

NIDA Clinical Trials Network

Adverse Events (AD1)

Web Version: 1.0; 4.00; 10-02-15

Adverse event onset date (AEDATE):

Event number (AESEQNUM):

1. Adverse event name: (A1DESCPT)

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

3. Severity of event: (A1SEVRTY)

4. Is there a reasonable possibility that the extended-release naltrexone caused the event? (A1RDRUG1)

If "Yes", action taken with extended-release naltrexone: (A1ADRUG1)

5. If "Unrelated" to the study drug, alternative etiology: (A1ALTESD)

If "Other," specify: (A1AEPSP)

6. Outcome of event: (A1OUTCM)

7. Date of resolution or medically stable: (A1RESDT)

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)

a. If "Death", date of death: (A1DTHDT)

b. If "Inpatient admission to hospital or prolongation of hospitalization":

Date of hospital admission: (A1HOSPAD)

Date of hospital discharge: (A1HOSPDC)

(mm/dd/yyyy)

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

No Yes

0-None
1-Decreased drug
2-Increased drug
3-Temporarily stopped drug
4-Permanently stopped drug

0-None apparent
1-Study disease
2-Concomitant medication
3-Other pre-existing disease or condition
4-Accident, trauma, or external factors
*Additional Options Listed Below

1-Ongoing
2-Resolved without sequelae
3-Resolved with sequelae
4-Resolved by convention
5-Death

(mm/dd/yyyy)

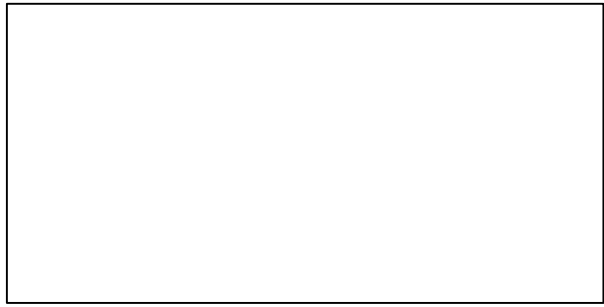
0-None of the following
1-Death
2-Life-threatening event
3-Inpatient admission to hospital or prolongation of existing hospitalization
4-Persistent or significant incapacity
*Additional Options Listed Below

(mm/dd/yyyy)

(mm/dd/yyyy)

(mm/dd/yyyy)

Comments:(AD1 COMM)



Additional Selection Options for AD1

Event number (AESEQNUM) (key field):

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

Was this event associated with:

- 5- Congenital anomaly or birth defect
- 6- 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; 1.00; 02-25-15

Adverse event onset date (AEDATE):

Event number (AESEQNUM):

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: (A2SAETR7) No Yes Unknown

Treatment	Indication	Date Treated (mm/dd/yyyy)
(A2_1TNME)	(A2_1TIND)	(A2_1LTD7)

(A2_2TNME)	(A2_2TIND)	(A2_2LTD T)
(A2_3TNME)	(A2_3TIND)	(A2_3LTD T)
(A2_4TNME)	(A2_4TIND)	(A2_4LTD T)
(A2_5TNME)	(A2_5TIND)	(A2_5LTD T)

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:

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

(A2FOLLUP)

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 (*AESQNUM*) (key field):

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

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Serious Adverse Event Medical Reviewer (AD3)

Web Version: 1.0; 3.00; 08-19-14

Adverse event onset date (AEDATE):

Event number (AESEQNUM):

- 1. Was this determined to be a serious adverse event?(A3SAE) No Yes
- 2. Was this event considered associated with extended-release naltrexone?
(A3RXRNTX) 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 (*AESQNUM*) (key field):

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

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ARV Medication Log (ARV)

