Adverse Event (AD1)

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

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

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

1. Adverse event name:*(A1DESCPT)*
2. Date site became aware of the event:*(A1AWARDT)* *(mm/dd/yyyy)*
3. Severity of event:*(A1SEVRTY)*
   - Grade 1 - Mild
   - Grade 2 - Moderate
   - Grade 3 - Severe
4. Is there a reasonable possibility that the injectable study medication caused the event?*(A1RINJ)* ☐ No ☐ Yes
   If "Yes", action taken with the injectable study medication:*(A1AINJ)*
   - None
   - Temporarily stopped injection
   - Permanently stopped injection
5. If not caused by the injectable study medication, alternative etiology:*(A1ALTESD)*
   - None apparent
   - Study disease
   - Concomitant medication
   - Other pre-existing disease or condition
   - Accident, trauma, or external factors
   - *Additional Options Listed Below

   If "Other", specify:*(A1AEPSP)*
6. Outcome of event:*(A1OUTCM)*
   - Ongoing
   - Resolved without sequelae
   - Resolved with sequelae
   - Resolved by convention
   - Death
7. Date of resolution or medically stable:*(A1RESDT)* *(mm/dd/yyyy)*

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

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

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

   b. If "Inpatient admission to hospital or prolongation of exisiting hospitalization":
   Date of hospital admission:*(A1HOSPAD)* *(mm/dd/yyyy)*
   Date of hospital discharge:*(A1HOSPDC)* *(mm/dd/yyyy)*

Comments:*(AD1COMM)*

Additional Selection Options for AD1

Event number *(AESEQNO)* (key field):
1st Adverse Event of the day
2nd Adverse Event of the day
3rd Adverse Event of the day
4th Adverse Event of the day
5th Adverse Event of the day
6th Adverse Event of the day
7th Adverse Event of the day
8th Adverse Event of the day
9th Adverse Event of the day
10th Adverse Event of the day

If not caused by the injectable study medication, alternative etiology:
Concurrent illness/condition (not pre-exisitng)
Study procedures
Other

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

NIDA Clinical Trials Network

Serious Adverse Event Summary (AD2)

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

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

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

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

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

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

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

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

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

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

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

Lab/Test	**Findings**	**Date of Test** *(mm/dd/yyyy)*
(A2_1LBNM)	*(A2_1LBIN)*	*(A2_1LBDT)*
(A2_2LBNM)	*(A2_2LBIN)*	*(A2_2LBDT)*
(A2_3LBNM)	*(A2_3LBIN)*	*(A2_3LBDT)*
(A2_4LBNM)	*(A2_4LBIN)*	*(A2_4LBDT)*
(A2_5LBNM)	*(A2_5LBIN)*	*(A2_5LBDT)*

6. Follow-up:*(A2FOLLUP)*

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

---

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

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

☐ Yes

Additional Selection Options for AD2

Event number *(AESEQNO)* (key field):
1st Adverse Event of the day
2nd Adverse Event of the day
3rd Adverse Event of the day
4th Adverse Event of the day
5th Adverse Event of the day
6th Adverse Event of the day
7th Adverse Event of the day
8th Adverse Event of the day
9th Adverse Event of the day
10th Adverse Event of the day

Serious Adverse Event Medical Reviewer (AD3)

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

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

1. Was this determined to be a serious adverse event?*(A3SAE)*	☐ No ☐ Yes
2. Is there a reasonable possibility that the injectable study medication caused the event?*(A3RINJ)*	☐ No ☐ Yes
3. Was this event expected?*(A3EXPECT)*	☐ No ☐ Yes
4. Is this a standard expedited/reportable event? *(i.e., is it serious, unexpected and related to therapy)(A3EXPFDA)*	☐ No ☐ Yes
If "No", is this an expedited/reportable event for other reasons?*(A3EXPOTH)*	☐ No ☐ Yes
5. Does the protocol need to be modified based on this event?*(A3MPROT)*	☐ No ☐ Yes
6. Does the consent form need to be modified based on this event?*(A3MCNST)*	☐ No ☐ Yes
7. Is the review complete?*(A3REVDNE)*	☐ No ☐ Yes
If "No", what additional information is required:*(A3ADDINF)*	

Assessed by:*(A3ASRID)* ☐ (initials)

Reviewed by:*(A3REVID)* ☐ (initials)

Comments:*(A3COMM)*

Additional Selection Options for AD3

Event number *(AESEQNO)* (key field):
1st Adverse Event of the day
2nd Adverse Event of the day
3rd Adverse Event of the day
4th Adverse Event of the day
5th Adverse Event of the day
6th Adverse Event of the day
7th Adverse Event of the day
8th Adverse Event of the day
9th Adverse Event of the day
10th Adverse Event of the day

NIDA Clinical Trials Network

ARV Medication Log (Abstracted Records) (ARM)

Web Version: 1.0; 2.01; 08-15-18

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

1. Has the participant been prescribed antiretroviral medications **since the baseline visit**?*(ARRXARV)* ☐ No ☐ Yes

*Indicate what the participant has been prescribed **since the baseline visit**.*

	Drug Name	Most Recent Prescription Date	Estimated Start Date	If Stopped, Last Prescription Date	Estimated Stop Date	Ongoing at Study Termination
a.	*(ARDRUG01)* Aptivus - TPV; Atripla - EFV + TDF +FTC; Combivir - ZDV + 3TC or AZT + 3TC; Complera - RPV + TDF + FTV; Crixivan - IDV; *Additional Options Listed Below	*(ARST01DT)* *(mm/dd/yyyy)*	*(ARETST01)* ☐	*(ARSP01DT)* *(mm/dd/yyyy)*	*(ARETSP01)* ☐	*(ARONG01)* ☐
b.	*(ARDRUG02)* Aptivus - TPV; Atripla - EFV + TDF +FTC; Combivir - ZDV + 3TC or AZT + 3TC; Complera - RPV + TDF + FTV; Crixivan - IDV; *Additional Options Listed Below	*(ARST02DT)* *(mm/dd/yyyy)*	*(ARETST02)* ☐	*(ARSP02DT)* *(mm/dd/yyyy)*	*(ARETSP02)* ☐	*(ARONG02)* ☐
c.	*(ARDRUG03)* Aptivus - TPV; Atripla - EFV + TDF +FTC; Combivir - ZDV + 3TC or AZT + 3TC; Complera - RPV + TDF + FTV; Crixivan - IDV; *Additional Options Listed Below	*(ARST03DT)* *(mm/dd/yyyy)*	*(ARETST03)* ☐	*(ARSP03DT)* *(mm/dd/yyyy)*	*(ARETSP03)* ☐	*(ARONG03)* ☐
d.	*(ARDRUG04)* Aptivus - TPV; Atripla - EFV + TDF +FTC; Combivir - ZDV + 3TC or AZT + 3TC; Complera - RPV + TDF + FTV; Crixivan - IDV; *Additional Options Listed Below	*(ARST04DT)* *(mm/dd/yyyy)*	*(ARETST04)* ☐	*(ARSP04DT)* *(mm/dd/yyyy)*	*(ARETSP04)* ☐	*(ARONG04)* ☐
e.	*(ARDRUG05)* Aptivus - TPV; Atripla - EFV + TDF +FTC; Combivir - ZDV + 3TC or AZT + 3TC; Complera - RPV + TDF + FTV; Crixivan - IDV; *Additional Options Listed Below	*(ARST05DT)* *(mm/dd/yyyy)*	*(ARETST05)* ☐	*(ARSP05DT)* *(mm/dd/yyyy)*	*(ARETSP05)* ☐	*(ARONG05)* ☐
f.	*(ARDRUG06)* Aptivus - TPV; Atripla - EFV + TDF +FTC; Combivir - ZDV + 3TC or AZT + 3TC; Complera - RPV + TDF + FTV; Crixivan - IDV; *Additional Options Listed Below	*(ARST06DT)* *(mm/dd/yyyy)*	*(ARETST06)* ☐	*(ARSP06DT)* *(mm/dd/yyyy)*	*(ARETSP06)* ☐	*(ARONG06)* ☐
g.	*(ARDRUG07)* Aptivus - TPV; Atripla - EFV + TDF +FTC; Combivir - ZDV + 3TC or AZT + 3TC; Complera - RPV + TDF + FTV; Crixivan - IDV; *Additional Options Listed Below	*(ARST07DT)* *(mm/dd/yyyy)*	*(ARETST07)* ☐	*(ARSP07DT)* *(mm/dd/yyyy)*	*(ARETSP07)* ☐	*(ARONG07)* ☐
h.	*(ARDRUG08)*	*(ARST08DT)* *(mm/dd/yyyy)*	*(ARETST08)* ☐	*(ARSP08DT)* *(mm/dd/yyyy)*	*(ARETSP08)* ☐	*(ARONG08)* ☐

	Aptivus - TPV Atripla - EFV + TDF +FTC Combivir - ZDV + 3TC or AZT + 3TC Complera - RPV + TDF + FTV Crixivan - IDV *Additional Options Listed Below					
i.	*(ARDRUG09)* Aptivus - TPV Atripla - EFV + TDF +FTC Combivir - ZDV + 3TC or AZT + 3TC Complera - RPV + TDF + FTV Crixivan - IDV *Additional Options Listed Below	*(ARST09DT)* *(mm/dd/yyyy)*	*(ARETST09)* ☐	*(ARSP09DT)* *(mm/dd/yyyy)*	*(ARETSP09)* ☐	*(ARONG09)* ☐
j.	*(ARDRUG10)* Aptivus - TPV Atripla - EFV + TDF +FTC Combivir - ZDV + 3TC or AZT + 3TC Complera - RPV + TDF + FTV Crixivan - IDV *Additional Options Listed Below	*(ARST10DT)* *(mm/dd/yyyy)*	*(ARETST10)* ☐	*(ARSP10DT)* *(mm/dd/yyyy)*	*(ARETSP10)* ☐	*(ARONG10)* ☐
k.	*(ARDRUG11)* Aptivus - TPV Atripla - EFV + TDF +FTC Combivir - ZDV + 3TC or AZT + 3TC Complera - RPV + TDF + FTV Crixivan - IDV *Additional Options Listed Below	*(ARST11DT)* *(mm/dd/yyyy)*	*(ARETST11)* ☐	*(ARSP11DT)* *(mm/dd/yyyy)*	*(ARETSP11)* ☐	*(ARONG11)* ☐
l.	*(ARDRUG12)* Aptivus - TPV Atripla - EFV + TDF +FTC Combivir - ZDV + 3TC or AZT + 3TC Complera - RPV + TDF + FTV Crixivan - IDV *Additional Options Listed Below	*(ARST12DT)* *(mm/dd/yyyy)*	*(ARETST12)* ☐	*(ARSP12DT)* *(mm/dd/yyyy)*	*(ARETSP12)* ☐	*(ARONG12)* ☐
m.	*(ARDRUG13)* Aptivus - TPV Atripla - EFV + TDF +FTC Combivir - ZDV + 3TC or AZT + 3TC Complera - RPV + TDF + FTV Crixivan - IDV *Additional Options Listed Below	*(ARST13DT)* *(mm/dd/yyyy)*	*(ARETST13)* ☐	*(ARSP13DT)* *(mm/dd/yyyy)*	*(ARETSP13)* ☐	*(ARONG13)* ☐
n.	*(ARDRUG14)* Aptivus - TPV Atripla - EFV + TDF +FTC Combivir - ZDV + 3TC or AZT + 3TC Complera - RPV + TDF + FTV Crixivan - IDV *Additional Options Listed Below	*(ARST14DT)* *(mm/dd/yyyy)*	*(ARETST14)* ☐	*(ARSP14DT)* *(mm/dd/yyyy)*	*(ARETSP14)* ☐	*(ARONG14)* ☐
o.	*(ARDRUG15)* Aptivus - TPV Atripla - EFV + TDF +FTC Combivir - ZDV + 3TC or AZT + 3TC Complera - RPV + TDF + FTV Crixivan - IDV *Additional Options Listed Below	*(ARST15DT)* *(mm/dd/yyyy)*	*(ARETST15)* ☐	*(ARSP15DT)* *(mm/dd/yyyy)*	*(ARETSP15)* ☐	*(ARONG15)* ☐
p.	*(ARDRUG16)* Aptivus - TPV Atripla - EFV + TDF +FTC Combivir - ZDV + 3TC or AZT + 3TC Complera - RPV + TDF + FTV Crixivan - IDV *Additional Options Listed Below	*(ARST16DT)* *(mm/dd/yyyy)*	*(ARETST16)* ☐	*(ARSP16DT)* *(mm/dd/yyyy)*	*(ARETSP16)* ☐	*(ARONG16)* ☐
q.	*(ARDRUG17)* Aptivus - TPV Atripla - EFV + TDF +FTC Combivir - ZDV + 3TC or AZT + 3TC Complera - RPV + TDF + FTV Crixivan - IDV *Additional Options Listed Below	*(ARST17DT)* *(mm/dd/yyyy)*	*(ARETST17)* ☐	*(ARSP17DT)* *(mm/dd/yyyy)*	*(ARETSP17)* ☐	*(ARONG17)* ☐
r.	*(ARDRUG18)*	*(ARST18DT)* *(mm/dd/yyyy)*	*(ARETST18)* ☐	*(ARSP18DT)* *(mm/dd/yyyy)*	*(ARETSP18)* ☐	*(ARONG18)* ☐

