-Self-pay; 3-No-cost	*(ETCOVRD2)* 1-Insurance; 2-Self-pay; 3-No-cost	*(ETCOVRD3)* 1-Insurance; 2-Self-pay; 3-No-cost

2. On **[insert 30day Target Date]**, are/were you engaged in mutual help (e.g., NA, AA, faith-based)?*(ETMUTHLP)* ☐ No ☐ Yes

3. On **[insert 30day Target Date]** are/were you:*(ETLIVE)*
   - 1-Living in the community
   - 2-Incarcerated
   - 3-An inpatient (e.g., overnight in hospital, substance abuse treatment)
   - 99-Other

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

Comments:*(ETPCOMM)*

ED Visit Review (EVR)

Web Version: 1.0; 1.01; 12-21-18

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

1. Date of ED admission: *(EVRASMDT)* ____ *(mm/dd/yyyy)*
2. Time of ED admission: *(EVADMTM)* ____ *(hh:mm)* *(24 hour time)*
3. Did the reason for the visit, as documented per triage note, include substance use, intoxication, withdrawal or overdose? *(EVVTRSN)* ☐ No ☐ Yes
   a. Was there specific mention of opioids? *(EVVSTOPI)* ☐ No ☐ Yes
   b. Was there specific mention of overdose (including found down or unresponsive) OR administration of naloxone? *(EVOVRDSE)* ☐ No ☐ Yes
   c. Was there specific mention of seeking detox or treatment? *(EVDETOX)* ☐ No ☐ Yes
4. Did the discharge diagnosis specifically include substance use disorder? *(EVDSCDG)*
   - 1-Any opioid use disorder diagnosis
   - 2-Any substance use disorder diagnosis (not opioids)
   - 0-No
5. If available, what are the ICD 10 code(s) for the discharge diagnosis?
   a. Code 1: *(EVICDCD1)*
   b. Code 2: *(EVICDCD2)*
   c. Code 3: *(EVICDCD3)*
   d. Code 4: *(EVICDCD4)*
   e. Code 5: *(EVICDCD5)*
   f. Code 6: *(EVICDCD6)*
   g. Code 7: *(EVICDCD7)*
   h. Code 8: *(EVICDCD8)*
   i. Code 9: *(EVICDCD9)*
   j. Code 10: *(EVICDC10)*
6. Date of ED discharge: *(EVDISCDT)* ____ *(mm/dd/yyyy)*
7. Time of ED discharge: *(EVDISCTM)* ____ *(hh:mm)* *(24 hour time)*
8. What was the patient's ED disposition? *(EVDISPOS)*
   - 01-Discharge
   - 02-Admitted to inpatient (non-detox)
   - 03-Admitted to detox
   - 04-Eloped
   - 05-AMA
   - 06-Observation
   - 07-Transferred to another facility
   - 99-Other

   If "Other", specify: *(EVDISPSP)*
9. Did the patient come to the ED specifically for a referral to substance use treatment? *(EVEDREFR)* ☐ No ☐ Yes
10. Was an addiction related consult performed? *(EVCONSUL)* ☐ No ☐ Yes

    If "Yes", who performed the consult? *(Select all that apply)*

    1. Social worker:

(EVCONLSW) ☐ No ☐ Yes

2. Substance use counselor / health promotion advocate (on-site hospital employee): *(EVCONSUD)* ☐ No ☐ Yes
3. Recovery coach / peer consult (not on-site hospital employee):*(EVCONREC)* ☐ No ☐ Yes
4. General psychiatrist: *(EVCONPSY)* ☐ No ☐ Yes
5. Addiction MD specialist: *(EVCONMD)* ☐ No ☐ Yes
6. Other:*(EVCONOT)* ☐ No ☐ Yes

11. Was it documented that patient met criteria for moderate to severe opioid use disorder?*(EVOUDDOC)* ☐ No ☐ Yes
12. Was formal assessment of opioid withdrawal severity (e.g., COWS) documented?*(EVCOWDOC)* ☐ No ☐ Yes
13. Were any of the following tests performed:
    a. HIV:*(EVHIVTST)* ☐ No ☐ Yes
    b. Hepatitis C:*(EVHCVTST)* ☐ No ☐ Yes
    c. Liver functions tests (AST, ALT): *(EVLFTOBT)* ☐ No ☐ Yes
    d. Urine toxicology:*(EVTOXOBT)* ☐ No ☐ Yes
        If "Yes", documented as positive for opioids: *(EVTOXDOC)* ☐ No ☐ Yes

14. Were any of the following medications administered in the ED, prescribed at discharge, and/or given a take home dose?

	^2 Medications Administered		^2 Medications Prescribed		^2 Medications Provided for Take Home Administration	
	No	Yes	No	Yes	No	Yes
a. Opioids:	*(EVOPIMED)* ☐	☐	*(EVOPIRX)* ☐	☐	*(EVOPITH)* ☐	☐
b. Benzodiazepines:	*(EVBZOMED)* ☐	☐	*(EVBZORX)* ☐	☐	*(EVBZOTH)* ☐	☐
c. Methadone:	*(EVMTDMED)* ☐	☐	*(EVMTDRX)* ☐	☐	*(EVMTDTH)* ☐	☐
d. Buprenorphine:	*(EVBUPMED)* ☐	☐	*(EVBUPRX)* ☐	☐	*(EVBUPTH)* ☐	☐
SL-Buprenorphine:	*(EVSLBMED)* ☐	☐	*(EVSLBRX)* ☐	☐	*(EVSLBTH)* ☐	☐
XR-Buprenorphine 7 day:	*(EVX7BMD)* ☐	☐	*(EVX7BRX)* ☐	☐	*(EVX7BTH)* ☐	☐
XR-Buprenorphine 30 day:	*(EVX30BMD)* ☐	☐	*(EVX30BRX)* ☐	☐	*(EVX30BTH)* ☐	☐
e. Naltrexone:	*(EVNALTMD)* ☐	☐	*(EVNALTRX)* ☐	☐	*(EVNALTTH)* ☐	☐
f. Naloxone:	*(EVNALXMD)* ☐	☐	*(EVNALXRX)* ☐	☐	*(EVNALXTH)* ☐	☐

15. If a naloxone prescription was received, did the patient receive a kit or a prescription?*(EVKITRX)* ☐ Kit ☐ Prescription
16. If buprenorphine was received, did the patient receive buprenorphine education and induction instructions?*(EVEDDOC)* ☐ No ☐ Yes

17. Did the patient receive a direct referral to opioid use disorder (OUD) treatment?*(EVOPIREF)* ☐ No ☐ Yes
    a. Was this referral to a provider of MAT?*(EVREFMAT)* ☐ No ☐ Yes
    b. How detailed was this referral? *(EVREFSP)*
        1-Patient was given a specific time and location to follow up
        2-Patient was given a specific location but told to schedule it themselves
        3-Patient was given a list of OUD treatment resources to call (or general referral helpline number)
        4-Patient was told someone would call to schedule
        5-Patient was told to return to the ED for next/first dose of buprenorphine treatment

    Site name of OUD specific referral:*(EVREFSIT)*

    Location type of OUD specific referral: *(EVREFLOC)*

- 1-Office-based provider
- 2-Opioid treatment program
- 3-Residential program
- 99-Other

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

18. If no direct referral to OUD treatment was given, was anything specific to OUD noted in the discharge instructions? *(EVNOREFR)* ☐ No ☐ Yes
    a. Told to return to the ED within 24 hours: *(EVRETNED)* ☐ No ☐ Yes
    b. General pamphlets/information regarding OUD services: *(EVPAMPH)* ☐ No ☐ Yes
    c. Indirect referral (i.e., advice to go to specific place without appointment) for OUD services: *(EVINDREF)* ☐ No ☐ Yes

If "Indirect referral", select the type of place: *(EVREFNOT)*

- 01-Opioid treatment program
- 02-Office-based provider
- 99-Other

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

Comments: *(EVRCOMM)*

0079B (ENR)

Web Version: 1.0; 1.00; 07-02-18

Date eligibility confirmed:*(STARTDT)* (mm/dd/yyyy)

Inclusion Criteria

In order to meet eligibility ALL Inclusion answers must be "Yes".

1. Participant is 18 years of age or older:*(R9PTAGE)* ☐ No ☐ Yes ☐ Unknown
2. Patient eligible for and willing to receive ED-initiated buprenorphine:*(R9BUPOK)* ☐ No ☐ Yes ☐ Unknown

Exclusion Criteria

In order to meet eligibility ALL Exclusion answers must be "No".

1. Participant is not able to speak English sufficiently to understand study procedures and provide written informed consent:*(R9ENGLIS)* ☐ No ☐ Yes ☐ Unknown
2. Participant is unable or unwilling to provide written informed consent, sign a release of medical records or to participate in study procedures:*(R9NOINFR)* ☐ No ☐ Yes ☐ Unknown
3. Participant is currently receiving medication treatment for OUD at the time of index ED visit:*(R9RECTRT)* ☐ No ☐ Yes ☐ Unknown
4. Participant is currently participating in a substance use intervention study or previous participation in the current study:*(R9INVST)* ☐ No ☐ Yes ☐ Unknown
5. Participant is currently in jail, prison or any inpatient overnight facility as required by court of law or has pending legal action that could prevent participation in the study:*(R9JAIL)* ☐ No ☐ Yes ☐ Unknown
6. Participant is unable to provide adequate locator information (unable to provide 2 unique means of contact):*(R9LOCATE)* ☐ No ☐ Yes ☐ Unknown

Eligibility for Enrollment

1. Is the participant eligible for the study?*(R9ELGSTY)* ☐ No ☐ Yes
2. Will the participant be enrolled?*(R9BEENR)* ☐ No ☐ Yes

Comments:*(R9COMM)*

NIDA Clinical Trials Network

Timeline Followback Page 2 (F79)

Web Version: 1.0; 1.00; 01-22-18

TFB week start date *(TFWKSTDT)*:

Day	**Sunday**	**Monday**	**Tuesday**	**Wednesday**	**Thursday**	**Friday**	**Saturday**
Date	*(TLDATE1)*	*(TLDATE2)*	*(TLDATE3)*	*(TLDATE4)*	*(TLDATE5)*	*(TLDATE6)*	*(TLDATE7)*
1. Have any pain relievers, pain medications, sedatives, alcohol, methamphetamine, cocaine, heroin, or other illicit substances been used on this day?	*(TLSUBAL1)* No Yes	*(TLSUBAL2)* No Yes	*(TLSUBAL3)* No Yes	*(TLSUBAL4)* No Yes	*(TLSUBAL5)* No Yes	*(TLSUBAL6)* No Yes	*(TLSUBAL7)* No Yes
2. Pentazocine (Talwin):							
Route:	*(TLPENZ1)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLPENZ2)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLPENZ3)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLPENZ4)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLPENZ5)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLPENZ6)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLPENZ7)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below
Prescribed:	*(TLPPENZ1)* No Yes	*(TLPPENZ2)* No Yes	*(TLPPENZ3)* No Yes	*(TLPPENZ4)* No Yes	*(TLPPENZ5)* No Yes	*(TLPPENZ6)* No Yes	*(TLPPENZ7)* No Yes
# Times Used Each Day:	*(TLTPENZ1)* *(xxx)*	*(TLTPENZ2)* *(xxx)*	*(TLTPENZ3)* *(xxx)*	*(TLTPENZ4)* *(xxx)*	*(TLTPENZ5)* *(xxx)*	*(TLTPENZ6)* *(xxx)*	*(TLTPENZ7)* *(xxx)*
3. Codeine:							
Route:	*(TLCODE1)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLCODE2)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLCODE3)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLCODE4)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLCODE5)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLCODE6)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLCODE7)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below
Prescribed:	*(TLPCODE1)* No Yes	*(TLPCODE2)* No Yes	*(TLPCODE3)* No Yes	*(TLPCODE4)* No Yes	*(TLPCODE5)* No Yes	*(TLPCODE6)* No Yes	*(TLPCODE7)* No Yes
# Times Used Each Day:	*(TLTCODE1)* *(xxx)*	*(TLTCODE2)* *(xxx)*	*(TLTCODE3)* *(xxx)*	*(TLTCODE4)* *(xxx)*	*(TLTCODE5)* *(xxx)*	*(TLTCODE6)* *(xxx)*	*(TLTCODE7)* *(xxx)*
4. Benzodiazepines (Valium, Serpax, Ativan, Xanax, Librium, Rohypnol):							
Route:	*(TLBZO1)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLBZO2)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLBZO3)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLBZO4)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLBZO5)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLBZO6)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLBZO7)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below
Prescribed:	*(TLPBZO1)* No Yes	*(TLPBZO2)* No Yes	*(TLPBZO3)* No Yes	*(TLPBZO4)* No Yes	*(TLPBZO5)* No Yes	*(TLPBZO6)* No Yes	*(TLPBZO7)* No Yes
# Times Used Each Day:	*(TLTBZO1)* *(xxx)*	*(TLTBZO2)* *(xxx)*	*(TLTBZO3)* *(xxx)*	*(TLTBZO4)* *(xxx)*	*(TLTBZO5)* *(xxx)*	*(TLTBZO6)* *(xxx)*	*(TLTBZO7)* *(xxx)*
5. Methamphetamine (speed, crystal meth, ice):							
Route:	*(TLMET1)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLMET2)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLMET3)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLMET4)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLMET5)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLMET6)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLMET7)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below
Prescribed:	*(TLPMET1)* No Yes	*(TLPMET2)* No Yes	*(TLPMET3)* No Yes	*(TLPMET4)* No Yes	*(TLPMET5)* No Yes	*(TLPMET6)* No Yes	*(TLPMET7)* No Yes
# Times Used Each Day:	*(TLTMET1)* *(xxx)*	*(TLTMET2)* *(xxx)*	*(TLTMET3)* *(xxx)*	*(TLTMET4)* *(xxx)*	*(TLTMET5)* *(xxx)*	*(TLTMET6)* *(xxx)*	*(TLTMET7)* *(xxx)*
6. Cocaine (coke, crack):							
Route:	*(TLCOC1)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLCOC2)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLCOC3)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLCOC4)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLCOC5)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLCOC6)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLCOC7)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below
# Times Used Each Day:							

