

Adverse Events (AD1)

Adverse event onset date (AEDATE):

Event number (AESEQNUM):

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

For the purposes of this protocol, only overdoses, whether hospitalized or not, and all deaths will be reported in AdvantageEDC.

1. Adverse event outcome: (A1AEOUT)

- 1-Overdose
- 2-Overdose resulting in death
- 3-Other death

(mm/dd/yyyy)

(mm/dd/yyyy)

a. If "Overdose" or "Overdose resulting in death", date of overdose: (A1ODDT)

b. If "Overdose resulting in death" or "Other death", date of death: (A1DTHDT)

2. If "Overdose", severity of overdose: (A1ODSEVE)

- 1-Grade 1 - Mild
- 2-Grade 2 - Moderate
- 3-Grade 3 - Severe

No  Yes  Unknown

3. If "Overdose" or "Overdose resulting in death", were opioids involved in the overdose? (A1OPIOID)

4. If "Other death", primary cause of death: (A1CAUSE)

(mm/dd/yyyy)

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

6. Hospitalization: (A1HOSPIT)

No  Yes  Unknown

Comments: (AD1COMM)

**Additional Selection Options for AD1**

**Event number (AESEQNUM) (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

NIDA Clinical Trials Network

Demographics (DEM)

Web Version: 1.0; 2.02; 07-11-14

1. Date of birth:(DEBRTHDT)

 (mm/dd/yyyy)

2. Age:(DEAGE)

 (xx)

3. Gender:(DEGENDER)

 Male  Female  Don't know  Refused

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

 No  Yes  Don't know  Refused

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

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

5. What race does the participant consider him or herself to represent:

(Check all that apply)

White: (DEWHITE)

Black/ African American: (DEBLACK)

Indian (American): (DEAMEIND)

Alaska native: (DEALASKA)

Native Hawaiian: (DEHAWAII)

Guamanian: (DEGUAM)

Samoan: (DESAMOAN)

Other Pacific Islander: (DEPACISL)  Specify: (DEPACISO)

Asian Indian: (DEASAIND)

Chinese: (DECHINA)

Filipino: (DEFILIPN)

Japanese: (DEJAPAN)

Korean: (DEKOREA)

Vietnamese: (DEVIETNM)

Other Asian: (DEASIAN)  Specify: (DEASIAOT)

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 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:

- 6-Cuban
- 7-Cuban American
- 8-Central or South American
- 9-Other Latin American
- 99-Other Hispanic
- 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 married, widowed, divorced, separated, never married, or living with a partner?

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

NIDA Clinical Trials Network

DSM - 5 - Substance Use Disorders (DSM)

Web Version: 1.0; 2.00; 02-27-14

Segment (PROTSEG): A

Visit number (VISNO):

Date of assessment (DSMASMDT)

(mm/dd/yyyy)

|                                      | Opioids                     | Alcohol                     | Amphetamines                | Cannabis                    | Cocaine                     | Sedatives                   |
|--------------------------------------|-----------------------------|-----------------------------|-----------------------------|-----------------------------|-----------------------------|-----------------------------|
| Have you used in the past 12 months: | 0-No<br>1-Yes<br>(DSOPI12M) | 0-No<br>1-Yes<br>(DSALC12M) | 0-No<br>1-Yes<br>(DSAMP12M) | 0-No<br>1-Yes<br>(DSTHC12M) | 0-No<br>1-Yes<br>(DSCOC12M) | 0-No<br>1-Yes<br>(DSSED12M) |

Answer the following for drugs used in the past 12 months

| Criteria   | Opioids                     | Alcohol                     | Amphetamines                 | Cannabis                    | Cocaine                     | Sedatives                   |
|--|-----------------------------|-----------------------------|------------------------------|-----------------------------|-----------------------------|-----------------------------|
| 1. Recurrent substance use resulting in a failure to fulfill major role obligations at work, school, or home (e.g., repeated absences or poor work performance related to substance use; substance-related absences, suspensions, or expulsions from school; neglect of children or household):  | 0-No<br>1-Yes<br>(DSOPIOBL) | 0-No<br>1-Yes<br>(DSALCOBL) | 0-No<br>1-Yes<br>(DSAMP OBL) | 0-No<br>1-Yes<br>(DSTHCOBL) | 0-No<br>1-Yes<br>(DSCOCOBL) | 0-No<br>1-Yes<br>(DSSEDOBL) |
| 2. Recurrent substance use in situations in which it is physically hazardous (e.g., driving an automobile or operating a machine when impaired by substance use):  | 0-No<br>1-Yes<br>(DSOPHAZ)  | 0-No<br>1-Yes<br>(DSALCHAZ) | 0-No<br>1-Yes<br>(DSAMPHAZ)  | 0-No<br>1-Yes<br>(DSTHCHAZ) | 0-No<br>1-Yes<br>(DSCOCHAZ) | 0-No<br>1-Yes<br>(DSSEDHAZ) |
| 3. Continued substance use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of the substance (e.g., arguments with spouse about consequences of intoxication, physical fights):  | 0-No<br>1-Yes<br>(DSOPISOC) | 0-No<br>1-Yes<br>(DSALCSOC) | 0-No<br>1-Yes<br>(DSAMP SOC) | 0-No<br>1-Yes<br>(DSTHCSOC) | 0-No<br>1-Yes<br>(DSCOCSOC) | 0-No<br>1-Yes<br>(DSSEDSOC) |
| 4. Tolerance, as defined by either of the following:<br>a. a need for markedly increased amounts of the substance to achieve intoxication or desired effect<br>b. markedly diminished effect with continued use of the same amount of the substance<br>(Note: Tolerance is not counted for those taking medications under medical supervision such as analgesics, antidepressants, anti-anxiety medications or beta-blockers.) | 0-No<br>1-Yes<br>(DSOPTOL)  | 0-No<br>1-Yes<br>(DSALCTOL) | 0-No<br>1-Yes<br>(DSAMP TOL) | 0-No<br>1-Yes<br>(DSTHCTOL) | 0-No<br>1-Yes<br>(DSCOCTOL) | 0-No<br>1-Yes<br>(DSSEDTOL) |
| 5. Withdrawal, as manifested by either of the following:<br>a. the characteristic withdrawal syndrome for the substance<br>b. the same (or a closely related) substance is taken to relieve or avoid withdrawal symptoms<br>(Note: Withdrawal is not counted for those taking medications under medical supervision such as analgesics, antidepressants, anti-anxiety medications or beta-blockers.)                           | 0-No<br>1-Yes<br>(DSOPWIT)  | 0-No<br>1-Yes<br>(DSALCWIT) | 0-No<br>1-Yes<br>(DSAMPWIT)  | 0-No<br>1-Yes<br>(DSTHCWIT) | 0-No<br>1-Yes<br>(DSCOCWIT) | 0-No<br>1-Yes<br>(DSSEDWIT) |