	Aptivus - TPV Atripla - EFV + TDF +FTC Combivir - ZDV + 3TC or AZT + 3TC Complera - RPV + TDF + FTV Crixivan - IDV *Additional Options Listed Below					
s.	*(ARDRUG19)* Aptivus - TPV Atripla - EFV + TDF +FTC Combivir - ZDV + 3TC or AZT + 3TC Complera - RPV + TDF + FTV Crixivan - IDV *Additional Options Listed Below	*(ARST19DT)* *(mm/dd/yyyy)*	*(ARETST19)*	*(ARSP19DT)* *(mm/dd/yyyy)*	*(ARETSP19)*	*(ARONG19)*
t.	*(ARDRUG20)* Aptivus - TPV Atripla - EFV + TDF +FTC Combivir - ZDV + 3TC or AZT + 3TC Complera - RPV + TDF + FTV Crixivan - IDV *Additional Options Listed Below	*(ARST20DT)* *(mm/dd/yyyy)*	*(ARETST20)*	*(ARSP20DT)* *(mm/dd/yyyy)*	*(ARETSP20)*	*(ARONG20)*
u.	*(ARDRUG21)* Aptivus - TPV Atripla - EFV + TDF +FTC Combivir - ZDV + 3TC or AZT + 3TC Complera - RPV + TDF + FTV Crixivan - IDV *Additional Options Listed Below	*(ARST21DT)* *(mm/dd/yyyy)*	*(ARETST21)*	*(ARSP21DT)* *(mm/dd/yyyy)*	*(ARETSP21)*	*(ARONG21)*
v.	*(ARDRUG22)* Aptivus - TPV Atripla - EFV + TDF +FTC Combivir - ZDV + 3TC or AZT + 3TC Complera - RPV + TDF + FTV Crixivan - IDV *Additional Options Listed Below	*(ARST22DT)* *(mm/dd/yyyy)*	*(ARETST22)*	*(ARSP22DT)* *(mm/dd/yyyy)*	*(ARETSP22)*	*(ARONG22)*
w.	*(ARDRUG23)* Aptivus - TPV Atripla - EFV + TDF +FTC Combivir - ZDV + 3TC or AZT + 3TC Complera - RPV + TDF + FTV Crixivan - IDV *Additional Options Listed Below	*(ARST23DT)* *(mm/dd/yyyy)*	*(ARETST23)*	*(ARSP23DT)* *(mm/dd/yyyy)*	*(ARETSP23)*	*(ARONG23)*
x.	*(ARDRUG24)* Aptivus - TPV Atripla - EFV + TDF +FTC Combivir - ZDV + 3TC or AZT + 3TC Complera - RPV + TDF + FTV Crixivan - IDV *Additional Options Listed Below	*(ARST24DT)* *(mm/dd/yyyy)*	*(ARETST24)*	*(ARSP24DT)* *(mm/dd/yyyy)*	*(ARETSP24)*	*(ARONG24)*
y.	*(ARDRUG25)* Aptivus - TPV Atripla - EFV + TDF +FTC Combivir - ZDV + 3TC or AZT + 3TC Complera - RPV + TDF + FTV Crixivan - IDV *Additional Options Listed Below	*(ARST25DT)* *(mm/dd/yyyy)*	*(ARETST25)*	*(ARSP25DT)* *(mm/dd/yyyy)*	*(ARETSP25)*	*(ARONG25)*
z.	*(ARDRUG26)* Aptivus - TPV Atripla - EFV + TDF +FTC Combivir - ZDV + 3TC or AZT + 3TC Complera - RPV + TDF + FTV Crixivan - IDV *Additional Options Listed Below	*(ARST26DT)* *(mm/dd/yyyy)*	*(ARETST26)*	*(ARSP26DT)* *(mm/dd/yyyy)*	*(ARETSP26)*	*(ARONG26)*
aa.	*(ARDRUG27)* Aptivus - TPV Atripla - EFV + TDF +FTC Combivir - ZDV + 3TC or AZT + 3TC Complera - RPV + TDF + FTV Crixivan - IDV *Additional Options Listed Below	*(ARST27DT)* *(mm/dd/yyyy)*	*(ARETST27)*	*(ARSP27DT)* *(mm/dd/yyyy)*	*(ARETSP27)*	*(ARONG27)*
ab.	*(ARDRUG28)*	*(ARST28DT)* *(mm/dd/yyyy)*	*(ARETST28)*	*(ARSP28DT)* *(mm/dd/yyyy)*	*(ARETSP28)*	*(ARONG28)*

	Aptivus - TPV Atripla - EFV + TDF +FTC Combivir - ZDV + 3TC or AZT + 3TC Complera - RPV + TDF + FTV Crixivan - IDV *Additional Options Listed Below					
ac.	*(ARDRUG29)* Aptivus - TPV Atripla - EFV + TDF +FTC Combivir - ZDV + 3TC or AZT + 3TC Complera - RPV + TDF + FTV Crixivan - IDV *Additional Options Listed Below	*(ARST29DT)* *(mm/dd/yyyy)*	*(ARETST29)* ☐	*(ARSP29DT)* *(mm/dd/yyyy)*	*(ARETSP29)* ☐	*(ARONG29)* ☐
ad.	*(ARDRUG30)* Aptivus - TPV Atripla - EFV + TDF +FTC Combivir - ZDV + 3TC or AZT + 3TC Complera - RPV + TDF + FTV Crixivan - IDV *Additional Options Listed Below	*(ARST30DT)* *(mm/dd/yyyy)*	*(ARETST30)* ☐	*(ARSP30DT)* *(mm/dd/yyyy)*	*(ARETSP30)* ☐	*(ARONG30)* ☐
ae.	*(ARDRUG31)* Aptivus - TPV Atripla - EFV + TDF +FTC Combivir - ZDV + 3TC or AZT + 3TC Complera - RPV + TDF + FTV Crixivan - IDV *Additional Options Listed Below	*(ARST31DT)* *(mm/dd/yyyy)*	*(ARETST31)* ☐	*(ARSP31DT)* *(mm/dd/yyyy)*	*(ARETSP31)* ☐	*(ARONG31)* ☐
af.	*(ARDRUG32)* Aptivus - TPV Atripla - EFV + TDF +FTC Combivir - ZDV + 3TC or AZT + 3TC Complera - RPV + TDF + FTV Crixivan - IDV *Additional Options Listed Below	*(ARST32DT)* *(mm/dd/yyyy)*	*(ARETST32)* ☐	*(ARSP32DT)* *(mm/dd/yyyy)*	*(ARETSP32)* ☐	*(ARONG32)* ☐
ag.	*(ARDRUG33)* Aptivus - TPV Atripla - EFV + TDF +FTC Combivir - ZDV + 3TC or AZT + 3TC Complera - RPV + TDF + FTV Crixivan - IDV *Additional Options Listed Below	*(ARST33DT)* *(mm/dd/yyyy)*	*(ARETST33)* ☐	*(ARSP33DT)* *(mm/dd/yyyy)*	*(ARETSP33)* ☐	*(ARONG33)* ☐
ah.	*(ARDRUG34)* Aptivus - TPV Atripla - EFV + TDF +FTC Combivir - ZDV + 3TC or AZT + 3TC Complera - RPV + TDF + FTV Crixivan - IDV *Additional Options Listed Below	*(ARST34DT)* *(mm/dd/yyyy)*	*(ARETST34)* ☐	*(ARSP34DT)* *(mm/dd/yyyy)*	*(ARETSP34)* ☐	*(ARONG34)* ☐
ai.	*(ARDRUG35)* Aptivus - TPV Atripla - EFV + TDF +FTC Combivir - ZDV + 3TC or AZT + 3TC Complera - RPV + TDF + FTV Crixivan - IDV *Additional Options Listed Below	*(ARST35DT)* *(mm/dd/yyyy)*	*(ARETST35)* ☐	*(ARSP35DT)* *(mm/dd/yyyy)*	*(ARETSP35)* ☐	*(ARONG35)* ☐

Comments:*(ARVCOMM)*

Additional Selection Options for ARM

Drug name 01
Descovy - TAF + FTC
Edurant - RPV
Emtriva - FTC
Epivir - 3TC
Epzicom - ABC + 3TC
Evotaz - ATV/c
Fuzeon - T20
Genovya - TAF + FTC + EVG/c
Intelence - ETV
Invirase - SQV
Isentress - RAL
Kaletra - LPV/r
Lexiva - FPV
Norvir - RTV or r
Odefsy - TAF + FTC + RPV
Prezcobix - DRV/c
Prezista QD - DRV
Reyataz - ATV
Rescriptor - DLV
Retrovir - AZT (or ZDV)
Selzentry - MVC
Stribild - EVG + COBI + TDF + FTC
Sustiva - EFV
Tivicay - DTG
Triumeq - ABC + 3TC + DTG
Trizivir - ABC + 3TC + ZDV (or AZT)
Truvada - TDF + FTC
Videx - ddI
Viracept - NFV
Viramune - NVP
Viramune XR (QD) - NVP
Viread - TDF
Vitekta - EVG
Zerit - d4T
Ziagen - ABC
Biktarvy - BIC + TAF + FTC
Don't know
Other/Experimental/Blinded study - OTHR

NIDA Clinical Trials Network

CTN-ASI Lite v1.0: Drug/Alcohol Use Modified (ASX)

Web Version: 1.0; 1.00; 10-02-18

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

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

CTN-ASI Lite v1.0 Follow-Up: Drug/Alcohol Use

Route of Administration:
1 = Oral 2 = Nasal 3 = Smoking 4 = Non-IV injection 5 = IV injection
*Note the **usual or most recent route.** For more than one route, choose the most severe. The routes are listed from least severe to most severe.*
If "Past 30" day use is zero, "Route of Administration" must be "Not applicable".

Substance	A. Past 30 Days (days)	D. Route of Administration	Comments
D1 Alcohol *(any use at all)*:	*(ADALA30D)*	-	*(ADALACOM)*
D2 Alcohol *(to intoxication)*:	*(ADALI30D)*	-	*(ADALICOM)*
D3 Heroin:	*(ADHER30D)*	*(ADHERRTE)* (1) Oral (2) Nasal (3) Smoking (4) Non IV injection (5) IV injection (96) Not applicable (97) Not answered	*(ADHERCOM)*
D4 Methadone/LAAM *(prescribed)*:	*(ADMDP30D)*	*(ADMDPRTE)* (1) Oral (2) Nasal (3) Smoking (4) Non IV injection (5) IV injection (96) Not applicable (97) Not answered	*(ADMDPCOM)*
D4a Methadone/LAAM *(illicit)*:	*(ADMDI30D)*	*(ADMDIRTE)* (1) Oral (2) Nasal (3) Smoking (4) Non IV injection (5) IV injection (96) Not applicable (97) Not answered	*(ADMDICOM)*
D5 Other Opiates/Analgesics:	*(ADOPI30D)*	*(ADOPIRTE)* (1) Oral (2) Nasal (3) Smoking (4) Non IV injection (5) IV injection (96) Not applicable (97) Not answered	*(ADOPICOM)*
D6 Barbiturates:	*(ADBAR30D)*	*(ADBARRTE)* (1) Oral (2) Nasal (3) Smoking (4) Non IV injection (5) IV injection (96) Not applicable (97) Not answered	*(ADBARCOM)*
D7 Other Sedatives/Hypnotics/Tranquilizers:	*(ADSHT30D)*		*(ADSHTCOM)*

		(1) Oral (2) Nasal (3) Smoking (4) Non IV injection (5) IV injection (96) Not applicable (97) Not answered *(ADSHTRTE)*	
D8 Cocaine:	*(ADCOC30D)*	(1) Oral (2) Nasal (3) Smoking (4) Non IV injection (5) IV injection (96) Not applicable (97) Not answered *(ADCOCRTE)*	*(ADCOCCOM)*
D9 Amphetamines:	*(ADAMP30D)*	(1) Oral (2) Nasal (3) Smoking (4) Non IV injection (5) IV injection (96) Not applicable (97) Not answered *(ADAMPRTE)*	*(ADAMPCOM)*
D9a Methamphetamine:	*(ADMET30D)*	(1) Oral (2) Nasal (3) Smoking (4) Non IV injection (5) IV injection (96) Not applicable (97) Not answered *(ADMETRTE)*	*(ADMETCOM)*
D10 Cannabis:	*(ADTHC30D)*	(1) Oral (2) Nasal (3) Smoking (4) Non IV injection (5) IV injection (96) Not applicable (97) Not answered *(ADTHCRTE)*	*(ADTHCCOM)*
D11 Hallucinogens:	*(ADHAL30D)*	(1) Oral (2) Nasal (3) Smoking (4) Non IV injection (5) IV injection (96) Not applicable (97) Not answered *(ADHALRTE)*	*(ADHALCOM)*
D12 Inhalants:	*(ADINH30D)*	(1) Oral (2) Nasal (3) Smoking (4) Non IV injection (5) IV injection (96) Not applicable (97) Not answered *(ADINHRTE)*	*(ADINHCOM)*
D36 Nicotine:	*(ADNIC30D)*	-	*(ADNICCOM)*
D13 More than 1 substance per day *(including alcohol, excluding nicotine)*:	*(ADGT130D)*	-	*(ADGT1COM)*

D14 Currently, which substance is the major problem?

- *Interviewer should determine the major drug or drugs of abuse (excluding nicotine use). Code the number next to the drug in 01-12 (code prescribed or illicit methadone as **04**).*
  ***00** = no problem,*
  ***15** = alcohol and one or more drugs,*
  ***16** = more than one drug but no alcohol. Ask participant when not clear.*

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

OR

(ADMJDGNA) ☐ (97) Not answered

Comments:*(ADMJDGCM)*

D26 How many days in the past 30 have you experienced alcohol problems?

- *Include: Craving, withdrawal symptoms, disturbing effects of use, or wanting to stop and being unable to.*

(ADALCPRB) _____ *days*

OR

(ADAPRBNA) ☐ (97) Not answered

Comments:*(ADAPRBCM)*

For questions D28-D31, please ask participant to use the Participant Rating Scale. The participant is rating the need for additional substance abuse treatment.

D28 How troubled or bothered have you been in the past 30 days by these alcohol problems?

(ADALCBOT)
- (0) Not at all
- (1) Slightly
- (2) Moderately
- (3) Considerably
- (4) Extremely

OR

(ADABOTNA) ☐ (97) Not answered

Comments:*(ADABOTCM)*

D30 How important to you **now** is treatment for these alcohol problems?

(ADALCIMP)
- (0) Not at all
- (1) Slightly
- (2) Moderately
- (3) Considerably
- (4) Extremely

OR

(ADAIMPNA) ☐ (97) Not answered

Comments:*(ADAIMPCM)*

D27 How many days in the past 30 have you experienced drug problems?

- *Include: Craving, withdrawal symptoms, disturbing effects of use, or wanting to stop and being unable to.*

(ADDRGPRB) _____ *days*

OR

(ADDPRBNA) ☐ (97) Not answered

Comments:*(ADDPRBCM)*

D29 How troubled or bothered have you been in the past 30 days by these drug problems?

(0) Not at all
(1) Slightly
(2) Moderately
(3) Considerably
(4) Extremely

(ADDRGBOT)

OR

(ADDBOTNA) ☐ (97) Not answered

Comments:*(ADDBOTCM)*

D31 How important to you **now** is treatment for these drug problems?

(0) Not at all
(1) Slightly
(2) Moderately
(3) Considerably
(4) Extremely

(ADDRGIMP)

OR

(ADDIMPNA) ☐ (97) Not answered

Comments:*(ADDIMPCM)*

Confidence Ratings: Is the above information **significantly** distorted by:

D34 Participant's misrepresentation?

(ADMISREP) ☐ (0) No ☐ (1) Yes

D35 Participant's inability to understand?