	(TLTCOC1) (xxx)	(TLTCOC2) (xxx)	(TLTCOC3) (xxx)	(TLTCOC4) (xxx)	(TLTCOC5) (xxx)	(TLTCOC6) (xxx)	(TLTCOC7) (xxx)
7. Alcohol:							
# Times Used Each Day:	(TLTALCH1) (xxx)	(TLTALCH2) (xxx)	(TLTALCH3) (xxx)	(TLTALCH4) (xxx)	(TLTALCH5) (xxx)	(TLTALCH6) (xxx)	(TLTALCH7) (xxx)
8. Cannabis (marijuana, pot, grass, hash):							
Route:	(TLTHC1) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLTHC2) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLTHC3) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLTHC4) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLTHC5) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLTHC6) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLTHC7) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below
Prescribed:	(TLPTHC1) No Yes	(TLPTHC2) No Yes	(TLPTHC3) No Yes	(TLPTHC4) No Yes	(TLPTHC5) No Yes	(TLPTHC6) No Yes	(TLPTHC7) No Yes
# Times Used Each Day:	(TLTTHC1) (xxx)	(TLTTHC2) (xxx)	(TLTTHC3) (xxx)	(TLTTHC4) (xxx)	(TLTTHC5) (xxx)	(TLTTHC6) (xxx)	(TLTTHC7) (xxx)
9. Other drug 1 use:							
Route:	(TLOT11) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLOT12) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLOT13) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLOT14) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLOT15) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLOT16) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLOT17) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below
Prescribed:	(TLPOT11) No Yes	(TLPOT12) No Yes	(TLPOT13) No Yes	(TLPOT14) No Yes	(TLPOT15) No Yes	(TLPOT16) No Yes	(TLPOT17) No Yes
# Times Used Each Day:	(TLTOT11) (xxx)	(TLTOT12) (xxx)	(TLTOT13) (xxx)	(TLTOT14) (xxx)	(TLTOT15) (xxx)	(TLTOT16) (xxx)	(TLTOT17) (xxx)
Specify other drug 1:	(TLOTSP11)	(TLOTSP12)	(TLOTSP13)	(TLOTSP14)	(TLOTSP15)	(TLOTSP16)	(TLOTSP17)
10. Other drug 2 use:							
Route:	(TLOT21) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLOT22) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLOT23) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLOT24) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLOT25) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLOT26) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLOT27) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below
Prescribed:	(TLPOT21) No Yes	(TLPOT22) No Yes	(TLPOT23) No Yes	(TLPOT24) No Yes	(TLPOT25) No Yes	(TLPOT26) No Yes	(TLPOT27) No Yes
# Times Used Each Day:	(TLTOT21) (xxx)	(TLTOT22) (xxx)	(TLTOT23) (xxx)	(TLTOT24) (xxx)	(TLTOT25) (xxx)	(TLTOT26) (xxx)	(TLTOT27) (xxx)
Specify other drug 2:	(TLOTSP21)	(TLOTSP22)	(TLOTSP23)	(TLOTSP24)	(TLOTSP25)	(TLOTSP26)	(TLOTSP27)

Comments:*(TFBCOMM)*

Additional Selection Options for F79

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

Follow-Up Visit Scheduling (FVT)

Web Version: 1.0; 2.01; 07-02-18

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

1. Estimated date of ED discharge:*(FVEDDCDT)* *(mm/dd/yyyy)*

   *Please schedule the follow up visit date and time with this participant. The target date range for the 30 day follow-up visit is from **FVT_FVEDDCDT+30** to **FVT_FVEDDCDT+37***

2. Date of 30 day follow-up visit:*(FVAPPTDT)* *(mm/dd/yyyy)*
3. Appointment time:*(FVAPPTTM)* *(hh:mm)* (24-hour time)

   Comments:*(FVTCOMM)*

Health Services Utilization Page 1: Inpatient (HS1)

Web Version: 1.0; 1.01; 10-03-18

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

*Now I would like to review, in detail, any facilities in which you have been hospitalized overnight for any reason (physical, emotional, or substance abuse) during the **past 30 days**. Please include residential detox facilities but do not include sober houses or halfway house stays.*

Were any inpatient services used in the past 30 days?*(HS1SU)* ☐ No ☐ Yes

If "Yes", how many inpatient facilities were utilized in the past 30 days?*(HS1FAC)* ______ *(xx)* facilities

Health Services Utilization Page 1: Outpatient (HS2)

Web Version: 1.0; 1.01; 08-20-18

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

Next, I want to ask you about when you were an outpatient. Please include regular doctor visits, visits to Emergency Departments/Rooms (ED), and any treatment centers (e.g., methadone maintenance centers). Let's review, in detail, each practitioner or community service you received as an outpatient for any reason (physical, emotional, or substance abuse) during the past 30 days.

Next, I want to ask you about when you were an outpatient. Please include regular doctor visits, visits to Emergency Departments/Rooms (ED), not including ED enrollment visit, and any treatment centers (e.g., methadone maintenance centers). Let's review, in detail, each practitioner or community service you received as an outpatient for any reason (physical, emotional, or substance abuse) during the past 30 days.

Were any outpatient services used in the past 30 days? *(HS2SU)* ☐ No ☐ Yes

If "Yes", how many outpatient facilities were utilized in the past 30 days?*(HS2FAC)* ____ *(xx)* facilities

Were any outpatient services used in the 30 days prior to the follow up visit target date?*(HS2SU)* ☐ No ☐ Yes

If "Yes", how many outpatient facilities were utilized in the 30 days prior to the follow up visit target date?*(HS2FAC)* ____ *(xx)* facilities

Health Services Utilization: Inpatient (HSI)

Web Version: 1.0; 2.04; 10-03-18

Segment *(PROTSEG)*: B
Visit number *(VISNO)*:
Facility name *(FACPRLC)*:
Sequence number *(SEQNUM2)*:

Please describe your stay including the type of inpatient service that was provided.

1. Provider code:*(HSPRCODE)*
   - 1-Medical hospital
   - 2-Psychiatric hospital
   - 3-Inpatient substance abuse treatment (residential)
   - 4-Skilled nursing/extended care facility
   - 99-Other inpatient facility

   If "Other inpatient facility", specify:*(HSOTHISP)*

2. Service type:*(HSSRTYPE)*
   - 1-Medical/surgical
   - 2-Psychiatric (non-substance abuse)
   - 3-Substance abuse
   - 4-Psychiatric and substance abuse

3. What was the reason for the hospitalization? *(HSHSPRSN)*

4. Number of nights stayed this visit: *Include all days in the facility, including days arising from a stay which began prior to the start of the **30 DAY period.(HSNITNUM)*** *(xxx)*

5. Number of admissions in PAST 30 days: *Include any admission during the **30 DAYS** (e.g., if a patient was hospitalized continuously there would have been no admissions in **30 DAYS**). Consider transfers as new admissions if they involve a different kind of service (i.e., service type).(HSADMNUM)* *(xx)*

6. Visit(s) paid for by:*(HSVSPAID)* ☐ Insurance ☐ Self-pay ☐ No-cost

   Comments:*(HSICOMM)*

Additional Selection Options for HSI

Sequence number *(SEQNUM2)* (key field):
01-1
02-2
03-3
04-4
05-5
06-6
07-7
08-8
09-9
10-10

Health Services Utilization: Outpatient (HSO)

Web Version: 1.0; 2.02; 08-20-18

Segment *(PROTSEG)*: B
Visit number *(VISNO)*:
Facility name *(FACPRLC)*:

Please describe the type of outpatient service that was provided and about your stay.

1. Provider code:*(HSPVCODE)*
   - 1-Hospital-based clinic
   - 2-Federally-qualified (community) health center
   - 3-Private doctor's office
   - 4-Emergency department
   - 5-Urgent care center/walk-in facility
   - *Additional Options Listed Below

   If "Other", specify:*(HSPVOTSP)*
2. Service type:*(HSSERVTP)*
   - 1-Medical/surgical
   - 2-Psychiatric (non-substance abuse)
   - 3-Substance abuse
   - 4-Psychiatric and substance abuse
3. Provider type:*(HSPVTYPE)*
   - 1-Doctor
   - 2-Nurse
   - 3-Nurse practitioner
   - 4-Physician's Assistant (PA)
   - 5-Chiropractor
   - *Additional Options Listed Below

   If "Other", specify:*(HSPVOTH)*
4. Number of visits in PAST 30 days:*(HSNUMVIS)* *(xx)*
5. Number of visits in the 30 days prior to your follow up visit target date:*(HSNUMVIS)* *(xx)*
6. Average minutes per visit:
   Include time spent with the provider.(HSAVGMIN) *(xxxx)*
7. Visit(s) paid for by:*(HSPAIDBY)* ☐ Insurance ☐ Self-pay ☐ No-cost
8. Medications received/amount in the past 30 days:
   Include substance abuse medications.
9. Medications received/amount in the 30 days prior to your follow up visit target date:
   Include substance abuse medications.

^2Drug	Use	Number of Days
a. ^2Methadone:	*(HSMETHAD)* ☐ No ☐ Yes	*(HSMETDAY)* *(xx)*
b. ^2Buprenorphine:	*(HSBUPREN)* ☐ No ☐	

Yes

	Oral:	(HSBUPORL) No Yes	(HSBPORDY) (xx)	
@2	@2Implant:	(HSBUPIMP) No Yes	(HSBPIMDY) (xx)	Implant date:(HSIMPDT) (mm/dd/yyyy)
			Removal date: (HSREMDT) (mm/dd/yyyy)	
	Other:	(HSBUPOT) No Yes	(HSBPOTDY) (xx)	
c. ^2Naltrexone:		(HSXRNTX) No Yes		
	Oral:	(HSNALORL) No Yes	(HSNAORDY) (xx)	
	Injectable:	(HSNALINJ) No Yes		Injection date:(HSINJDT) (mm/dd/yyyy)
				Date of second injection:(HSINJ2DT) (mm/dd/yyyy)
	Other:	(HSNALOT) No Yes	(HSNAOTDY) (xx)	
d. ^2Naloxone (Narcan):		(HSNARCAN) No Yes		Number of doses:(HSNLNDOS) (xx)
e. ^2Other medication:		(HSOTHER) No Yes	(HSOTHDY) (xx)	^2Specify medication:(HSOTHSP)

Comments:(HSOCOMM)

Additional Selection Options for HSO

Provider code:
6-Day surgery
7-Opioid treatment program
99-Other

Provider type:
6-Dentist
7-Counselor/psychologist
8-Self-help (e.g., NA, AA)
99-Other

Health Status (HST)

Web Version: 1.0; 2.00; 04-11-18

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

1. Did you come to the Emergency Department today primarily to receive treatment or a referral for your opioid use?*(HSEDRSN)* — ☐ No ☐ Yes
2. Do you have a medical care provider whom you usually see?*(HSMEDPRO)* — ☐ No ☐ Yes
3. Where do you usually or most often go for medical care?*(HSMEDLOC)*
   - 1-Hospital-based clinic
   - 2-Federally-qualified (community) health center
   - 3-Private doctor's office
   - 4-Emergency department
   - 5-Urgent care center/walk in facility
   - *Additional Options Listed Below

   If "Other", specify:*(HSLOCSP)*
4. Do you know your HIV status?*(HSKNOHIV)* — ☐ No ☐ Yes ☐ Never tested

   If "Yes", what is your HIV status?*(HSSTAHIV)* — ☐ Negative ☐ Positive
5. Do you know your Hepatitis C status? *(HSKNOHEP)* — ☐ No ☐ Yes ☐ Never tested

   If "Yes", what is your Hepatitis C status? *(HSSTAHEP)* — ☐ Negative ☐ Positive

The following questions are about your sexual and drug use behaviors, things that happened, or that you have done in the past month. Think back over this time about the places you have been, the things that you have done, and the people that you have been with. The most important thing is that you respond HONESTLY and ACCURATELY. OK, let's start.

