# Adverse Event (AD1)

Version: 1.01; 12-10-20

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

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

## For the purpose of this protocol, Adverse Events are captured on the Targeted Safety Events form. Only Serious Adverse Events are reported on this form.

1. Adverse event name:*(A1DESCPT)*
2. Date site became aware of the event:*(A1AWARDT)* *(mm/dd/yyyy)*
3. Severity of event:*(A1SEVRTY)*
   - 01-Grade 1 - Mild
   - 02-Grade 2 - Moderate
   - 03-Grade 3 - Severe
4. Is there a reasonable possibility that study medication caused the event?*(A1STDMED)* ☐ 0-No ☐ 1-Yes
   a. If "Yes", action taken with study medication:*(A1MEDACT)*
   - 00-None
   - 01-Decreased drug
   - 02-Increased drug
   - 03-Temporarily stopped drug
   - 04-Permanently stopped drug
   - 05-Participant terminated from study
5. If not caused by the study medication, alternative etiology:*(A1ALTETI)*
   - 00-None apparent
   - 01-Study disease
   - 02-Concomitant medication
   - 03-Other pre-existing disease or condition
   - 04-Accident, trauma, or external factors
   - *Additional Options Listed Below

   a. If "Other", Specify:*(A1ALTSP)*
6. Outcome of event:*(A1OUTCM)*
   - 01-Recovering/resolving
   - 02-Recovered/resolved
   - 03-Recovered/resolved with sequelae
   - 04-Not recovered/not resolved
   - 05-Fatal
   - 97-Unknown
7. Date of resolution or medically stable:*(A1RESDT)* *(mm/dd/yyyy)*

***A response of "Yes" to any of the following will designate this as a Serious Adverse Event (SAE). The Serious Adverse Event Summary (AD2) form should be completed for all Serious Adverse Events reported.***

8. Was this event associated with:
   *If more than one option applies, select the most serious.*
   a. Is the adverse event associated with a congenital anomaly or birth defect?*(A1ANOM)* ☐ 0-No ☐ 1-Yes
   b. Did the adverse event result in persistent or significant disability or incapacity? *(A1DISABL)* ☐ 0-No ☐ 1-Yes
   c. Did the adverse event result in death?*(A1DTH)* ☐ 0-No ☐ 1-Yes
      1. If "Yes", date of death:*(A1DTHDT)* *(mm/dd/yyyy)*
   d. Did the adverse event result in initial or prolonged hospitalization for the participant? *(A1HOSP)* ☐ 0-No ☐ 1-Yes
      If "Yes",
      1. Date of hospital admission:*(A1HOSPAD)* *(mm/dd/yyyy)*
      2. Date of hospital discharge:*(A1HOSPDC)* *(mm/dd/yyyy)*
   e. Is the adverse event life threatening?*(A1LIFETH)* ☐ 0-No ☐ 1-Yes
   f. Is the adverse event an "other serious" event (Important Medical Event)?*(A1OTCRIT)* ☐ 0-No ☐ 1-Yes

Comments:*(AD1COMM)*

# Additional Selection Options for AD1

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

**If not caused by the study medication, alternative etiology:**
05-Concurrent illness/condition (not pre-existing)
06-Study procedures
07-Naloxone challenge
99-Other

# Serious Adverse Event Summary (AD2)

Version: 3.00; 07-02-21

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

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

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

2. Relevant past medical history:*(A2SAEMHX)* ☐ 00-No ☐ 01-Yes ☐ 97-Unknown

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

3. Medications at the time of the event:*(A2SAEMED)* ☐ 00-No ☐ 01-Yes ☐ 97-Unknown

*Be sure to assess for dosage and date of last dose for the study medication, and any prior/concomitant medications as needed.*

| **Medication** (Generic Name) | **Indication** |
|---|---|
| a. *(A2_01DNM)* | *(A2_01DIN)* |
| b. *(A2_02DNM)* | *(A2_02DIN)* |
| c. *(A2_03DNM)* | *(A2_03DIN)* |
| d. *(A2_04DNM)* | *(A2_04DIN)* |
| e. *(A2_05DNM)* | *(A2_05DIN)* |
| f. *(A2_06DNM)* | *(A2_06DIN)* |
| g. *(A2_07DNM)* | *(A2_07DIN)* |
| h. *(A2_08DNM)* | *(A2_08DIN)* |
| i. *(A2_09DNM)* | *(A2_09DIN)* |
| j. *(A2_10DNM)* | *(A2_10DIN)* |

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

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

5. Labs/tests performed in conjunction with this event:*(A2SAELAB)* ☐ 00-No ☐ 01-Yes ☐ 97-Unknown

| Lab/Test | Findings | Date of Test *(mm/dd/yyyy)* |
|---|---|---|
| a. *(A2_1LBNM)* | *(A2_1LBIN)* | *(A2_1LBDT)* |
| b. *(A2_2LBNM)* | *(A2_2LBIN)* | *(A2_2LBDT)* |
| c. *(A2_3LBNM)* | *(A2_3LBIN)* | *(A2_3LBDT)* |
| d. *(A2_4LBNM)* | *(A2_4LBIN)* | *(A2_4LBDT)* |
| e. *(A2_5LBNM)* | *(A2_5LBIN)* | *(A2_5LBDT)* |

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

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

   a. Have all Medical Monitor requests been addressed?*(A2RQADDR)*

   ☐ 01-Yes

# Additional Selection Options for AD2

**Sequence number *(AESEQNO)* (key field):**

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

# Serious Adverse Event Medical (AD3)

Version: 1.01; 12-10-20

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

1. Was this determined to be a serious adverse event?*(A3SAE)* ☐ 0-No ☐ 1-Yes
2. Was this event considered associated with the study medication?*(A3RELDRG)* ☐ 00-No ☐ 01-Yes ☐ 96-N/A
3. Was this event expected?*(A3EXPECT)* ☐ 0-No ☐ 1-Yes
4. Is this a standard expedited/reportable event *(i.e., is it serious, unexpected and related to therapy)*?*(A3EXPFDA)* ☐ 00-No ☐ 01-Yes ☐ 96-N/A
   a. If "No", is this an expedited/reportable event for other reasons?*(A3EXPOTH)* ☐ 0-No ☐ 1-Yes
5. Does the protocol need to be modified based on this event?*(A3MPROT)* ☐ 0-No ☐ 1-Yes
6. Does the consent form need to be modified based on this event?*(A3MCNST)* ☐ 0-No ☐ 1-Yes
7. Is the review complete?*(A3REVDNE)* ☐ 0-No ☐ 1-Yes
   a. If "No", what additional information is required:*(A3ADDINF)*

Assessed by:*(A3ASRID)* (initials)

Reviewed by:*(A3REVID)* (initials)