(ADUNDRST) ☐ (0) No ☐ (1) Yes

Comments:*(ASXCOMM)*

NIDA Clinical Trials Network

Buprenorphine and Methadone Chart Abstraction (BMA)

Web Version: 1.0; 2.00; 04-02-19

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

Date medical records abstracted: *(BMABSDT)* *(mm/dd/yyyy)*

Earliest medical record date used to complete abstraction: *(BMEARLDT)* *(mm/dd/yyyy)*

1. In the past 28 days, was the participant prescribed buprenorphine for addiction treatment? *(BMBUPRX)* ☐ No ☐ Yes

   If "Yes", buprenorphine dose prescribed: *(BMBUPDOS)* *(xx.x)* mg

2. In the past 28 days, was the participant prescribed methadone for addiction treatment? *(BMMTDRX)* ☐ No ☐ Yes

   If "Yes", methadone dose prescribed: *(BMMTDDOS)* *(xxx)* mg

Comments: *(BMACOMM)*

Concise Health Risk Tracking (CHRT) - Clinician Rated Module (CHC)

Web Version: 1.0; 1.00; 07-03-17

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

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

1. **Suicidal Ideation** - Passive (i.e. wanting to be dead) and/or active (i.e. method, intent, plan) SI present.*(CHSCIDTN)* ☐ No ☐ Yes
   This last week did you think you might be better off dead or wish you were dead?
   Did you have any thoughts of harming or injuring yourself in any way?
   If "Yes": **Have you thought about how you might do this?**
   Have there been times when you seriously considered harming or injuring yourself?
   Do you intend to kill yourself or harm yourself in any way? Do you have a plan?
   How often have you had these thoughts? How long do they last?

2. **Suicide Attempt** - Patient made a suicide attempt (i.e. they engaged in a potentially self-injurious behavior associated with intent to die. Intent can be stated by patient or inferred by rater). *(CHSCATMP)* ☐ No ☐ Yes
   This last week did you attempt to harm or injure yourself in any way?
   If "Yes": **Can you tell me what happened? Was this an accident or on purpose?**
   If On Purpose: **Why did you _____? Were you trying to kill yourself when you _____?**
   If **"Yes"**, list method:*(CHMETHOD)* _____

3. **Self-injurious Behavior - No Intent to Die** - Purposeful self-injurious behavior with no intent to die. *(CHSIBDIE)* ☐ No ☐ Yes
   This last week, have you done anything to prepare yourself for suicide or take any steps towards killing yourself?
   If "Yes": **What did you do? Were you thinking about killing yourself when you _____?**
   Did you stop yourself, or did someone else stop you before you harmed yourself?

4. **Preparatory Acts** - Making preparatory acts toward imminent suicidal behavior (Person takes steps to injure self but is stopped by self or others. Intent to die is either stated by patient or inferred by rater).*(CHPREPAT)* ☐ No ☐ Yes

5. **Completed Suicide** - Confirmed (i.e. Coroner's report, suicide note, other collateral information). *(CHSCCMPL)* ☐ No ☐ Yes

6. **Self-injurious Behavior - Unknown Intent**- Purposeful self-injurious behavior where associated intent to die is unknown and cannot be inferred.*(CHSIBUNK)* ☐ No ☐ Yes

7. **Death (not enough information to classify as suicide)***(CHDEATH)* ☐ No ☐ Yes

8. **Other Injury -** Other not purposeful injury (accidental, psychiatric, medical), no deliberate self-harm. *(CHINJOTH)* ☐ No ☐ Yes

9. **Nonfatal Injury (not enough information to classify)***(CHINJURY)* ☐ No ☐ Yes

Comments:*(CHCCOMM)* _____

NIDA Clinical Trials Network

Concise Health Risk Tracking (CHRT) - Participant Rated Module (CHP)

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

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

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

Please rate the extent to which each of the following statements describes how you have been feeling or acting in the past week.

For example, if you feel the statement very accurately describes how you have been feeling in the past week, you would give a rating of "Strongly Agree." If you feel the statement is not at all how you have been feeling in the past week, you would give a rating of "Strongly Disagree."

		Strongly Disagree	**Disagree**	**Neither Agree nor Disagree**	**Agree**	**Strongly Agree**
1. I feel as if things are never going to get better.	*(CHNVRBTR)*	☐	☐	☐	☐	☐
2. I have no future.	*(CHNOFUTR)*	☐	☐	☐	☐	☐
3. It seems as if I can do nothing right.	*(CHNORGHT)*	☐	☐	☐	☐	☐
4. Everything I do turns out wrong.	*(CHWRONG)*	☐	☐	☐	☐	☐
5. There is no one I can depend on.	*(CHDPNDON)*	☐	☐	☐	☐	☐
6. The people I care the most for are gone.	*(CHPPLGNE)*	☐	☐	☐	☐	☐
7. I wish my suffering could just all be over.	*(CHSUFOVR)*	☐	☐	☐	☐	☐
8. I feel that there is no reason to live.	*(CHRSLIVE)*	☐	☐	☐	☐	☐
9. I wish I could just go to sleep and not wake up.	*(CHSLPNTW)*	☐	☐	☐	☐	☐
10. I find myself saying or doing things without thinking.	*(CHNOTHNK)*	☐	☐	☐	☐	☐
11. I often make decisions quickly or "on impulse."	*(CHIMPULS)*	☐	☐	☐	☐	☐
12. I often feel irritable or easily angered.	*(CHIRRITE)*	☐	☐	☐	☐	☐
13. I often overreact with anger or rage over minor things.	*(CHOVRRCT)*	☐	☐	☐	☐	☐
14. I have been having thoughts of killing myself.	*(CHKILLMS)*	☐	☐	☐	☐	☐
15. I have thoughts about how I might kill myself.	*(CHHOWKIL)*	☐	☐	☐	☐	☐
16. I have a plan to kill myself.	*(CHPLNKIL)*	☐	☐	☐	☐	☐

Participant required research staff assistance in reading the questions in this assessment: ☐ Yes
Note: this includes if participant could not see well enough to read the questions or if the participant was unable to read well enough to read the questions.(CHHELP)

Comments:*(CHPCOMM)*

Criminal Justice (CRJ)

Web Version: 1.0; 1.00; 09-05-17

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

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

1. Not counting minor traffic violations, how many times during the **past 3 months** have you been arrested and booked for breaking a law?*(CRARRBK)* _____ *(xx)*

2. Were you on probation at any time during the **past 3 months**?*(CRPROB)* ☐ No ☐ Yes

3. Were you on parole, supervised release, or other conditional release from prison or jail at any time during the **past 3 months**?*(CRPAROLE)* ☐ No ☐ Yes

4. If you were released in the **past 3 months**, were you released from any of the following:

		No	Yes
a.	Jail: *(CRJAILRL)*	☐	☐
b.	Prison or prison/jail unified system: *(CRPRSRL)*	☐	☐
c.	Probation or parole: *(CRPROBRL)*	☐	☐
d.	Drug court: *(CRDRGRL)*	☐	☐

5. While incarcerated, did you miss any doses of Vivitrol/naltrexone, buprenorphine, or methadone that had been prescribed before you went to jail?*(CRMISRX)* ☐ No ☐ Yes
   If "Yes", specify what happened:*(CRMSRXSP)*

6. While incarcerated in the **past 3 months**, did you receive any of the following:

		No	Yes
a.	Naltrexone pill: *(CRNTXPDI)*	☐	☐
b.	Naltrexone shot: *(CRNTXSDI)*	☐	☐
c.	Buprenorphine: *(CRBUPDI)*	☐	☐
d.	Methadone: *(CRMTDDI)*	☐	☐

7. In the **past 3 months** has a probation or parole officer or drug court encouraged you to use any of the following medicines:

		No	Yes
a.	Naltrexone pill: *(CRNTXPUS)*	☐	☐
b.	Naltrexone shot: *(CRNTXSUS)*	☐	☐
c.	Buprenorphine: *(CRBUPUS)*	☐	☐
d.	Methadone: *(CRMTDUS)*	☐	☐

Comments:*(CRJCOMM)*

NIDA Clinical Trials Network

Demographics (DEM)

Web Version: 1.0; 6.00; 11-25-19

1. Date of birth:*(DEBRTHDT)* _____ *(mm/dd/yyyy)*

2. Sex:*(DESEX)* ☐ Male ☐ Female ☐ Don't know ☐ Refused to answer

3. Does the participant consider him or herself to be Hispanic/Latino?*(DEHISPNC)* ☐ No ☐ Yes ☐ Don't know ☐ Refused to answer

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

   - Puerto Rican
   - Dominican (Republic)
   - Mexican/Mexican American
   - Chicano
   - Cuban/Cuban American
   - *Additional Options Listed Below

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

   - American Indian or Alaska Native:*(DEAMEIND)* ☐
   - Asian:*(DEASIAN)* ☐
     - Asian Indian:*(DEASAIND)* ☐
     - Chinese:*(DECHINA)* ☐
     - Filipino:*(DEFILIPN)* ☐
     - Japanese:*(DEJAPAN)* ☐
     - Korean:*(DEKOREA)* ☐
     - Vietnamese:*(DEVIETNM)* ☐
     - Specify other Asian:*(DEASIAOT)* _____
   - Black or African American:*(DEBLACK)* ☐
   - Native Hawaiian or Pacific Islander:*(DEHAWAII)* ☐
     - Native Hawaiian:*(DENATHAW)* ☐
     - Guamanian or Chamorro:*(DEGUAM)* ☐
     - Samoan:*(DESAMOAN)* ☐
     - Specify other Pacific Islander:*(DEPACISO)* _____
   - White:*(DEWHITE)* ☐
   - Some other race:*(DERACEOT)* ☐ Specify:*(DERACESP)* _____

   -or-

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

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

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

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

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

   If "Other", specify:*(DEJOBSP)* _____

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

   - Married
   - Widowed
   - Divorced
   - Separated
   - 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:
Central or South American
Other Latin American
Other Hispanic or Latino
Refused
Don't know

What is the highest grade or level of school the participant has completed or the highest degree they have received?
5th grade
6th grade
7th grade
8th grade
9th grade
10th grade
11th grade
12th grade, no diploma
High school graduate
GED or equivalent
Some college, no degree
Associate's degree: occupational, technical, or vocational program
Associate's degree: academic program
Bachelor's degree (e.g., BA, AB, BS, BBA)
Master's degree (e.g., MA, MS, MEng, MEd, MBA)
Professional school degree (e.g., MD, DDS, DVM, JD)
Doctoral degree (e.g., PhD, EdD)
Refused
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?
Keeping house
Student
Other

Is the participant currently married, widowed, divorced, separated, never married, or living with a partner?
Living with partner
Refused
Don't know

Detoxification (DTX)

Web Version: 1.0; 2.01; 07-16-18

Segment *(PROTSEG)*: B
Visit number *(VISNO)*:
Detox sequence number *(DTSEQNUM)*:

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

1. Did the participant initiate medically supervised withdrawal (detoxification) for opioids?*(DTDTXOPI)* ☐ No ☐ Yes
   a. If "Yes", in what setting was the medically supervised withdrawal (detoxification) for opioids conducted?*(DTLOCOPI)*
      - Inpatient
      - Outpatient, on-site
      - Outpatient, off-site
      - Residential
      - Other

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

   If "Outpatient, on-site" or "Outpatient, off-site":
   1. How many days since the participant's last use of opioids?*(DTLSTOPI)* *(xxx)*
   2. What medications were used during treatment of medically supervised withdrawal (detoxification) for opioids?

Day 1 medication(s):	*(DTRX01M1)* -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	*(DTRX01M2)* -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	*(DTRX01M3)* -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	*(DTRX01M4)* -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	*(DTRX01M5)* -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	*(DTRX01M6)* -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	*(DTRX01M7)* -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below
Total daily dose:	*(DTRX01D1)* *(xx)* mg	*(DTRX01D2)* *(xx)* mg	*(DTRX01D3)* *(xx)* mg	*(DTRX01D4)* *(xx)* mg	*(DTRX01D5)* *(xx)* mg	*(DTRX01D6)* *(xx)* mg	*(DTRX01D7)* *(xx)* mg
Day 2 medication(s):	*(DTRX02M1)* -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	*(DTRX02M2)* -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	*(DTRX02M3)* -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	*(DTRX02M4)* -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	*(DTRX02M5)* -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	*(DTRX02M6)* -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	*(DTRX02M7)* -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below
Total daily dose:	*(DTRX02D1)* *(xx)* mg	*(DTRX02D2)* *(xx)* mg	*(DTRX02D3)* *(xx)* mg	*(DTRX02D4)* *(xx)* mg	*(DTRX02D5)* *(xx)* mg	*(DTRX02D6)* *(xx)* mg	*(DTRX02D7)* *(xx)* mg
Day 3 medication(s):	*(DTRX03M1)* -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	*(DTRX03M2)* -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	*(DTRX03M3)* -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	*(DTRX03M4)* -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	*(DTRX03M5)* -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	*(DTRX03M6)* -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	*(DTRX03M7)* -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below
Total daily dose:	*(DTRX03D1)* *(xx)* mg	*(DTRX03D2)* *(xx)* mg	*(DTRX03D3)* *(xx)* mg	*(DTRX03D4)* *(xx)* mg	*(DTRX03D5)* *(xx)* mg	*(DTRX03D6)* *(xx)* mg	*(DTRX03D7)* *(xx)* mg
Day 4 medication(s):	*(DTRX04M1)* -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	*(DTRX04M2)* -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	*(DTRX04M3)* -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	*(DTRX04M4)* -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	*(DTRX04M5)* -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	*(DTRX04M6)* -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	*(DTRX04M7)* -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below