Drug Use Section

6. How many **times** have you hit up (i.e., injected yourself with any drugs or were injected by someone else) in the last month?*(HSHITUP)*
   - 0-No times
   - 1-Once
   - 2-More than once
   - 3-Once a day
   - 4-2-3 times a day
   - 5-More than 3 times a day
7. How many **times** in the last month have you used a needle **after** someone else had already used it? Please include the number of times you used a needle after your partner in addition to the number of times you used a needle after others. *(HSYOUAFT)*
   - 0-No times
   - 1-One time
   - 2-Two times
   - 3-3-5 times
   - 4-6-10 times
   - 5-More than 10 times
8. How many **different** people (including your partner) have used a needle **before** you in the last month?*(HSPPLBEF)*

0-None
1-One person
2-Two people
3-3-5 people
4-6-10 people
5-More than 10 people

9. How many **times** in the last month has **someone else** used a needle **after** you used it? *(HSPPLAFT)*

0-No times
1-One time
2-Two times
3-3-5 times
4-6-10 times
5-More than 10 times

10. How **often**, in the last month, have you cleaned needles before re-using them?*(HSCLNEED)*

0-Doesn't re-use
1-Every time
2-Often
3-Sometimes
4-Rarely
5-Never

11. Before using needles again, how **often** in the last month did you use bleach to clean them? *(HSCLBLEC)*

0-Doesn't re-use
1-Every time
2-Often
3-Sometimes
4-Rarely
5-Never

Pain Section

Please use the range of 0 to 10 to answer the following questions.

12. What number best describes your pain on average in the past week?*(HSPAINAV)* (0 = No pain, 10 = Pain as bad as you can imagine)
13. What number best describes how, during the past week, pain has interfered with your enjoyment of life?*(HSENJOY)* (0 = Pain has not interfered at all, 10 = Pain has interfered extremely)
14. What number best describes how, during the past week, pain has interfered with your general activity?*(HSACTVTY)* (0 = Pain has not interfered at all, 10 = Pain has interfered extremely)

Psychological Section

15. In your lifetime, have you ever been treated for any psychological or emotional problems in a hospital or inpatient setting?*(HSHOSP)* ☐ No ☐ Yes
16. In your lifetime, have you ever been treated for any psychological or emotional problems as an outpatient/private patient?*(HSOUTPT)* ☐ No ☐ Yes
17. In the past 30 days, have you been treated for any psychological or emotional problems with counseling or medication?*(HSCNMED)* ☐ No ☐ Yes

18. 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
a. Little interest or pleasure in doing things:	*(HSINTPL)*	☐	☐	☐	☐
b. Feeling down, depressed, or hopeless:	*(HSDEPR)*		☐	☐	☐

c. Trouble falling or staying asleep, or sleeping too much: *(HSSLEEP)*

d. Feeling tired or having little energy: *(HSTIRED)*

e. Poor appetite or overeating: *(HSEAT)*

f. Feeling bad about yourself-or that you are a failure or have let yourself or your family down: *(HSFAIL)*

g. Trouble concentrating on things, such as reading the newspaper or watching television: *(HSCONCEN)*

h. 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: *(HSMOVE)*

i. Thoughts that you would be better off dead, or of hurting yourself in some way: *(HSDEAD)*

19. How difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?*(HSDIFFC)*

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

Additional Selection Options for HST

Where do you usually or most often go for medical care?
6-No place
99-Other

Adverse Event (AD1)

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

Adverse event onset date *(AEDATE)*:

Event number *(AESEQNO)*:

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

---

1. Adverse event name:*(A1DESCPT)*
2. Date site became aware of the event: *(A1AWARDT)* *(mm/dd/yyyy)*
3. Severity of event:*(A1SEVRTY)*
   - 1-Grade 1 - Mild
   - 2-Grade 2 - Moderate
   - 3-Grade 3 - Severe
4. Outcome of event:*(A1OUTCM)*
   - 1-Ongoing
   - 2-Resolved without sequelae
   - 3-Resolved with sequelae
   - 4-Resolved by convention
   - 5-Death

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

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

   a. If "Death," was it related to an overdose event?*(A1DTHODE)* ☐ No ☐ Yes ☐ Unknown

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

Comments:*(AD1COMM)*

Additional Selection Options for AD1

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

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

Healthcare Visit Logistics (HVL)

Web Version: 1.0; 1.01; 05-23-17

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

Please answer the following questions about the time it takes to travel to your usual healthcare provider.
If you are unsure about this information, give your best estimate.

1. About how many miles do you travel **ONE WAY** to get to your usual health care provider (e.g., medical doctor)? *(If you have more than one usual provider, choose one.) (HVDISTSP)* — *(xxx.xx)* miles

2. About how long does it typically take to travel **ONE WAY** to your provider?*(HVTMHRSP)* — Hours: *(xx)* *(HVTMMNSP)*Minutes: *(xx)*

   Comments:*(HVLCOMM)*

Inventory - Medication and Supplies (INV)

Web Version: 1.0; 13.00; 02-05-19

Date of inventory *(INVTRYDT)*:

A new form must be submitted by the last business day of each week.

	Current Inventory Level	Earliest Expiration Date
^3**Biological Assessments**		
1. Rapid Dip Drug Tests (RDDT)	*(INUDSEA)* *(xxx)* units	*(INUDSEX)*
2. Urine Cups with Temperature Strips	*(INTEMPEA)* *(xxx)* cups	N/A
3. FEN 50 Single Test Strip	*(INFENEA)* *(xxx)* each	*(INFENEX)* *(mm/dd/yyyy)*
4. Opiate 2000 ng (DOP-114) Single Test Strip	*(INOPI2EA)* *(xxx)* each	*(INOPI2EX)* *(mm/dd/yyyy)*
5. BUP10 Single Test Strip	*(INBUPUEA)* *(xxx)* each	*(INBUPUEX)* *(mm/dd/yyyy)*

Comments:*(INVCOMM)*

NIDA Clinical Trials Network

Locator Information Form (LIF)

Web Version: 1.0; 2.01; 09-27-18

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

RA Instruction: Fill out as much tracking information as possible. Participant may withhold certain pieces of data he or she chooses not to share.

Information collected on this form will be used to reach you when it is time for your follow-up interviews. The information you provide will be kept in a separate place from your answers to any questions you have provided. It will only be used to locate you during the study and will not be given to anyone else. If we need to reach any of your contacts, they will not be told anything except that you have been asked to take part in a survey. May we have the following information and your permission to use the information to try to find you in case we lose touch?

Date form completed or updated:*(LASTUPDT)* ________ *(mm/dd/yyyy)*

PARTICIPANT INFORMATION

Participant's Medical Record Number (MRN):*(MEDRECID)* ________

Participant's Full Legal Name:

First:*(PATFIRST)* ________

Middle:*(PATMIDD)* ________

Last:*(PATLAST)* ________

Nickname:*(PATNKNME)* ________

Participant's Home Address:

Number and street: *(PATHADDR)* ________

City or town:*(PATHCITY)* ________ State:*(PATHST)*

AK-Alaska - AK
AL-Alabama - AL
AR-Arkansas - AR
AZ-Arizona - AZ
CA-California - CA
*Additional Options Listed Below

Zip code:*(PATHZIP)* ________ *(xxxxx)*

Can we send you information at this address?*(PATSNDML)* ☐ No ☐ Yes

Participant's Contact Information:

Phone 1 number: *(PATHMTEL)* ________ *((xxx) xxx-xxxx)* Type:*(PATPH1TP)*

1-Home phone
2-Cell phone
3-Message phone
4-Other phone

If you are not available, is it okay to leave a message at this number regarding the research project?*(PATLVMSG)* ☐ No ☐ Yes

Phone 2 number: *(PATCLTEL)* ________ *((xxx) xxx-xxxx)* Type:*(PATPH2TP)*

1-Home phone
2-Cell phone
3-Message phone
4-Other phone

If you are not available, is it okay to leave a message at this number regarding the research project?*(PATCLMSG)* ☐ No ☐ Yes

Phone 3 number: *(PATMSTEL)*

((xxx) xxx-xxxx) Type: *(PATPH3TP)*

1-Home phone
2-Cell phone
3-Message phone
4-Other phone

If you are not available, is it okay to leave a message at this number regarding the research project? *(PATMSMSG)* ☐ No ☐ Yes

E-mail address (e.g., xxx@xx.xxx): *(PATEMAIL)* *(xxx@xx.xxx)*

Can we send you a text message to a cell phone to remind you about your follow-up visits? *(PATTEXT)* ☐ No ☐ Yes ☐ N/A (no access to a cell phone)

If "Yes", cell phone number: *(PACELL1)*

((xxx) xxx-xxxx) Service provider: *(PACLL1CR)*

1-Alltel Wireless
15-Alltel Wireless pre-paid
2-AT&T
16-AT&T GoPhone
17-Boost Mobile
*Additional Options Listed Below

If "Yes", cell phone number: *(PACELL2)*

((xxx) xxx-xxxx) Service provider: *(PACLL2CR)*

1-Alltel Wireless
15-Alltel Wireless pre-paid
2-AT&T
16-AT&T GoPhone
17-Boost Mobile
*Additional Options Listed Below

Name on Facebook or URL: *(LIFACEBK)*

Name on MySpace or URL: *(LIMYSPAC)*

Other social media contact information: *(LIMEDIA)*

Can I make a copy of one of your identification cards (a picture identification card is preferred)? We will only use this to help us locate you if we have trouble contacting you. *(PAIDCARD)* ☐ No ☐ Yes ☐ N/A (doesn't have identification)

RA Instruction: If "No", participant refuses to allow staff to make a photocopy of ID card, then ask or say: "We would like to write down the ID number."

Enter ID number: *(LIIDNUM)*

Participant's Identifying Information:

Has participant ever had another name (such as before marriage)? *(PATOTHNM)* ☐ No ☐ Yes

If "Yes", participant's other name: *(PATNM2SP)*

Date of birth: *(PATDOBDT)* *(MM/DD/YYYY)*

City and state, or country of birth: *(PATBTPL)*

Social Security number: *(PATSSNUM)* *(xxx-xx-xxxx)*

Sometimes participants forget their study visits, where to go, or they don't have transportation. For this reason, we sometimes go looking for participants. To be able to find you, we would appreciate your answering the following questions:

Where do you usually eat the following meals and around what time?

Usual breakfast place: *(LIBKPL)* Breakfast time (24-hour format): *(LIBKTM)* *(hh:mm)*

Usual lunch place: *(LILNCHPL)* Lunch time (24-hour format): *(LILNCHTM)* *(hh:mm)*

Usual dinner place: *(LIDNRPL)* Dinner time (24-hour format): *(LIDNRTM)*

(hh:mm)

Where do you usually sleep at night?*(LISLEEP)*

When not eating or sleeping, where do you usually hang out? *Provide name and/or location of park, street corner, bridge, own apartment, friend's apartment, etc. (LIHANGOT)*

Where do you usually go for health care or other services? *Provide name and/or location. (LIHEALTH)*

We like to record a physical description of study participants to make it easier for us to find you. For this reason, we would like to know the following:

Height:*(LIHGTFT)* *(x)* ft *(LIHGTIN)* *(xx)* in

Weight:*(LIWEIGHT)* *(xxx)* lbs

Eye color:*(LIEYE)*

1-Dark brown
2-Light brown
3-Hazel
4-Green
5-Blue
*Additional Options Listed Below

Type and location of any physical markings (e.g., tattoo, scar, mole): *(LIPHYSCL)*

Other distinctive attributes (e.g., wears yellow or red wigs, uses a wheelchair, typically uses a cane, limps, piercing):*(LIDSTATR)*

Participant's Employer Information:

Employer name: *(PATEMPNM)*

Number and street address: *(PATEMPAD)*

City or town:*(PATEMPCY)*

State:*(PATEMPST)*

AK-Alaska - AK
AL-Alabama - AL
AR-Arkansas - AR
AZ-Arizona - AZ
CA-California - CA
*Additional Options Listed Below

Zip code:*(PATEMPZP)* *(xxxxx)*

Can we send you information at this address?*(PATEMPSN)* ☐ No ☐ Yes

Employer work phone number:*(PATEMPPH)* *((xxx) xxx-xxxx)*

Hours typically work (e.g., 9am to 5pm, midnight to 7am, 4-8 pm):*(LIWRKHR)*

Usual employment pattern: *(LIWRKTM)*

1-Full time (35+ hrs/week)
2-Part time (regular hours)
3-Part time (irregular, day work)
4-Student
5-Military service
*Additional Options Listed Below

LOCATOR INFORMATION

We would also like to have the names of 3 or 4 people who might be able to help us locate you if we lose touch with you.

These should be:

People with whom you are likely to keep in touch and who would know how to contact you.

People who are likely to have the same address and telephone number for the next few years.

These people need not be told anything about the nature of the research program in which you are participating. We would contact them ***only*** *if we are unable to locate you. In each case, you can indicate whether or not it is okay for the person to know about the research project in which you are participating.*

Person #1:

For this first contact we would like to know who is the one person that you would turn to if you were in trouble.