Comments:*(A3COMM)*

# Additional Selection Options for AD3

**Sequence number *(AESEQNO)* (key field):**

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

# Concomitant Medications (CMX)

Version: 1.01; 05-19-21

**Segment *(PROTSEG)*:** B, E
**Visit Number *(VISNO)*:**

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

*Please use this form to capture concomitant medications taken in the past week other than MOUD.*

Medications

1.*( CMMED01)*
2.*( CMMED02)*
3.*( CMMED03)*
4.*( CMMED04)*
5.*( CMMED05)*
6.*( CMMED06)*
7.*( CMMED07)*
8.*( CMMED08)*
9.*( CMMED09)*
10.*(C MMED10)*

Comments:*(CMXCOMM)*

# Clinic Urine Toxicology (CUT)

Version: 1.01; 02-15-22

**Segment *(PROTSEG)*:** B, C, D, E
**Sequence number *(SEQNUM2)*:**

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

1. Was a urine drug screen performed?*(UDTEST1)* ☐ 0-No ☐ 1-Yes

   a. If "No", reason:*(UDNORSN1)*

   01-Participant reported being unable to provide sample
   02-Participant refused to provide sample
   04-Study staff error
   92-COVID-19: Illness
   93-COVID-19: Public health measures
   94-COVID-19: Other
   99-Other

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

2. Date urine specimen collected:*(UDCOLDT)* *(mm/dd/yyyy)*
3. Was the urine specimen temperature within range? (90 - 100 °F)*(UDTEMP1)* ☐ 00-No ☐ 01-Yes ☐ 97-Not measured
4. Was the urine specimen determined to be adulterated?*(UDADULT1)* ☐ 00-No ☐ 01-Yes ☐ 97-Not measured
5. Urine Drug Screen Result(s):

| Drug Name (Abbreviation) | 00-Negative | 01-Positive | 02-Invalid | 97-Not Measured |
|---|---|---|---|---|
| Amphetamine (500 ng) (AMP): | *(UDAMP1)* ☐ | ☐ | ☐ | ☐ |
| Barbiturate (300 ng) (BAR): | *(UDBAR1)* ☐ | ☐ | ☐ | ☐ |
| Buprenorphine (10 ng) (BUP): | *(UDBUP1)* ☐ | ☐ | ☐ | ☐ |
| Benzodiazepines (300 ng) (BZO): | *(UDBZO1)* ☐ | ☐ | ☐ | ☐ |
| Cocaine (150 ng) (COC): | *(UDCOC1)* ☐ | ☐ | ☐ | ☐ |
| Ecstasy (500 ng) (MDMA): | *(UDMDA1)* ☐ | ☐ | ☐ | ☐ |
| Methamphetamine (500 ng) (MET): | *(UDMET1)* ☐ | ☐ | ☐ | ☐ |
| Methadone (300 ng) (MTD): | *(UDMTD1)* ☐ | ☐ | ☐ | ☐ |
| Opiates (300 ng) (OPI): | *(UDOPI31)* ☐ | ☐ | ☐ | ☐ |
| Oxycodone (100 ng) (OXY): | *(UDOXY1)* ☐ | ☐ | ☐ | ☐ |
| Phencyclidine (25 ng) (PCP): | *(UDPCP1)* ☐ | ☐ | ☐ | ☐ |
| Marijuana (50 ng) (THC): | *(UDTHC1)* ☐ | ☐ | ☐ | ☐ |
| Fentanyl (20 ng) (FEN): | *(UDFEN1)* ☐ | ☐ | ☐ | ☐ |

Comments:*(CUTCOMM)*

# Additional Selection Options for CUT

**Sequence number *(SEQNUM2)* (key field):**

01-1
02-2
03-3
04-4
05-5
06-6
07-7
08-8
09-9
10-10

# DSM-5 Checklist (DSM)

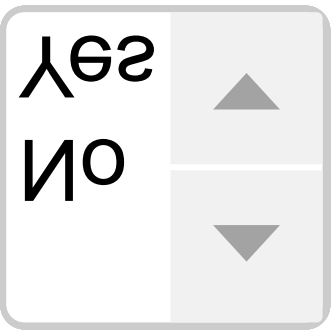
Version: 1.01; 03-02-21

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

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

| | Opioids | Alcohol | Amphetamines | Cannabis | Cocaine | Sedatives |
|---|---|---|---|---|---|---|
| **1** Have you used [insert substance] in the past 12 months? | No Yes *(DSOPI12M)* | No Yes *(DSALC12M)* | No Yes *(DSAMP12M)* | No Yes *(DSTHC12M)* | No Yes *(DSCOC12M* | No Yes *(DSSED12M)* |
| **2** *Suggested prompt*: "Have you often found that when you start using [insert substance], you ended up taking more than you intended to? For example, you planned to have a small amount of [insert substance], but you needed up having much more; or you ended up using for a longer period than intended?"<br>The substance is often taken in larger amounts or over a longer period than was intended: | No Yes *(DSOPIDOS)* | No Yes *(DSALCDOS)* | No Yes *(DSAMPDOS)* | No Yes *(DSTHCDOS)* | No Yes *(DSCOCDOS)* | No Yes *(DSSEDDOS)* |
| **3** *Suggested prompt*: "Have you wanted to stop or cut down or control your use of [insert substance]?"<br><br>There is a persistent desire or unsuccessful efforts to cut down or control substance use: | No Yes *(DSOPICUT)* | No Yes *(DSALCCUT)* | No Yes *(DSAMPCUT)* | No Yes *(DSTHCCUT)* | No Yes *(DSCOCCUT)* | No Yes *(DSSEDCUT* |
| **4** *Suggested prompt*: "Have you spent a lot of time getting or using [insert substance]? Or has it taken a lot of time for you to get over the effect?"<br><br>A great deal of time is spent in activities necessary to obtain the substance, use the substance, or recover from its effects: | No Yes *(DSOPITIM)* | No Yes *(DSALCTIM)* | No Yes *(DSAMPTIM)* | No Yes *(DSTHCTIM)* | No Yes *(DSCOCTIM)* | No Yes *(DSSEDTIM)* |
| **5** *Suggested prompt*: "Have you had a strong desire or urge to use [insert substance] in between those times when you were using? Has there been a time when you had such strong cravings or urges to use that you had trouble thinking about anything else?"<br><br>Craving or a strong desire or urge to use a specific substance: | No Yes *(DSOPICRA)* | No Yes *(DSALCCRA)* | No Yes *(DSAMPCRA)* | No Yes *(DSTHCCRA)* | No Yes *(DSCOCCRA)* | No Yes *(DSSEDCRA)* |