Web Version: 1.0; 2.00; 03-10-14

	Drug Name	Start Date (mm/dd/yyyy)	Estimated Start Date	Stop Date (mm/dd/yyyy)	Estimated Stop Date	Ongoing at Study Termination
1.	(ARDRUG01) 01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below	(ARST01DT)	(ARETST01) <input type="checkbox"/>	(ARSP01DT)	(ARETSP01) <input type="checkbox"/>	(ARONG01) <input type="checkbox"/>
2.	(ARDRUG02) 01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below	(ARST02DT)	(ARETST02) <input type="checkbox"/>	(ARSP02DT)	(ARETSP02) <input type="checkbox"/>	(ARONG02) <input type="checkbox"/>
3.	(ARDRUG03) 01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below	(ARST03DT)	(ARETST03) <input type="checkbox"/>	(ARSP03DT)	(ARETSP03) <input type="checkbox"/>	(ARONG03) <input type="checkbox"/>
4.	(ARDRUG04) 01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below	(ARST04DT)	(ARETST04) <input type="checkbox"/>	(ARSP04DT)	(ARETSP04) <input type="checkbox"/>	(ARONG04) <input type="checkbox"/>
5.	(ARDRUG05) 01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below	(ARST05DT)	(ARETST05) <input type="checkbox"/>	(ARSP05DT)	(ARETSP05) <input type="checkbox"/>	(ARONG05) <input type="checkbox"/>
6.	(ARDRUG06) 01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below	(ARST06DT)	(ARETST06) <input type="checkbox"/>	(ARSP06DT)	(ARETSP06) <input type="checkbox"/>	(ARONG06) <input type="checkbox"/>
7.	(ARDRUG07) 01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below	(ARST07DT)	(ARETST07) <input type="checkbox"/>	(ARSP07DT)	(ARETSP07) <input type="checkbox"/>	(ARONG07) <input type="checkbox"/>
8.	(ARDRUG08)	(ARST08DT)	(ARETST08) <input type="checkbox"/>	(ARSP08DT)	(ARETSP08) <input type="checkbox"/>	(ARONG08) <input type="checkbox"/>

	<p>01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below</p>					
9.	<p>(ARDRUG09)</p> <p>01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below</p>	(ARST09DT)	(ARETST09)	(ARSP09DT)	(ARETSP09)	(ARONG09)
10.	<p>(ARDRUG10)</p> <p>01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below</p>	(ARST10DT)	(ARETST10)	(ARSP10DT)	(ARETSP10)	(ARONG10)
11.	<p>(ARDRUG11)</p> <p>01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below</p>	(ARST11DT)	(ARETST11)	(ARSP11DT)	(ARETSP11)	(ARONG11)
12.	<p>(ARDRUG12)</p> <p>01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below</p>	(ARST12DT)	(ARETST12)	(ARSP12DT)	(ARETSP12)	(ARONG12)
13.	<p>(ARDRUG13)</p> <p>01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below</p>	(ARST13DT)	(ARETST13)	(ARSP13DT)	(ARETSP13)	(ARONG13)
14.	<p>(ARDRUG14)</p> <p>01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below</p>	(ARST14DT)	(ARETST14)	(ARSP14DT)	(ARETSP14)	(ARONG14)
15.	<p>(ARDRUG15)</p> <p>01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below</p>	(ARST15DT)	(ARETST15)	(ARSP15DT)	(ARETSP15)	(ARONG15)
16.	<p>(ARDRUG16)</p> <p>01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below</p>	(ARST16DT)	(ARETST16)	(ARSP16DT)	(ARETSP16)	(ARONG16)
17.	<p>(ARDRUG17)</p>	(ARST17DT)	(ARETST17)	(ARSP17DT)	(ARETSP17)	(ARONG17)