| Criteria   | Opioids                      | Alcohol                     | Amphetamines                 | Cannabis                     | Cocaine                      | Sedatives                   |
|--|------------------------------|-----------------------------|------------------------------|------------------------------|------------------------------|-----------------------------|
| 6. The substance is often taken in larger amounts or over a longer period than was intended:   | 0-No<br>1-Yes<br>(DSOPIDOS)  | 0-No<br>1-Yes<br>(DSALCDOS) | 0-No<br>1-Yes<br>(DSAMPDOS)  | 0-No<br>1-Yes<br>(DSTHCDOS)  | 0-No<br>1-Yes<br>(DSCOCDOS)  | 0-No<br>1-Yes<br>(DSSEDDOS) |
| 7. There is a persistent desire or unsuccessful efforts to cut down or control substance use:  | 0-No<br>1-Yes<br>(DSOPI CUT) | 0-No<br>1-Yes<br>(DSALCCUT) | 0-No<br>1-Yes<br>(DSAMP CUT) | 0-No<br>1-Yes<br>(DSTHC CUT) | 0-No<br>1-Yes<br>(DSCOC CUT) | 0-No<br>1-Yes<br>(DSSEDCUT) |
| 8. A great deal of time is spent in activities necessary to obtain the substance, use the substance, or recover from its effects:  | 0-No<br>1-Yes<br>(DSOPI TIM) | 0-No<br>1-Yes<br>(DSALCTIM) | 0-No<br>1-Yes<br>(DSAMP TIM) | 0-No<br>1-Yes<br>(DSTHCTIM)  | 0-No<br>1-Yes<br>(DSCOCTIM)  | 0-No<br>1-Yes<br>(DSSEDTIM) |
| 9. Important social, occupational, or recreational activities are given up or reduced because of substance use:  | 0-No<br>1-Yes<br>(DSOPIACT)  | 0-No<br>1-Yes<br>(DSALCACT) | 0-No<br>1-Yes<br>(DSAMPACT)  | 0-No<br>1-Yes<br>(DSTHCACT)  | 0-No<br>1-Yes<br>(DSCOCACT)  | 0-No<br>1-Yes<br>(DSSEDACT) |
| 10. The substance use is continued despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance: | 0-No<br>1-Yes<br>(DSOPICON)  | 0-No<br>1-Yes<br>(DSALCCON) | 0-No<br>1-Yes<br>(DSAMP CON) | 0-No<br>1-Yes<br>(DSTHCCON)  | 0-No<br>1-Yes<br>(DSCOCCON)  | 0-No<br>1-Yes<br>(DSSEDCON) |

|   |            |            |            |           |           |            |
|---|------------|------------|------------|-----------|-----------|------------|
| 11. Craving or a strong desire or urge to use a specific substance: | 0-No       | 0-No       | 0-No       | 0-No      | 0-No      | 0-No       |
|   | 1-Yes      | 1-Yes      | 1-Yes      | 1-Yes     | 1-Yes     | 1-Yes      |
|   | (DSOPICRA) | (DSALCCRA) | (DSAMPCRA) | (DSTHCRA) | (DSCOCRA) | (DSSEDCRA) |

|  | Opioids                                    | Alcohol                                    | Amphetamines                               | Cannabis                                   | Cocaine                                    | Sedatives                                 |
|--|--|--|--|--|--|---|
| Meets criteria for Substance Use Disorder: | (DSOPISCO) <input type="checkbox"/> Severe | (DSALCSCO) <input type="checkbox"/> Severe | (DSAMPSCO) <input type="checkbox"/> Severe | (DSTHCSCO) <input type="checkbox"/> Severe | (DSCOCSCO) <input type="checkbox"/> Severe | (DSSEDCO) <input type="checkbox"/> Severe |
|  | <input type="checkbox"/> Moderate          | <input type="checkbox"/> Moderate          | <input type="checkbox"/> Moderate          | <input type="checkbox"/> Moderate          | <input type="checkbox"/> Moderate          | <input type="checkbox"/> Moderate         |
|  | <input type="checkbox"/> Mild              | <input type="checkbox"/> Mild              | <input type="checkbox"/> Mild              | <input type="checkbox"/> Mild              | <input type="checkbox"/> Mild              | <input type="checkbox"/> Mild             |
|  | <input type="checkbox"/> None              | <input type="checkbox"/> None              | <input type="checkbox"/> None              | <input type="checkbox"/> None              | <input type="checkbox"/> None              | <input type="checkbox"/> None             |

Comments: (DSMCOMM)

Detoxification Utilization Summary (DXS)

Web Version: 1.0; 3.01; 06-23-16

Segment (PROTSEG): A

Visit number (VISNO):

Detox unit

1. Admission date to detox unit: (DXADMNDT)  (mm/dd/yyyy)

2. Admission time (24-hour format): (DXADMNTM)  (hh:mm)

Comments: (DXSCOMM)



Detox Utilization (DXU)

Web Version: 1.0; 2.01.06.24-16

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

Medications used for detoxification

| Detox                              | Day 01<br>(Admission to Detox)   | Day 02   | Day 03   |
|------------------------------------|--|--|--|
| Date (mm/dd/yyyy):                 | (D TD XD T01) <input type="text"/>   | (D TD XD T02) <input type="text"/>   | (D TD XD T03) <input type="text"/>   |
| 1. Drug 1:                         | 00--- None<br>01--- BUP-NX Sublingual<br>02--- BUP only Sublingual<br>03--- Methadone PO<br>04--- Methadone IM<br>*Additional Options Listed Below<br>(D TD 1DR01) | 00--- None<br>01--- BUP-NX Sublingual<br>02--- BUP only Sublingual<br>03--- Methadone PO<br>04--- Methadone IM<br>*Additional Options Listed Below<br>(D TD 2DR01) | 00--- None<br>01--- BUP-NX Sublingual<br>02--- BUP only Sublingual<br>03--- Methadone PO<br>04--- Methadone IM<br>*Additional Options Listed Below<br>(D TD 3DR01) |
| Specify total daily dose (xxx.xx): | (D TD 1TL01) <input type="text"/> mg   | (D TD 2TL01) <input type="text"/> mg   | (D TD 3TL01) <input type="text"/> mg   |
| 2. Drug 2:                         | 00--- None<br>01--- BUP-NX Sublingual<br>02--- BUP only Sublingual<br>03--- Methadone PO<br>04--- Methadone IM<br>*Additional Options Listed Below<br>(D TD 1DR02) | 00--- None<br>01--- BUP-NX Sublingual<br>02--- BUP only Sublingual<br>03--- Methadone PO<br>04--- Methadone IM<br>*Additional Options Listed Below<br>(D TD 2DR02) | 00--- None<br>01--- BUP-NX Sublingual<br>02--- BUP only Sublingual<br>03--- Methadone PO<br>04--- Methadone IM<br>*Additional Options Listed Below<br>(D TD 3DR02) |
| Specify total daily dose (xxx.xx): | (D TD 1TL02) <input type="text"/> mg   | (D TD 2TL02) <input type="text"/> mg   | (D TD 3TL02) <input type="text"/> mg   |
| 3. Drug 3:                         | 00--- None<br>01--- BUP-NX Sublingual<br>02--- BUP only Sublingual<br>03--- Methadone PO<br>04--- Methadone IM<br>*Additional Options Listed Below<br>(D TD 1DR03) | 00--- None<br>01--- BUP-NX Sublingual<br>02--- BUP only Sublingual<br>03--- Methadone PO<br>04--- Methadone IM<br>*Additional Options Listed Below<br>(D TD 2DR03) | 00--- None<br>01--- BUP-NX Sublingual<br>02--- BUP only Sublingual<br>03--- Methadone PO<br>04--- Methadone IM<br>*Additional Options Listed Below<br>(D TD 3DR03) |
| Specify total daily dose (xxx.xx): | (D TD 1TL03) <input type="text"/> mg   | (D TD 2TL03) <input type="text"/> mg   | (D TD 3TL03) <input type="text"/> mg   |
| 4. Drug 4:                         | 00--- None<br>01--- BUP-NX Sublingual<br>02--- BUP only Sublingual<br>03--- Methadone PO<br>04--- Methadone IM<br>*Additional Options Listed Below<br>(D TD 1DR04) | 00--- None<br>01--- BUP-NX Sublingual<br>02--- BUP only Sublingual<br>03--- Methadone PO<br>04--- Methadone IM<br>*Additional Options Listed Below<br>(D TD 2DR04) | 00--- None<br>01--- BUP-NX Sublingual<br>02--- BUP only Sublingual<br>03--- Methadone PO<br>04--- Methadone IM<br>*Additional Options Listed Below<br>(D TD 3DR04) |
| Specify total daily dose (xxx.xx): | (D TD 1TL04) <input type="text"/> mg   | (D TD 2TL04) <input type="text"/> mg   | (D TD 3TL04) <input type="text"/> mg   |
| 5. Drug 5:                         | 00--- None<br>01--- BUP-NX Sublingual<br>02--- BUP only Sublingual<br>03--- Methadone PO<br>04--- Methadone IM<br>*Additional Options Listed Below<br>(D TD 1DR05) | 00--- None<br>01--- BUP-NX Sublingual<br>02--- BUP only Sublingual<br>03--- Methadone PO<br>04--- Methadone IM<br>*Additional Options Listed Below<br>(D TD 2DR05) | 00--- None<br>01--- BUP-NX Sublingual<br>02--- BUP only Sublingual<br>03--- Methadone PO<br>04--- Methadone IM<br>*Additional Options Listed Below<br>(D TD 3DR05) |
| Specify total daily dose (xxx.xx): | (D TD 1TL05) <input type="text"/> mg   | (D TD 2TL05) <input type="text"/> mg   | (D TD 3TL05) <input type="text"/> mg   |
| 6. Drug 6:                         | 00--- None<br>01--- BUP-NX Sublingual<br>02--- BUP only Sublingual<br>03--- Methadone PO<br>04--- Methadone IM<br>*Additional Options Listed Below<br>(D TD 1DR06) | 00--- None<br>01--- BUP-NX Sublingual<br>02--- BUP only Sublingual<br>03--- Methadone PO<br>04--- Methadone IM<br>*Additional Options Listed Below<br>(D TD 2DR06) | 00--- None<br>01--- BUP-NX Sublingual<br>02--- BUP only Sublingual<br>03--- Methadone PO<br>04--- Methadone IM<br>*Additional Options Listed Below<br>(D TD 3DR06) |
| Specify total daily dose (xxx.xx): | (D TD 1TL06) <input type="text"/> mg   | (D TD 2TL06) <input type="text"/> mg   | (D TD 3TL06) <input type="text"/> mg   |