| | Opioids | Alcohol | Amphetamines | Cannabis | Cocaine | Sedatives |
|---|---|---|---|---|---|---|
| **6** *Suggested prompt*: "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?"<br><br>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): | *(DSOPIOBL)* | *(DSALCOBL)* | *(DSAMPOBL)* | *(DSTHCOBL)* | *(DSCOCOBL)* | *(DSSEDOBL)* |
| **7** *Suggested prompt*: "Have you continued to use even though you knew that the drug 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?"<br><br>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: | *(DSOPICON)* | *(DSALCCON)* | *(DSAMPCON)* | *(DSTHCCON)* | *(DSCOCCON)* | *(DSSEDCON* |
| **8** *Suggested prompt*: "Have you had to give up or spend less time working, enjoying hobbies, or being with others because of your drug use?"<br><br>Important social, occupational, or recreational activities are given up or reduced because of substance use: | *(DSOPIACT)* | *(DSALCACT)* | *(DSAMPACT)* | *(DSTHCACT)* | *(DSCOCACT)* | *(DSSEDACT)* |
| **9** *Suggested prompt*: "Have you ever gotten high before doing something that requires coordination or concentration like driving, boating, climbing a ladder, or operating heavy machinery?"<br><br>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): | *(DSOPIHAZ)* | *(DSALCHAZ)* | *(DSAMPHAZ)* | *(DSTHCHAZ)* | *(DSCOCHAZ)* | *(DSSEDHAZ)* |
| **10** *Suggested prompt*: "Has your use of [insert substance] caused problems with other people such as with family members, friends or people at work? Did you get into arguments about your use or fights when you are using? Did you keep using despite these problems?"<br><br>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): | *(DSOPISOC)* | *(DSALCSOC)* | *(DSAMPSOC)* | *(DSTHCSOC)* | *(DSCOCSOC)* | *(DSSEDSOC)* |



| | Opioids | Alcohol | Amphetamines | Cannabis | Cocaine | Sedatives |
|---|---|---|---|---|---|---|
| **11** *Suggested prompt*: "Have you found you needed to use much more [insert substance] to get the same effect that you did when you first started taking it?"<br><br>Tolerance, as defined by either of the following:<br>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><br>*(Note: Tolerance is not counted for those taking medications under medical supervision such as analgesics, antidepressants, anti-anxiety medications or beta-blockers.)* | *(DSOPITOL)* | *(DSALCTOL)* | *(DSAMPTOL)* | *(DSTHCTOL)* | *(DSCOCTOL)* | *(DSSEDTOL)* |
| **12** *Suggested prompt*: "Have you had 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?"<br><br>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><br>*(Note: Withdrawal is not counted for those taking medications under medical supervision such as analgesics, antidepressants, anti-anxiety medications or beta-blockers.)* | *(DSOPIWIT)* | *(DSALCWIT)* | *(DSAMPWIT)* | *(DSTHCWIT)* | *(DSCOCWIT)* | *(DSSEDWIT)* |
| | **Opioids** | **Alcohol** | **Amphetamines** | **Cannabis** | **Cocaine** | **Sedatives** |
| **Severity of Substance Use Disorder:** | *(DSOPISO)* | *(DSALCSO)* | *(DSAMPSO)* | *(DSTHCSO)* | *(DSCOCSO)* | *(DSSEDSO)* |

Comments:
*(DSMCOMM)*

None
Mild
Moderate
Severe

# Death Form (DTH)

Version: 1.00; 02-10-21

1. Date of Death:*(DTDTHDT)* *(mm/dd/yyyy)*
2. Date staff notified of death:*(DTNTFYDT)* *(mm/dd/yyyy)*
3. Date of last contact with participant:*(DTCNTCDT)* *(mm/dd/yyyy)*
4. Was there suspected or confirmed opioid overdose?*(DTOPIOD)* ☐ 00-No ☐ 01-Yes ☐ 97-Unknown
   a. If "Yes", date of suspected or confirmed opioid overdose?*(DTOPIDT)* *(mm/dd/yyyy)*

5. Primary and secondary causes of death:
   *This should be a "verbatim" extraction of the text from the source document.*
   a. Primary Cause of Death:*(DTPCOD)*
   b. Secondary Cause of Death:*(DT2COD)*

6. Source for cause of death:*(DTSOURCE)*

   01-Medical chart
   02-Death certificate
   03-Autopsy report
   04-Treating physician
   05-NDI
   99-Other

   a. If "Other", specify:*(DTSRCESP)*

7. Was an autopsy performed?*(DTAUTPSY)* ☐ 00-No ☐ 01-Yes ☐ 97-Unknown
   a. If "Yes", can a copy of the autopsy report be obtained?*(DTAUTCPY)* ☐ 00-No ☐ 01-Yes ☐ 97-Unknown

8. Did death occur while the participant was hospitalized?*(DTHSPDTH)* ☐ 00-No ☐ 01-Yes ☐ 97-Unknown
   a. If "No", where did the death occur?*(DTDTHLOC)*

9. Was drug use a contributing factor in the death?*(DTDRUG)* ☐ 00-No ☐ 01-Yes ☐ 97-Unknown
   a. If "Yes", was the drug an opioid?*(DTOPIDRG)* ☐ 00-No ☐ 01-Yes ☐ 97-Unknown
10. Was alcohol a contributing factor in the death?*(DTALCOHL)* ☐ 00-No ☐ 01-Yes ☐ 97-Unknown

11. Short narrative about the circumstance surrounding the death of the participant: *(DTNARRTV)*

Comments:*(DTHCOMM)*

**If available, upload the autopsy, death report, discharge note, or any other supporting documentation.**

# 0097B (ENR)

Version: 2.01; 08-11-21

1. Date of written informed consent:*(STARTDT)* _____ *(mm/dd/yyyy)*
2. Was consent for genetics sample obtained?*(S97GCSNT)* ☐ 0-No ☐ 1-Yes