First name:*(RF1FIRST)* Last name:*(RF1LAST)*

Relationship to participant: *(RF1RELAT)*
1-Family
2-Friend
3-Co-worker
99-Other

Number and street address: *(RF1ADDR)*

City or town:*(RF1CITY)* State:*(RF1ST)*
AK-Alaska - AK
AL-Alabama - AL
AR-Arkansas - AR
AZ-Arizona - AZ
CA-California - CA
*Additional Options Listed Below
Zip code:*(RF1ZIP)* *(xxxxx)*

Phone 1 number: *(RF1HMPH)* *((xxx) xxx-xxxx)* Type:*(RF1PH1TP)*
1-Home phone
2-Cell phone
3-Message phone
4-Other phone

Phone 2 number: *(RF1CELPH)* *((xxx) xxx-xxxx)* Type:*(RF1PH2TP)*
1-Home phone
2-Cell phone
3-Work phone

Phone 3 number: *(RF1WKPH)* *((xxx) xxx-xxxx)* Type:*(RF1PH3TP)*
1-Home phone
2-Cell phone
3-Work phone

E-mail address (e.g., xxx@xx.xxx):*(RF1EMAIL)* *(xxx@xx.xxx)*

Is it ok for this person to know about the research? *(RF1CNTC)* No Yes

Does this person speak and understand English? *(RF1ENGSH)* No Yes

If "No", in what language must we communicate when contacting this person?*(RF1LANGE)*
1-Spanish
2-French
3-Creole
99-Other
If "Other", specify:*(RF1LNGSP)*

Person #2:

First name:*(RF2FIRST)* Last name:*(RF2LAST)*

Relationship to participant: *(RF2RELAT)*
1-Family
2-Friend
3-Co-worker
99-Other

Number and street address: *(RF2ADDR)*

City or town:*(RF2CITY)* State:*(RF2ST)*
AK-Alaska - AK
AL-Alabama - AL
AR-Arkansas - AR
AZ-Arizona - AZ
CA-California - CA
*Additional Options Listed Below
Zip code:*(RF2ZIP)* *(xxxxx)*

Phone 1 number: *(RF2HMPH)* *((xxx) xxx-xxxx)* Type:*(RF2PH1TP)*
1-Home phone
2-Cell phone
3-Work phone

Phone 2 number: *(RF2CELPH)* ((xxx) xxx-xxxx) Type:*(RF2PH2TP)* 1-Home phone / 2-Cell phone / 3-Work phone

Phone 3 number: *(RF2WKPH)* ((xxx) xxx-xxxx) Type:*(RF2PH3TP)* 1-Home phone / 2-Cell phone / 3-Work phone

E-mail address (e.g., xxx@xx.xxx):*(RF2EMAIL)* (xxx@xx.xx)

Is it ok for this person to know about the research? *(RF2CNTC)* No Yes

Does this person speak and understand English? *(RF2ENGSH)* No Yes

If "No", in what language must we communicate when contacting this person?*(RF2LANGE)* 1-Spanish / 2-French / 3-Creole / 99-Other If "Other", specify:*(RF2LNGSP)*

Person #3:

First name:*(RF3FIRST)* Last name:*(RF3LAST)*

Relationship to participant: *(RF3RELAT)* 1-Family / 2-Friend / 3-Co-worker / 99-Other

Number and street address: *(RF3ADDR)*

City or town:*(RF3CITY)* State:*(RF3ST)* AK-Alaska - AK / AL-Alabama - AL / AR-Arkansas - AR / AZ-Arizona - AZ / CA-California - CA / *Additional Options Listed Below Zip code:*(RF3ZIP)* (xxxxx)

Phone 1 number: *(RF3HMPH)* ((xxx) xxx-xxxx) Type:*(RF3PH1TP)* 1-Home phone / 2-Cell phone / 3-Work phone

Phone 2 number: *(RF3CELPH)* ((xxx) xxx-xxxx) Type:*(RF3PH2TP)* 1-Home phone / 2-Cell phone / 3-Work phone

Phone 3 number: *(RF3WKPH)* ((xxx) xxx-xxxx) Type:*(RF3PH3TP)* 1-Home phone / 2-Cell phone / 3-Work phone

E-mail address (e.g., xxx@xx.xxx):*(RF3EMAIL)* (xxx@xx.xxx)

Is it ok for this person to know about the research? *(RF3CNTC)* No Yes

Does this person speak and understand English? *(RF3ENGSH)* No Yes

If "No", in what language must we communicate when contacting this person?*(RF3LANGE)* 1-Spanish / 2-French / 3-Creole / 99-Other If "Other", specify:*(RF3LNGSP)*

Person #4:

First name:*(RF4FIRST)* Last name:*(RF4LAST)*

Relationship to participant: *(RF4RELAT)*

1-Family
2-Friend
3-Co-worker
99-Other

Number and street address: *(RF4ADDR)*

City or town:*(RF4CITY)*

State:*(RF4ST)*
AK-Alaska - AK
AL-Alabama - AL
AR-Arkansas - AR
AZ-Arizona - AZ
CA-California - CA
*Additional Options Listed Below

Zip code:*(RF4ZIP)* *(xxxxx)*

Phone 1 number: *(RF4HMPH)* *((xxx) xxx-xxxx)* Type:*(RF4PH1TP)*
1-Home phone
2-Cell phone
3-Work phone

Phone 2 number: *(RF4CELPH)* *((xxx) xxx-xxxx)* Type:*(RF4PH2TP)*
1-Home phone
2-Cell phone
3-Work phone

Phone 3 number: *(RF4WKPH)* *((xxx) xxx-xxxx)* Type:*(RF4PH3TP)*
1-Home phone
2-Cell phone
3-Work phone

E-mail address (e.g., xxx@xx.xxx):*(RF4EMAIL)* *(xxx@xx.xxx)*

Is it ok for this person to know about the research? *(RF4CNTC)* ☐ No ☐ Yes

Does this person speak and understand English? *(RF4ENGSH)* ☐ No ☐ Yes

If "No", in what language must we communicate when contacting this person?*(RF4LANGE)*
1-Spanish
2-French
3-Creole
99-Other

If "Other", specify:*(RF4LNGSP)*

It is crucial that this information is correct. Was all the data reviewed with the participant before saving?*(RAREVEW)* ☐ No ☐ Yes

Comments:*(LIFCOMM)*

Additional Selection Options for LIF

State:
CO-Colorado - CO
CT-Connecticut - CT
DC-District of Columbia - DC
DE-Delaware - DE
FL-Florida - FL
GA-Georgia - GA
HI-Hawaii - HI
IA-Iowa - IA
ID-Idaho - ID
IL-Illinois - IL
IN-Indiana - IN
KS-Kansas - KS
KY-Kentucky - KY
LA-Louisiana - LA
MA-Massachusetts - MA
MD-Maryland - MD
ME-Maine - ME
MI-Michigan - MI
MN-Minnesota - MN
MO-Missouri - MO
MS-Mississippi - MS
MT-Montana - MT
NC-North Carolina - NC
ND-North Dakota - ND
NE-Nebraska - NE
NH-New Hampshire - NH
NJ-New Jersey - NJ
NM-New Mexico - NM
NV-Nevada - NV
NY-New York - NY
OH-Ohio - OH
OK-Oklahoma - OK
OR-Oregon - OR
PA-Pennsylvania - PA
PR-Puerto Rico - PR
RI-Rhode Island - RI
SC-South Carolina - SC
SD-South Dakota - SD
TN-Tennessee - TN
TX-Texas - TX
UT-Utah - UT
VA-Virginia - VA
VI-Virgin Islands - VI
VT-Vermont - VT
WA-Washington - WA
WI-Wisconsin - WI
WV-West Virginia - WV
WY-Wyoming - WY

Service provider:
3-CellularOne
18-Cricket Communications
9-Edge Wireless
10-Helio
19-Liberty Wireless
20-MetroPCS
21-Net10
4-Nextel
11-NTELOS Wireless
12-Qwest
13-SoutherLINC Wireless
5-Sprint
14-SureWest
6-T-Mobile
22-T-Mobile To Go
23-TracFone
7-US Cellular
24-Verizon Pay As You Go
8-Verizon Wireless
25-Virgin Mobile

Eye color:
99-Other

Usual employment pattern:
6-Retired/disability
7-Unemployed
8-In controlled environment
97-Not answered

Motivation for Participating, Attitudes and Expectations (MOT)

Web Version: 1.0; 1.00; 07-03-18

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

1. Date of assessment:*(MOASMDT)* ______ *(mm/dd/yyyy)*
2. What is the reason for your ED visit today? *(Select one)(MOEDRSON)*
   - 1-Seeking buprenorphine treatment for your opioid problem
   - 2-Seeking general/other treatment for your opioid problem
   - 3-Taking too much opioids/overdose (or combination including opioids)
   - 4-Problem that is caused, at least in part, by drug use (e.g., abscess)
   - 5-Not at all related to opioid use
3. What is your primary motivation for participating in this project? *(Select one) (MOMOTVTN)*
   - 1-Helping others and contributing to science
   - 2-Friends/family encouraged participation
   - 3-Doctor, nurse or other hospital staff encouraged participation
   - 4-Positive experience in another study
   - 5-To access treatment to help in recovery
   - 6-Payment/study compensation
4. Do you have a primary care doctor or clinic where you have received medical care in the last year?*(MOPRMYCR)* ☐ No ☐ Yes
5. In the last year, have you missed a health care appointment because transportation was not available (or because of transportation problems)?*(MOTRANSP)* ☐ No ☐ Yes
6. Have you ever taken any of the following medications through a program or by prescription? (Prior to index ED visit)

SL-Buprenorphine	*(MOSLBUP)*	☐ No	☐ Yes
XR-Buprenorphine, 7 Day	*(MOXBUP7)*	☐ No	☐ Yes
XR-Buprenorphine, 30 Day	*(MOXBUP30)*	☐ No	☐ Yes
Naltrexone (oral)	*(MOORLNAL)*	☐ No	☐ Yes
Naltrexone (injection)	*(MOINJNAL)*	☐ No	☐ Yes
Methadone	*(MOMTD)*	☐ No	☐ Yes

If none endorsed, why have you not been treated with medications to treat opioid use disorder? *(Select one)(MONOMEDS)*
- 1-Don't think I have a problem or need treatment
- 2-Unable to afford and/or lack of adequate insurance
- 3-Unable to get into a treatment program or to a prescribing doctor
- 4-Unaware of treatment options
- 5-Interested in treatment but not interested in medications
- 6-Never got around to it
- 99-Other

If "Other", specify:*(MONOMDSP)* ______

7. On a scale of 1 to 10, with 1 being not at all

important and 10 being extremely important, how important is it to you to cut back or stop using opioids?*(MOIMPRT)*

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

8. On a scale of 1 to 10, with 1 being not at all confident and 10 being extremely confident, how confident are you in your ability to cut back or stop using opioids?*(MOCONFID)*

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

9. On a scale of 1 to 10, with 1 being not at all likely and 10 being extremely likely, to what extent has your ED visit made you more likely to seek medication treatment for opioid use disorder?*(MOEDVST)*

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

We would like to know your opinion on which medications should be offered in the Emergency Department. The next few questions will ask about medications that may or may not interest you. You may have received one of these during your recent visit to the ED.

10. If you were offered an injection of buprenorphine that would last for one week, would you accept this medication? *(MOINJBUP)* — ☐ No ☐ Yes
11. If you were offered an injection of buprenorphine that would last for 30 days, would you accept this medication? *(MOXRBUP)* — ☐ No ☐ Yes
12. If you were offered sublingual buprenorphine, taken daily, would you accept this medication?*(MOSBBUP)* — ☐ No ☐ Yes
13. What is your medication preference? *(MOMEDPRF)*

    0-No medication
    1-XR-Buprenorphine, once weekly
    2-XR-Buprenorphine, once monthly
    3-SL-Buprenorphine, taken daily
    4-Methadone
    5-Naltrexone

Comments:*(MOCOMM)*

Additional Selection Options for MOT

On a scale of 1 to 10, with 1 being not at all important and 10 being extremely important, how important is it to you to cut back or stop using opioids?

06-6
07-7
08-8
09-9
10-10

Overdose Events and Risk Factors (OER)

Web Version: 1.0; 1.00; 06-28-18

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

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

Section 1: Opioid Use Patterns

1. How often do you use opioids with the following other substances (i.e., in combination or at the same time)?

Substance		Never	Sometimes	All or most of the time
a. Other opioids	*(OEOTHOPI)*	☐	☐	☐
b. Alcohol	*(OEOPIALC)*	☐	☐	☐
c. Sedatives, benzodiazepines, sleeping pills	*(OEOPISED)*	☐	☐	☐
d. Cocaine, amphetamines or other stimulants	*(OEOPICOC)*	☐	☐	☐

2. Have you recently cut back or stopped using opioids, including if you were in treatment, a hospital, or in jail? *(OESTPOPI)* ☐ No ☐ Yes

Section 2: Overdose Risk

3. How often have you, if ever, intentionally or knowingly used fentanyl? This means that you knew it was fentanyl before you used it.*(OEIFNTYL)* ☐ Never ☐ Sometimes ☐ All or most of the time
4. How often do you use opioids while you are alone (i.e., not using with other people around)?*(OEOPIALN)* ☐ Never ☐ Sometimes ☐ All or most of the time

Section 3: Overdose Prevention

Section 2: Overdose Prevention

All questions relating to past 30 days refer to Days 1-30, post ED discharge.