Total daily dose:	(DTRX04D1) (xx) mg	(DTRX04D2) (xx) mg	(DTRX04D3) (xx) mg	(DTRX04D4) (xx) mg	(DTRX04D5) (xx) mg	(DTRX04D6) (xx) mg	(DTRX04D7) (xx) mg
Day 5 medication(s):	(DTRX05M1) -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	(DTRX05M2) -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	(DTRX05M3) -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	(DTRX05M4) -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	(DTRX05M5) -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	(DTRX05M6) -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	(DTRX05M7) -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below
Total daily dose:	(DTRX05D1) (xx) mg	(DTRX05D2) (xx) mg	(DTRX05D3) (xx) mg	(DTRX05D4) (xx) mg	(DTRX05D5) (xx) mg	(DTRX05D6) (xx) mg	(DTRX05D7) (xx) mg
Day 6 medication(s):	(DTRX06M1) -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	(DTRX06M2) -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	(DTRX06M3) -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	(DTRX06M4) -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	(DTRX06M5) -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	(DTRX06M6) -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	(DTRX06M7) -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below
Total daily dose:	(DTRX06D1) (xx) mg	(DTRX06D2) (xx) mg	(DTRX06D3) (xx) mg	(DTRX06D4) (xx) mg	(DTRX06D5) (xx) mg	(DTRX06D6) (xx) mg	(DTRX06D7) (xx) mg
Day 7 medication(s):	(DTRX07M1) -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	(DTRX07M2) -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	(DTRX07M3) -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	(DTRX07M4) -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	(DTRX07M5) -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	(DTRX07M6) -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	(DTRX07M7) -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below
Total daily dose:	(DTRX07D1) (xx) mg	(DTRX07D2) (xx) mg	(DTRX07D3) (xx) mg	(DTRX07D4) (xx) mg	(DTRX07D5) (xx) mg	(DTRX07D6) (xx) mg	(DTRX07D7) (xx) mg
Day 8 medication(s):	(DTRX08M1) -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	(DTRX08M2) -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	(DTRX08M3) -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	(DTRX08M4) -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	(DTRX08M5) -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	(DTRX08M6) -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	(DTRX08M7) -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below
Total daily dose:	(DTRX08D1) (xx) mg	(DTRX08D2) (xx) mg	(DTRX08D3) (xx) mg	(DTRX08D4) (xx) mg	(DTRX08D5) (xx) mg	(DTRX08D6) (xx) mg	(DTRX08D7) (xx) mg
Day 9 medication(s):	(DTRX09M1) -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	(DTRX09M2) -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	(DTRX09M3) -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	(DTRX09M4) -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	(DTRX09M5) -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	(DTRX09M6) -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	(DTRX09M7) -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below
Total daily dose:	(DTRX09D1) (xx) mg	(DTRX09D2) (xx) mg	(DTRX09D3) (xx) mg	(DTRX09D4) (xx) mg	(DTRX09D5) (xx) mg	(DTRX09D6) (xx) mg	(DTRX09D7) (xx) mg
Day 10 medication(s):	(DTRX10M1) -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	(DTRX10M2) -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	(DTRX10M3) -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	(DTRX10M4) -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	(DTRX10M5) -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	(DTRX10M6) -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	(DTRX10M7) -- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below
Total daily dose:	(DTRX10D1) (xx) mg	(DTRX10D2) (xx) mg	(DTRX10D3) (xx) mg	(DTRX10D4) (xx) mg	(DTRX10D5) (xx) mg	(DTRX10D6) (xx) mg	(DTRX10D7) (xx) mg

Day 11 medication(s):	(DTRX11M1)	(DTRX11M2)	(DTRX11M3)	(DTRX11M4)	(DTRX11M5)	(DTRX11M6)	(DTRX11M7)
	-- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	-- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	-- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	-- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	-- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	-- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	-- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below
Total daily dose:	*(DTRX11D1)* ____ *(xx)* mg	*(DTRX11D2)* ____ *(xx)* mg	*(DTRX11D3)* ____ *(xx)* mg	*(DTRX11D4)* ____ *(xx)* mg	*(DTRX11D5)* ____ *(xx)* mg	*(DTRX11D6)* ____ *(xx)* mg	*(DTRX11D7)* ____ *(xx)* mg

Day 12 medication(s):	(DTRX12M1)	(DTRX12M2)	(DTRX12M3)	(DTRX12M4)	(DTRX12M5)	(DTRX12M6)	(DTRX12M7)
	-- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	-- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	-- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	-- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	-- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	-- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	-- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below
Total daily dose:	*(DTRX12D1)* ____ *(xx)* mg	*(DTRX12D2)* ____ *(xx)* mg	*(DTRX12D3)* ____ *(xx)* mg	*(DTRX12D4)* ____ *(xx)* mg	*(DTRX12D5)* ____ *(xx)* mg	*(DTRX12D6)* ____ *(xx)* mg	*(DTRX12D7)* ____ *(xx)* mg

Day 13 medication(s):	(DTRX13M1)	(DTRX13M2)	(DTRX13M3)	(DTRX13M4)	(DTRX13M5)	(DTRX13M6)	(DTRX13M7)
	-- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	-- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	-- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	-- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	-- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	-- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	-- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below
Total daily dose:	*(DTRX13D1)* ____ *(xx)* mg	*(DTRX13D2)* ____ *(xx)* mg	*(DTRX13D3)* ____ *(xx)* mg	*(DTRX13D4)* ____ *(xx)* mg	*(DTRX13D5)* ____ *(xx)* mg	*(DTRX13D6)* ____ *(xx)* mg	*(DTRX13D7)* ____ *(xx)* mg

Day 14 medication(s):	(DTRX14M1)	(DTRX14M2)	(DTRX14M3)	(DTRX14M4)	(DTRX14M5)	(DTRX14M6)	(DTRX14M7)
	-- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	-- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	-- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	-- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	-- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	-- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below	-- Buprenorphine sublingual -- Oral naltrexone -- Intramuscular XR-naltrexone -- Other Autonomic dysfunction agents *Additional Options Listed Below
Total daily dose:	*(DTRX14D1)* ____ *(xx)* mg	*(DTRX14D2)* ____ *(xx)* mg	*(DTRX14D3)* ____ *(xx)* mg	*(DTRX14D4)* ____ *(xx)* mg	*(DTRX14D5)* ____ *(xx)* mg	*(DTRX14D6)* ____ *(xx)* mg	*(DTRX14D7)* ____ *(xx)* mg

b. Was medically supervised withdrawal (detoxification) for opioids completed? *(DTCMPOPI)* — ☐ No ☐ Yes

2. Did the participant require medically supervised withdrawal (detoxification) for alcohol? *(DTDTXALC)* — ☐ No ☐ Yes

Comments: *(DTXCOMM)*

Additional Selection Options for DTX

Detox sequence number *(DTSEQNUM)* (key field):
1
2
3
4
5
6

Detox med 1 day 1
-- Diphenhydramine
-- Tizanidine
-- Clonidine
-- Other autonomic dysfunction agents
Non-Benzodiazepine anxiolytics
-- Hydroxyzine
-- Gabapentin
-- Other non-benzodiazepine anxiolytics
Benzodiazepine anxiolytics
-- Chlordiazepoxide
-- Clonazepam
-- Lorazepam
-- Other benzodiazepine anxiolytics
Sleep aids
-- Trazodone
-- Zolpidem
-- Quetiapine
-- Mirtazapine
-- Other sleep aids
Analgesics
-- Acetaminophen
-- Naproxen
-- Ibuprofen
-- Other analgesics
Anti-emetics, anti-diarrheals
-- Aggressive oral hydration
-- Loperamide
-- Ondansetron
-- Prochlorperazine
-- Dicyclomine
-- Other anti-emetics, anti-diarrheals

End of Treatment (EOT)

Web Version: 1.0; 1.00; 11-20-17

Segment *(PROTSEG)*: B

1. Did the participant permanently discontinue XR-NTX for treatment of opioid use early?*(EOTEARLY)* No Yes
2. Did the participant permanently discontinue medication early?*(EOTEARLY)* No Yes

Primary reason for stopping XR-NTX early:*(EOREASON)*

- Participant failed to return to site and unable to contact
- Participant moved from area
- Participant incarcerated
- Participant deceased
- Participant became pregnant
- *Additional Options Listed Below

Primary reason for stopping medication early:*(EOREASON)*

- Participant failed to return to site and unable to contact
- Participant moved from area
- Participant incarcerated
- Participant deceased
- Participant became pregnant
- *Additional Options Listed Below

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

3. Date of last dose of XR-NTX:*(EOTRTDT)* *(mm/dd/yyyy)*
4. Date of last dose of medication:*(EOTRTDT)* *(mm/dd/yyyy)*

Comments:*(EOTCOMM)*

Additional Selection Options for EOT

Primary reason for stopping XR-NTX early:
Participant withdrew consent/assent
Participant reports intolerable symptoms or side effects
Participant feels treatment no longer necessary, cured
Participant feels treatment no longer necessary, not working
Participant in hospital, in-patient, or residential treatment (not for substance use treatment)
Participant is in detox, residential, or intensive outpatient treatment for substance use treatment
Participant met criteria for prisoner status
Participant refused, non-specific
Physical illness or condition that precludes taking study medication
Contraindicted concomitant medication
Clinical deterioration: New onset of psychiatric or medical condition
Participant stopped due to AE/SAE
Other

EQ-5D-3L (EQD)

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

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

Health Questionnaire

English version for the USA

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

Mobility
(EQ5MBTLY)

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

Self-Care
(EQ5SLFCR)

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

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

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

Pain / Discomfort
(EQ5PAIND)

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

Anxiety / Depression
(EQ5ANXDE)

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

We would like to know how good or bad your health is TODAY.
This scale is numbered 0 to 100.
100 means the best health you can imagine.
0 means the worst health you can imagine.
Please tap on the scale to indicate how your health is TODAY.

YOUR
HEALTH
TODAY*(EQ5HLTTD)*

(xxx)
The best health you can imagine
The worst health you can imagine

Participant required research staff assistance in reading the questions in this assessment:
Note: this includes if participant could not see well enough to read the questions or if the participant was unable to read well enough to read the questions.
(EQHELP)

Yes

0067B (ENR)

Web Version: 1.0; 2.00; 04-20-18

Date participant is being randomized or screen failed:*(STARTDT)* *(mm/dd/yyyy)*

Inclusion Criteria

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

1. Participant is 18 years of age or older:*(R7PTAGE)*	No	Yes		
2. Participant is willing and able to provide written informed consent and HIPAA Authorization (if applicable) for medical record abstraction:*(R7MRAB)*	No	Yes	Unknown	
3. Participant meets DSM-5 criteria for moderate or severe opioid use disorder:*(R7OPIDIS)*	No	Yes	Unknown	
4. Participant is willing to be randomized to antagonist-based therapy or TAU:*(R7OKRAND)*	No	Yes	Unknown	
5. Participant has an HIV viral RNA count > 200 copies/ml: *HIV viral RNA may be drawn with screening blood draw or abstracted from medical records if drawn in the 90 days prior to the date of consent. (R7HIVRNA)*	No	Yes	Unknown	
6. Participant is willing to establish ongoing HIV care at the site if not already receiving ongoing care: *(R7HIVCAR)*	No	Yes	Unknown	
7. Participant is willing to take at least one evidence-based measure to avoid becoming pregnant: *(R7BCUSE)*	No	Yes	Unknown	Not applicable

Exclusion Criteria

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

1. Participant has a severe medical, psychiatric or substance use disorder that, in the opinion of the study physician, would make study participation hazardous to the participant, compromise study findings, or prevent the participant from completing the study due to imminent risk of death: *Hospitalized patients who do not meet these conditions remain eligible for participation.* *(R7MEDRSK)*	No	Yes	Unknown	
2. Participant has aspartate aminotransferase (AST) or alanine aminotransferase (ALT) liver enzymes greater than 5 times upper limit of normal on screening phlebotomy: *Results from tests conducted within the past 30 days from date of consent may be abstracted from medical records.(R7ASTALT)*	No	Yes	Unknown	
3. Participant has INR > 1.5 or platelet count <100k: *Results from tests conducted within the past 30 days from date of consent may be abstracted from medical records.(R7INRPLT)*	No	Yes	Unknown	
4. Participant has known allergy or sensitivity to naloxone, naltrexone, polylactide-co-glycolide, carboxymethylcellulose, or other components of the Vivitrol® diluents:*(R7SENSIT)*	No	Yes	Unknown	
5. Participant anticipates undergoing surgery during study participation:*(R7SURGRY)*	No	Yes	Unknown	
6. Participant has chronic pain requiring ongoing pain management with opioid analgesics: *(R7CHRONP)*	No	Yes	Unknown	
7. Participant (at time of consent) is pregnant or breastfeeding or planning on conceiving in the coming months:*(R7PRGBF)*	No	Yes	Unknown	Not applicable
8. Participant has body habitus that, in the judgment of the study physician, precludes safe intramuscular injection of XR-NTX (e.g., excess fat tissue over the buttocks):*(R7HABITU)*	No	Yes	Unknown	
9. Participant has received methadone or buprenorphine maintenance therapy for treatment of opioid use disorder in the 4 weeks prior to consent: *(medically supervised withdrawal therapy is allowed)(R7BUPTRT)*	No	Yes	Unknown	
10. Participant has received ongoing XR-NTX injections as maintenance therapy for opioid or alcohol use disorder in the 4 weeks prior to consent: *(does not exclude individuals leaving incarceration with a single injection and no specific follow up)* *(R7PRITRT)*	No	Yes	Unknown	
11. Participant has taken an investigational drug in another study within 30 days of study consent: *(R7INVDRG)*	No	Yes	Unknown	
12. Participant is currently in jail, prison or any overnight facility as required by court of law or have pending legal action that could prevent participation in study activities:*(R7JAIL)*	No	Yes	Unknown	

Eligibility for Randomization

1. Is the participant eligible for the study?*(R7ELGSTY)*	No	Yes
2. Will the participant be randomized?*(R7ELGRND)*	No	Yes

a. If "No", specify:*(R7NORAND)*

- Participant refused
- Declined study participation
- Death
- Judgement of site/research staff
- Failed to return to clinic prior to randomization
- Other

If "Judgement of site/research staff" or "Other", specify:*(R7NORDSP)*

b. If "Yes", date eligibility was confirmed by clinician:*(R7ELIGDT)* *(mm/dd/yyyy)*

Comments:*(R7COMM)*

Fatal Opioid Overdose (FOO)

Web Version: 1.0; 1.00; 08-15-17

1. Date of suspected or confirmed opioid overdose:*(FOODDT)* *(mm/dd/yyyy)*
2. Date site became aware of fatal overdose:*(FOAWARDT)* *(mm/dd/yyyy)*
3. Source of information:*(FOSOURCE)*

Medical record
Locator form inquiry
Other

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

Comments:*(FOOCOMM)*

HIV Care Utilization (Abstracted Records) (HCU)

Web Version: 1.0; 1.00; 09-15-17

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

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

This form collects abstracted medical record data only.

Number of HIV primary care visits attended between baseline and week 24:*(HCVISITS)* *(xx)*

If a visit was attended, did at least one HIV primary care visit occur in the past 12 weeks? *(HCPC12WK)* No Yes

Comments:*(HCUCOMM)*

Injection Site Abnormality (INA)

Web Version: 1.0; 2.00; 09-13-17

Segment *(PROTSEG)*: B

If abnormality results in a Serious Adverse Event (SAE), complete the Adverse Event forms as well.