|                                    |   |   |   |
|------------------------------------|---|---|---|
| Comments:                          | <input type="text"/>  | <input type="text"/>  | <input type="text"/>  |
|                                    | (D TDCOM 01)  | (D TDCOM 02)  | (D TDCOM 03)  |
| Detox                              | Day 04  | Day 05  | Day 06  |
| Date (mm/dd/yyyy):                 | (D TD XD T04) <input type="text"/>  | (D TD XD T05) <input type="text"/>  | (D TD XD T06) <input type="text"/>  |
| 1. Drug 1:                         | 00-- None<br>01-- BUP-NX Sublingual<br>02-- BUP only Sublingual<br>03-- Methadone PO<br>04-- Methadone IM<br>*Additional Options Listed Below | 00-- None<br>01-- BUP-NX Sublingual<br>02-- BUP only Sublingual<br>03-- Methadone PO<br>04-- Methadone IM<br>*Additional Options Listed Below | 00-- None<br>01-- BUP-NX Sublingual<br>02-- BUP only Sublingual<br>03-- Methadone PO<br>04-- Methadone IM<br>*Additional Options Listed Below |
|                                    | (D TD 4DR 01)   | (D TD 5DR 01)   | (D TD 6DR 01)   |
| Specify total daily dose (xxx.xx): | (D TD 4TL 01) <input type="text"/> mg   | (D TD 5TL 01) <input type="text"/> mg   | (D TD 6TL 01) <input type="text"/> mg   |
| 2. Drug 2:                         | 00-- None<br>01-- BUP-NX Sublingual<br>02-- BUP only Sublingual<br>03-- Methadone PO<br>04-- Methadone IM<br>*Additional Options Listed Below | 00-- None<br>01-- BUP-NX Sublingual<br>02-- BUP only Sublingual<br>03-- Methadone PO<br>04-- Methadone IM<br>*Additional Options Listed Below | 00-- None<br>01-- BUP-NX Sublingual<br>02-- BUP only Sublingual<br>03-- Methadone PO<br>04-- Methadone IM<br>*Additional Options Listed Below |
|                                    | (D TD 4DR 02)   | (D TD 5DR 02)   | (D TD 6DR 02)   |
| Specify total daily dose (xxx.xx): | (D TD 4TL 02) <input type="text"/> mg   | (D TD 5TL 02) <input type="text"/> mg   | (D TD 6TL 02) <input type="text"/> mg   |
| 3. Drug 3:                         | 00-- None<br>01-- BUP-NX Sublingual<br>02-- BUP only Sublingual<br>03-- Methadone PO<br>04-- Methadone IM<br>*Additional Options Listed Below | 00-- None<br>01-- BUP-NX Sublingual<br>02-- BUP only Sublingual<br>03-- Methadone PO<br>04-- Methadone IM<br>*Additional Options Listed Below | 00-- None<br>01-- BUP-NX Sublingual<br>02-- BUP only Sublingual<br>03-- Methadone PO<br>04-- Methadone IM<br>*Additional Options Listed Below |
|                                    | (D TD 4DR 03)   | (D TD 5DR 03)   | (D TD 6DR 03)   |
| Specify total daily dose (xxx.xx): | (D TD 4TL 03) <input type="text"/> mg   | (D TD 5TL 03) <input type="text"/> mg   | (D TD 6TL 03) <input type="text"/> mg   |
| 4. Drug 4:                         | 00-- None<br>01-- BUP-NX Sublingual<br>02-- BUP only Sublingual<br>03-- Methadone PO<br>04-- Methadone IM<br>*Additional Options Listed Below | 00-- None<br>01-- BUP-NX Sublingual<br>02-- BUP only Sublingual<br>03-- Methadone PO<br>04-- Methadone IM<br>*Additional Options Listed Below | 00-- None<br>01-- BUP-NX Sublingual<br>02-- BUP only Sublingual<br>03-- Methadone PO<br>04-- Methadone IM<br>*Additional Options Listed Below |
|                                    | (D TD 4DR 04)   | (D TD 5DR 04)   | (D TD 6DR 04)   |
| Specify total daily dose (xxx.xx): | (D TD 4TL 04) <input type="text"/> mg   | (D TD 5TL 04) <input type="text"/> mg   | (D TD 6TL 04) <input type="text"/> mg   |
| 5. Drug 5:                         | 00-- None<br>01-- BUP-NX Sublingual<br>02-- BUP only Sublingual<br>03-- Methadone PO<br>04-- Methadone IM<br>*Additional Options Listed Below | 00-- None<br>01-- BUP-NX Sublingual<br>02-- BUP only Sublingual<br>03-- Methadone PO<br>04-- Methadone IM<br>*Additional Options Listed Below | 00-- None<br>01-- BUP-NX Sublingual<br>02-- BUP only Sublingual<br>03-- Methadone PO<br>04-- Methadone IM<br>*Additional Options Listed Below |
|                                    | (D TD 4DR 05)   | (D TD 5DR 05)   | (D TD 6DR 05)   |
| Specify total daily dose (xxx.xx): | (D TD 4TL 05) <input type="text"/> mg   | (D TD 5TL 05) <input type="text"/> mg   | (D TD 6TL 05) <input type="text"/> mg   |
| 6. Drug 6:                         | 00-- None<br>01-- BUP-NX Sublingual<br>02-- BUP only Sublingual<br>03-- Methadone PO<br>04-- Methadone IM<br>*Additional Options Listed Below | 00-- None<br>01-- BUP-NX Sublingual<br>02-- BUP only Sublingual<br>03-- Methadone PO<br>04-- Methadone IM<br>*Additional Options Listed Below | 00-- None<br>01-- BUP-NX Sublingual<br>02-- BUP only Sublingual<br>03-- Methadone PO<br>04-- Methadone IM<br>*Additional Options Listed Below |
|                                    | (D TD 4DR 06)   | (D TD 5DR 06)   | (D TD 6DR 06)   |
| Specify total daily dose (xxx.xx): | (D TD 4TL 06) <input type="text"/> mg   | (D TD 5TL 06) <input type="text"/> mg   | (D TD 6TL 06) <input type="text"/> mg   |
| Comments:                          | <input type="text"/>  | <input type="text"/>  | <input type="text"/>  |
|                                    | (D TDCOM 04)  | (D TDCOM 05)  | (D TDCOM 06)  |