	<p>01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below</p>					
18.	<p>(ARDRUG18)</p> <p>01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below</p>	(ARST18DT)	(ARETST18)	(ARSP18DT)	(ARETSP18)	(ARONG18)
19.	<p>(ARDRUG19)</p> <p>01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below</p>	(ARST19DT)	(ARETST19)	(ARSP19DT)	(ARETSP19)	(ARONG19)
20.	<p>(ARDRUG20)</p> <p>01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below</p>	(ARST20DT)	(ARETST20)	(ARSP20DT)	(ARETSP20)	(ARONG20)
21.	<p>(ARDRUG21)</p> <p>01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below</p>	(ARST21DT)	(ARETST21)	(ARSP21DT)	(ARETSP21)	(ARONG21)
22.	<p>(ARDRUG22)</p> <p>01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below</p>	(ARST22DT)	(ARETST22)	(ARSP22DT)	(ARETSP22)	(ARONG22)
23.	<p>(ARDRUG23)</p> <p>01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below</p>	(ARST23DT)	(ARETST23)	(ARSP23DT)	(ARETSP23)	(ARONG23)
24.	<p>(ARDRUG24)</p> <p>01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below</p>	(ARST24DT)	(ARETST24)	(ARSP24DT)	(ARETSP24)	(ARONG24)
25.	<p>(ARDRUG25)</p> <p>01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below</p>	(ARST25DT)	(ARETST25)	(ARSP25DT)	(ARETSP25)	(ARONG25)
26.	(ARDRUG26)	(ARST26DT)	(ARETST26)	(ARSP26DT)	(ARETSP26)	(ARONG26)

	<p>01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below</p>					
27.	<p>(ARDRUG27)</p> <p>01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below</p>	(ARST27DT)	(ARETST27)	(ARSP27DT)	(ARETSP27)	(ARONG27)
28.	<p>(ARDRUG28)</p> <p>01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below</p>	(ARST28DT)	(ARETST28)	(ARSP28DT)	(ARETSP28)	(ARONG28)
29.	<p>(ARDRUG29)</p> <p>01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below</p>	(ARST29DT)	(ARETST29)	(ARSP29DT)	(ARETSP29)	(ARONG29)
30.	<p>(ARDRUG30)</p> <p>01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below</p>	(ARST30DT)	(ARETST30)	(ARSP30DT)	(ARETSP30)	(ARONG30)
31.	<p>(ARDRUG31)</p> <p>01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below</p>	(ARST31DT)	(ARETST31)	(ARSP31DT)	(ARETSP31)	(ARONG31)
32.	<p>(ARDRUG32)</p> <p>01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below</p>	(ARST32DT)	(ARETST32)	(ARSP32DT)	(ARETSP32)	(ARONG32)
33.	<p>(ARDRUG33)</p> <p>01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below</p>	(ARST33DT)	(ARETST33)	(ARSP33DT)	(ARETSP33)	(ARONG33)
34.	<p>(ARDRUG34)</p> <p>01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below</p>	(ARST34DT)	(ARETST34)	(ARSP34DT)	(ARETSP34)	(ARONG34)
35.	(ARDRUG35)	(ARST35DT)	(ARETST35)	(ARSP35DT)	(ARETSP35)	(ARONG35)

	01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below						
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Comments:(ARVCOMM)

Additional Selection Options for ARV

Drug name 01

06-Edurant - RPV
07-Emtriva - FTC
08-Epivir - 3TC
09-Epizcom - ABC + 3TC
10-Fuzeon - T20
11-Intelligence - ETV
12-Invirase - SQV
13-Isentress - RAL
14-Isentress + Truvada - RAL + TDF + FTC
15-Kaletra - LPV/r
16-Lexiva - FPV
17-Norvir - RTV
99-Other/Experimental/Blinded study - OTHR
18-Prezista BID - DRV
19-Prezista QD - DRV
20-Prezista + Norvir +Truvada (DRV/r twice daily) - DRV/r + TDF + FTC
21-Prezista + Norvir + Truvada (once daily) - DRV/r + TDF + FTC
22-Reyataz - ATV
23-Reyataz + Norvir + Truvada
- ATV/r + TDF + FTC
24-Rescriptor - DLV
25-Retrovir - AZT (or ZDV)
26-Selzentry - MVC
27-Selzentry + Truvada - MVC + TDF + FTC
28-Stribild - EVG + COBI + TDF + FTC
29-Sustiva - EFV
30-Tivacay (dolutegravir)
31-Trizivir - ABC + 3TC + ZDV (or AZT)
32-Truvada - TDF + FTC
33-Videx - ddl
34-Viracept - NFV
35-Viramune - NVP
36-Viramune XR (QD) - NVP
37-Viread - TDF
38-Zerit - d4T
39-Ziagen - ABC

NIDA Clinical Trials Network

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

Web Version: 1.0; 2.00; 03-10-14

Segment (PROTSEG):

Visit number (VISNO):

CTN-ASI Lite v. 1: 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 Days and Lifetime Use are zero, route should be "Not applicable".