	Abnormal Event *(If "Other", specify in comments)*	Event Start Date	Severity	Treatment *(If "Yes", specify in comments)*		Event Resolution Date	Comments
1.	*(INTYP1)* Pain, Tenderness, Induration, Swelling, Erythema (redness), *Additional Options Listed Below	*(INSDT1)*	*(INSVR1)* Mild, Moderate, Severe	*(INTRT1)*	No / Yes	*(INRDT1)*	*(INCOM1)*
2.	*(INTYP2)* Pain, Tenderness, Induration, Swelling, Erythema (redness), *Additional Options Listed Below	*(INSDT2)*	*(INSVR2)* Mild, Moderate, Severe	*(INTRT2)*	No / Yes	*(INRDT2)*	*(INCOM2)*
3.	*(INTYP3)* Pain, Tenderness, Induration, Swelling, Erythema (redness), *Additional Options Listed Below	*(INSDT3)*	*(INSVR3)* Mild, Moderate, Severe	*(INTRT3)*	No / Yes	*(INRDT3)*	*(INCOM3)*
4.	*(INTYP4)* Pain, Tenderness, Induration, Swelling, Erythema (redness), *Additional Options Listed Below	*(INSDT4)*	*(INSVR4)* Mild, Moderate, Severe	*(INTRT4)*	No / Yes	*(INRDT4)*	*(INCOM4)*
5.	*(INTYP5)* Pain, Tenderness, Induration, Swelling, Erythema (redness), *Additional Options Listed Below	*(INSDT5)*	*(INSVR5)* Mild, Moderate, Severe	*(INTRT5)*	No / Yes	*(INRDT5)*	*(INCOM5)*
6.	*(INTYP6)* Pain, Tenderness, Induration, Swelling, Erythema (redness), *Additional Options Listed Below	*(INSDT6)*	*(INSVR6)* Mild, Moderate, Severe	*(INTRT6)*	No / Yes	*(INRDT6)*	*(INCOM6)*
7.	*(INTYP7)* Pain, Tenderness, Induration, Swelling, Erythema (redness), *Additional Options Listed Below	*(INSDT7)*	*(INSVR7)* Mild, Moderate, Severe	*(INTRT7)*	No / Yes	*(INRDT7)*	*(INCOM7)*
8.	*(INTYP8)* Pain, Tenderness, Induration, Swelling, Erythema (redness), *Additional Options Listed Below	*(INSDT8)*	*(INSVR8)* Mild, Moderate, Severe	*(INTRT8)*	No / Yes	*(INRDT8)*	*(INCOM8)*

/

9. *(INTYP9)* Pain Tenderness Induration Swelling Erythema (redness) *Additional Options Listed Below	*(INSDT9)*	*(INSVR9)* Mild Moderate Severe	*(INTRT9)* Yes	No	*(INRDT9)*	*(INCOM9)*
10. *(INTYP_10)* Pain Tenderness Induration Swelling Erythema (redness) *Additional Options Listed Below	*(INSDT_10)*	*(INSVR_10)* Mild Moderate Severe	*(INTRT_10)* Yes	No	*(INRDT_10)*	*(INCOM_10)*
11. *(INTYP_11)* Pain Tenderness Induration Swelling Erythema (redness) *Additional Options Listed Below	*(INSDT_11)*	*(INSVR_11)* Mild Moderate Severe	*(INTRT_11)* Yes	No	*(INRDT_11)*	*(INCOM_11)*
12. *(INTYP_12)* Pain Tenderness Induration Swelling Erythema (redness) *Additional Options Listed Below	*(INSDT_12)*	*(INSVR_12)* Mild Moderate Severe	*(INTRT_12)* Yes	No	*(INRDT_12)*	*(INCOM_12)*
13. *(INTYP_13)* Pain Tenderness Induration Swelling Erythema (redness) *Additional Options Listed Below	*(INSDT_13)*	*(INSVR_13)* Mild Moderate Severe	*(INTRT_13)* Yes	No	*(INRDT_13)*	*(INCOM_13)*
14. *(INTYP_14)* Pain Tenderness Induration Swelling Erythema (redness) *Additional Options Listed Below	*(INSDT_14)*	*(INSVR_14)* Mild Moderate Severe	*(INTRT_14)* Yes	No	*(INRDT_14)*	*(INCOM_14)*
15. *(INTYP_15)* Pain Tenderness Induration Swelling Erythema (redness) *Additional Options Listed Below	*(INSDT_15)*	*(INSVR_15)* Mild Moderate Severe	*(INTRT_15)* Yes	No	*(INRDT_15)*	*(INCOM_15)*
16. *(INTYP_16)* Pain Tenderness Induration Swelling Erythema (redness) *Additional Options Listed Below	*(INSDT_16)*	*(INSVR_16)* Mild Moderate Severe	*(INTRT_16)* Yes	No	*(INRDT_16)*	*(INCOM_16)*
17. *(INTYP_17)* Pain Tenderness Induration Swelling Erythema (redness) *Additional Options Listed Below	*(INSDT_17)*	*(INSVR_17)* Mild Moderate Severe	*(INTRT_17)* Yes	No	*(INRDT_17)*	*(INCOM_17)*
18. *(INTYP_18)* Pain Tenderness Induration Swelling Erythema (redness) *Additional Options Listed Below	*(INSDT_18)*	*(INSVR_18)* Mild Moderate Severe	*(INTRT_18)* Yes	No	*(INRDT_18)*	*(INCOM_18)*
19. *(INTYP_19)*	*(INSDT_19)*	*(INSVR_19)*	*(INTRT_19)*	No	*(INRDT_19)*	*(INCOM_19)*

/

Pain Tenderness Induration Swelling Erythema (redness) *Additional Options Listed Below		Mild Moderate Severe	Yes			
20. *(INTYP_20)* Pain Tenderness Induration Swelling Erythema (redness) *Additional Options Listed Below	*(INSDT_20)*	*(INSVR_20)* Mild Moderate Severe	*(INTRT_20)* Yes	No	*(INRDT_20)*	*(INCOM_20)*

Comments:*(INACOMM)*

Additional Selection Options for INA

Event 1 type
Bruising
Pruritus
Nodule
Hematoma
Abscess
Sterile abscess
Necrosis
Cellulitis
Warmth
Other

XR-NTX Administration (INJ)

Web Version: 1.0; 1.01; 04-19-18

Segment *(PROTSEG)*: B
Injection number *(INJNUM)*:

Date of injection:*(INJINJDT)* *(mm/dd/yyyy)*

1. Location of previous injection:*(INPREV)* Right buttock Left buttock
2. Injection location:*(ININJLOC)* Right buttock Left buttock

3. Did you experience difficulty with XR-NTX administration?*(INDIFFCT)* No Yes
   If "Yes", describe:*(INDIFRES)*

4. Did the participant experience precipitated withdrawal following extended-release naltrexone injection?*(INWTHDRW)* No Yes

Comments:*(INJCOMM)*

Additional Selection Options for INJ

Injection number *(INJNUM)* (key field):
1
2
3
4
5
6
7
8

Injection Site Examination (IX2)

Web Version: 1.0; 1.01; 04-19-18

Segment *(PROTSEG)*: B
Injection number *(INJNUM)*:
Examination number *(EXAMNUM)*:

Date of examination:*(INXEXMDT)* *(mm/dd/yyyy)*

1. Location of previous injection:*(INXPREV)* Right buttock Left buttock
2. Location of injection:*(IXINJLOC)* Right buttock Left buttock
3. Is this injection site normal?*(INJNORM)* Normal Abnormal

If the injection site is "abnormal", complete the Injection Site Abnormality log.
If abnormality results in a Serious Adverse Event (SAE), complete the Adverse Event forms as well.

Comments:*(IX2COMM)*

Additional Selection Options for IX2

Injection number *(INJNUM)* (key field):
1
2
3
4
5
6
7
8

Examination number *(EXAMNUM)* (key field):
1
2
3

NIDA Clinical Trials Network

Clinical Laboratory Tests (LAB)

Web Version: 1.0; 9.01; 01-30-20

Segment *(PROTSEG)*: B
Visit number *(VISNO)*: 00

Hepatitis *Specimen from abstracted records must be within 90 days prior to enrollment*	**Result**	**Date of Specimen Collection**	**Abstracted from Medical Record**
1 Hep B surface antigen (HBsAG):	☐ Negative ☐ Positive (LAHEPB)	MM/DD/YYYY (LAHEPBDT)	☐ Yes (LAHEPBMR)
2 Hep C antibody:	☐ Negative ☐ Positive ☐ Not done (LAHCVA)	MM/DD/YYYY (LAHCVADT)	☐ Yes (LAHCVAMR)
3 Hep C PCR confirmation:	☐ Negative ☐ Positive ☐ Not done (LAHCVP)	MM/DD/YYYY (LAHCVPDT)	☐ Yes (LAHCVPMR)
HIV Measures *Specimen from abstracted records must be within 90 days prior to enrollment*	**Result**	**Date of Specimen Collection**	**Abstracted from Medical Records**
4 CD4 Count:	xxxxx cells/µL (LACD4)	MM/DD/YYYY (LACD4DT)	☐ Yes (LACD4MR)

5 Was a sample submitted for PBMCs (peripheral blood mononuclear cells)? ☐ No ☐ Yes (LAPBMCS)

If "Yes":

a Date PBMC sample was drawn: MM/DD/YYYY (LAPBMCDT)

b Date PBMC sample was shipped: MM/DD/YYYY (LAPBMCSH)

Comments: (LABCOMM)

NIDA Clinical Trials Network

Clinical Laboratory Tests (LAB)

Web Version: 1.0; 9.01; 01-30-20

Segment *(PROTSEG)*: B
Visit number *(VISNO)*: 12

Date of lab collection: MM/DD/YYYY (LABCOLDT)

1 HIV-1 RNA PCR: xxxxxxxx (LAHIV)
copies/mL **- or -** ☐ Undetectable

LFTs	Result
2 Aspartate Aminotransferase (AST/SGOT):	xxxx.x IU/L (LAAST)
3 Alanine Aminotransferase (ALT/SGPT):	xxxx.x IU/L (LAALT)
4 INR:	x.xx (LAINR)
HIV Measures	**Result**
5 CD4 Count:	xxxxx cells/µL (LACD4)

6 Was a sample submitted for PBMCs (peripheral blood mononuclear cells)? ☐ No ☐ Yes (LAPBMCS)

If "Yes":

a Date PBMC sample was drawn: MM/DD/YYYY (LAPBMCDT)

b Date PBMC sample was shipped: MM/DD/YYYY (LAPBMCSH)

Comments: (LABCOMM)

Clinical Laboratory Tests (LAB)

Date of lab collection: MM/DD/YYYY

1 HIV-1 RNA PCR: xxxxxxxx copies/mL **- or -** ☐ Undetectable

CBC	Result
2 Hemoglobin:	xx.x g/dL
3 Platelets:	xxxx.x $x10^3/\mu L$
Metabolic Panel	**Result**
4 Serum Creatinine:	xx.xx mg/dL
LFTs	**Result**
5 Aspartate Aminotransferase (AST/SGOT):	xxxx.x IU/L
6 Alanine Aminotransferase (ALT/SGPT):	xxxx.x IU/L
7 INR:	x.xx
Hepatitis	**Result**
8 Hep C antibody:	☐ Negative ☐ Positive ☐ Not done

11 Was a sample submitted for PBMCs (peripheral blood mononuclear cells)? ☐ No ☐ Yes (LAPBMCS)

If "Yes":

a Date PBMC sample was drawn: MM/DD/YYYY (LAPBMCDT)

b Date PBMC sample was shipped: MM/DD/YYYY (LAPBMCSH)

Comments: (LABCOMM)

Medication Adherence (MAD)

Web Version: 1.0; 3.00; 04-02-19

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

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

HIV Antiretroviral Medications

Now we are going to ask you about your HIV medications (antiretroviral medications). Many patients find it difficult to take all of their HIV medications exactly as prescribed.

1. Are you currently prescribed any anti-HIV medications?*(MAART)* No Yes
2. Thinking about the **past 4 weeks**, on average, how would you rate your ability to take all of your HIV antiretroviral medications as your doctor prescribed?*(MATKART)*
   Very poor / Poor / Fair / Good / Very good / Excellent
3. Think about your HIV medications over the **past month**. Click on the line below or click and drag the blue circle to the spot that most closely reflects the percentage of HIV medications that have been taken in the **past month**.*(MAARTPRC)* *(xxx)*
4. How many doses of your medications did you miss in the **past 7 days**?*(MAMISART)*
   0 / 1 / 2 / 3 / 4 / More than 4
5. When was the last time you missed any of your anti-HIV medications?*(MALSTART)*
   Within the past week / 1-2 weeks ago / 2-4 weeks ago / 1-3 months ago / More than 3 months ago / Never skip medications

Opioid Use Disorder Medications

Now we are going to ask you about medications to treat opioid use disorder.

6. Are you currently receiving methadone treatment?*(MAMTD)* No Yes
   What is your current daily methadone dose?*(MAMTDDOS)* *(xxx)* mg
7. Thinking about the **past 4 weeks**, on average, how would you rate your ability to take all of your methadone doses?*(MATKMTD)*
   Very poor / Poor / Fair / Good / Very good / Excellent
8. Think about your methadone treatment over the **past month**. Click on the line below or click and drag the blue circle to the spot that most closely reflects the percentage of methadone doses that have been taken in the **past month**.*(MAMTDPRC)* *(xxx)*
9. How many doses of your methadone did you miss in the **past 7 days**?*(MAMISMTD)*
   0 / 1 / 2 / 3 / 4 / More than 4
10. How many days in the **past 28 days** did you take at least 1 dose of methadone?*(MATAKMTD)* *(xx)* days
11. When was the last time you missed any of your methadone doses?*(MALSTMTD)*
    Within the past week / 1-2 weeks ago / 2-4 weeks ago / 1-3 months ago / More than 3 months ago / Never skip medications
12. Are you currently prescribed buprenorphine?*(MABUP)* No Yes
    What is your current daily buprenorphine dose?*(MABUPDOS)* *(xx.x)* mg

/

13. Thinking about the **past 4 weeks**, on average, how would you rate your ability to take all of your buprenorphine doses?*(MATKBUP)*

Very poor
Poor
Fair
Good
Very good
Excellent

14. Think about your buprenorphine treatment over the **past month**. Click on the line below or click and drag the blue circle to the spot that most closely reflects the percentage of buprenorphine doses that have been taken in the **past month**.*(MABUPPRC)*

(xxx)

15. How many doses of your buprenorphine did you miss in the **past 7 days**?*(MAMISBUP)*

0
1
2
3
4
More than 4

16. How many days in the **past 28 days** did you take at least 1 dose of buprenorphine?*(MATAKBUP)*

(xx) days

17. When was the last time you missed any of your buprenorphine doses?*(MALSTBUP)*

Within the past week
1-2 weeks ago
2-4 weeks ago
1-3 months ago
More than 3 months ago
Never skip medications

18. Are you currently receiving extended-release naltrexone (Vivitrol) treatment?*(MATAKNTX)*

No Yes

Participant required research staff assistance in reading the questions in this assessment:
Note: this includes if participant could not see well enough to read the questions or if the participant was unable to read well enough to read the questions.(MAHELP)

Yes

Comments:*(MADCOMM)*

/

Missed Visit (MVF)

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

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

Reason for missed visit:*(MVREASON)*

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

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

Comments:*(MVFCOMM)*

Additional Selection Options for MVF

Reason for missed visit:
Participant moved from area
Participant incarcerated
Site closed
Participant withdrew consent
Participant deceased
Other

Non-Fatal Opioid Overdose (Self-Report) (NFO)

Web Version: 1.0; 1.00; 09-08-17

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

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

An opioid overdose occurs when someone turns blue, has little or no breathing, or passes out and cannot be woken up without help after using opioids (drugs like heroin, oxycodone, methadone, fentanyl, dilaudid, or percocet).