   Comments:*(S97COMM)*

# Medical Psychiatric History (MHX)

Version: 1.00; 01-19-21

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

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

## Medical and Psychiatric History

| Medical Condition | History of the Condition | If "Yes", Specify | Condition Present Currently | Medication Taken Currently |
|---|---|---|---|---|
| 1. Eye disorders: | *(MHEYEH)* ☐ 0-No ☐ 1-Yes | *(MHEYESP)* | *(MHEYEC)* ☐ 0-No ☐ 1-Yes | *(MHEYEM)* ☐ 0-No ☐ 1-Yes |
| 2. Ear disorders: | *(MHEARH)* ☐ 0-No ☐ 1-Yes | *(MHEARSP)* | *(MHEARC)* ☐ 0-No ☐ 1-Yes | *(MHEARM)* ☐ 0-No ☐ 1-Yes |
| 3. Respiratory and throat disorders: | *(MHRESPH)* ☐ 0-No ☐ 1-Yes | *(MHRESPSP)* | *(MHRESPC)* ☐ 0-No ☐ 1-Yes | *(MHRESPM)* ☐ 0-No ☐ 1-Yes |
| 4. Cardiovascular disorders: | *(MHCARDH)* ☐ 0-No ☐ 1-Yes | *(MHCARDSP)* | *(MHCARDC)* ☐ 0-No ☐ 1-Yes | *(MHCARDM)* ☐ 0-No ☐ 1-Yes |
| 5. Endocarditis: | *(MHENDH)* ☐ 0-No ☐ 1-Yes | *(MHENDSP)* | *(MHENDC)* ☐ 0-No ☐ 1-Yes | *(MHENDM)* ☐ 0-No ☐ 1-Yes |
| 6. Liver and gallbladder disorders: | *(MHLIVRH)* ☐ 0-No ☐ 1-Yes | *(MHLIVRSP)* | *(MHLIVRC)* ☐ 0-No ☐ 1-Yes | *(MHLIVRM)* ☐ 0-No ☐ 1-Yes |
| 7. Other gastrointestinal disorders: | *(MHGIH)* ☐ 0-No ☐ 1-Yes | *(MHGISP)* | *(MHGIC)* ☐ 0-No ☐ 1-Yes | *(MHGIM)* ☐ 0-No ☐ 1-Yes |
| 8. Skin disorders: | *(MHSKINH)* ☐ 0-No ☐ 1-Yes | *(MHSKINSP)* | *(MHSKINC)* ☐ 0-No ☐ 1-Yes | *(MHSKINM)* ☐ 0-No ☐ 1-Yes |
| 9. Cellulitis: | *(MHCELH)* ☐ 0-No ☐ 1-Yes | *(MHCELSP)* | *(MHCELC)* ☐ 0-No ☐ 1-Yes | *(MHCELM)* ☐ 0-No ☐ 1-Yes |
| 10. Musculoskeletal disorders: | *(MHMUSCH)* ☐ 0-No ☐ 1-Yes | *(MHMUSCSP)* | *(MHMUSCC)* ☐ 0-No ☐ 1-Yes | *(MHMUSCM)* ☐ 0-No ☐ 1-Yes |
| 11. Osteomyelitis: | *(MHOSTH)* ☐ 0-No ☐ 1-Yes | *(MHOSTSP)* | *(MHOSTC)* ☐ 0-No ☐ 1-Yes | *(MHOSTM)* ☐ 0-No ☐ 1-Yes |
| 12. Metabolic disorders: | *(MHMETAH)* ☐ 0-No ☐ 1-Yes | *(MHMETASP)* | *(MHMETAC)* ☐ 0-No ☐ 1-Yes | *(MHMETAM)* ☐ 0-No ☐ 1-Yes |
| 13. Endocrine disorders: | *(MHENDOH)* ☐ 0-No ☐ 1-Yes | *(MHENDOSP)* | *(MHENDOC)* ☐ 0-No ☐ 1-Yes | *(MHENDOM)* ☐ 0-No ☐ 1-Yes |
| 14. Renal and urinary tract disorders: | *(MHRENLH)* ☐ 0-No ☐ 1-Yes | *(MHRENLSP)* | *(MHRENLC)* ☐ 0-No ☐ 1-Yes | *(MHRENLM)* ☐ 0-No ☐ 1-Yes |
| 15. Reproductive system and breast disorders: | *(MHREPOH)* ☐ 0-No ☐ 1-Yes | *(MHREPOSP)* | *(MHREPOC)* ☐ 0-No ☐ 1-Yes | *(MHREPOM)* ☐ 0-No ☐ 1-Yes |
| 16. Epilepsy or seizure disorder: | *(MHELPYH)* ☐ 0-No ☐ 1-Yes | *(MHELPYSP)* | *(MHELPYC)* ☐ 0-No ☐ 1-Yes | *(MHELPYM)* ☐ 0-No ☐ 1-Yes |
| 17. Clinically significant neurological damage: | *(MHNEURH)* ☐ 0-No ☐ 1-Yes | *(MHNEURSP)* | *(MHNEURC)* ☐ 0-No ☐ 1-Yes | *(MHNEURM)* ☐ 0-No ☐ 1-Yes |
| 18. Other nervous system disorders: | *(MHNERVH)* ☐ 0-No ☐ 1-Yes | *(MHNERVSP)* | *(MHNERVC)* ☐ 0-No ☐ 1-Yes | *(MHNERVM)* ☐ 0-No ☐ 1-Yes |
| 19. HIV: | *(MHHIVH)* ☐ 0-No ☐ 1-Yes | *(MHHIVSP)* | *(MHHIVC)* ☐ 0-No ☐ 1-Yes | *(MHHIVM)* ☐ 0-No ☐ 1-Yes |
| 20. Hepatitis C: | *(MHHEPCH)* ☐ 0-No ☐ 1-Yes | *(MHHEPCSP)* | *(MHHEPCC)* ☐ 0-No ☐ 1-Yes | *(MHHEPCM)* ☐ 0-No ☐ 1-Yes |

| Psychiatric Condition | History of the Condition | If "Yes", Specify | Condition Present Currently | Medication Taken Currently |
|---|---|---|---|---|
| 21. Anxiety or panic disorder: | *(MHANXH)* ☐ 0-No ☐ 1-Yes | *(MHANXSP)* | *(MHANXC)* ☐ 0-No ☐ 1-Yes | *(MHANXM)* ☐ 0-No ☐ 1-Yes |
| 22. Attention Deficit Hyperactivity Disorder: | *(MHADHDH)* ☐ 0-No ☐ 1-Yes | *(MHADHDSP)* | *(MHADHDC)* ☐ 0-No ☐ 1-Yes | *(MHADHDM)* ☐ 0-No ☐ 1-Yes |
| 23. Bipolar Disorder: | *(MHBPLRH)* ☐ 0-No ☐ 1-Yes | *(MHBPLRSP)* | *(MHBPLRC)* ☐ 0-No ☐ 1-Yes | *(MHBPLRM)* ☐ 0-No ☐ 1-Yes |
| 24. Eating Disorder: | *(MHEATH)* ☐ 0-No ☐ 1-Yes | *(MHEATSP)* | *(MHEATC)* ☐ 0-No ☐ 1-Yes | *(MHEATM)* ☐ 0-No ☐ 1-Yes |
| 25. Major Depressive Disorder: | *(MHMDDH)* ☐ 0-No ☐ 1-Yes | *(MHMDDSP)* | *(MHMDDC)* ☐ 0-No ☐ 1-Yes | *(MHMDDM)* ☐ 0-No ☐ 1-Yes |
| 26. Schizophrenia: | *(MHSCHZH)* ☐ 0-No ☐ 1-Yes | *(MHSCHZSP)* | *(MHSCHZC)* ☐ 0-No ☐ 1-Yes | *(MHSCHZM)* ☐ 0-No ☐ 1-Yes |
| 27. Suicidal ideation: | *(MHSIDH)* ☐ 0-No ☐ 1-Yes | *(MHSIDSP)* | *(MHSIDC)* ☐ 0-No ☐ 1-Yes | *(MHSIDM)* ☐ 0-No ☐ 1-Yes |
| 28. Suicidal behavior: | *(MHSBEHH)* ☐ 0-No ☐ 1-Yes | *(MHSBEHSP)* | *(MHSBEHC)* ☐ 0-No ☐ 1-Yes | *(MHSBEHM)* ☐ 0-No ☐ 1-Yes |
| 29. Homicidal ideation: | *(MHHIDH)* ☐ 0-No ☐ 1-Yes | *(MHHIDSP)* | *(MHHIDC)* ☐ 0-No ☐ 1-Yes | *(MHHIDM)* ☐ 0-No ☐ 1-Yes |
| 30. Homicidal behavior: | *(MHHBEHH)* ☐ 0-No ☐ 1-Yes | *(MHHBEHSP)* | *(MHHBEHC)* ☐ 0-No ☐ 1-Yes | *(MHHBEHM)* ☐ 0-No ☐ 1-Yes |
| 31. Violent behavior: | *(MHVBEHH)* ☐ 0-No ☐ 1-Yes | *(MHVBEHSP)* | *(MHVBEHC)* ☐ 0-No ☐ 1-Yes | *(MHVBEHM)* ☐ 0-No ☐ 1-Yes |
| 32. Psychotic episodes not specified above: | *(MHPSYEH)* ☐ 0-No ☐ 1-Yes | *(MHPSYESP)* | *(MHPSYEC)* ☐ 0-No ☐ 1-Yes | *(MHPSYEM)* ☐ 0-No ☐ 1-Yes |
| 33. Other psychiatric disorder: | *(MHPSYOH)* ☐ 0-No ☐ 1-Yes | *(MHPSYOSP)* | *(MHPSYOC)* ☐ 0-No ☐ 1-Yes | *(MHPSYOM)* ☐ 0-No ☐ 1-Yes |