5. Overdose prevention kits contain a medicine called Naloxone or Narcan™, which is used to reverse an overdose. Have you ever obtained or been given a Naloxone kit?*(OENALKIT)* ☐ No ☐ Yes
6. Overdose prevention kits contain a medicine called Naloxone or Narcan™, which is used to reverse an overdose. In the past 30 days, have you obtained or been given a Naloxone kit?*(OENALKIT)* ☐ No ☐ Yes

   Do you still currently have a kit?*(OECURKIT)* ☐ No ☐ Yes ☐ Not sure

   If "No", what happened to it?*(OEHAPKIT)*

   0-Lost it or unsure
   1-Threw it away
   2-Gave it away
   3-It was used to reverse an overdose
   4-Stolen
   *Additional Options Listed Below

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

7. How many times, if ever, have you given someone Naloxone (either a kit that belonged to you or someone else) to reverse an overdose?*(OEUSEKIT)* *(xx)*

8. In the past 30 days, how many times, if ever, have you given someone Naloxone (either a kit that belonged to you or someone else) to reverse an overdose?*(OEUSEKIT)* (xx)
9. How many times, if ever, have you seen someone else use a Naloxone kit to reverse an overdose? Do not include use in the hospital or by EMS.*(OESEEKIT)* (xx)
10. In the past 30 days, how many times, if ever, have you seen someone else use a Naloxone kit to reverse an overdose? Do not include use in the hospital or by EMS.*(OESEEKIT)* (xx)
11. How many times, if ever, has Naloxone been used on you to reverse an overdose (including today)? Do not include use in the hospital or by EMS.*(OEYOUKIT)* (xx)
12. In the past 30 days, how many times, if ever, has Naloxone been used on you to reverse an overdose (including today)? Do not include use in the hospital or by EMS. *(OEYOUKIT)* (xx)

    Of those times, how many times did you go to the ED after administration of Naloxone?*(OEEDKIT)* (xx)

Section 4: Overdose Events

Section 3: Overdose Events

13. On how many days in your life, do you think you overdosed on opioids (you used more than you should have used and were more sedated, drugged, or high than you wanted to be)?*(OEODOPIL)* (xxx)
14. On how many days in the past 12 months do you think you overdosed on opioids (you used more than you should have used and were more sedated, drugged, or high than you wanted to be)?*(OEODOPIY)* (xxx)
15. On how many days in the past 30 days do you think you overdosed on opioids (you used more than you should have used and were more sedated, drugged, or high than you wanted to be)?*(OEODOPIM)* (xx)
16. This question is similar to the last, but we use a different definition for overdose. In your life, how many times have you had an overdose involving opioids? This could be where you lost consciousness, OR needed medical care, OR used more than you should have and were more sedated, drugged, or high than you wanted to be? *(OEOIOPIL)* (xxx)
17. How many times in the past 12 months have you had an overdose involving opioids? This could be where you lost consciousness, OR needed medical care, OR used more than you should have and were more sedated, drugged, or high than you wanted to be?*(OEOIOPIY)* (xxx)
18. How many times in the past 30 days have you had an overdose involving opioids? This could be where you lost consciousness, OR needed medical care, OR used more than you should have and were more sedated, drugged, or high than you wanted to be?*(OEMOIOPM)* (xx)
19. This question is similar to the last, but we use a different definition for overdose. How many times in the past 30 days have you had an overdose involving opioids? This could be where you lost consciousness, OR needed medical care, OR used more than you should have and were more sedated, drugged, or high than you wanted to be? *(OEMOIOPM)* (xx)

    Of those times, how many times did you go to the ED after an overdose involving opioids?*(OEOPIED)* (xx)

Comments:*(OERCOMM)*

Additional Selection Options for OER

If "No", what happened to it?
5-Other

Other Substance Use (OSU)

Web Version: 1.0; 2.00; 06-25-18

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

*These questions ask about psychoactive substances in the **PAST 3 MONTHS ONLY**.*

1. Did you smoke a cigarette containing tobacco? *(OSSMKCIG)* ☐ No ☐ Yes
   a. Did you usually smoke more than 10 cigarettes each day?*(OSSMK10)* ☐ No ☐ Yes
   b. Did you usually smoke within 30 minutes after waking?*(OSSMK30)* ☐ No ☐ Yes
2. Did you smoke (or vape) an e-cigarette containing nicotine?*(OSNICOTN)* ☐ No ☐ Yes

3. Did you have a drink containing alcohol?*(OSALCOH)* ☐ No ☐ Yes
   a. On any occasion, did you drink more than 5 standard* drinks of alcohol? (*1 standard drink is about 1 small glass of wine, or one can of medium strength beer, or one single shot of spirits.) *(OSALBING)* ☐ No ☐ Yes
   b. On any occasion, did you drink more than 4 standard* drinks of alcohol? (*1 standard drink is about 1 small glass of wine, or one can of medium strength beer, or one single shot of spirits.) *(OSALBING)* ☐ No ☐ Yes
   c. Have you tried and failed to control, cut down or stop drinking?*(OSALSTOP)* ☐ No ☐ Yes
   d. Has anyone expressed concern about your drinking?*(OSALCNR)* ☐ No ☐ Yes

4. Did you use cannabis?*(OSCANNAB)* ☐ No ☐ Yes
   a. Have you had a strong desire or urge to use cannabis at least once a week or more often? *(OSCANDES)* ☐ No ☐ Yes
   b. Has anyone expressed concern about your use of cannabis?*(OSCANCNR)* ☐ No ☐ Yes

5. Did you use an amphetamine-type stimulant, or cocaine, or a stimulant medication not as prescribed? *(OSSTMULN)* ☐ No ☐ Yes
   a. Did you use a stimulant at least once each week or more often?*(OSSTMOFT)* ☐ No ☐ Yes
   b. Has anyone expressed concern about your use of a stimulant?*(OSSTMCNR)* ☐ No ☐ Yes

6. Did you use a sedative or sleeping medication not as prescribed?*(OSSEDUSE)* ☐ No ☐ Yes
   a. Have you had a strong desire or urge to use a sedative or sleeping medication at least once a ☐ No ☐ Yes

week or more often?*(OSSEDDES)*

b. Has anyone expressed concern about your use of a sedative or sleeping medication?*(OSSEDSNR)*

☐ No ☐ Yes

7. Did you use any other psychoactive altering substance?*(OSPSYCH)*

☐ No ☐ Yes

If "Yes", what did you take?*(OSPSYSP)*

Comments:*(OSUCOMM)*

Prescription Drug Monitoring (PDM)

Web Version: 1.0; 1.00; 06-29-18

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

The reporting period for this form is the 30-day study follow-up period (including the day the participant was discharged from the ED). Review the States' Prescription Drug Monitoring Program (PDMP) and print a copy of the report generated. Complete the questions below while referencing the report. The printed report should be stored as a source document.

1. Date of assessment:*(PDMASMDT)* ______ *(mm/dd/yyyy)*
2. Date of discharge from index ED visit:*(PDDISDT)* ______ *(mm/dd/yyyy)*
3. Day 30 *(30 days after discharge from index ED visit):* *(PDD30DT)* ______ *(mm/dd/yyyy)*
4. Date PDMP reviewed:*(PDPMPRDT)* ______ *(mm/dd/yyyy)*
5. Number of buprenorphine prescriptions (not doses) dispensed in the follow-up period:*(PDBUPDI)* ______ *(xx)*
   a. Number of sublingual buprenorphine prescriptions (not doses) dispensed:*(PDSBUPDI)* ______ *(xx)*
   b. Number of extended-release buprenorphine prescriptions (not doses) dispensed:*(PDXBUPDI)* ______ *(xx)*
6. Were other opioid prescriptions dispensed?*(PDOPIOTH)* ☐ No ☐ Yes

   If "Yes", number of other opioid prescriptions (not doses) dispensed in the follow-up period:*(PDOPIOTF)* ______ *(xx)*
7. Did participant have prescriptions dispensed from more than one state?*(PDRXOTST)* ☐ No ☐ Yes

   Comments:*(PDMCOMM)* ______

Protocol Deviation Review (PDR)

Web Version: 1.0; 2.01; 08-20-18

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

Completed by Protocol Specialist:

1. What section of the protocol does this deviation refer to? *(PDSECTN)*
2. Does the report of this deviation require site staff retraining? *(PDTRAIN)* ☐ No ☐ Yes
   If "Yes", specify plan for retraining: *(PDPLATRA)*
3. Date deviation was discussed with Lead Investigative Team: *(PDDISCDT)* _______ *(mm/dd/yyyy)*
4. Deviation is categorized as: *(PDCATGRY)* ☐ Major ☐ Minor
5. Deviation assessment by Protocol Specialist complete: *(PDPSCMP)* ☐ No ☐ Yes
   Protocol Specialist reviewer: *(PDPSRVID)* _______ (initials)

   Protocol Specialist comments: *(PDRCOMM2)*

Completed by Protocol Monitor:

6. Deviation requires review by Protocol Monitor: *(PDPMREVW)* ☐ No ☐ Yes
7. Corrective action for this deviation was completed and documented on-site as described: *(PDACTDOC)* ☐ No ☐ Yes
   If "No", specify reason: *(PDSITESP)*
8. Deviation was reported to the IRB as required: *(PDIRBRPT)* ☐ No ☐ Yes
   If "No", specify reason: *(PDIRBSP)*
9. Preventive action plan related to this event was completed and documented on-site as described: *(PDPREVNT)* ☐ No ☐ Yes
10. Review by Protocol Monitor is complete: *(PDPMCMP)* ☐ No ☐ Yes
    Protocol Monitor reviewer: *(PDPMRVID)* _______ (initials)

    Protocol Monitor comments: *(PDRCOMM)*

Additional Selection Options for PDR

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

Protocol Deviation (PDV)

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

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

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

If "Yes", how many participants?*(PDPRELNO)*
01-1
02-2
03-3
04-4
05-5
*Additional Options Listed Below

Select related participants:

Participant ID 1:*(PDPPT01)* 9999999999999-DUMMYPARTICIPANTID
Participant ID 2:*(PDPPT02)* 9999999999999-DUMMYPARTICIPANTID
Participant ID 3:*(PDPPT03)*
Participant ID 4:*(PDPPT04)* 9999999999999-DUMMYPARTICIPANTID
Participant ID 5:*(PDPPT05)* 9999999999999-DUMMYPARTICIPANTID
Participant ID 6:*(PDPPT06)* 9999999999999-DUMMYPARTICIPANTID
Participant ID 7:*(PDPPT07)* 9999999999999-DUMMYPARTICIPANTID
Participant ID 8:*(PDPPT08)* 9999999999999-DUMMYPARTICIPANTID
Participant ID 9:*(PDPPT09)* 9999999999999-DUMMYPARTICIPANTID
Participant ID 10:*(PDPPT10)* 9999999999999-DUMMYPARTICIPANTID
Participant ID 11:*(PDPPT11)* 9999999999999-DUMMYPARTICIPANTID
Participant ID 12:*(PDPPT12)* 9999999999999-DUMMYPARTICIPANTID
Participant ID 13:*(PDPPT13)* 9999999999999-DUMMYPARTICIPANTID
Participant ID 14:*(PDPPT14)* 9999999999999-DUMMYPARTICIPANTID
Participant ID 15:*(PDPPT15)* 9999999999999-DUMMYPARTICIPANTID
Participant ID 16:*(PDPPT16)* 9999999999999-DUMMYPARTICIPANTID
Participant ID 17:*(PDPPT17)* 9999999999999-DUMMYPARTICIPANTID
Participant ID 18:*(PDPPT18)* 9999999999999-DUMMYPARTICIPANTID
Participant ID 19:*(PDPPT19)*

9999999999999-DUMMYPARTICIPANTID

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

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

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

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

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

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

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

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

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

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

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

Comments:*(PDVCOMM)*

Additional Selection Options for PDV

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

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

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

Study Completion (STC)

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

Segment *(PROTSEG)*: B

1. Did the participant complete the 30 day follow-up visit within 7 days of **[insert enrollment date + 30d]**?*(STCOMPLT)* ☐ No ☐ Yes
   a. If "No," did the participant complete the 30 day follow-up visit at a later date? *(STLTEFUP)* ☐ No ☐ Yes
   b. If "No", select the primary reason for not completing the follow-up visit: *(STEARLY)*
      - 1-Participant failed to return to clinic 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
      - 6-Participant terminated for other clinical reasons
      - *Additional Options Listed Below

      If "Participant terminated for other clinical reasons", "Participant terminated for administrative issues", or "Participant terminated for other reason", specify: *(STCMPOSP)*