Baseline visit date:*(NFBASEDT)* *(mm/dd/yyyy)*

1. Have you had an opioid overdose since the baseline visit date?*(NFOPIOD)* No Yes

   If "Yes", number of times:*(NFODNUM)* *(xx)*

Comments:*(NFOCOMM)*

Naloxone Challenge (NXC)

Web Version: 1.0; 3.00; 09-21-18

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

Date of naloxone administration:*(NXCDOSDT)* *(mm/dd/yyyy)*

First Dose

1. Time of administration *(24-hour format)*:*(NXDOSTM1)* *(hh:mm)*
2. Total dose:*(NXDOS1)* *(x.xx)* mg
3. Route of administration:*(NXROUTE1)*

I.V. (Intravenous)
I.M. (Intramuscular injection)
S.C. (Subcutaneous injection)
Intranasal

Second Dose (if applicable)

If a second dose was administered within 30 seconds of the first dose, the total quantity should be entered above as a first dose.

4. Time of administration *(24-hour format)*:*(NXDOSTM2)* *(hh:mm)*
5. Total dose:*(NXDOS2)* *(x.xx)* mg
6. Route of administration:*(NXROUTE2)*

I.V. (Intravenous)
I.M. (Intramuscular injection)
S.C. (Subcutaneous injection)
Intranasal

Third Dose (if applicable)

If a third dose was administered within 30 seconds of the second dose, the total quantity should be entered above as a second dose.

7. Time of administration *(24-hour format)*:*(NXDOSTM3)* *(hh:mm)*
8. Total dose:*(NXDOS3)* *(x.xx)* mg
9. Route of administration:*(NXROUTE3)*

I.V. (Intravenous)
I.M. (Intramuscular injection)
S.C. (Subcutaneous injection)
Intranasal

Results

10. Precipitated withdrawal upon naloxone challenge:*(NXWTHDRW)* No Yes
11. Will the participant proceed with administration of study medication?*(NXADMMED)* No Yes

Comments:*(NXCCOMM)*

Additional Selection Options for NXC

Challenge number *(NXC_CHNO)* (key field):
1
2
3
4
5
6
7
8
9
10
11
12
13
14
15

Pain Assessment (PAA)

Web Version: 1.0; 1.00; 09-08-17

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

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

1. Have you experienced pain in the past 4 weeks?*(PAPAIN)* No Yes

If "Yes", what did you use to treat the pain in the **past 4 weeks**?

		^2Did it work to relieve the pain:
	No	**Yes**
a. Acupuncture:	*(PAACUPNT)*	
b. Massage:	*(PAMASSGE)*	
c. Exercise:	*(PAEXRCSE)*	
d. Non-opioid medications (e.g., ibuprofen, acetaminophen, gabapentin):	*(PAMEDS)*	
e. Prescribed opioid medications:	*(PAOPIRX)*	
f. Non-prescribed opioids:	*(PAOPINRX)*	
g. Consultation with a doctor:	*(PAMD)*	
h. Meditation:	*(PAMEDIT)*	
i. Marijuana/cannabis:	*(PATHC)*	
j. Other, specify:*(PAPNOSP)*	*(PAPAINOT)*	

		0	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
2.	What number best describes your average level of pain in the past week? *'0' represents no pain and '10' represents the worst pain you can imagine.*	*(PAPAINAV)*										
3.	What number best describes how pain has interfered with your enjoyment of life in the past week? *'0' represents no interference and '10' represents complete interference.*	*(PAENJOY)*										
4.	What number best describes how pain has interfered with your general activity in the past week? *'0' represents no interference and '10' represents complete interference.*	*(PAACTVTY)*										

Comments:*(PAACOMM)*

/

Pregnancy and Birth Control Assessment (PBC)

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

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

Complete this form only for females.

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

1. Is the participant continuing to use an effective method of birth control?*(PBUSEBC)* No Yes
2. Date of the first day of the participant's last menstrual period:*(PBMNTDT)* *(mm/dd/yyyy)*
3. Was a pregnancy test performed?*(PBPRGTST)* No Yes
   a. Date of pregnancy test:*(PBPTSTDT)* *(mm/dd/yyyy)*
   b. Result of pregnancy test:*(PBRESULT)* Negative Positive

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

Comments:*(PBCCOMM)*

Protocol Deviation (PDV)

Web Version: 1.0; 3.01; 12-09-19

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

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

No Yes

If "Yes", how many participants?*(PDPRELNO)*

1
2
3
4
5
*Additional Options Listed Below

Select related participants:

Participant ID 1:*(PDPPT01)* DUMMYPARTICIPANTID

Participant ID 2:*(PDPPT02)* DUMMYPARTICIPANTID

Participant ID 3:*(PDPPT03)* DUMMYPARTICIPANTID

Participant ID 4:*(PDPPT04)* DUMMYPARTICIPANTID

Participant ID 5:*(PDPPT05)* DUMMYPARTICIPANTID

Participant ID 6:*(PDPPT06)* DUMMYPARTICIPANTID

Participant ID 7:*(PDPPT07)* DUMMYPARTICIPANTID

Participant ID 8:*(PDPPT08)* DUMMYPARTICIPANTID

Participant ID 9:*(PDPPT09)* DUMMYPARTICIPANTID

Participant ID 10:*(PDPPT10)* DUMMYPARTICIPANTID

Participant ID 11:*(PDPPT11)* DUMMYPARTICIPANTID

Participant ID 12:*(PDPPT12)* DUMMYPARTICIPANTID

Participant ID 13:*(PDPPT13)* DUMMYPARTICIPANTID

Participant ID 14:*(PDPPT14)* DUMMYPARTICIPANTID

Participant ID 15:*(PDPPT15)* DUMMYPARTICIPANTID

Participant ID 16:*(PDPPT16)* DUMMYPARTICIPANTID

Participant ID 17:*(PDPPT17)* DUMMYPARTICIPANTID

Participant ID 18:*(PDPPT18)* DUMMYPARTICIPANTID

Participant ID 19:*(PDPPT19)* DUMMYPARTICIPANTID

Participant ID 20:*(PDPPT20)* DUMMYPARTICIPANTID

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

3. Deviation type:*(PDTYPE)*

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

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

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

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

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

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

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

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

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

Comments:*(PDVCOMM)*

Additional Selection Options for PDV

Protocol deviation number *(PDSEQNO)* (key field):
1st Protocol Deviation of the day
2nd Protocol Deviation of the day
3rd Protocol Deviation of the day
4th Protocol Deviation of the day
5th Protocol Deviation of the day
6th Protocol Deviation of the day
7th Protocol Deviation of the day
8th Protocol Deviation of the day
9th Protocol Deviation of the day
10th Protocol Deviation of the day

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

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

Patient Health Questionnaire (PHQ-9) (PHQ)

Web Version: 1.0; 5.01; 11-19-19

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

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

Please answer the following to the best of your ability.

Over the **last 2 weeks**, how often have you been bothered by any of the following problems?	**Not At All**	**Several Days**	**More Than Half The Days**	**Nearly Every Day**
1. Little interest or pleasure in doing things:	*(PHINTPLE)*			
2. Feeling down, depressed, or hopeless:	*(PHDEPRES)*			
3. Trouble falling or staying asleep, or sleeping too much:	*(PH2SLEEP)*			
4. Feeling tired or having little energy:	*(PH2TIRED)*			
5. Poor appetite or overeating:	*(PHAPPEAT)*			
6. Feeling bad about yourself - or that you are a failure or have let yourself or your family down:	*(PHFAILUR)*			
7. Trouble concentrating on things, such as reading the newspaper or watching television:	*(PH2CONC)*			
8. Moving or speaking so slowly that other people could have noticed. Or the opposite - being so fidgety or restless that you have been moving around a lot more than usual:	*(PHMOVSPK)*			
9. Thoughts that you would be better off dead, or of hurting yourself in some way:	*(PHDEADHU)*			

Participant required research staff assistance in reading the questions in this assessment:
Note: this includes if participant could not see well enough to read the questions or if the participant was unable to read well enough to read the questions.(PHHELP)
Yes

Comments:*(PHQCOMM)*

Confirmed Pregnancy and Outcome (PRG)

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

Pregnancy number *(PGSEQNUM)*:

Information About Pregnancy

1. Date on which study staff became aware of pregnancy:*(PRGAWRDT)* *(mm/dd/yyyy)*
2. How was the pregnancy confirmed? *(select all that apply)*
   a. Urine pregnancy test result:*(PRURICNF)* No Yes
   b. Serum pregnancy test result:*(PRSERCNF)* No Yes
   c. Ultrasound result:*(PRULTCNF)* No Yes
   d. Other:*(PROTHCNF)* No Yes
      If "Other", specify:*(PROTCNSP)*
3. Date on which the pregnancy was confirmed:*(PRCNFMDT)* *(mm/dd/yyyy)*
4. Action taken with study medication:*(PRACTIND)*
   None
   Dose reduced
   Temporarily stopped medication
   Permanently stopped medication
5. Approximate due date:*(PRAPXDDT)* *(mm/dd/yyyy)* *(PRDDTUNK)***OR** Unknown
6. Outcome of pregnancy:*(PROUTCME)*
   Vaginal delivery
   Cesarean delivery
   Miscarriage
   Termination
   Other
   *Additional Options Listed Below
   If "Other", specify:*(PROTCMSP)*
7. Date of pregnancy outcome:*(PROTCMDT)* *(mm/dd/yyyy)*
8. Number of live births:*(PRNMLIVB)*
   0
   1
   2
   3
   4
   *Additional Options Listed Below
   If "0" live births, indicate reason:*(PRRSOBSP)*

Comments:*(PRGCOMM)*

Additional Selection Options for PRG

Pregnancy number *(PGSEQNUM)* (key field):
1
2
3
4

Outcome of pregnancy:
Unknown

Number of live births:
Other
Unknown

Risk Assessment Battery (RAB)

Web Version: 1.0; 2.00; 02-23-18

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

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

Read each of the following questions very carefully. As you will see, many of these questions are very personal. We understand this and have taken great care to protect the privacy of your answers. It is very important that you answer EVERY question honestly. In fact, it's better not to answer a question at all than to tell us something that is not accurate or true. Some questions may not seem to have an answer that is true for you. When this happens, you should simply choose the answer that is most right. Don't spend too much time on any one question. Remember, always ask for help if you're unsure about what to do. Thank you for your time and cooperation.

A. Needle Use

1. In the past month, have you injected drugs?*(RADRGINJ)* No Yes
2. In the past month, have you shared needles or works?*(RASHNDLE)* No or I have not shot up in the past month Yes
3. With how many different people did you share needles in the past month?*(RANDLWNO)*
   - Zero or I have not shot up in the past month
   - 1 other person
   - 2 or 3 different people
   - 4 or more different people
4. In the past month, how often have you used a needle after someone (with or without cleaning)? *(RAUSOTND)*
   - Never or I have not shot up or shared in the past month
   - A few times (1 or 2 times)
   - About once a week (3 or 4 times)
   - More than once a week (5 or more times)
5. In the past month, how often have others used after you (with or without cleaning)?*(RANDLEOT)*
   - Never or I have not shot up or shared in the past month
   - A few times (1 or 2 times)
   - About once a week (3 or 4 times)
   - More than once a week (5 or more times)
6. In the past month, how often have you shared needles with someone you knew (or later found out) was negative for HIV, the AIDS virus?*(RAAIDSND)*
   - Never or I have not shot up or shared in the past month
   - A few times (1 or 2 times)
   - About once a week (3 or 4 times)
   - More than once a week (5 or more times)
7. In the past month, did you get your needles from any of the following:

a. I have not shot up in the past month	*(RANDLNOT)*	No	Yes
b. From a diabetic	*(RANDLDBT)*	No	Yes
c. On the street	*(RANDLSRT)*	No	Yes
d. Drugstore	*(RANDLDST)*	No	Yes
e. Shooting gallery or other place where users go to shoot up	*(RANDLSGY)*	No	Yes
f. Needle Exchange Program	*(RANDLEXC)*	No	Yes
g. Other, specify:*(RANDLOSP)*	*(RANDLOTH)*	No	Yes

8. In the past month, how often have you been to a shooting gallery/house or other place where users go to shoot up?*(RASHTGLY)*
   - Never
   - A few times (1 or 2 times)
   - About once a week (3 or 4 times)
   - More than once a week (5 or more times)
9. In the past month, how often have you been to a Crack House or other place where people go to smoke crack?*(RACRCKHS)*
   - Never
   - A few times (1 or 2 times)
   - About once a week (3 or 4 times)
   - More than once a week (5 or more times)
10. Which statement best describes the way you cleaned your needles during the past month? *(RANDLCLN)*
    - I have not shot up in the past month
    - I ALWAYS use new needles
    - I ALWAYS clean my needle just BEFORE I shoot up
    - After I shoot up, I ALWAYS clean my needle
    - SOMETIMES I clean my needle, sometimes I don't
    - I NEVER clean my needle
11. If you cleaned your needles and works in the past month, how did you clean them?
    a. I have not shot up in the past month

	(RANLNOT)	No	Yes
b. Soap and water only	*(RANLSOAP)*	No	Yes
c. Alcohol	*(RANLALCH)*	No	Yes
d. Bleach	*(RANLBLCH)*	No	Yes
e. Boiling water	*(RANDLWTR)*	No	Yes
f. Other, specify:*(RANLCOSP)*	*(RANLOTHC)*	No	Yes
g. I did not clean my needles in the past month	*(RANOTCLN)*	No	Yes
h. I ALWAYS used new needles in the past month	*(RAALWAYS)*	No	Yes

	Never or I have not shot up or shared in the past month	A few times (1 or 2 times)	About once a week (3 or 4 times)	More than once a week (5 or more times)
12. In the past month, how often have you shared rinse-water?	*(RARH20SH)*			
13. In the past month, how often have you shared a cooker?	*(RACOKRSH)*			
14. In the past month, how often have you shared cotton?	*(RACTNSH)*			
15. In the past month, how often have you divided or shared drugs with others by using one syringe(yours or someone else's) to squirt or load the drugs into the other syringe(s) (backloading, for example)?	*(RABCKLD)*			

B. Sexual Practices

16. How would you describe yourself?*(RASEXPRF)* Straight or heterosexual Gay or homosexual Bisexual

PLEASE NOTE: For the following questions, sex means any vaginal intercourse, anal intercourse (in the butt) or oral sex (blowjobs, for example).