|                    |                                    |                                    |                                    |
|--------------------|------------------------------------|------------------------------------|------------------------------------|
| Detox              | Day 07                             | Day 08                             | Day 09                             |
| Date (mm/dd/yyyy): | (D TD XD T07) <input type="text"/> | (D TD XD T08) <input type="text"/> | (D TD XD T09) <input type="text"/> |

|                                    |   |   |   |
|------------------------------------|---|---|---|
| 1. Drug 1:                         | <p>00-- None<br/>01-- BUP-NX Sublingual<br/>02-- BUP only Sublingual<br/>03-- Methadone PO<br/>04-- Methadone IM<br/>*Additional Options Listed Below</p> <p>(D TD 7D R0 1)</p> | <p>00-- None<br/>01-- BUP-NX Sublingual<br/>02-- BUP only Sublingual<br/>03-- Methadone PO<br/>04-- Methadone IM<br/>*Additional Options Listed Below</p> <p>(D TD 8D R0 1)</p> | <p>00-- None<br/>01-- BUP-NX Sublingual<br/>02-- BUP only Sublingual<br/>03-- Methadone PO<br/>04-- Methadone IM<br/>*Additional Options Listed Below</p> <p>(D TD 9D R0 1)</p> |
| Specify total daily dose (xxx.xx): | (D TD 7TL 01) <input type="text"/> mg   | (D TD 8TL 01) <input type="text"/> mg   | (D TD 9TL 01) <input type="text"/> mg   |
| 2. Drug 2:                         | <p>00-- None<br/>01-- BUP-NX Sublingual<br/>02-- BUP only Sublingual<br/>03-- Methadone PO<br/>04-- Methadone IM<br/>*Additional Options Listed Below</p> <p>(D TD 7D R0 2)</p> | <p>00-- None<br/>01-- BUP-NX Sublingual<br/>02-- BUP only Sublingual<br/>03-- Methadone PO<br/>04-- Methadone IM<br/>*Additional Options Listed Below</p> <p>(D TD 8D R0 2)</p> | <p>00-- None<br/>01-- BUP-NX Sublingual<br/>02-- BUP only Sublingual<br/>03-- Methadone PO<br/>04-- Methadone IM<br/>*Additional Options Listed Below</p> <p>(D TD 9D R0 2)</p> |
| Specify total daily dose (xxx.xx): | (D TD 7TL 02) <input type="text"/> mg   | (D TD 8TL 02) <input type="text"/> mg   | (D TD 9TL 02) <input type="text"/> mg   |
| 3. Drug 3:                         | <p>00-- None<br/>01-- BUP-NX Sublingual<br/>02-- BUP only Sublingual<br/>03-- Methadone PO<br/>04-- Methadone IM<br/>*Additional Options Listed Below</p> <p>(D TD 7D R0 3)</p> | <p>00-- None<br/>01-- BUP-NX Sublingual<br/>02-- BUP only Sublingual<br/>03-- Methadone PO<br/>04-- Methadone IM<br/>*Additional Options Listed Below</p> <p>(D TD 8D R0 3)</p> | <p>00-- None<br/>01-- BUP-NX Sublingual<br/>02-- BUP only Sublingual<br/>03-- Methadone PO<br/>04-- Methadone IM<br/>*Additional Options Listed Below</p> <p>(D TD 9D R0 3)</p> |
| Specify total daily dose (xxx.xx): | (D TD 7TL 03) <input type="text"/> mg   | (D TD 8TL 03) <input type="text"/> mg   | (D TD 9TL 03) <input type="text"/> mg   |
| 4. Drug 4:                         | <p>00-- None<br/>01-- BUP-NX Sublingual<br/>02-- BUP only Sublingual<br/>03-- Methadone PO<br/>04-- Methadone IM<br/>*Additional Options Listed Below</p> <p>(D TD 7D R0 4)</p> | <p>00-- None<br/>01-- BUP-NX Sublingual<br/>02-- BUP only Sublingual<br/>03-- Methadone PO<br/>04-- Methadone IM<br/>*Additional Options Listed Below</p> <p>(D TD 8D R0 4)</p> | <p>00-- None<br/>01-- BUP-NX Sublingual<br/>02-- BUP only Sublingual<br/>03-- Methadone PO<br/>04-- Methadone IM<br/>*Additional Options Listed Below</p> <p>(D TD 9D R0 4)</p> |
| Specify total daily dose (xxx.xx): | (D TD 7TL 04) <input type="text"/> mg   | (D TD 8TL 04) <input type="text"/> mg   | (D TD 9TL 04) <input type="text"/> mg   |
| 5. Drug 5:                         | <p>00-- None<br/>01-- BUP-NX Sublingual<br/>02-- BUP only Sublingual<br/>03-- Methadone PO<br/>04-- Methadone IM<br/>*Additional Options Listed Below</p> <p>(D TD 7D R0 5)</p> | <p>00-- None<br/>01-- BUP-NX Sublingual<br/>02-- BUP only Sublingual<br/>03-- Methadone PO<br/>04-- Methadone IM<br/>*Additional Options Listed Below</p> <p>(D TD 8D R0 5)</p> | <p>00-- None<br/>01-- BUP-NX Sublingual<br/>02-- BUP only Sublingual<br/>03-- Methadone PO<br/>04-- Methadone IM<br/>*Additional Options Listed Below</p> <p>(D TD 9D R0 5)</p> |
| Specify total daily dose (xxx.xx): | (D TD 7TL 05) <input type="text"/> mg   | (D TD 8TL 05) <input type="text"/> mg   | (D TD 9TL 05) <input type="text"/> mg   |
| 6. Drug 6:                         | <p>00-- None<br/>01-- BUP-NX Sublingual<br/>02-- BUP only Sublingual<br/>03-- Methadone PO<br/>04-- Methadone IM<br/>*Additional Options Listed Below</p> <p>(D TD 7D R0 6)</p> | <p>00-- None<br/>01-- BUP-NX Sublingual<br/>02-- BUP only Sublingual<br/>03-- Methadone PO<br/>04-- Methadone IM<br/>*Additional Options Listed Below</p> <p>(D TD 8D R0 6)</p> | <p>00-- None<br/>01-- BUP-NX Sublingual<br/>02-- BUP only Sublingual<br/>03-- Methadone PO<br/>04-- Methadone IM<br/>*Additional Options Listed Below</p> <p>(D TD 9D R0 6)</p> |
| Specify total daily dose (xxx.xx): | (D TD 7TL 06) <input type="text"/> mg   | (D TD 8TL 06) <input type="text"/> mg   | (D TD 9TL 06) <input type="text"/> mg   |
| Comments:                          | (D TD COM 07) <input type="text"/>  | (D TD COM 08) <input type="text"/>  | (D TD COM 09) <input type="text"/>  |
| Detox                              | <b>Day 10</b>   | <b>Day 11</b>   | <b>Day 12</b>   |
| Date (mm/dd/yyyy):                 | (D TD XD T1 0) <input type="text"/>   | (D TD XD T1 1) <input type="text"/>   | (D TD XD T1 2) <input type="text"/>   |
| 1. Drug 1:                         | <p>00-- None<br/>01-- BUP-NX Sublingual<br/>02-- BUP only Sublingual<br/>03-- Methadone PO<br/>04-- Methadone IM<br/>*Additional Options Listed Below</p> <p>(D TD 10D 0 1)</p> | <p>00-- None<br/>01-- BUP-NX Sublingual<br/>02-- BUP only Sublingual<br/>03-- Methadone PO<br/>04-- Methadone IM<br/>*Additional Options Listed Below</p> <p>(D TD 11D 0 1)</p> | <p>00-- None<br/>01-- BUP-NX Sublingual<br/>02-- BUP only Sublingual<br/>03-- Methadone PO<br/>04-- Methadone IM<br/>*Additional Options Listed Below</p> <p>(D TD 12D 0 1)</p> |
| Specify total daily dose (xxx.xx): | (D TD 10T 01) <input type="text"/> mg   | (D TD 11T 01) <input type="text"/> mg   | (D TD 12T 01) <input type="text"/> mg   |