| Other Conditions Not Listed Above | Specific Details | Condition Present Currently | Medication Taken Currently |
|---|---|---|---|
| 34. *(MHOTHR1)* | *(MHOTH1SP)* | *(MHOTHR1C)* ☐ 0-No ☐ 1-Yes | *(MHOTHR1M)* ☐ 0-No ☐ 1-Yes |
| 35. *(MHOTHR2)* | *(MHOTH2SP)* | *(MHOTHR2C)* ☐ 0-No ☐ 1-Yes | *(MHOTHR2M)* ☐ 0-No ☐ 1-Yes |
| 36. *(MHOTHR3)* | *(MHOTH3SP)* | *(MHOTHR3C)* ☐ 0-No ☐ 1-Yes | *(MHOTHR3M)* ☐ 0-No ☐ 1-Yes |

## Medications

37. Are you currently taking any medications?*(MHMEDUSE)* ☐ 0-No ☐ 1-Yes

a. If "Yes", what medications are you taking?*(MHMEDSP)*

## History of Surgical/Medical Procedures and Hospitalizations

38. Does the participant have a history of surgical and/or medical procedures and/or medical hospitalizations? ☐ 0-No ☐ 1-Yes *(MHSUGHOS)*

*If the participant has had major surgery, provide most important/significant surgical/medical event data below, including date of surgery/event. If the participant remembers only the year, then record "06" for the month and "15" for the day.*

| Type of Surgery and/or Medical Procedure and/or Medical Hospitalization | Surgery/Procedure Date |
|---|---|
| a.*(MHSGH1)* | *(MHSGH1DT)* *(mm/dd/yyyy)* |
| b.*(MHSGH2)* | *(MHSGH2DT)* *(mm/dd/yyyy)* |
| c.*(MHSGH3)* | *(MHSGH3DT)* *(mm/dd/yyyy)* |
| d.*(MHSGH4)* | *(MHSGH4DT)* *(mm/dd/yyyy)* |
| e.*(MHSHG5)* | *(MHSGH5DT)* *(mm/dd/yyyy)* |

## Withdrawal

39. On a scale of 0 to 10, how uncomfortable would the participant describe opioid withdrawal to be, with 0 being none, 1 being little discomfort, 5 being moderate discomfort, and 10 being almost unbearable? *(MHUNCOMF)* *(xx)*

## Opioid Treatment History

| | Has the participant previously engaged in MOUD with: | If "Yes" , was the treatment successful? |
|---|---|---|
| 40. Sublingual buprenorphine: | *(MHSLBUP)* ☐ 0-No ☐ 1-Yes | *(MHSLBUPS)* ☐ 0-No ☐ 1-Yes |
| 41. Injectable buprenorphine: | *(MHINJBUP)* ☐ 0-No ☐ 1-Yes | *(MHINBUPS)* ☐ 0-No ☐ 1-Yes |
| 42. Implantable buprenorphine: | *(MHIMPBUP)* ☐ 0-No ☐ 1-Yes | *(MHIMBUPS)* ☐ 0-No ☐ 1-Yes |
| 43. Methadone: | *(MHMTD)* ☐ 0-No ☐ 1-Yes | *(MHMTDS)* ☐ 0-No ☐ 1-Yes |
| 44. Oral naltrexone: | *(MHORNAL)* ☐ 0-No ☐ 1-Yes | *(MHORNALS)* ☐ 0-No ☐ 1-Yes |
| 45. Implantable naltrexone: | *(MHIMPNAL)* ☐ 0-No ☐ 1-Yes | *(MHIPNALS)* ☐ 0-No ☐ 1-Yes |
| 46. Injectable naltrexone: | *(MHINJNAL)* ☐ 0-No ☐ 1-Yes | *(MHIJNALS)* ☐ 0-No ☐ 1-Yes |
| 47. Other, specify:*(MHOPTXSP)* | *(MHOPTXOT)* ☐ 0-No ☐ 1-Yes | *(MHOTOPIS)* ☐ 0-No ☐ 1-Yes |

48. How many times have you attempted opioid detoxification?*(MHOPIDTX)* *(xx)*

49. How many did you complete?*(MHCOMPLT)* *(xx)*

50. Have you previously attempted induction onto XR-NTX but were not successful?*(MHNALNOS)* ☐ 0-No ☐ 1-Yes

Comments:*(MHXCOMM)*

# Pregnancy and Birth Control Assessment (PBC)

Version: 1.00; 01-19-21

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

*Complete this form only for biologically female participants.*

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

1. Is the participant of childbearing potential?*(PBCHILD)* ☐ 0-No ☐ 1-Yes
2. Is the participant breastfeeding?*(PBBSTFED)* ☐ 0-No ☐ 1-Yes
3. Does the participant agree to use an acceptable method of birth control?*(PBUSEBC)* ☐ 0-No ☐ 1-Yes