17. With how many men have you had sex in the past month?*(RASEXMEN)* 0 / 1 / 2 or 3 / 4 or more — men/man

18. With how many women have you had sex in the past month?*(RASEXWMN)* 0 / 1 / 2 or 3 / 4 or more — women/woman

	Never	A few times (1 or 2 times)	About once a week (3 or 4 times)	More than once a week (5 or more times)
19. In the past month, how often have you had sex so you could get drugs?	*(RASEX4DG)*			
20. In the past month, how often have you given drugs to someone so you could have sex with them?	*(RADG4SEX)*			
21. In the past month, how often were you paid money to have sex with someone?	*(RAPOSTUT)*			
22. In the past month, how often did you give money to someone so you could have sex with them?	*(RAPD4SEX)*			
23. In the past month, how often have you had sex with someone you knew (or later found out) was negative for HIV, the AIDS virus?	*(RASEXHIV)*			

24. In the past month, how often did you use condoms when you had sex?
This also includes female condoms and dental dams.(RASEXSFE)
I have not had sex in the past month / All the time / Most of the time / Some of the time / None of the time

25. In the past 30 days, how many times did you have penetrative sex (vaginal or anal sex)? *(RASEXPEN)* *(xx)*

26. In the past 30 days, how many times did you have penetrative sex (vaginal or anal sex) without a condom?*(RASEXUPR)* *(xx)*

Participant required research staff assistance in reading the questions in this assessment: Yes
Note: this includes if participant could not see well enough to read the questions or if the participant was unable to read well enough to read the questions.(RAHELP)

Comments:*(RABCOMM)*

/

Study Completion (STC)

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

Segment *(PROTSEG)*: B

1. Did the participant permanently stop attending visits prior to study completion *(completion of week 24)*?*(STSTPERL)* No Yes

   If "Yes", select the primary reason for study discontinuation:*(STERLY67)*

   - Participant failed to return to site and unable to contact
   - Participant moved from area
   - Participant incarcerated
   - Participant terminated due to AE/SAE
   - Participant withdrew consent/assent
   - *Additional Options Listed Below

   If "Participant terminated for other reason", specify:*(STCM67SP)*

2. Date of last data collection or date of withdrawn consent:*(STCOMPDT)* *(mm/dd/yyyy)*

Comments:*(STCCOMM)*

Investigator's Signature

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

Principal Investigator:*(STPISIGN)*

Date:*(STPISGDT)* *(mm/dd/yyyy)*

Additional Selection Options for STC

If "Yes", select the primary reason for study discontinuation:
Participant deceased
Participant feels treatment no longer necessary, cured
Participant feels treatment no longer necessary, not working
Participant in hospital, in-patient, or residential treatment (not for substance use treatment)
Participant became pregnant
Participant reports intolerable symptoms or side effects
Clinical deterioration: New onset of psychiatric or medical condition
Participant is in detox, residential, or intensive outpatient treatment for substance use treatment
Participant met criteria for prisoner status
Contraindicated concomitant medication
Participant refused, non-specific
Physical illness or condition that precludes taking study medication
Participant terminated for other reason

Suicidal Risk (SUR)

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

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

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

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

Was an assessment of suicidal risk performed?*(SUASSESS)* No Yes

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

NIDA Clinical Trials Network

Timeline Followback (T67)

Web Version: 1.0; 1.00; 08-10-17

TFB week start date *(TFWKSTDT)*:

Day	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Date	*(TLDATE1)*	*(TLDATE2)*	*(TLDATE3)*	*(TLDATE4)*	*(TLDATE5)*	*(TLDATE6)*	*(TLDATE7)*
1. Have any cigarettes or e-cigarettes, alcohol, marijuana or non-prescribed drugs been used during this assessment period?	*(TLSUBAL1)* ☐ 0-No ☐ 1-Yes	*(TLSUBAL2)* ☐ 0-No ☐ 1-Yes	*(TLSUBAL3)* ☐ 0-No ☐ 1-Yes	*(TLSUBAL4)* ☐ 0-No ☐ 1-Yes	*(TLSUBAL5)* ☐ 0-No ☐ 1-Yes	*(TLSUBAL6)* ☐ 0-No ☐ 1-Yes	*(TLSUBAL7)* ☐ 0-No ☐ 1-Yes
2. Number of cigarettes (xx):	*(TLNMCIG1)*	*(TLNMCIG2)*	*(TLNMCIG3)*	*(TLNMCIG4)*	*(TLNMCIG5)*	*(TLNMCIG6)*	*(TLNMCIG7)*
3. E-cigarettes:	*(TLECIG1)* ☐ 0-No ☐ 1-Yes	*(TLECIG2)* ☐ 0-No ☐ 1-Yes	*(TLECIG3)* ☐ 0-No ☐ 1-Yes	*(TLECIG4)* ☐ 0-No ☐ 1-Yes	*(TLECIG5)* ☐ 0-No ☐ 1-Yes	*(TLECIG6)* ☐ 0-No ☐ 1-Yes	*(TLECIG7)* ☐ 0-No ☐ 1-Yes
4. Number of standard alcoholic drinks (xx):	*(TLALCHL1)*	*(TLALCHL2)*	*(TLALCHL3)*	*(TLALCHL4)*	*(TLALCHL5)*	*(TLALCHL6)*	*(TLALCHL7)*
5. Cannabinoids/ Marijuana:	*(TLTHCR1)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLTHCR2)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLTHCR3)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLTHCR4)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLTHCR5)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLTHCR6)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLTHCR7)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below
6. Cocaine:	*(TLCOCR1)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLCOCR2)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLCOCR3)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLCOCR4)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLCOCR5)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLCOCR6)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLCOCR7)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below
7. Crack:	*(TLCRAKR1)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLCRAKR2)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLCRAKR3)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLCRAKR4)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLCRAKR5)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLCRAKR6)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLCRAKR7)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below
8. Amphetamine-type stimulants:	*(TLAMPR1)*	*(TLAMPR2)*	*(TLAMPR3)*	*(TLAMPR4)*	*(TLAMPR5)*	*(TLAMPR6)*	*(TLAMPR7)*

	0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below
9. Opioid analgesics, including methadone:	*(TLMTDR1)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLMTDR2)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLMTDR3)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLMTDR4)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLMTDR5)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLMTDR6)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLMTDR7)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below
10. Heroin:	*(TLHERR1)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLHERR2)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLHERR3)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLHERR4)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLHERR5)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLHERR6)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLHERR7)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below
11. Hallucinogens, including MDMA/ecstasy:	*(TLMDAR1)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLMDAR2)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLMDAR3)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLMDAR4)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLMDAR5)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLMDAR6)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLMDAR7)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below
12. Sedatives and hypnotics, excluding Benzodiazepines:	*(TLBARR1)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLBARR2)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLBARR3)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLBARR4)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLBARR5)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLBARR6)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLBARR7)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below
13. Benzodiazepines:	*(TLBZOR1)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLBZOR2)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLBZOR3)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLBZOR4)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLBZOR5)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLBZOR6)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLBZOR7)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below
14. Inhalants:	*(TLINHR1)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLINHR2)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLINHR3)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLINHR4)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLINHR5)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLINHR6)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLINHR7)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below
Other Drugs							
15. Other drug 1	*(TLOT1R1)*	*(TLOT1R2)*	*(TLOT1R3)*	*(TLOT1R4)*	*(TLOT1R5)*	*(TLOT1R6)*	*(TLOT1R7)*

use:	0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below
Specify other drug 1:	*(TLOTSP11)*	*(TLOTSP12)*	*(TLOTSP13)*	*(TLOTSP14)*	*(TLOTSP15)*	*(TLOTSP16)*	*(TLOTSP17)*
16. Other drug 2 use:	*(TLOT2R1)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLOT2R2)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLOT2R3)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLOT2R4)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLOT2R5)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLOT2R6)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	*(TLOT2R7)* 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below
Specify other drug 2:	*(TLOTSP21)*	*(TLOTSP22)*	*(TLOTSP23)*	*(TLOTSP24)*	*(TLOTSP25)*	*(TLOTSP26)*	*(TLOTSP27)*

Comments:*(TFBCOMM)*

Additional Selection Options for T67

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

TLFB Assessment Period (TAP)

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

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

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

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

2. Have any cigarettes or e-cigarettes, alcohol, marijuana or non-prescribed drugs been used during this assessment period?*(TASUBALC)* No Yes

Comments:*(TAPCOMM)*

Translated Form Documentation (TFD)

Web Version: 1.0; 1.00; 09-04-18

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

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

Indicate "No" or "Yes" if the participant used the translated documents.
If participant was not re-consented, indicate "N/A".
Otherwise, indicate "No" or "Yes" if the participant used the translated documents.

1. Was the translated informed consent used for this participant?*(TFICF)*	No	Yes	
2. Was the translated re-consent used for this participant?*(TFRECONS)*	No	Yes	N/A
3. Did the participant use the translated ePRO system or paper ePRO forms at this visit?*(TFEPRO)*	No	Yes	
4. Were the translated paper eClinical CRFs used for this participant at this visit?*(TFPAPER)*	No	Yes	

Comments:*(TFDCOMM)*

Treatment Satisfaction (TS1)

Web Version: 1.0; 2.00; 02-23-18

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

Date of assessment:*(TS1ASMDT)* *(mm/dd/yyyy)*

1. Overall, how helpful do you think the treatment to which you were assigned was in reducing your **opioid** use?*(T1TXOPI)*

Not helpful
A little bit helpful
Somewhat helpful
Quite helpful
Very helpful

2. Which part of the treatment do you think was most helpful in reducing your **opioid** use?*(T1BSOPI)*

Inpatient detoxification
Outpatient detoxification
Residential rehabilitation
Outpatient rehabilitation
Group therapy sessions
12-step groups (NA/AA)
One-on-one addiction counseling
Methadone maintenance therapy
Buprenorphine maintenance therapy
Extended-release naltrexone (Vivitrol)
Oral naltrexone for alcohol dependence
Disulfiram
Accamprosate
Topiramate
Other

If "Other", specify:*(T1BOPISP)*

3. How satisfied are you with receiving treatment for opioid use disorder in the same clinic in which you receive HIV care?*(T1SFYTX)*

Very satisfied
Satisfied
Neither satisfied nor dissatisfied
Dissatisfied
Very dissatisfied

4. Overall, how helpful do you think the treatment to which you were assigned was in reducing your **alcohol** use?*(T1TXALC)*

Not at all
A little bit
Moderately
Quite a bit
Extremely
Not applicable

5. How satisfied are you with your overall experience in the study?*(T1SFYEXP)*

Very satisfied
Satisfied
Neither satisfied nor dissatisfied
Dissatisfied
Very dissatisfied

6. If you had to do it all over again, would you still choose to participate in this study?*(T1PARTPT)*

Definitely participate
Probably participate
Probably not participate
Definitely not participate

7. Please answer "No" or "Yes" as to why you would choose to participate again:

a. I liked the compensation/cash or gift cards:*(T1CASH)*	No	Yes	
b. I liked the counseling:*(T1COUNSL)*	No	Yes	
c. I liked how the medication made me feel:*(T1MEDS)*	No	Yes	Not applicable
d. I didn't have to pay to participate in the study:*(T1NOPAY)*	No	Yes	
e. The study/treatment helped me:*(T1HELPED)*	No	Yes	
f. I was able to get into the study quickly:*(T1QUICK)*	No	Yes	
g. There aren't many other treatment options available to me:*(T1NOOPT)*	No	Yes	
h. My participation may help others/contribute to science:*(T1SCIENC)*	No	Yes	
i. The staff treated me well:*(T1STAFF)*	No	Yes	
j. Desirable location/easy to get to clinic:*(T1LOCATN)*	No	Yes	

/

k. Convenient clinic hours/days:*(T1HOURS)* — No Yes

l. Other:*(T1DOAGOT)* — No Yes

If "Other", specify:*(T1DOOTSP)*

8. What is the primary reason you would choose to participate again?*(T1PRIMDO)*

I liked the compensation/cash or gift cards
I liked the counseling
I liked how the medication made me feel
I didn't have to pay to participate in the study
The study/treatment helped me
*Additional Options Listed Below

If "Other", specify:*(T1PRIMSP)*

9. Please answer "No" or "Yes" as to why you would choose not to participate again:

a. There was not enough compensation/cash or gift cards:*(T1NOCASH)* — No Yes

b. I didn't like the counseling:*(T1NOCNSL)* — No Yes

c. I didn't like how the medication made me feel:*(T1NOMEDS)* — No Yes Not applicable

d. The medication caused undesirable side effects:*(T1SDEFFC)* — No Yes Not applicable

e. The study/treatment didn't help me:*(T1NOHELP)* — No Yes

f. There were too many visits:*(T1VISITS)* — No Yes

g. There were too many procedures/visits that lasted too long:*(T1LNGVST)* — No Yes

h. There wasn't enough counseling:*(T1MRCNSL)* — No Yes

i. I would rather enroll in a usual treatment program:*(T1TAUBTR)* — No Yes

j. The staff didn't treat me well:*(T1NOSTAF)* — No Yes

k. Undesirable location/difficult to get to clinic:*(T1NOLOC)* — No Yes

l. Inconvenient clinic hours/days:*(T1NOHOUR)* — No Yes

m. Other:*(T1NODOOT)* — No Yes

If "Other", specify:*(T1NODOSP)*

10. What is the primary reason you would choose to not participate again?*(T1PRIMNO)*

There was not enough compensation/cash or gift cards
I didn't like the counseling
I didn't like how the medication made me feel
The medication caused undesirable side effects
The study/treatment didn't help me
*Additional Options Listed Below

If "Other", specify:*(T1PMNOSP)*

Participant required research staff assistance in reading the questions in this assessment: Yes
Note: this includes if participant could not see well enough to read the questions or if the participant was unable to read well enough to read the questions.(T1HELP)

Comments:*(TS1SCOMM)*

/

Additional Selection Options for TS1

What is the primary reason you would choose to participate again?
I was able to get into the study quickly
There aren't many other treatment options available to me
My participation may help others/contribute to science
The staff treated me well
Desirable location/easy to get to clinic
Convenient clinic hours/days
Other

What is the primary reason you would choose to not participate again?
There were too many visits
There were too many procedures/visits lasted too long
There wasn't enough counseling
I would rather enroll in a usual treatment program
The staff didn't treat me well
Undesirable location/difficult to get to clinic
Inconvenient clinic hours/days
Other

Tobacco Use History (TUH)

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

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

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

1. Have you smoked at least 100 cigarettes in your entire life?*(TUSMK100)* — No Yes Don't know/refused
2. Do you now smoke cigarettes every day, some days, or not at all?*(TUSMFREQ)*
   - Every day
   - Some days
   - Not at all
   - Don't know/refused
3. Have you EVER smoked cigarettes EVERY DAY for at least 6 months?*(TUEVERY)* — No Yes Don't know/refused
4. How old were you when you first started smoking cigarettes FAIRLY REGULARLY?*(TUSTRTRG)* — *(xx)* years old *(TUSTRGDR)* Don't know/refused