|                                    |   |   |   |
|------------------------------------|---|---|---|
| 2. Drug 2:                         | 00--- None<br>01--- BUP-NX Sublingual<br>02--- BUP only Sublingual<br>03--- Methadone PO<br>04--- Methadone IM<br>*Additional Options Listed Below<br>(D TD 10 D02) | 00--- None<br>01--- BUP-NX Sublingual<br>02--- BUP only Sublingual<br>03--- Methadone PO<br>04--- Methadone IM<br>*Additional Options Listed Below<br>(D TD 11 D02) | 00--- None<br>01--- BUP-NX Sublingual<br>02--- BUP only Sublingual<br>03--- Methadone PO<br>04--- Methadone IM<br>*Additional Options Listed Below<br>(D TD 12 D02) |
| Specify total daily dose (xxx.xx): | (D TD 10 T02) <input type="text"/> mg   | (D TD 11 T02) <input type="text"/> mg   | (D TD 12 T02) <input type="text"/> mg   |
| 3. Drug 3:                         | 00--- None<br>01--- BUP-NX Sublingual<br>02--- BUP only Sublingual<br>03--- Methadone PO<br>04--- Methadone IM<br>*Additional Options Listed Below<br>(D TD 10 D03) | 00--- None<br>01--- BUP-NX Sublingual<br>02--- BUP only Sublingual<br>03--- Methadone PO<br>04--- Methadone IM<br>*Additional Options Listed Below<br>(D TD 11 D03) | 00--- None<br>01--- BUP-NX Sublingual<br>02--- BUP only Sublingual<br>03--- Methadone PO<br>04--- Methadone IM<br>*Additional Options Listed Below<br>(D TD 12 D03) |
| Specify total daily dose (xxx.xx): | (D TD 10 T03) <input type="text"/> mg   | (D TD 11 T03) <input type="text"/> mg   | (D TD 12 T03) <input type="text"/> mg   |
| 4. Drug 4:                         | 00--- None<br>01--- BUP-NX Sublingual<br>02--- BUP only Sublingual<br>03--- Methadone PO<br>04--- Methadone IM<br>*Additional Options Listed Below<br>(D TD 10 D04) | 00--- None<br>01--- BUP-NX Sublingual<br>02--- BUP only Sublingual<br>03--- Methadone PO<br>04--- Methadone IM<br>*Additional Options Listed Below<br>(D TD 11 D04) | 00--- None<br>01--- BUP-NX Sublingual<br>02--- BUP only Sublingual<br>03--- Methadone PO<br>04--- Methadone IM<br>*Additional Options Listed Below<br>(D TD 12 D04) |
| Specify total daily dose (xxx.xx): | (D TD 10 T04) <input type="text"/> mg   | (D TD 11 T04) <input type="text"/> mg   | (D TD 12 T04) <input type="text"/> mg   |
| 5. Drug 5:                         | 00--- None<br>01--- BUP-NX Sublingual<br>02--- BUP only Sublingual<br>03--- Methadone PO<br>04--- Methadone IM<br>*Additional Options Listed Below<br>(D TD 10 D05) | 00--- None<br>01--- BUP-NX Sublingual<br>02--- BUP only Sublingual<br>03--- Methadone PO<br>04--- Methadone IM<br>*Additional Options Listed Below<br>(D TD 11 D05) | 00--- None<br>01--- BUP-NX Sublingual<br>02--- BUP only Sublingual<br>03--- Methadone PO<br>04--- Methadone IM<br>*Additional Options Listed Below<br>(D TD 12 D05) |
| Specify total daily dose (xxx.xx): | (D TD 10 T05) <input type="text"/> mg   | (D TD 11 T05) <input type="text"/> mg   | (D TD 12 T05) <input type="text"/> mg   |
| 6. Drug 6:                         | 00--- None<br>01--- BUP-NX Sublingual<br>02--- BUP only Sublingual<br>03--- Methadone PO<br>04--- Methadone IM<br>*Additional Options Listed Below<br>(D TD 10 D06) | 00--- None<br>01--- BUP-NX Sublingual<br>02--- BUP only Sublingual<br>03--- Methadone PO<br>04--- Methadone IM<br>*Additional Options Listed Below<br>(D TD 11 D06) | 00--- None<br>01--- BUP-NX Sublingual<br>02--- BUP only Sublingual<br>03--- Methadone PO<br>04--- Methadone IM<br>*Additional Options Listed Below<br>(D TD 12 D06) |
| Specify total daily dose (xxx.xx): | (D TD 10 T06) <input type="text"/> mg   | (D TD 11 T06) <input type="text"/>  | (D TD 12 T06) <input type="text"/> mg   |
| Comments:                          | (D TD COM 10) <input type="text"/>  | (D TD COM 11) <input type="text"/>  | (D TD COM 12) <input type="text"/>  |

| Detox                              | Day 13  | Day 14  | Day 15  |
|------------------------------------|---|---|---|
| Date (mm/dd/yyyy):                 | (D TD XD T1 3) <input type="text"/>   | (D TD XD T1 4) <input type="text"/>   | (D TD XD T1 5) <input type="text"/>   |
| 1. Drug 1:                         | 00--- None<br>01--- BUP-NX Sublingual<br>02--- BUP only Sublingual<br>03--- Methadone PO<br>04--- Methadone IM<br>*Additional Options Listed Below<br>(D TD 13 D01) | 00--- None<br>01--- BUP-NX Sublingual<br>02--- BUP only Sublingual<br>03--- Methadone PO<br>04--- Methadone IM<br>*Additional Options Listed Below<br>(D TD 14 D01) | 00--- None<br>01--- BUP-NX Sublingual<br>02--- BUP only Sublingual<br>03--- Methadone PO<br>04--- Methadone IM<br>*Additional Options Listed Below<br>(D TD 15 D01) |
| Specify total daily dose (xxx.xx): | (D TD 13 T01) <input type="text"/> mg   | (D TD 14 T01) <input type="text"/> mg   | (D TD 15 T01) <input type="text"/> mg   |
| 2. Drug 2:                         | 00--- None<br>01--- BUP-NX Sublingual<br>02--- BUP only Sublingual<br>03--- Methadone PO<br>04--- Methadone IM<br>*Additional Options Listed Below<br>(D TD 13 D02) | 00--- None<br>01--- BUP-NX Sublingual<br>02--- BUP only Sublingual<br>03--- Methadone PO<br>04--- Methadone IM<br>*Additional Options Listed Below<br>(D TD 14 D02) | 00--- None<br>01--- BUP-NX Sublingual<br>02--- BUP only Sublingual<br>03--- Methadone PO<br>04--- Methadone IM<br>*Additional Options Listed Below<br>(D TD 15 D02) |
| Specify total daily dose (xxx.xx): | (D TD 13 T02) <input type="text"/> mg   | (D TD 14 T02) <input type="text"/> mg   | (D TD 15 T02) <input type="text"/> mg   |