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 follow-up visit:
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
34-Participant was ineligible and should not have been enrolled in study
99-Participant terminated for other reason

NIDA Clinical Trials Network

Serious Adverse Event Summary (AD2)

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

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

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

---

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

2. Relevant past medical history:*(A2SAEMHX)* ☐ No ☐ Yes ☐ Unknown

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

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

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

4. Treatments for the event:*(A2SAETRT)* ☐ No ☐ Yes ☐ Unknown

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

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

Lab/Test	**Findings**	**Date of Test** *(mm/dd/yyyy)*
(A2_1LBNM)	*(A2_1LBIN)*	*(A2_1LBDT)*

(A2_2LBNM)	*(A2_2LBIN)*	*(A2_2LBDT)*
(A2_3LBNM)	*(A2_3LBIN)*	*(A2_3LBDT)*
(A2_4LBNM)	*(A2_4LBIN)*	*(A2_4LBDT)*
(A2_5LBNM)	*(A2_5LBIN)*	*(A2_5LBDT)*

6. Follow-up:*(A2FOLLUP)*

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

---

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

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

Additional Selection Options for AD2

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

Timeline Followback Page 1 (T79)

Web Version: 1.0; 1.00; 01-22-18

TFB week start date *(TFWKSTDT)*:

Day	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Date	*(TLDATE1)*	*(TLDATE2)*	*(TLDATE3)*	*(TLDATE4)*	*(TLDATE5)*	*(TLDATE6)*	*(TLDATE7)*
1. Have any pain relievers, pain medications, sedatives, alcohol, methamphetamine, cocaine, heroin, or other illicit substances been used on this day?	*(TLSUBAL1)* No Yes	*(TLSUBAL2)* No Yes	*(TLSUBAL3)* No Yes	*(TLSUBAL4)* No Yes	*(TLSUBAL5)* No Yes	*(TLSUBAL6)* No Yes	*(TLSUBAL7)* No Yes
2. Heroin:							
Route:	*(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
# Times Used Each Day:	*(TLTHERR1)* *(xxx)*	*(TLTHERR2)* *(xxx)*	*(TLTHERR3)* *(xxx)*	*(TLTHERR4)* *(xxx)*	*(TLTHERR5)* *(xxx)*	*(TLTHERR6)* *(xxx)*	*(TLTHERR7)* *(xxx)*
3. Oxycodone (Percocet, Percodan, Roxicet, Oxycotin, Roxicodone, Endocet, Tylox):							
Route:	*(TLOXYC1)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLOXYC2)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLOXYC3)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLOXYC4)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLOXYC5)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLOXYC6)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLOXYC7)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below
Prescribed:	*(TLPOXYC1)* No Yes	*(TLPOXYC2)* No Yes	*(TLPOXYC3)* No Yes	*(TLPOXYC4)* No Yes	*(TLPOXYC5)* No Yes	*(TLPOXYC6)* No Yes	*(TLPOXYC7)* No Yes
# Times Used Each Day:	*(TLTOXYC1)* *(xxx)*	*(TLTOXYC2)* *(xxx)*	*(TLTOXYC3)* *(xxx)*	*(TLTOXYC4)* *(xxx)*	*(TLTOXYC5)* *(xxx)*	*(TLTOXYC6)* *(xxx)*	*(TLTOXYC7)* *(xxx)*
4. Hydrocodone (Vicodin, Lorcet, Lortab, Hycodan, Norco, Vicoprofen):							
Route:	*(TLHYDC1)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLHYDC2)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLHYDC3)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLHYDC4)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLHYDC5)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLHYDC6)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLHYDC7)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below
Prescribed:	*(TLPHYDC1)* No Yes	*(TLPHYDC2)* No Yes	*(TLPHYDC3)* No Yes	*(TLPHYDC4)* No Yes	*(TLPHYDC5)* No Yes	*(TLPHYDC6)* No Yes	*(TLPHYDC7)* No Yes
# Times Used Each Day:	*(TLTHYDC1)* *(xxx)*	*(TLTHYDC2)* *(xxx)*	*(TLTHYDC3)* *(xxx)*	*(TLTHYDC4)* *(xxx)*	*(TLTHYDC5)* *(xxx)*	*(TLTHYDC6)* *(xxx)*	*(TLTHYDC7)* *(xxx)*
5. Fentanyl (Duragesic, Actiq, Sublimaze):							
Route:	*(TLFENT1)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLFENT2)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLFENT3)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLFENT4)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLFENT5)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLFENT6)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLFENT7)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below
Prescribed:	*(TLPFENT1)* No Yes	*(TLPFENT2)* No Yes	*(TLPFENT3)* No Yes	*(TLPFENT4)* No Yes	*(TLPFENT5)* No Yes	*(TLPFENT6)* No Yes	*(TLPFENT7)* No Yes
# Times Used Each Day:	*(TLTFENT1)* *(xxx)*	*(TLTFENT2)* *(xxx)*	*(TLTFENT3)* *(xxx)*	*(TLTFENT4)* *(xxx)*	*(TLTFENT5)* *(xxx)*	*(TLTFENT6)* *(xxx)*	*(TLTFENT7)* *(xxx)*
6. Morphine (MS Contin, Kadian, Duramorph):							
Route:	*(TLMORH1)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLMORH2)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLMORH3)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLMORH4)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLMORH5)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLMORH6)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLMORH7)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below
Prescribed:	*(TLPMORH1)* No Yes	*(TLPMORH2)* No Yes	*(TLPMORH3)* No Yes	*(TLPMORH4)* No Yes	*(TLPMORH5)* No Yes	*(TLPMORH6)* No Yes	*(TLPMORH7)* No Yes
# Times Used Each Day:							

	1	2	3	4	5	6	7
	(TLTMORH1) (xxx)	(TLTMORH2) (xxx)	(TLTMORH3) (xxx)	(TLTMORH4) (xxx)	(TLTMORH5) (xxx)	(TLTMORH6) (xxx)	(TLTMORH7) (xxx)

7. Hydromorphone (Dilaudid, Palladone):

	1	2	3	4	5	6	7
Route:	(TLHYMR1) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLHYMR2) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLHYMR3) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLHYMR4) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLHYMR5) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLHYMR6) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLHYMR7) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below
Prescribed:	(TLPHYMR1) No Yes	(TLPHYMR2) No Yes	(TLPHYMR3) No Yes	(TLPHYMR4) No Yes	(TLPHYMR5) No Yes	(TLPHYMR6) No Yes	(TLPHYMR7) No Yes
# Times Used Each Day:	(TLTHYMR1) (xxx)	(TLTHYMR2) (xxx)	(TLTHYMR3) (xxx)	(TLTHYMR4) (xxx)	(TLTHYMR5) (xxx)	(TLTHYMR6) (xxx)	(TLTHYMR7) (xxx)

8. Meperidine (Demerol):

	1	2	3	4	5	6	7
Route:	(TLMEPR1) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLMEPR2) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLMEPR3) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLMEPR4) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLMEPR5) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLMEPR6) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLMEPR7) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below
Prescribed:	(TLPMEPR1) No Yes	(TLPMEPR2) No Yes	(TLPMEPR3) No Yes	(TLPMEPR4) No Yes	(TLPMEPR5) No Yes	(TLPMEPR6) No Yes	(TLPMEPR7) No Yes
# Times Taken Each Day:	(TLTMEPR1) (xxx)	(TLTMEPR2) (xxx)	(TLTMEPR3) (xxx)	(TLTMEPR4) (xxx)	(TLTMEPR5) (xxx)	(TLTMEPR6) (xxx)	(TLTMEPR7) (xxx)

9. Methadone (Dolophine, Methadose):

	1	2	3	4	5	6	7
Route:	(TLMEDN1) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLMEDN2) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLMEDN3) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLMEDN4) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLMEDN5) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLMEDN6) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLMEDN7) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below
Prescribed:	(TLPMEDN1) No Yes	(TLPMEDN2) No Yes	(TLPMEDN3) No Yes	(TLPMEDN4) No Yes	(TLPMEDN5) No Yes	(TLPMEDN6) No Yes	(TLPMEDN7) No Yes
# Times Used Each Day:	(TLTMEDN1) (xxx)	(TLTMEDN2) (xxx)	(TLTMEDN3) (xxx)	(TLTMEDN4) (xxx)	(TLTMEDN5) (xxx)	(TLTMEDN6) (xxx)	(TLTMEDN7) (xxx)

10. Buprenorphine (Suboxone, Zubsolv, Bunavail):

	1	2	3	4	5	6	7
Route:	(TLBUPR1) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLBUPR2) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLBUPR3) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLBUPR4) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLBUPR5) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLBUPR6) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLBUPR7) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below
Prescribed:	(TLPBUPR1) No Yes	(TLPBUPR2) No Yes	(TLPBUPR3) No Yes	(TLPBUPR4) No Yes	(TLPBUPR5) No Yes	(TLPBUPR6) No Yes	(TLPBUPR7) No Yes
# Times Used Each Day:	(TLTBUPR1) (xxx)	(TLTBUPR2) (xxx)	(TLTBUPR3) (xxx)	(TLTBUPR4) (xxx)	(TLTBUPR5) (xxx)	(TLTBUPR6) (xxx)	(TLTBUPR7) (xxx)

11. Oxymorphone (Opana):

	1	2	3	4	5	6	7
Route:	(TLOXYM1) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLOXYM2) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLOXYM3) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLOXYM4) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLOXYM5) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLOXYM6) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLOXYM7) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below
Prescribed:	(TLPOXYM1) No Yes	(TLPOXYM2) No Yes	(TLPOXYM3) No Yes	(TLPOXYM4) No Yes	(TLPOXYM5) No Yes	(TLPOXYM6) No Yes	(TLPOXYM7) No Yes
# Times Used Each Day:	(TLTOXYM1) (xxx)	(TLTOXYM2) (xxx)	(TLTOXYM3) (xxx)	(TLTOXYM4) (xxx)	(TLTOXYM5) (xxx)	(TLTOXYM6) (xxx)	(TLTOXYM7) (xxx)

Comments:*(TFBCOMM)*

Additional Selection Options for T79

D1 heroin
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)*:

Target day for 30 day followup:*(TAPASMDT)* ______ *(mm/dd/yyyy)*

1. Assessment period:*(TATFSTDT)* From: ______ *(mm/dd/yyyy)*

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

2. Have any pain relievers, pain medications, sedatives, alcohol, methamphetamine, cocaine, heroin, or other illicit substances been used during this assessment period? *(TASUBALC)* ☐ No ☐ Yes
3. Does the participant have a prescription for any substances including opiates and marijuana for any days in this assessment period?*(TAPRXSUB)* ☐ No ☐ Yes

Comments:*(TAPCOMM)* ______

Treatment Decision (TXD)

Web Version: 1.0; 1.00; 06-12-18

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

Date of assessment: *(TXDASMDT)* — *(mm/dd/yyyy)*

1. What medication, if any, did you receive at your ED visit? *(TXEDMED)*
   - 0-No buprenorphine, methadone, or naltrexone
   - 1-Sublingual buprenorphine (administered and/or prescribed)
   - 2-Extended-release buprenorphine (weekly or monthly injection)
   - 3-Methadone
   - 4-Naltrexone
2. Did you receive a prescription in the ED for buprenorphine? *(TXEDBUP)*
   - No
   - Yes
3. Which answer best explains why you did not receive buprenorphine? *(RA - Select closest answer.)(TXTXDEC)*
   - 1-I wanted treatment but without medication
   - 2-I did not want any treatment
   - 3-I wanted treatment for withdrawal today but without continuing treatment
   - 4-I wanted to start treatment with buprenorphine but it was not offered
   - 5-I wanted to start treatment with methadone
   - 6-I wanted to start treatment with naltrexone
   - 7-I wanted buprenorphine but can't afford it or access it for another reason
   - 8-Neither buprenorphine, methadone, nor naltrexone were offered to me
   - 10-I was told to return to the ED on another day for buprenorphine
4. Did you receive information on where to go for more treatment after the ED visit (resource list, referral, return to ED, etc.)? *(TXINFO)*
   - 0-No, I refused it
   - 2-No, they didn't give it (confirm no resource sheet)
   - 3-No, I didn't need it, because I already have follow up arranged
   - 4-No, but I was told someone will call me to schedule
   - 1-Yes
5. I would like to know how detailed that referral was - including if they were able to schedule a specific time and place to follow up. Which of the following is most accurate? *(TXDREFER)*
   - 1-I was given a specific time and place to follow up
   - 2-I was given a specific place and told to schedule it myself
   - 3-I was given a list of OUD treatment resources to call (or general referral helpline phone number)
   - 4-I was told someone will call me to schedule
   - 5-I was told to return to the ED for next/first dose of buprenorphine treatment
6. What type of OUD treatment were you referred to, if any? *(TXOUDTX)*
   - 1-Outpatient medication treatment
   - 2-Inpatient treatment (e.g., detox)
   - 3-Non-medication outpatient treatment
   - 4-General resource list (or general referral helpline phone number) without specific plan regarding
   - 5-Return to the ED for medication treatment (without other referral)
   - 0-No referral
   - 99-Other