If "Yes", select all that apply:

a. Oral contraceptives:*(PBORALCN)* ☐ 0-No ☐ 1-Yes
b. Contraceptive patch:*(PBPATCH)* ☐ 0-No ☐ 1-Yes
c. Barrier (diaphragm or condom):*(PBBARRIR)* ☐ 0-No ☐ 1-Yes
d. Levonorgestrel implant:*(PBLEVIMP)* ☐ 0-No ☐ 1-Yes
e. Medroxyprogesterone acetate injection:*(PBMEDINJ)* ☐ 0-No ☐ 1-Yes
f. Complete abstinence from sexual intercourse:*(PBABSTIN)* ☐ 0-No ☐ 1-Yes
g. Hormonal vaginal contraceptive ring:*(PBRING)* ☐ 0-No ☐ 1-Yes
h. Surgical sterilization:*(PBSURGSZ)* ☐ 0-No ☐ 1-Yes
i. Intrauterine contraceptive device (IUD):*(PBINTDEV)* ☐ 0-No ☐ 1-Yes
j. Other:*(PBBCOTH)* ☐ 0-No ☐ 1-Yes

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

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

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

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

Comments:*(PBCCOMM)*

# Protocol Deviation (PDV)

Version: 2.02; 02-24-22

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

1. Is this deviation related to one or more participants?*(PDPPTREL)* ☐ 0-No ☐ 1-Yes
   a. If "Yes", how many participants?*(PDPRELNO)*

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

*Select related participants:*

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

Participant ID 20:*(PDPPT20)*

999999999999999-DUMMYPARTICIPANTID

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

3. Deviation type:*(PDTYPE)*

010-INFORMED CONSENT/ASSENT PROCEDURES
01A--- No consent/assent obtained
01B--- Unauthorized assessments and/or procedures conducted prior to obtaining informed consent/assent
01C--- Non IRB approved/outdated/obsolete informed consent/assent documents used
01Y--- Other major informed consent/assent procedures issues (specify)
*Additional Options Listed Below

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

4. Reason for Protocol Deviation: *(select all that apply)*

a. Research staff error:*(PDRSSTFF)* ☐ 0-No ☐ 1-Yes
b. Hospital error:*(PDRSHSP)* ☐ 0-No ☐ 1-Yes
c. Laboratory error:*(PDRSLAB)* ☐ 0-No ☐ 1-Yes
d. Pharmacy error:*(PDRSPHRM)* ☐ 0-No ☐ 1-Yes
e. Equipment/supply failure:*(PDRSEQSP)* ☐ 0-No ☐ 1-Yes
f. Issue with Advantage eClinical (e.g., system down, system glitch):*(PDRSEDC)* ☐ 0-No ☐ 1-Yes
g. Participant unable to comply:*(PDRSPTNC)* ☐ 0-No ☐ 1-Yes
h. Participant refusal:*(PDRSPTRF)* ☐ 0-No ☐ 1-Yes
i. Investigator/study decision:*(PDRSINDC)* ☐ 0-No ☐ 1-Yes
j. Other:*(PDRSOTHR)* ☐ 0-No ☐ 1-Yes
1. If "Other", specify:*(PDRSOTSP)*

5. Is this deviation related to COVID-19?*(PDCVD19)* ☐ 0-No ☐ 1-Yes

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

7. Was/will there be corrective action for this event?*(PDCORRNY)* ☐ 0-No ☐ 1-Yes

a. If "No", describe why corrective action was not or will not be taken:*(PDNOCRSP)*

b. If "Yes", which of the following corrective actions were/will be taken: *(select all that apply)*

1. Participant consent/reconsent was/will be obtained:*(PDCACNST)* ☐ 0-No ☐ 1-Yes
2. Research staff corrected/will correct error(s) and/or completed/will complete document(s):*(PDCASTCR)* ☐ 0-No ☐ 1-Yes
3. Participant corrected/will correct error(s) and/or completed/will complete document(s):*(PDCAPTCR)* ☐ 0-No ☐ 1-Yes
4. Document(s) was/will be moved to correct file location(s):*(PDCADCMV)* ☐ 0-No ☐ 1-Yes
5. Participant was/will be withdrawn from study:*(PDCAPTWD)* ☐ 0-No ☐ 1-Yes
6. Study drug administration was/will be halted:*(PDCADGSP)* ☐ 0-No ☐ 1-Yes
7. Study assessment was/will be performed or repeated:*(PDCAASAD)* ☐ 0-No ☐ 1-Yes
8. Other:*(PDCAOTHR)* ☐ 0-No ☐ 1-Yes
**1.** If "Other", specify:*(PDCAOTSP)*

c. As needed or requested, provide additional details about the corrective action plan:*(PDCAPSP)*

8. Brief description of the plan to prevent recurrence: *(select all that apply)*

a. Complete local retraining:*(PDPLPTRN)* ☐ 0-No ☐ 1-Yes
1. If "Complete local retraining", specify:*(PDPLPSP)*
b. Revise local SOP(s):*(PDPLPRV)* ☐ 0-No ☐ 1-Yes
c. Recalibrate/fix or replace faulty equipment/supplies:*(PDPLPEQ)* ☐ 0-No ☐ 1-Yes
d. Remove and/or replace incorrect/outdated document(s) from file(s)*(PDPLPDOC)* ☐ 0-No ☐ 1-Yes
e. No site action needed:*(PDPLPNAN)* ☐ 0-No ☐ 1-Yes
f. Other:*(PDPLPOTH)* ☐ 0-No ☐ 1-Yes
1. If "Other", specify:*(PDPLPOSP)*

9. Is this deviation reportable to your IRB?*(PDIRBREP)* ☐ 0-No ☐ 1-Yes

a. If "Yes", will the IRB be notified at the time of continuing review?*(PDIRBCON)* ☐ 0-No ☐ 1-Yes

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

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

Comments:*(PDVCOMM)*

# Additional Selection Options for PDV

**Protocol deviation number *(PDSEQNO)* (key field):**

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

**If "Yes", how many participants?**

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

**Deviation type:**

010--- INFORMED CONSENT/ASSENT PROCEDURES
01A--- No consent/assent obtained
01B--- Unauthorized assessments and/or procedures conducted prior to obtaining informed consent/assent
01C--- Non IRB approved/outdated/obsolete informed consent/assent documents used
01Y--- Other major informed consent/assent procedures issues (specify)
020-INCLUSION/EXCLUSIONCRITERIA
02A--- Ineligible participant enrolled/inclusion/exclusion criteria not met or eligibility not fully assessed prior to enrollment
02Z--- Other inclusion/exclusion criteria issues (specify)
040-LABORATORY ASSESSMENTS
04Y--- Other laboratory assessment issues - Minor (specify)
04Z--- Other laboratory assessments issues - Major (specify)
050-STUDY PROCEDURES/ASSESSMENTS
05A--- Study assessment/procedures not followed in accordance with study protocol
05Z--- Other study procedures/assessments issues (specify)
060-ADVERSE EVENT
06A--- AE not reported
06B--- SAE not reported
06C--- AE/SAE reported out of protocol specified reporting timeframe
06D--- AE/SAE not elicited, observed and/or documented as per protocol
06E--- Safety assessment (e.g., labs, ECG, clinical referral to care) not conducted per protocol
06Z--- Other adverse events issues (specify)
070-RANDOMIZATION PROCEDURES
07A--- Stratification error
07Z--- Other randomization procedures issues (specify)
080-STUDY MEDICATION MANAGEMENT
08A--- Medication not dispensed/administered in accordance with the study protocol
08B--- Participant use of protocol prohibited medication
08Z--- Other study medication management issues (specify)
990-OTHER SIGNIFICANT DEVIATIONS
99A--- Destruction of study materials without prior authorization from sponsor
99B--- Breach of Confidentiality
99Y--- Other significant deviations issues - Minor (specify)
99Z--- Other significant deviations issues - Major (specify)