|                                    |   |   |   |
|------------------------------------|---|---|---|
| 3. Drug 3:                         | 00--- None<br>01--- BUP-NX Sublingual<br>02--- BUP only Sublingual<br>03--- Methadone PO<br>04--- Methadone IM<br>*Additional Options Listed Below<br>(D TD 13 D03) | 00--- None<br>01--- BUP-NX Sublingual<br>02--- BUP only Sublingual<br>03--- Methadone PO<br>04--- Methadone IM<br>*Additional Options Listed Below<br>(D TD 14 D03) | 00--- None<br>01--- BUP-NX Sublingual<br>02--- BUP only Sublingual<br>03--- Methadone PO<br>04--- Methadone IM<br>*Additional Options Listed Below<br>(D TD 15 D03) |
| Specify total daily dose (xxx.xx): | (D TD 13 T03) <input type="text"/> mg   | (D TD 14 T03) <input type="text"/> mg   | (D TD 15 T03) <input type="text"/> mg   |
| 4. Drug 4:                         | 00--- None<br>01--- BUP-NX Sublingual<br>02--- BUP only Sublingual<br>03--- Methadone PO<br>04--- Methadone IM<br>*Additional Options Listed Below<br>(D TD 13 D04) | 00--- None<br>01--- BUP-NX Sublingual<br>02--- BUP only Sublingual<br>03--- Methadone PO<br>04--- Methadone IM<br>*Additional Options Listed Below<br>(D TD 14 D04) | 00--- None<br>01--- BUP-NX Sublingual<br>02--- BUP only Sublingual<br>03--- Methadone PO<br>04--- Methadone IM<br>*Additional Options Listed Below<br>(D TD 15 D04) |
| Specify total daily dose (xxx.xx): | (D TD 13 T04) <input type="text"/> mg   | (D TD 14 T04) <input type="text"/> mg   | (D TD 15 T04) <input type="text"/> mg   |
| 5. Drug 5:                         | 00--- None<br>01--- BUP-NX Sublingual<br>02--- BUP only Sublingual<br>03--- Methadone PO<br>04--- Methadone IM<br>*Additional Options Listed Below<br>(D TD 13 D05) | 00--- None<br>01--- BUP-NX Sublingual<br>02--- BUP only Sublingual<br>03--- Methadone PO<br>04--- Methadone IM<br>*Additional Options Listed Below<br>(D TD 14 D05) | 00--- None<br>01--- BUP-NX Sublingual<br>02--- BUP only Sublingual<br>03--- Methadone PO<br>04--- Methadone IM<br>*Additional Options Listed Below<br>(D TD 15 D05) |
| Specify total daily dose (xxx.xx): | (D TD 13 T05) <input type="text"/> mg   | (D TD 14 T05) <input type="text"/> mg   | (D TD 15 T05) <input type="text"/> mg   |
| 6. Drug 6:                         | 00--- None<br>01--- BUP-NX Sublingual<br>02--- BUP only Sublingual<br>03--- Methadone PO<br>04--- Methadone IM<br>*Additional Options Listed Below<br>(D TD 13 D06) | 00--- None<br>01--- BUP-NX Sublingual<br>02--- BUP only Sublingual<br>03--- Methadone PO<br>04--- Methadone IM<br>*Additional Options Listed Below<br>(D TD 14 D06) | 00--- None<br>01--- BUP-NX Sublingual<br>02--- BUP only Sublingual<br>03--- Methadone PO<br>04--- Methadone IM<br>*Additional Options Listed Below<br>(D TD 15 D06) |
| Specify total daily dose (xxx.xx): | (D TD 13 T06) <input type="text"/> mg   | (D TD 14 T06) <input type="text"/> mg   | (D TD 15 T06) <input type="text"/> mg   |
| Comments:                          | (D TDCOM 13) <input type="text"/>   | (D TDCOM 14) <input type="text"/>   | (D TDCOM 15) <input type="text"/>   |

Comments: (DXUCOMM)

**Additional Selection Options for DXU****Detox day 1 drug used 01**

05--- Clonidine  
Z01-BENZODIAZEPINES  
01A--- Chlordiazepoxide  
02A--- Clonazepam  
03A--- Diazepam  
04A--- Lorazepam  
99A--- Other  
Z02-GABA AGENTS/MUSCLE RELAXANTS  
01B--- Gabapentin  
02B--- Baclofen  
03B--- Cyclobenzaprine  
99B--- Other  
Z03-SLEEP/ANXIETY/ANTI-HISTAMINE AGENTS  
01C--- Trazodone  
02C--- Diphenhydramine  
03C--- Hydroxyzine  
04C--- Zolpidem  
05C--- Mirtazapine  
99C--- Other  
Z04-GI AGENTS  
01D--- Anti-acid agent  
02D--- Anti-diarrheal  
03D--- Laxative agent  
99D--- Other  
Z05-NON-STEROIDAL ANTI-INFLAMMATORY AGENTS  
01E--- Ibuprofen  
02E--- Naproxen  
03E--- Acetaminophen  
04E--- Aspirin  
99E--- Other

NIDA Clinical Trials Network

A251A (ENR)

Web Version: 1.0; 1.00; 09-13-16

Date of informed consent signature: (S8CNSTDT)

 (mm.dd/yyyy)

Date of medical record release signature: (S8M DRCDT)

 (mm.dd/yyyy)

Comments: (S8COMM)

**Original main consent**

IRB approval date of IC F: (S8IRB DT)

 (mm.dd/yyyy)

**Main study re-consent**

IRB approval date of IC F: (S8IRB 2DT)

 (mm.dd/yyyy)

Date informed consent signed: (S8CST2DT)

 (mm.dd/yyyy)

**Main study re-consent**

IRB approval date of IC F: (S8IRB 3DT)

 (mm.dd/yyyy)

Date informed consent signed: (S8CST3DT)

 (mm.dd/yyyy)

**Main study re-consent**

IRB approval date of IC F: (S8IRB 4DT)

 (mm.dd/yyyy)

Date informed consent signed: (S8CST4DT)

 (mm.dd/yyyy)

Medical Management Termination (Community Discharge Plan) (MMD)

Web Version: 1.0; 2.01; 09-13-16

Segment (PROTSEG): A

Visit number (VISNO):

Date of assessment (MMDASMDT)

 (mm.ttd/yyyy)

1. Are you currently homeless or living in a shelter? (MDHMLSS)

 No  Yes

2. Currently, which substance is the major problem?

Interviewer should determine the major drug or drugs of abuse (excluding Nicotine use). 00 = no problem, 15 = alcohol and one or more drugs; 16 = more than one drug but no alcohol. Ask participant when not clear. (MDMAJDRG)