   If "Other", specify: *(TXOUDSP)*
7. If a referral was received, how soon after being discharged from the ED are you supposed to follow up (attend your first visit)?*(TXFLWUP)*

1-Within 24 hours
2-Within 3 days
3-Within 8 days
4-Longer than 8 days
0-Never or not specified

8. How satisfied or dissatisfied are you with the way your opioid use was addressed during your ED visit? *(TXSATIS)*

1-Very dissatisfied
2-Dissatisfied
3-Somewhat satisfied
4-Satisfied
5-Very satisfied

9. How satisfied or dissatisfied are you with the process of receiving your buprenorphine in the ED?*(TXBUPSAT)*

1-Very dissatisfied
2-Dissatisfied
3-Somewhat satisfied
4-Satisfied
5-Very satisfied

10. How satisfied or dissatisfied are you with how the buprenorphine worked, or is working?*(TXBUPWRK)*

1-Very dissatisfied
2-Dissatisfied
3-Somewhat satisfied
4-Satisfied
5-Very satisfied

11. Did you plan to continue use of buprenorphine?*(TXCONBUP)* ☐ No ☐ Yes

If no, why not?*(TXNOBUP)*

1-Unable to pay
2-Unable to find a provider
3-Unable to make appointments because of work, family, transportation, other
4-Just needed something for withdrawal; not interested in treatment
5-Going to try without medications
6-Going to try a different medication
7-Side effects
99-Other

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

Comments:*(TXCOMM)*

NIDA Clinical Trials Network

Treatment Satisfaction and Acceptability (TXS)

Web Version: 1.0; 1.00; 06-28-18

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

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

1. When we last met, you indicated you received the following medication:*(TXMEDREC)*
   - 0-No buprenorphine, methadone, or naltrexone
   - 1-Sublingual buprenorphine (administered and/or prescribed)
   - 2-Extended-release buprenorphine (weekly or monthly injection)
   - 3-Methadone
   - 4-Naltrexone

2. How soon after you were discharged from the hospital did you attend your first visit for opioid use treatment?*(TXFIRVIS)*
   - 0-Never
   - 1-Within 24 hours
   - 2-Within 3 days
   - 3-Within 8 days
   - 4-Longer than 8 days

   a. If visit attended, how satisfied or dissatisfied are you with when you attended your first visit at your referral program?*(TXDISFV)*
   - 1-Very dissatisfied
   - 2-Dissatisfied
   - 3-Somewhat satisfied
   - 4-Satisfied
   - 5-Very satisfied

   b. If "Never", select primary reason why you did not attend the program:*(TXPRNPRG)*
   - 1-Transportation
   - 2-Returned to drug use ("relapse")
   - 3-Family or work obligations
   - 4-Changed mind about receiving any treatment
   - 5-Unable to pay
   - *Additional Options Listed Below

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

3. If you received buprenorphine, how satisfied or dissatisfied are you with how buprenorphine worked or is working?*(TXDBUPW)*
   - 1-Very dissatisfied
   - 2-Dissatisfied
   - 3-Somewhat satisfied
   - 4-Satisfied
   - 5-Very satisfied

4. Did you discontinue use of this medication? *(TXMEDDIS)* ☐ No ☐ Yes

   If "Yes", select the primary reason why medication was discontinued:*(TXPRMEDD)*
   - 1-Unable to pay
   - 2-Unable to find a provider
   - 3-Unable to make appointments because of work, family, transportation
   - 4-Just needed something for withdrawal; not interested in treatment
   - 5-Going to try without medications
   - *Additional Options Listed Below

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

5. Based on your experience, how likely are you to recommend to others that they consider this treatment?

	1 - Not likely at all	2	3	4	5	6	7	8	9	10 - Extremely likely
(TXRECOTX)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

6. Based on your experience with this study, how likely are you to recommend to others that they consider participation in this research study?

	1 - Not likely at all	2	3	4	5	6	7	8	9	10 - Extremely likely
(TXRECOST)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Comments:*(TXSCOMM)*

Additional Selection Options for TXS

If "Never", select primary reason why you did not attend the program:
6-Attended a different program
99-Other

If "Yes", select the primary reason why medication was discontinued:
6-Going to try a different medication
7-Side effects
99-Other

Urine Drug Screen (UDS)

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

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

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

   If "No", reason:*(UDNORSN1)*
   1-Participant reported being unable to provide sample
   2-Participant refused to provide sample
   3-Study staff error
   99-Other

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

2. Date urine specimen collected:*(UDCOLDT)* *(mm/dd/yyyy)*

3. 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)* ☐	☐	☐
Buprenorphine (10 ng) (BUP):	*(UDBUP1)* ☐	☐	☐
Fentanyl (FEN):	*(UDFEN1)* ☐	☐	☐

Comments:*(UDSCOMM)*

Secure Document Upload Page 1 (ZC1)

Web Version: 1.0; 6.00; 05-28-19

Segment *(PROTSEG)*: B
Document type *(DOCTYPE)*:
Document sequence number *(SEQNUM)*:

1. Was written informed consent obtained?*(Z1WICF)* ☐ No ☐ Yes
2. Was written informed consent obtained?*(Z1WICF)* ☐ No ☐ Yes ☐ N/A

   If "Yes", date written informed consent obtained: *(Z1WICFDT)* ______ *(mm/dd/yyyy)*

3. Did the required site staff sign the informed consent? *(Z1PISG)* ☐ No ☐ Yes ☐ N/A
4. Did an impartial witness sign the informed consent? *(Z1WTSG)* ☐ No ☐ Yes ☐ N/A
5. Was a written medical information release form(s) obtained? *(Z1MDRL)* ☐ No ☐ Yes ☐ N/A

   a. If "Yes", date medical information release signature obtained:*(Z1MDR1DT)* ______ *(mm/dd/yyyy)*

   Additional medical information release signatures dates (if applicable):*(Z1MDR2DT)* ______ *(mm/dd/yyyy)*

   (Z1MDR3DT) ______ *(mm/dd/yyyy)*

   (Z1MDR4DT) ______ *(mm/dd/yyyy)*

   (Z1MDR5DT) ______ *(mm/dd/yyyy)*

   (Z1MDR6DT) ______ *(mm/dd/yyyy)*

6. Was the state required form obtained? *For example: HIPAA or California state required document(Z1STREQ)* ☐ No ☐ Yes ☐ N/A

   If "Yes", date of signature for state required document: *(Z1STDT)* ______ *(mm/dd/yyyy)*

7. Is this upload a corrected document(s) due to a previously identified error?*(Z1CORDOC)* ☐ No ☐ Yes

Comments:*(ZC1COMM)*

Additional Selection Options for ZC1

Document type *(DOCTYPE)* (key field):
0-Compound informed consent
1-Informed consent
2-Assent
3-Medical release
4-Ancillary study
5-Genetics
6-HIV
7-State required document
8-Multiple documents
99-Other

Document sequence number *(SEQNUM)* (key field):
01-1
02-2
03-3
04-4
05-5
06-6
07-7
08-8
09-9
10-10
11-11
12-12
13-13
14-14
15-15
16-16
17-17
18-18
19-19
20-20

Secure Document Upload Page 2 (ZC2)

Web Version: 1.0; 5.01; 05-01-19

Segment *(PROTSEG)*: B
Document type *(DOCTYPE)*:
Document sequence number *(SEQNUM)*:

All consent/assent/HIPAA/medical release documents should be attached/uploaded via this form. They may be attached as one or multiple files.

Throughout the form, "document" refers to the applicable consent/assent/HIPAA/medical release document being reviewed.

1. I confirm that the filename(s) in this upload does **not** contain PHI: *(Z2PHI)* ☐ No ☐ Yes

2. Indicate the document types that are included in the upload file *(check all that apply)*:

   Informed consent: *(Z2DOCIC)* ☐

   Medical information release: *(Z2DOCMR)* ☐

   State required document: *(Z2DOCST)* ☐

Upload File Name

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

For example: 0201100640001_ICFHIPAA_20150623.pdf

Additional Selection Options for ZC2

Document type *(DOCTYPE)* (key field):
0-Compound informed consent
1-Informed consent
2-Assent
3-Medical release
4-Ancillary study
5-Genetics
6-HIV
7-State required document
8-Multiple documents
99-Other

Document sequence number *(SEQNUM)* (key field):
01-1
02-2
03-3
04-4
05-5
06-6
07-7
08-8
09-9
10-10
11-11
12-12
13-13
14-14
15-15
16-16
17-17
18-18
19-19
20-20

Secure Document Upload Page 3 (ZC3)

Web Version: 1.0; 9.00; 05-01-19

Segment *(PROTSEG)*: B
Document type *(DOCTYPE)*:
Document sequence number *(SEQNUM)*:

This form is to be completed by the document upload reviewer.
Throughout the form, "document" refers to the applicable consent/assent document being reviewed.

Date file(s) uploaded:*(Z3UPLDDT)*

Did the document upload correspond to the correct participant ID?*(Z3CORPPT)*

	Document 1	
1. Document type(s) included in the upload:	*(Z31DOCTP)* 1-Informed consent 2-Assent 3-Medical release 4-Ancillary study 5-Genetics *Additional Options Listed Below	*(Z32I*
Facility name:	*(ZCPRLC01)*	*(ZCP*
2. The participant was consented/assented on the current IRB-approved version of the document:	*(Z31IRAP)* No Yes N/A	*(Z32I*
If "No", specify:	*(Z31IRASP)*	*(Z32I*
If "Yes", IRB document approval date:	*(Z31ICFVR)* *(mm/dd/yyyy)*	*(Z32I*
3. All pages of the document are present:	*(Z31ALPG)* No Yes	*(Z32A*
If "No", specify:	*(Z31ALPSP)*	*(Z32A*
4. Each page of the document is initialed by participant/guardian, if applicable:	*(Z31INIT)* No Yes N/A	*(Z32I*
If "No", specify:	*(Z31INISP)*	*(Z32I*
5. Participant/LAG signatures/date/times are correctly executed:	*(Z31PSDT)* No Yes	*(Z32I*
If "No", specify:	*(Z31PSDSP)*	*(Z32I*
6. Required staff's signature/dates are correctly executed:	*(Z31RSDT)* No Yes N/A	*(Z32I*
If "No", specify:	*(Z31RSDSP)*	*(Z32I*
7. Impartial witness's signature/dates are correctly executed:	*(Z31IWDT)* No Yes N/A	*(Z32I*
If "No", specify:	*(Z31IWDSP)*	*(Z32I*
8. Any opt-out/additional clauses in the consent/assent (e.g., genetic sample, future contact) have been documented correctly:	*(Z31OPT)* No Yes N/A	*(Z32O*
If "No", specify:	*(Z31OPTSP)*	*(Z32O*

Reviewer comments:*(ZC3COMM)*

Internal comments:*(ZC3INCOM)*

Additional Selection Options for ZC3

Document type *(DOCTYPE)* (key field):
0-Compound informed consent
1-Informed consent
2-Assent
3-Medical release
4-Ancillary study
5-Genetics
6-HIV
7-State required document
8-Multiple documents
99-Other

Document sequence number *(SEQNUM)* (key field):
01-1
02-2
03-3
04-4
05-5
06-6
07-7
08-8
09-9
10-10
11-11
12-12
13-13
14-14
15-15
16-16
17-17
18-18
19-19
20-20

Document 1 type
6-HIV
7-State required document
99-Other

Serious Adverse Event Medical Reviewer (AD3)

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

Adverse event onset date *(AEDATE)*:

Event number *(AESEQNO)*:

1. Was this determined to be a serious adverse event? *(A3SAE)* ☐ No ☐ Yes
2. Was this event expected?*(A3EXPECT)* ☐ No ☐ Yes
3. Is this a standard expedited/reportable event? *(i.e., is it serious, unexpected and related to therapy) (A3EXPFDA)* ☐ No ☐ Yes

   If "No", is this an expedited/reportable event for other reasons?*(A3EXPOTH)* ☐ No ☐ Yes
4. Does the protocol need to be modified based on this event? *(A3MPROT)* ☐ No ☐ Yes
5. Does the consent form need to be modified based on this event?*(A3MCNST)* ☐ No ☐ Yes
6. Is the review complete?*(A3REVDNE)* ☐ No ☐ Yes

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

Assessed by:*(A3ASRID)* (initials)

Reviewed by:*(A3REVID)* (initials)

Comments:*(A3COMM)*

Additional Selection Options for AD3

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

Demographics (DEM)