Section A: Every-Day Smokers

5. On the average, about how many cigarettes do you now smoke each day?*(TUNUMDY)* — *(xx)* cigarettes per day *(TUNMDYDR)* Don't know/refused
6. How old were you when you first started smoking cigarettes every day?*(TUSTRTAG)* — *(xx)* years old *(TUSTAGDR)* Don't know/refused

Section B: Some-Day Smokers

7. On how many of the past 30 days did you smoke cigarettes?*(TU30DAYS)* — *(xx)* days *(TU30DDR)* Don't know/refused
8. On the average, on those days, how many cigarettes did you usually smoke each day?*(TU30AVG)* — *(xx)* cigarettes per day *(TU30ADR)* Don't know/refused

Section C: Former Smokers

9. When you last smoked every day, on average how many cigarettes did you smoke each day? *(TUNUMEDY)* — *(xx)* cigarettes per day *(TUNMEDDR)* Don't know/refused
10. When you last smoked fairly regularly, on average how many cigarettes did you smoke each day? *(TUNUMRDY)* — *(xx)* cigarettes per day *(TUNMRDDR)* Don't know/refused

Participant required research staff assistance in reading the questions in this assessment: Yes
Note: this includes if participant could not see well enough to read the questions or if the participant was unable to read well enough to read the questions.(TUHELP)

Comments:*(TUHCOMM)*

TAU Treatment Initiation Status (TXI)

Web Version: 1.0; 1.00; 09-08-17

Segment *(PROTSEG)*: B

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

1. Was treatment initiated?*(TXTRTINT)* No Yes

   a. If "Yes":

      1. Indicate medication:*(TXMED)* Buprenorphine Methadone Other

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

      2. Date of first dose of medication:*(TXMEDDT)* *(mm/dd/yyyy)*

   b. If "No", indicate reason medication was not initiated:*(TXNOINT)*

Participant was not able to tolerate opioid withdrawal symptoms
Participant never attended referral appointment for medication
Participant left study and never returned
Clinical deterioration: new onset of psychiatric or medical condition
Physical illness or condition that precludes taking study medication
*Additional Options Listed Below

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

Comments:*(TXICOMM)*

Additional Selection Options for TXI

If "No", indicate reason medication was not initiated:
Participant feels study treatment no longer necessary
Participant became incarcerated
Participant withdrew consent
Participant moved from area
Participant deceased
Other

Treatment Plan (TXP)

Web Version: 1.0; 1.00; 09-18-17

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

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

1. What forms of treatment were recommended for opioid use disorder?
2. What forms of treatment were recommended for opioid use disorder in the past 28 days?

	No	Yes
a. Medically supervised withdrawal (detoxification) - inpatient: *(TXDTXIN)*		
b. Medically supervised withdrawal (detoxification) - outpatient: *(TXDTXOUT)*		
c. Residential rehabilitation: *(TXRHBIN)*		
d. Outpatient rehabilitation: *(TXRHBOUT)*		
e. Group therapy sessions: *(TXGROUP)*		
f. 12-step groups (NA/AA): *(TX12STEP)*		
g. One-on-one addiction counseling: *(TXCOUNSL)*		
h. Medication-assisted treatment: *(TXMAT)*		
i. Medication-assisted treatment: *(TXMAT)*		
j. Other treatment 1, specify:*(TXTX1OSP)* *(TXTX1OT)*		
k. Other treatment 2, specify:*(TXTX2OSP)* *(TXTX2OT)*		

3. If medication-assisted treatment was recommended, what type of medication-assisted treatment for opioid use disorder was recommended?
4. If medication-assisted treatment was recommended, what type of medication-assisted treatment for opioid use disorder was recommended?

	No	Yes
a. Methadone maintenance therapy: *(TXRXMTD)*		
b. Buprenorphine maintenance therapy: *(TXRXBUP)*		
c. XR-NTX maintenance therapy: *(TXRXXRNX)*		
d. Other medication, specify:*(TXRXOSP)* *(TXRXOT)*		

	No	Yes
e. Methadone maintenance therapy: *(TXRXMTD)*		
f. Buprenorphine maintenance therapy: *(TXRXBUP)*		
g. XR-NTX maintenance therapy: *(TXRXXRNX)*		
h. Other medication, specify:*(TXRXOSP)* *(TXRXOT)*		

5. Did the participant's medical provider address medical management issues during a clinic visit in the past 28 days?*(TXMEDMAN)* No Yes

If "Yes", what issues were addressed:

	No	Yes
a. Recent drug and alcohol use reviewed: *(TXMMUSE)*		
b. Abstinence recommended: *(TXMMABST)*		
c. Medication side effects reviewed: *(TXMMSDEF)*		
d. Adherence to medication-assisted treatment encouraged: *(TXMMADHR)*		
e. Participation in clinic and/or community support groups encouraged: *(TXMMSPRT)*		
f. Other, specify:*(TXMMOTSP)* *(TXMMOTH)*		

Comments:*(TXPCOMM)*

Treatment Services Review (TXR)

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

Beginning of assessment period:*(TXBEGDT)* *(mm/dd/yyyy)*

End of assessment period:*(TXENDDT)* *(mm/dd/yyyy)*

Number of days in the assessment period:*(TXDAYSPD)* *(xxx)*

A. HOUSING SERVICES:

		Number of Days *(xx)*
1.		
2.	Where did you stay since the last assessment?	
	a. Alone (in private house, apartment, hotel, etc.):	*(TXRESALN)*
	b. With others (in private house, apartment, hotel, etc.):	*(TXRESOTH)*
	c. Institution (e.g., hospital, jail, prison):	*(TXRESINT)*
	Specify:	
	(i) Hospital/residential treatment:	*(TXRESHSP)*
	(ii) Jail or prison:	*(TXRESPRN)*
	d. Structured living situation (e.g., recovery house, group home, halfway house):	*(TXRESSTR)*
	Specify:	
	(i) For alcohol or drug problems (including dual detox):	*(TXRESDRG)*
	(ii) For psychological or emotional problems:	*(TXRESPSY)*
	(iii) For medical problems:	*(TXRESMED)*
	(iv) For criminal behavior or legal problems:	*(TXRESLGL)*
	(v) For domestic violence:	*(TXRESDMV)*
	e. Homeless shelter:	*(TXRESHSH)*
	f. Homeless (i.e., on the street, in an abandoned building, in a car):	*(TXRESHLS)*

B. ALCOHOL AND DRUG SERVICES:

*QUESTIONS ABOUT **INPATIENT** TREATMENT FOR ALCOHOL AND/OR DRUGS RECEIVED SINCE THE LAST ASSESSMENT*

	NUMBER *(xx)*
3. How many nights did you stay at an inpatient/residential drug/alcohol treatment unit?	*(TXINDRGI)*
4. How many of those nights were detoxification only?	*(TXINDTXI)*
5. How many 12-Step/self-help group meeting for substance use (e.g., AA, NA, CA) did you attend?	*(TXIN12SI)*
6. How many meetings did you have with your sponsor/mentor during which your substance problem was the main purpose of the discussion?	*(TXINMTRI)*
7. How many other group therapy/counseling sessions for substance use (i.e., non-self-help groups) did you attend?	*(TXIGPMDI)*

*QUESTIONS ABOUT TREATMENT FOR ALCOHOL AND/OR DRUGS RECEIVED SINCE THE LAST ASSESSMENT WHEN **NOT** IN INPATIENT TREATMENT*

	NUMBER *(xx)*
8. How many days did you attend any outpatient treatment for substance use problems, excluding any 12-Step or self help group meetings?	*(TXOPDRGI)*
9. How many of these were at a day hospital or intensive outpatient program (i.e., several days per week, for several hours each day)?	*(TXOPHSP)*
10. How many individual (one-on-one) sessions did you attend during which substance use was the main purpose of the discussion?	*(TXOPIDVI)*
11. How many 12-Step/self-help group meeting for substance use (e.g., AA, NA, CA) did you attend?	*(TXOP12SI)*
12. How many meetings did you have with your sponsor/mentor during which	

your substance problem was the main purpose of the discussion? *(TXOPMTRI)*

13. How many other group therapy/counseling sessions for substance use (i.e., non-self-help groups) did you attend? *(TXOPGRPI)*

*QUESTIONS ABOUT TREATMENT RECEIVED ON **ANY** DAY SINCE THE LAST ASSESSMENT*

	NUMBER *(xx)*
14. How many times were you tested for alcohol and/or drug use?	
a. Urinalysis:	*(TXTSTURI)*
b. Breathalyzer:	*(TXTSTBRI)*
c. Any other test for alcohol/drug use (e.g., blood, saliva, hair):	*(TXTSTOT)*
If "Other", specify:	*(TXTSTSP)*

C. MEDICAL SERVICES:

*QUESTIONS ABOUT **ANY** MEDICAL TREATMENT RECEIVED SINCE THE LAST ASSESSMENT*

	NUMBER *(xx)*
15. How many nights were you an inpatient in a medical hospital, nursing home, or medical rehabilitation facility?	*(TXINPTI)*
Specify the number of nights in each facility:	
(i) Medical hospital:	*(TXINHSP)*
(ii) Nursing home or medical rehabilitation facility:	*(TXINRHBI)*

*QUESTIONS ABOUT MEDICAL TREATMENT RECEIVED SINCE THE LAST ASSESSMENT WHEN **NOT** IN A MEDICAL HOSPITAL*

	NUMBER *(xx)*
16. How many times did you visit an emergency room?	*(TXEDI)*
Indicate reason for emergency room visit:	
(i) Medical:	*(TXEDMEDI)*
(ii) Psychological:	*(TXEDPSYI)*
(iii) Substance use:	*(TXEDSBSI)*
17. How many times did you visit a medical doctor (e.g., physician, psychiatrist) for testing, examination, treatment, or care of medical concerns/problems?	*(TXMDI)*
18. How many times did you visit any other medical professional (e.g., dentist, optometrists, nurse, physcial therapist, X-ray or lab technician) for testing, examination, or treatment of medical concerns/problems?	*(TXOMPI)*

Comments:*(TXRCOMM)*

Urine Drug Screen (UDS)

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

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

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

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

   Participant reported being unable to provide sample
   Participant refused to provide sample
   Study staff error
   Other

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

1st Urine Drug Screen

2. Date 1st urine specimen collected:*(UDCOLDT)* *(mm/dd/yyyy)*
3. Was the 1st urine specimen temperature within range? (90 - 100 °F)*(UDTEMP1)* No Yes
4. Was the 1st urine specimen determined to be adulterated?*(UDADULT1)* No Yes
5. 1st Urine Drug Screen Result(s):

Drug Name (Abbreviation)	Negative	Positive	Invalid
Benzodiazepines (BZO):	*(UDBZO1)*		
Amphetamine (AMP):	*(UDAMP1)*		
Marijuana (THC):	*(UDTHC1)*		
Methamphetamine (MET):	*(UDMET1)*		
Opiates (2000 ng) (OPI):	*(UDOPI1)*		
Cocaine (COC):	*(UDCOC1)*		
Ecstasy (MDMA):	*(UDMDA1)*		
Oxycodone (OXY):	*(UDOXY1)*		
Methadone (MTD):	*(UDMTD1)*		
Barbiturate (BAR):	*(UDBAR1)*		
Opiates (300 ng) (OPI):	*(UDOPI31)*		
Buprenorphine (10 ng) (BUP):	*(UDBUP1)*		
Fentanyl (FEN):	*(UDFEN1)*		
EtG:	*(UDETG1)*		

2nd Urine Drug Screen

6. If the 1st urine specimen was determined to be adulterated, was a second specimen collected? *(UDTEST2)* No Yes
7. Date 2nd urine specimen collected:*(UDCOLDT2)* *(mm/dd/yyyy)*

   If "No", reason:*(UDNORSN2)*

   Participant reported being unable to provide sample
   Participant refused to provide sample
   Study staff error
   Other

   If "Other", specify:*(UDNOSP2)*

8. Was the 2nd urine specimen temperature within range? (90 - 100 °F)*(UDTEMP2)* No Yes
9. Was the 2nd urine specimen determined to be adulterated?*(UDADULT2)* No Yes
10. 2nd Urine Drug Screen Result(s):

Drug Name (Abbreviation)	Negative	Positive	Invalid
Benzodiazepines (BZO):	*(UDBZO2)*		
Amphetamine (AMP):	*(UDAMP2)*		
Marijuana (THC):	*(UDTHC2)*		
Methamphetamine (MET):	*(UDMET2)*		

Opiates (2000 ng) (OPI): *(UDOPI2)*

Cocaine (COC): *(UDCOC2)*

Ecstasy (MDMA): *(UDMDA2)*

Oxycodone (OXY): *(UDOXY2)*

Methadone (MTD): *(UDMTD2)*

Barbiturate (BAR): *(UDBAR2)*

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

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

Fentanyl (FEN): *(UDFEN2)*

EtG: *(UDETG2)*

Comments:*(UDSCOMM)*

/

Visual Analog Craving Scale (VAS)

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

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

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

Think about your current cravings.
How intense is your worst craving?
Click on the line below or click and drag the blue circle to the spot that indicates the intensity of the worst craving you are currently having for each of the substances.
You can leave your circle anywhere on the line to show how intense your craving is.

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

2. How much do you currently crave **alcohol**?*(VACRALC)* *(xxx)*

3. How much do you currently crave **tobacco**?*(VACRTOB)* *(xxx)*

Participant required research staff assistance in reading the questions in this assessment: Yes
Note: this includes if participant could not see well enough to read the questions or if the participant was unable to read well enough to read the questions.(VAHELP)

Comments:*(VASCOMM)*

Vital Signs (VIT)

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

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

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

1. Temperature:*(VITMPF)* *(xxx.x)* °F
2. Respiration:*(VIRESP)* *(xx)* breaths per minute
3. Heart rate/pulse:*(VIPULS)* *(xxx)* beats per minute
4. Systolic/diastolic blood pressure:*(VIBPSY)* *(xxx)* / *(VIBPDI)* *(xxx)* mmHg

Comments:*(VITCOMM)*

XR-NTX Non-Initiation (XNI)

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

Segment *(PROTSEG)*: B

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

1. Indicate the main reason the participant did not initiate XR-NTX:*(XNIRSN)*

- Participant was not able to tolerate opioid withdrawal symptoms
- Participant left study and never returned
- Clinical deterioration: new onset of psychiatric or medical condition
- Physical illness or condition that precludes taking study medication
- Participant feels study treatment no longer necessary
- *Additional Options Listed Below

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

Comments:*(XNICOMM)*

Additional Selection Options for XNI

Indicate the main reason the participant did not initiate XR-NTX:
Participant became incarcerated
Participant withdrew consent
Participant moved from area
Participant deceased
Other