- 0-00 - No problem
- 1-01 - Alcohol (any use at all)
- 2-02 - Alcohol (to intoxication)
- 3-03 - Heroin
- 4-04 - Methadone/LAAM (prescribed or illicit)
- 5-05 - Other Opiates/Analgesics
- 6-06 - Barbiturates
- 7-07 - Other Sedatives/Hypnotics/Tranquilizers
- 8-08 - Cocaine
- 9-09 - Amphetamines
- 9a-09a - Methamphetamine
- 10-10 - Cannabis
- 11-11 - Hallucinogens
- 12-12 - Inhalants
- 15-15 - Alcohol and one or more drugs
- 16-16 - More than one drug, but no alcohol

(MDMJDGNA)

-OR-  (97) Not answered

3. Lifetime use (years) of any opioid; (MDYRSUSE)

 (xx) years

4. Age of first use (onset) of any opioid; (MD1STUSE)

 (xx) years

Comments: (MMDCOMM)



NIDA Clinical Trials Network

Protocol Deviation (PDV)

Web Version: 1.0; 1.02; 04-04-17

Date of deviation (PDDATE):  
 Protocol deviation number (PDSEQNUM):

1. Date deviation identified (PDVDATE)

 (mm/dd/yyyy)

2. Deviation type (PDTYPE)

Z01-INFORMED CONSENT PROCEDURES  
 01A--- No consent/assent obtained  
 01B--- Invalid/incomplete informed consent form  
 01C--- Unauthorized assessments and/or procedures conducted prior to obtaining informed consent  
 01D--- Non IRB approved/outdated/obsolete informed consent documents used  
 \*Additional Options Listed Below

If "Other", specify (PDTPSP)

3. Brief description of what occurred (PDES CPT)

4. Brief description of the actual or expected corrective action for this event (PD ACTION)

5. Brief description of the plan to prevent recurrence (PDPREVRE)

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

 No  Yes

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

 No  Yes

If "Yes", date of planned submission (PDIRBPD T)

 (mm/dd/yyyy)

If "No", date of actual submission (PDIRBAD T)

 (mm/dd/yyyy)

Comments (PDVCOMM)

**Additional Selection Options for PDV****Protocol deviation number (PDSEQNUM) (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

**Deviation type:**

01E--- Informed consent process not properly conducted and/or documented  
 01Z--- Other (specify)  
 Z02-INCLUSION/EXCLUSION CRITERIA  
 02A--- Ineligible participant randomized/inclusion/exclusion criteria not met  
 02Z--- Other (specify)  
 Z04-LABORATORY ASSESSMENTS  
 04A--- Biologic specimen not collected/processed as per protocol  
 04Z--- Other (specify)  
 Z05-STUDY PROCEDURES/ASSESSMENTS  
 05A--- Protocol required visit/assessment not scheduled or conducted  
 05B--- Study assessments not completed/failed as per protocol  
 05C--- Inappropriate unblinding  
 05Z--- Other (specify)  
 Z06-ADVERSE EVENT  
 06A--- AE not reported  
 06B--- SAE not reported  
 06C--- AE/SAE reported out of protocol specified reporting time frame  
 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 (specify)  
 Z07-RANDOMIZATION PROCEDURES  
 07A--- Stratification error  
 07Z--- Other (specify)  
 Z08-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 (specify)  
 Z09-STUDY BEHAVIORAL INTERVENTION  
 09A--- Study behavioral intervention was not provided/performed as per protocol  
 09Z--- Other (specify)  
 Z99-OTHER SIGNIFICANT DEVIATIONS  
 99A--- Destruction of study materials without prior authorization from sponsor  
 99B--- Breach of Confidentiality  
 99Z--- Other (specify)

TLFB Assessment Period (TAP)

Web Version: 1.0; 5.01; 09-13-16

Segment (PROTSEG): A

Visit number (VISNO):

Date of assessment (TAPASMDT)

 (mm/dd/yyyy)

1. Assessment period (TATFS TDT)

From:  (mm/dd/yyyy)

(TATFENDT)

To:  (mm/dd/yyyy)

2. Have any illicit substances or alcohol been taken during this assessment period? (TASUBALC)

No  Yes

3. In the 7 days prior to detox admission, what was the primary opioid use? (TA51PDRG)

1-Buprenorphine  
 2-Opioid analgesics  
 3-Methadone  
 4-Heroin

a. Route: (TA51ROUT)

1-01- Oral  
 2-02-Nasal  
 3-03-Smoking  
 4-04-Non-IV Injection  
 5-05-IV Injection

b. Average amount used (per day): (TA51AMNT)

1-bag(s)  
 2-milligram(s)  
 3-dollars

(xxx) Units: (TA51UNIT)

c. Average cost (per day): (TA51COST)

\$  (xxx) dollars

Comments: (TAPCOMM)

Timeline Followback (TF1)

Web Version: 1.0; 1.01; 09-01-16

TFB week start date (TFWKSTD7):