# Pregnancy Outcome 1 (PO1)

Version: 1.00; 01-19-21

**Pregnancy number *(PGSEQNUM)*:**

## Newborn Information

1. Gender:*(PO1GENDR)* ☐ 01-Male ☐ 02-Female ☐ 97-Unknown
2. Gestational age at delivery:*(PO1GESWK)* ☐ *(xx)* weeks *(PO1GESDY)* ☐ *(x)* days *(PO1GESUN)* **OR** ☐ 97-Unknown
3. Weight at delivery:*(PO1WTLBS)* ☐ *(xx)* lbs *(PO1WTOZ)* ☐ *(xx)* oz *(PO1WTUNK)* **OR** ☐ 97-Unknown
4. Apgar score at 1 minute:*(PO1APG1M)* ☐ *(xx)* *(PO11APUK)* **OR** ☐ 97-Unknown
5. Apgar score at 5 minutes:*(PO1APG5M)* ☐ *(xx)* *(PO15APUK)* **OR** ☐ 97-Unknown
6. Normal infant?*(PO1NORML)* ☐ 0-No ☐ 1-Yes
   a. If "No", is there a congenital anomaly?*(PO1CONAN)* ☐ 00-No ☐ 01-Yes ☐ 97-Unknown
      1. If "Yes", specify abnormality and contributing factors:*(PO1ABNSP)*

Comments:*(PO1COMM)*

# Additional Selection Options for PO1

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

01-1

02-2

03-3

04-4

# Pregnancy Outcome 2 (PO2)

Version: 1.00; 01-29-21

**Pregnancy number *(PGSEQNUM)*:**

## Newborn Information

1. Gender:*(PO2GENDR)* ☐ 01-Male ☐ 02-Female ☐ 97-Unknown
2. Gestational age at delivery:*(PO2GESWK)* ☐ *(xx)* weeks *(PO2GESDY)* ☐ *(x)* days *(PO2GESUN)* **OR** ☐ 97-Unknown
3. Weight at delivery:*(PO2WTLBS)* ☐ *(xx)* lbs *(PO2WTOZ)* ☐ *(xx)* oz *(PO2WTUNK)* **OR** ☐ 97-Unknown
4. Apgar score at 1 minute:*(PO2APG1M)* ☐ *(xx)* *(PO21APUK)* **OR** ☐ 97-Unknown
5. Apgar score at 5 minutes:*(PO2APG5M)* ☐ *(xx)* *(PO25APUK)* **OR** ☐ 97-Unknown
6. Normal infant?*(PO2NORML)* ☐ 0-No ☐ 1-Yes
   a. If "No", is there a congenital anomaly?*(PO2CONAN)* ☐ 00-No ☐ 01-Yes ☐ 97-Unknown
      1. If "Yes", specify abnormality and contributing factors:*(PO2ABNSP)*

Comments:*(PO2COMM)*

# Additional Selection Options for PO2

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

01-1

02-2

03-3

04-4

# Pregnancy Outcome 3 (PO3)

Version: 1.00; 01-19-21

**Pregnancy number *(PGSEQNUM)*:**

## Newborn Information

1. Gender:*(PO3GENDR)* ☐ 01-Male ☐ 02-Female ☐ 97-Unknown
2. Gestational age at delivery:*(PO3GESWK)* ☐ *(xx)* weeks *(PO3GESDY)* ☐ *(x)* days *(PO3GESUN)* **OR** ☐ 97-Unknown
3. Weight at delivery:*(PO3WTLBS)* ☐ *(xx)* lbs *(PO3WTOZ)* ☐ *(xx)* oz *(PO3WTUNK)* **OR** ☐ 97-Unknown
4. Apgar score at 1 minute:*(PO3APG1M)* ☐ *(xx)* *(PO31APUK)* **OR** ☐ 97-Unknown
5. Apgar score at 5 minutes:*(PO3APG5M)* ☐ *(xx)* *(PO35APUK)* **OR** ☐ 97-Unknown
6. Normal infant?*(PO3NORML)* ☐ 0-No ☐ 1-Yes
   a. If "No", is there a congenital anomaly?*(PO3CONAN)* ☐ 00-No ☐ 01-Yes ☐ 97-Unknown
      1. If "Yes", specify abnormality and contributing factors:*(PO3ABNSP)*

Comments:*(PO3COMM)*

# Additional Selection Options for PO3

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

01-1

02-2

03-3

04-4

# Pregnancy Outcome 4 (PO4)

Version: 1.00; 01-19-21

**Pregnancy number *(PGSEQNUM)*:**

## Newborn Information

1. Gender:*(PO4GENDR)* ☐ 01-Male ☐ 02-Female ☐ 97-Unknown
2. Gestational age at delivery:*(PO4GESWK)* ☐ *(xx)* weeks *(PO4GESDY)* ☐ *(x)* days *(PO4GESUN)* **OR** ☐ 97-Unknown
3. Weight at delivery:*(PO4WTLBS)* ☐ *(xx)* lbs *(PO4WTOZ)* ☐ *(xx)* oz *(PO4WTUNK)* **OR** ☐ 97-Unknown
4. Apgar score at 1 minute:*(PO4APG1M)* ☐ *(xx)* *(PO41APUK)* **OR** ☐ 97-Unknown
5. Apgar score at 5 minutes:*(PO4APG5M)* ☐ *(xx)* *(PO45APUK)* **OR** ☐ 97-Unknown
6. Normal infant?*(PO4NORML)* ☐ 0-No ☐ 1-Yes
   a. If "No", is there a congenital anomaly?*(PO4CONAN)* ☐ 00-No ☐ 01-Yes ☐ 97-Unknown
      1. If "Yes", specify abnormality and contributing factors:*(PO4ABNSP)*