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

1. Date of birth:*(DEBRTHDT)* (mm/dd/yyyy)
2. Age:*(DEAGE)* (xx)
3. Sex:*(DESEX)* Male Female Don't know Refused to answer
4. Does the participant consider him or herself to be Hispanic/Latino? *(DEHISPNC)* No Yes Don't know 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
5. What race does the participant consider him or herself to represent? (Check all that apply)
   - American Indian or Alaska Native:*(DEAMEIND)*
   - Asian:*(DEASIAN)*
     - Asian Indian:*(DEASAIND)*
     - Chinese:*(DECHINA)*
     - Filipino:*(DEFILIPN)*
     - Japanese:*(DEJAPAN)*
     - Korean:*(DEKOREA)*
     - Vietnamese:*(DEVIETNM)*
     - Specify other Asian: *(DEASIAOT)*
   - Black or African American: *(DEBLACK)*
   - Native Hawaiian or Pacific Islander:*(DEHAWAII)*
     - Native Hawaiian: *(DENATHAW)*
     - Guamanian or Chamorro: *(DEGUAM)*
     - Samoan:*(DESAMOAN)*
     - Specify other Pacific Islander:*(DEPACISO)*
   - White:*(DEWHITE)*
   - Some other race:*(DERACEOT)* Specify:*(DERACESP)*

   -or-
   - Don't know:*(DERACEDK)*
   - Refused:*(DERACERF)*

6. 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

7. 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)*

8. 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

Additional Demographics (DM1)

Web Version: 1.0; 2.00; 06-18-18

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

1. Are you currently covered by health insurance or health coverage plans?
This does not include plans that pay for only one type of service (such as, nursing home care, accidents, family planning, or dental care) and plans that only provide extra cash when hospitalized.(DMHEALTH) — ☐ No ☐ Yes

If "Yes" indicate the type of plan:

a. Insurance through a current or former employer or union (of yours or another family member's): *This would include COBRA coverage. (DMINSEMP)* — ☐ Covered ☐ Not covered ☐ Not sure

b. Insurance purchased directly from an insurance company (by you or another family member): *This would include coverage purchased through an exchange or marketplace, such as HealthCare.gov.(DMINSCOM)* — ☐ Covered ☐ Not covered ☐ Not sure

If "Covered", does the coverage have a state-specific program name?*(DMSTCO)* — ☐ No ☐ Yes ☐ Not sure

If "Yes", specify the name:*(DMSTCOSP)*

c. Medicare, for people 65 and older, or people with certain disabilities:*(DMINSCAR)* — ☐ Covered ☐ Not covered ☐ Not sure

If "Covered", does the coverage have a state-specific program name?*(DMSTCR)* — ☐ No ☐ Yes ☐ Not sure

If "Yes", specify the name:*(DMSTCRSP)*

d. Medicaid, Medical Assistance (MA), the Children's Health Insurance Program (CHIP), or any kind of state or government-sponsored assistance plan based on income or a disability: *(DMINSCAI)* — ☐ Covered ☐ Not covered ☐ Not sure

If "Covered", does the coverage have a state-specific program name?*(DMSTCD)* — ☐ No ☐ Yes ☐ Not sure

If "Yes", specify the name:*(DMSTCDSP)*

e. TRICARE or other military health care, including VA health care:*(DMINSTRI)* — ☐ Covered ☐ Not covered ☐ Not sure

f. Indian Health Service:*(DMINSIHS)* — ☐ Covered ☐ Not covered ☐ Not sure

g. Any other type of health insurance coverage or health coverage plan:*(DMINSOTH)* — ☐ Covered ☐ Not covered ☐ Not sure

If "Covered" by another type, specify: *(DMOTSP)*

2. What has been your usual employment pattern in the past 12 months? *(DMEMPLOY)*

1-Full time (35+ hrs)
2-Part time (regular hours)
3-Part time (irregular hours)
4-Student
5-Military service
*Additional Options Listed Below

3. Have you ever served on active duty in the U.S. Armed Forces, Reserves, or National Guard? *(DMMILTRY)*

0-Never served in the military
1-Only on active duty for training in the Reserves or National Guard
2-Now on active duty
3-On active duty in the past, but not now

4. What is your combined household income? *(DMINCOME)*

1-<$35,000
2-$35,001-$50,000
3-$50,001-$75,000
4-$75,001-$100,000
5-$100,001-$250,000
*Additional Options Listed Below

5. In the last 12 months have you spent at least one night in any of the following places? *(DMNIGHT)* ☐ No ☐ Yes

If "Yes", select all that apply:

(DMSHLTR1) ☐ A shelter for homeless persons.

(DMSTRET1) ☐ On the street or in a public place not intended for sleeping (e.g., abandoned building, subway, or car).

(DMSRO1) ☐ In a welfare hotel or single room occupancy (SRO).

(DMHLFWY1) ☐ In any emergency, temporary, or transitional housing program, or a halfway house.

(DMSMELS1) ☐ Doubled up with others, in someone else's house/apartment.

6. Are you currently living in any of the places listed above? *(DMLIVING)* ☐ No ☐ Yes

a. If "Yes", select all that apply:

(DMSHLTR2) ☐ A shelter for homeless persons.

(DMSTRET2) ☐ On the street or in a public place not intended for sleeping (e.g., abandoned building, subway, or car).

(DMSRO2) ☐ In a welfare hotel or single room occupancy (SRO).

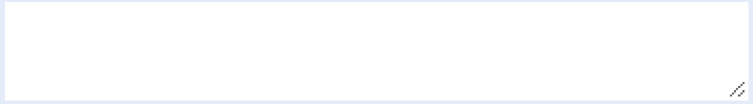
(DMHLFWY2) ☐ In any emergency, temporary, or transitional housing program, or a halfway house.

(DMSMELS2) ☐ Doubled up with others, in someone else's house/apartment.

b. How many months have you lived there? *(DMMONTHS)*

1-Less than a month
2-1-2 months
3-3-4 months
4-5-6 months
5-More than 6 months

Comments:*(DM1COMM)*



Additional Selection Options for DM1

What has been your usual employment pattern in the past 12 months?
6-Retirement/disability
7-Unemployment
8-In controlled environment
9-Service (volunteer)

What is your combined household income?
6->$250,000

DSM-5 - Opioids (DSO)

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

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

Date of assessment:*(DSOASMDT)* ____ *(mm/dd/yyyy)*

1. Have you used opioids in the past 12 months?*(DSOPI12M)* ☐ No ☐ Yes

*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)* ☐ No ☐ Yes
3. Have you wanted to stop or cut down using or control your use of **[xx]**?*(DSOPICUT)* ☐ No ☐ 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)* ☐ No ☐ 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)* ☐ No ☐ 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)* ☐ No ☐ 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)* ☐ No ☐ 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)* ☐ No ☐ 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)* ☐ No ☐ 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)* ☐ No ☐ 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?*(DSOPITOL)* ☐ No ☐ 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)* ☐ No ☐ Yes

Meets criteria for Opioid Use Disorder:*(DSOPISCO)*

- ☐ Severe
- ☐ Moderate
- ☐ Mild
- ☐ None

Comments:*(DSOCOMM)*

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ED Visits and Hospitalization (EDV)

Web Version: 1.0; 6.04; 05-28-19

Segment *(PROTSEG)*: B
Visit number *(VISNO)*:
ED visit hospitalization *(EDHOSPDT)*:
Document sequence number *(SEQNUM)*:

ED Index Visit

1. Index ED visit date:*(EDEDENRL)* ____ *(mm/dd/yyyy)*
2. Time of ED admission:*(EDIADMTM)* ____ *(hh:mm)*
3. Did the reason for the visit, as documented per triage note, include substance use, intoxication, withdrawal or overdose?*(EDVRRSN)* ☐ No ☐ Yes
4. Discharge date:*(EDIDISDT)* ____ *(mm/dd/yyyy)*
5. Time of ED discharge:*(EDIDISTM)* ____ *(hh:mm)*
6. Did the discharge diagnosis specifically include substance use disorder?*(EDDSCDG)*
   1-Any opioid use disorder diagnosis
   2-Any substance use disorder diagnosis (not opioids)
   0-No
7. ICD 10 code(s) for the discharge diagnosis:
   a. Code 1:*(EDIICD10)*
   b. Code 2:*(ED2ICD10)*
   c. Code 3:*(ED3ICD10)*
   d. Code 4:*(ED4ICD10)*
   e. Code 5:*(ED5ICD10)*
   f. Code 6:*(ED6ICD10)*
   g. Code 7:*(ED7ICD10)*
   h. Code 8:*(ED8ICD10)*
   i. Code 9:*(ED9ICD10)*
   j. Code 10:*(ED10ICD)*

ED Visit or Hospitalization After the ED Index Visit

8. Has the patient visited the ED or been hospitalized between the screening and follow-up visits?*(EDVVISIT)* ☐ No ☐ Yes
9. ED visit or hospitalization:*(EDVHOSP)* ☐ ED visit ☐ Hospitalization
10. Discharge date:*(EDVDISDT)* ____ *(mm/dd/yyyy)*
11. Visit discharge time:*(EDVDISTM)* ____ *(hh:mm)*
12. Was the primary discharge diagnosis related to substance use disorder?*(EDPRIMDX)* ☐ No ☐ Yes
13. Were any of the secondary diagnoses related to substance use disorder?*(EDSECDX)* ☐ No ☐ Yes ☐ N/A

    Comments:*(EDVCOMM)*

Additional Selection Options for EDV

Document sequence number *(SEQNUM)* (key field):
01-1
02-2
03-3
04-4
05-5
06-6
07-7
08-8
09-9
10-10
11-11
12-12
13-13
14-14
15-15
16-16
17-17
18-18
19-19
20-20

NIDA Clinical Trials Network

EQ-5D-3L (EQD)

Web Version: 1.0; 3.00; 03-28-18

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

Health Questionnaire

English version for the USA

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Under each heading, please tap the ONE box that best describes your health TODAY.

Mobility
(EQ5MBTLY)

☐ I have no problems in walking about ☐ I have some problems in walking about ☐ I am confined to bed

Self-Care
(EQ5SLFCR)

☐ I have no problems with self-care ☐ I have some problems washing or dressing myself ☐ I am unable to wash or dress myself

Usual Activities *(e.g. work, study, housework, family, or leisure activities)*
(EQ5ACTIV)

☐ I have no problems with performing my usual activities ☐ I have some problems with performing my usual activities ☐ I am unable to perform my usual activities

Pain / Discomfort
(EQ5PAIND)

☐ I have no pain or discomfort ☐ I have moderate pain or discomfort ☐ I have extreme pain or discomfort

Anxiety / Depression
(EQ5ANXDE)

☐ I am not anxious or depressed ☐ I am moderately anxious or depressed ☐ I am extremely anxious or depressed

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- **We would like to know how good or bad your health is TODAY.**
- **This scale is numbered 0 to 100.**

_____ *(xxx)*

The best health you can imagine

- **100 means the best health you can imagine.**
  0 means the worst health you can imagine.
- **Please tap on the scale to indicate how your health is TODAY.**

The worst health you can imagine

YOUR HEALTH TODAY*(EQ5HLTTD)*

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NIDA Clinical Trials Network

Engagement in Treatment: Facility (ETF)

Web Version: 1.0; 3.01; 01-14-19

Segment *(PROTSEG)*: B
Visit number *(VISNO)*:
Facility name *(FACPRLC)*:

Date of assessment:*(ETDATE)* ________ *(mm/dd/yyyy)*

1. What type of Provider/Program is this? *(ETPROGRM)*
   - 1-Office-based provider
   - 2-Opioid treatment program
   - 3-Residential program
   - 99-Other

   If "Other", specify:*(ETPROGSP)* ________

2. On **[Enter 30day Target Date]** was this patient engaged in a program at your facility or being treated at your office for their opioid use disorder?*(ETENGAGE)* ☐ No ☐ Yes

   If "Yes", review and answer the following questions:

   a. Indicate the type(s) of treatment they were receiving for their opioid use disorder on **[Enter 30day Target Date]**:

		No	Yes
Methadone:	*(ETMTD)*	☐	☐
Buprenorphine:	*(ETBUP)*	☐	☐
SL-Buprenorphine:	*(ETSLBUP)*	☐	☐
XR-Buprenorphine 7 day:	*(ETXR7BP)*	☐	☐
XR-Buprenorphine 30 day:	*(ETXR30BP)*	☐	☐
Naltrexone:	*(ETNAL)*	☐	☐
Short-term detoxification:	*(ETSTDETX)*	☐	☐
Inpatient/residential:	*(ETINPT)*	☐	☐
Counseling:	*(ETOTPT)*	☐	☐
Outpatient medication:	*(ETOTMED)*	☐	☐
Other, specify:*(ETOTRSP)* ________	*(ETOTHER)*	☐	☐

   b. On **[Enter 30day Target Date]**, how would you categorize the level of treatment received by this patient? *(ETCATGTR)*
   - 0-No care received
   - 1-Level I: Outpatient treatment
   - 2-Level II: Intensive outpatient treatment (including partial hospitalization)
   - 3-Level III: Residential/inpatient services
   - 4-Level IV: Medically managed intensive inpatient treatment
   - *Additional Options Listed Below

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

c. What was the date of their admission into your program or, if office-based, when did their care begin?*(ETADMSDT)* *(mm/dd/yyyy)*

d. Was the patient discharged?*(ETDISCH)* No Yes

If "Yes", date of discharge from your care:*(ETDSCDT)* *(mm/dd/yyyy)*

Comments:*(ETFCOMM)*

Additional Selection Options for ETF

On [Enter 30day Target Date], how would you categorize the level of treatment received by this patient?
99-Other