| Day  | Sunday   | Monday   | Tuesday  | Wednesday  | Thursday   | Friday   | Saturday   |
|--|--|--|--|--|--|--|--|
| Date   | (TLDATE1) <input type="text"/>   | (TLDATE2) <input type="text"/>   | (TLDATE3) <input type="text"/>   | (TLDATE4) <input type="text"/>   | (TLDATE5) <input type="text"/>   | (TLDATE6) <input type="text"/>   | (TLDATE7) <input type="text"/>   |
| 1. Have any illicit substances or alcohol been used on this day? | (TLSUBAL1) <input type="checkbox"/> No <input type="checkbox"/> Yes  | (TLSUBAL2) <input type="checkbox"/> No <input type="checkbox"/> Yes  | (TLSUBAL3) <input type="checkbox"/> No <input type="checkbox"/> Yes  | (TLSUBAL4) <input type="checkbox"/> No <input type="checkbox"/> Yes  | (TLSUBAL5) <input type="checkbox"/> No <input type="checkbox"/> Yes  | (TLSUBAL6) <input type="checkbox"/> No <input type="checkbox"/> Yes  | (TLSUBAL7) <input type="checkbox"/> No <input type="checkbox"/> Yes  |
| 2. Alcohol number of standard drinks (xx):                       | (TLALCHL1) <input type="text"/>  | (TLALCHL2) <input type="text"/>  | (TLALCHL3) <input type="text"/>  | (TLALCHL4) <input type="text"/>  | (TLALCHL5) <input type="text"/>  | (TLALCHL6) <input type="text"/>  | (TLALCHL7) <input type="text"/>  |
| 3. Cannabinoids / Marijuana:                                     | (TLTHCR1)<br>0-00-No use<br>1-01-Oral<br>2-02-Nasal<br>3-03-Smoking<br>4-04-Non-IV Injection<br>*Additional Options Listed Below | (TLTHCR2)<br>0-00-No use<br>1-01-Oral<br>2-02-Nasal<br>3-03-Smoking<br>4-04-Non-IV Injection<br>*Additional Options Listed Below | (TLTHCR3)<br>0-00-No use<br>1-01-Oral<br>2-02-Nasal<br>3-03-Smoking<br>4-04-Non-IV Injection<br>*Additional Options Listed Below | (TLTHCR4)<br>0-00-No use<br>1-01-Oral<br>2-02-Nasal<br>3-03-Smoking<br>4-04-Non-IV Injection<br>*Additional Options Listed Below | (TLTHCR5)<br>0-00-No use<br>1-01-Oral<br>2-02-Nasal<br>3-03-Smoking<br>4-04-Non-IV Injection<br>*Additional Options Listed Below | (TLTHCR6)<br>0-00-No use<br>1-01-Oral<br>2-02-Nasal<br>3-03-Smoking<br>4-04-Non-IV Injection<br>*Additional Options Listed Below | (TLTHCR7)<br>0-00-No use<br>1-01-Oral<br>2-02-Nasal<br>3-03-Smoking<br>4-04-Non-IV Injection<br>*Additional Options Listed Below |
| 4. Cocaine:  | (TLCOCR1)<br>0-00-No use<br>1-01-Oral<br>2-02-Nasal<br>3-03-Smoking<br>4-04-Non-IV Injection<br>*Additional Options Listed Below | (TLCOCR2)<br>0-00-No use<br>1-01-Oral<br>2-02-Nasal<br>3-03-Smoking<br>4-04-Non-IV Injection<br>*Additional Options Listed Below | (TLCOCR3)<br>0-00-No use<br>1-01-Oral<br>2-02-Nasal<br>3-03-Smoking<br>4-04-Non-IV Injection<br>*Additional Options Listed Below | (TLCOCR4)<br>0-00-No use<br>1-01-Oral<br>2-02-Nasal<br>3-03-Smoking<br>4-04-Non-IV Injection<br>*Additional Options Listed Below | (TLCOCR5)<br>0-00-No use<br>1-01-Oral<br>2-02-Nasal<br>3-03-Smoking<br>4-04-Non-IV Injection<br>*Additional Options Listed Below | (TLCOCR6)<br>0-00-No use<br>1-01-Oral<br>2-02-Nasal<br>3-03-Smoking<br>4-04-Non-IV Injection<br>*Additional Options Listed Below | (TLCOCR7)<br>0-00-No use<br>1-01-Oral<br>2-02-Nasal<br>3-03-Smoking<br>4-04-Non-IV Injection<br>*Additional Options Listed Below |
| 5. Crack:  | (TLCAKR1)<br>0-00-No use<br>1-01-Oral<br>2-02-Nasal<br>3-03-Smoking<br>4-04-Non-IV Injection<br>*Additional Options Listed Below | (TLCAKR2)<br>0-00-No use<br>1-01-Oral<br>2-02-Nasal<br>3-03-Smoking<br>4-04-Non-IV Injection<br>*Additional Options Listed Below | (TLCAKR3)<br>0-00-No use<br>1-01-Oral<br>2-02-Nasal<br>3-03-Smoking<br>4-04-Non-IV Injection<br>*Additional Options Listed Below | (TLCAKR4)<br>0-00-No use<br>1-01-Oral<br>2-02-Nasal<br>3-03-Smoking<br>4-04-Non-IV Injection<br>*Additional Options Listed Below | (TLCAKR5)<br>0-00-No use<br>1-01-Oral<br>2-02-Nasal<br>3-03-Smoking<br>4-04-Non-IV Injection<br>*Additional Options Listed Below | (TLCAKR6)<br>0-00-No use<br>1-01-Oral<br>2-02-Nasal<br>3-03-Smoking<br>4-04-Non-IV Injection<br>*Additional Options Listed Below | (TLCAKR7)<br>0-00-No use<br>1-01-Oral<br>2-02-Nasal<br>3-03-Smoking<br>4-04-Non-IV Injection<br>*Additional Options Listed Below |
| 6. Amphetamine-type stimulants:                                  | (TLAMP1)<br>0-00-No use<br>1-01-Oral<br>2-02-Nasal<br>3-03-Smoking<br>4-04-Non-IV Injection<br>*Additional Options Listed Below  | (TLAMP2)<br>0-00-No use<br>1-01-Oral<br>2-02-Nasal<br>3-03-Smoking<br>4-04-Non-IV Injection<br>*Additional Options Listed Below  | (TLAMP3)<br>0-00-No use<br>1-01-Oral<br>2-02-Nasal<br>3-03-Smoking<br>4-04-Non-IV Injection<br>*Additional Options Listed Below  | (TLAMP4)<br>0-00-No use<br>1-01-Oral<br>2-02-Nasal<br>3-03-Smoking<br>4-04-Non-IV Injection<br>*Additional Options Listed Below  | (TLAMP5)<br>0-00-No use<br>1-01-Oral<br>2-02-Nasal<br>3-03-Smoking<br>4-04-Non-IV Injection<br>*Additional Options Listed Below  | (TLAMP6)<br>0-00-No use<br>1-01-Oral<br>2-02-Nasal<br>3-03-Smoking<br>4-04-Non-IV Injection<br>*Additional Options Listed Below  | (TLAMP7)<br>0-00-No use<br>1-01-Oral<br>2-02-Nasal<br>3-03-Smoking<br>4-04-Non-IV Injection<br>*Additional Options Listed Below  |
| 7. Buprenorphine:  | (TLBUP1)<br>0-00-No use<br>1-01-Oral<br>2-02-Nasal<br>3-03-Smoking<br>4-04-Non-IV Injection<br>*Additional Options Listed Below  | (TLBUP2)<br>0-00-No use<br>1-01-Oral<br>2-02-Nasal<br>3-03-Smoking<br>4-04-Non-IV Injection<br>*Additional Options Listed Below  | (TLBUP3)<br>0-00-No use<br>1-01-Oral<br>2-02-Nasal<br>3-03-Smoking<br>4-04-Non-IV Injection<br>*Additional Options Listed Below  | (TLBUP4)<br>0-00-No use<br>1-01-Oral<br>2-02-Nasal<br>3-03-Smoking<br>4-04-Non-IV Injection<br>*Additional Options Listed Below  | (TLBUP5)<br>0-00-No use<br>1-01-Oral<br>2-02-Nasal<br>3-03-Smoking<br>4-04-Non-IV Injection<br>*Additional Options Listed Below  | (TLBUP6)<br>0-00-No use<br>1-01-Oral<br>2-02-Nasal<br>3-03-Smoking<br>4-04-Non-IV Injection<br>*Additional Options Listed Below  | (TLBUP7)<br>0-00-No use<br>1-01-Oral<br>2-02-Nasal<br>3-03-Smoking<br>4-04-Non-IV Injection<br>*Additional Options Listed Below  |
| 8. Opioid analgesic:   | (TLOPI1)<br>0-00-No use<br>1-01-Oral<br>2-02-Nasal<br>3-03-Smoking<br>4-04-Non-IV Injection<br>*Additional Options Listed Below  | (TLOPI2)<br>0-00-No use<br>1-01-Oral<br>2-02-Nasal<br>3-03-Smoking<br>4-04-Non-IV Injection<br>*Additional Options Listed Below  | (TLOPI3)<br>0-00-No use<br>1-01-Oral<br>2-02-Nasal<br>3-03-Smoking<br>4-04-Non-IV Injection<br>*Additional Options Listed Below  | (TLOPI4)<br>0-00-No use<br>1-01-Oral<br>2-02-Nasal<br>3-03-Smoking<br>4-04-Non-IV Injection<br>*Additional Options Listed Below  | (TLOPI5)<br>0-00-No use<br>1-01-Oral<br>2-02-Nasal<br>3-03-Smoking<br>4-04-Non-IV Injection<br>*Additional Options Listed Below  | (TLOPI6)<br>0-00-No use<br>1-01-Oral<br>2-02-Nasal<br>3-03-Smoking<br>4-04-Non-IV Injection<br>*Additional Options Listed Below  | (TLOPI7)<br>0-00-No use<br>1-01-Oral<br>2-02-Nasal<br>3-03-Smoking<br>4-04-Non-IV Injection<br>*Additional Options Listed Below  |
| 9. Methadone:  | (TLMTR1)   | (TLMTR2)   | (TLMTR3)   | (TLMTR4)   | (TLMTR5)   | (TLMTR6)   | (TLMTR7)   |



**Additional Selection Options for TF1**

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