Comments:*(PO4COMM)*

# Additional Selection Options for PO4

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

01-1

02-2

03-3

04-4

# Confirmed Pregnancy and Outcome (PRG)

Version: 1.00; 12-07-20

**Pregnancy number *(PGSEQNUM) (keyfield)*:** 01-1 02-2 03-3 04-4

## Information About Pregnancy

1. Date on which study staff became aware of pregnancy:*(PRGAWRDT)* _____ *(mm/dd/yyyy)*
2. How was the pregnancy confirmed? *(select all that apply)*
   a. Urine pregnancy test result:*(PRURICNF)* ☐ 0-No ☐ 1-Yes
   b. Serum pregnancy test result:*(PRSERCNF)* ☐ 0-No ☐ 1-Yes
   c. Ultrasound result:*(PRULTCNF)* ☐ 0-No ☐ 1-Yes
   d. Other:*(PROTHCNF)* ☐ 0-No ☐ 1-Yes
      1. If "Other", specify:*(PROTCNSP)* _____
3. Date on which the pregnancy was confirmed:*(PRCNFMDT)* _____ *(mm/dd/yyyy)*
4. Action taken with study medication:*(PRACTIND)*
   - 00-None
   - 01-Dose reduced
   - 02-Temporarily stopped medication
   - 03-Permanently stopped medication
5. Approximate due date:*(PRAPXDDT)* _____ *(mm/dd/yyyy)* *(PRDDTUNK)* **OR** ☐ 97-Unknown
6. Outcome of pregnancy:*(PROUTCME)*
   - 01-Vaginal delivery
   - 02-Cesarean delivery
   - 03-Miscarriage
   - 04-Termination
   - 99-Other
   - 97-Unknown

   a. If "Other", specify:*(PROTCMSP)* _____
7. Date of pregnancy outcome:*(PROTCMDT)* _____ *(mm/dd/yyyy)*
8. Number of live births:*(PRNMLIVB)*
   - 00-0
   - 01-1
   - 02-2
   - 03-3
   - 04-4
   - 99-Other
   - 97-Unknown

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

Comments:*(PRGCOMM)*

# Prisoner Status Assessment (PSA)

Version: 2.01; 09-20-21

**Segment *(PROTSEG)*:** B, E
**Visit Number *(VISNO)*:**

Date of assessment*(PSAASMDT)* _____ *(mm/dd/yyyy)*

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

1. Are you currently being made to stay in an institution (such as a substance use treatment program), by sentence of a court, due to a criminal or civil proceeding? *(PSINST)* ☐ 0-No ☐ 1-Yes
   a. If "Yes", please describe the situation:*(PSINSTSP)* _____
2. Are you currently being detained while awaiting trial, arraignment, or sentencing? *(PSTRIAL)* ☐ 0-No ☐ 1-Yes
3. Are you currently being detained as an alternative to criminal prosecution or incarceration in a jail or prison?*(PSALTPRS)* ☐ 0-No ☐ 1-Yes
4. Are you currently under house arrest, such that you are escorted to treatment or, upon discharge from treatment, you will be escorted to jail, prison, or any inpatient overnight facility as required by law?*(PSPROBHA)* ☐ 0-No ☐ 1-Yes
5. Does the participant meet the definition of "prisoner" by any local or state regulations? *(PSPRISON)* ☐ 0-No ☐ 1-Yes

Comments:*(PSACOMM)* _____

# Targeted Safety Event (TSE)

Version: 1.00; 01-19-21

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

1. Event type:*(TSEVNTYP)*

01-Fall event (likely related to medical/psychiatric condition such as dizziness, confusion with head
02-Acute change in mental status (i.e., disorientation, amnesia, cerebrovascular accident, coma)
03-Acute medical complication likely exacerbated by the stress of withdrawal (i.e., hypertensive crisis
04-Acute psychiatric symptoms (i.e., psychosis, hypomania, severe agitation, violence)

2. Specify details of event:*(TSDETLSP)*

3. Is this event related to study regimen (including all medications):*(TSRELSR)*

☐ 0-No ☐ 1-Yes

4. Date site became aware of event:*(TSAWARDT)*

*(mm/dd/yyyy)*

5. Severity:*(TSSEVERE)*

01-Mild
02-Moderate
03-Severe

6. Is this event a serious adverse event as defined by the protocol?*(TSSAE)*

☐ 0-No ☐ 1-Yes

If "Yes", SAE onset date:*(TSSAEDT)*

*(mm/dd/yyyy)*

*If "Yes", please also compete an SAE form.*

Comments:*(TSECOMM)*

# Additional Selection Options for TSE

**TSE sequence number *(TSSEQNO)* (key field):**

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

# Urine Drug Screen (UDS)

Version: 3.01; 07-30-21

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

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

1. Was a urine drug screen performed?*(UDTEST1)* ☐ 0-No ☐ 1-Yes
   a. If "No", reason:*(UDNORSN1)*

01-Participant reported being unable to provide sample
02-Participant refused to provide sample
04-Study staff error
92-COVID-19: Illness
93-COVID-19: Public health measures
94-COVID-19: Other
99-Other

   1. If "Other", specify:*(UDNOSP1)* _____

## First Urine Drug Screen

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

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

## Second Urine Drug Screen

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

01-Participant reported being unable to provide sample
02-Participant refused to provide sample
04-Study staff error
92-COVID-19: Illness
93-COVID-19: Public health measures
94-COVID-19: Other
99-Other

   1. If "Other", specify:*(UDNOSP2)* _____

8. Time 2nd urine specimen collected:*(UDCOLTM2)* ☐ *(hh:mm)*
9. Was the 2nd urine specimen temperature within the range? (90-100 °F)*(UDTEMP2)* ☐ 0-No ☐ 1-Yes
10. Was the 2nd urine specimen determined to be adulterated?*(UDADULT2)* ☐ 0-No ☐ 1-Yes

Second Urine Drug Screen Results:

| Drug Name (Abbreviation) | 00-Negative | 01-Positive | 02-Invalid |
|---|---|---|---|
| Amphetamine (500 ng) (AMP): | *(UDAMP2)* ☐ | ☐ | ☐ |
| Barbiturate (300 ng) (BAR): | *(UDBAR2)* ☐ | ☐ | ☐ |
| Buprenorphine (10 ng) (BUP): | *(UDBUP2)* ☐ | ☐ | ☐ |
| Benzodiazepines (300 ng) (BZO): | *(UDBZO2)* ☐ | ☐ | ☐ |
| Cocaine (150 ng) (COC): | *(UDCOC2)* ☐ | ☐ | ☐ |
| Ecstasy (500 ng) (MDMA): | *(UDMDA2)* ☐ | ☐ | ☐ |
| Methamphetamine (500 ng) (MET): | *(UDMET2)* ☐ | ☐ | ☐ |
| Methadone (300 ng) (MTD): | *(UDMTD2)* ☐ | ☐ | ☐ |
| *Turn urine dip card over* | | | |
| Opiates (300 ng) (OPI): | *(UDOPI32)* ☐ | ☐ | ☐ |
| Oxycodone (100 ng) (OXY): | *(UDOXY2)* ☐ | ☐ | ☐ |
| Phencyclidine (25 ng) (PCP): | *(UDPCP2)* ☐ | ☐ | ☐ |
| Marijuana (50 ng) (THC): | *(UDTHC2)* ☐ | ☐ | ☐ |
| *Single Dipstick* | | | |
| Fentanyl (20 ng) (FEN): | *(UDFEN2)* ☐ | ☐ | ☐ |

Comments:*(UDSCOMM)*