Substance	A Past 30 (Days)	B Lifetime Use (Years)	C Age of First Use (onset)	C Age of First Use (onset) Not Applicable	D Route of Administration	Comments
D1 Alcohol (any use at all):	(ADALA30D) _____ (xx)	(ADALALFT) _____ (xx)	(ADALONST) _____ (xx)	Onset: (ADALONNA) <input type="checkbox"/> NA	-	(ADALACOM) _____
D2 Alcohol (to intoxication):	(ADALI30D) _____ (xx)	(ADALILFT) _____ (xx)	(ADALIONS) _____ (xx)	Onset: (ADALIONA) <input type="checkbox"/> NA	-	(ADALICOM) _____
D3 Heroin	(ADHER30D) _____ (xx)	(ADHERLFT) _____ (xx)	(ADHERONS) _____ (xx)	Onset: (ADHERONA) <input type="checkbox"/> NA	(ADHERRTE) 1-(1) Oral 2-(2) Nasal 3-(3) Smoking 4-(4) Non IV injection 5-(5) IV injection 96-(96) Not applicable 97-(97) Not answered	(ADHERCOM) _____
D4 Methadone/LAAM (prescribed):	(ADMDP30D) _____ (xx)	(ADMDDLFT) _____ (xx)	(ADMDPONS) _____ (xx)	Onset: (ADMDPONA) <input type="checkbox"/> NA	(ADMDP RTE) 1-(1) Oral 2-(2) Nasal 3-(3) Smoking 4-(4) Non IV injection 5-(5) IV injection 96-(96) Not applicable 97-(97) Not answered	(ADMDP COM) _____
D4a Methadone/LAAM (illicit):	(ADMDI30D) _____ (xx)	(ADMDILFT) _____ (xx)	(ADMDIONS) _____ (xx)	Onset: (ADMDIONA) <input type="checkbox"/> NA	(ADMDIRTE) 1-(1) Oral 2-(2) Nasal 3-(3) Smoking 4-(4) Non IV injection 5-(5) IV injection 96-(96) Not applicable 97-(97) Not answered	(ADMDICOM) _____
D5 Other Opiates/Analgesics:	(ADOPI30D) _____ (xx)	(ADOPI LFT) _____ (xx)	(ADOPIONS) _____ (xx)	Onset: (ADOPIONA) <input type="checkbox"/> NA	(ADOPI RTE) 1-(1) Oral 2-(2) Nasal 3-(3) Smoking 4-(4) Non IV injection 5-(5) IV injection 96-(96) Not applicable 97-(97) Not answered	(ADOPI COM) _____
D6 Barbiturates:	(ADBAR30D) _____ (xx)	(ADBARLFT) _____ (xx)	(ADBARONS) _____ (xx)	Onset: (ADBARONA) <input type="checkbox"/> NA	(ADBARRTE)	(ADBARCOM) _____

					1-(1) Oral 2-(2) Nasal 3-(3) Smoking 4-(4) Non IV injection 5-(5) IV injection 96-(96) Not applicable 97-(97) Not answered	
D7 Other Sedatives/ Hypnotics/Tranquilizers:	(ADSHT30D) (xx)	(ADSHLFT) (xx)	(ADSHTONS) (xx)	Onset: (ADSHTONA) <input type="checkbox"/> NA	(ADSHTRTE) 1-(1) Oral 2-(2) Nasal 3-(3) Smoking 4-(4) Non IV injection 5-(5) IV injection 96-(96) Not applicable 97-(97) Not answered	(ADSHTCOM)
D8 Cocaine:	(ADCOC30D) (xx)	(ADCOCLFT) (xx)	(ADCOCONS) (xx)	Onset: (ADCOCONA) <input type="checkbox"/> NA	(ADCOCRTE) 1-(1) Oral 2-(2) Nasal 3-(3) Smoking 4-(4) Non IV injection 5-(5) IV injection 96-(96) Not applicable 97-(97) Not answered	(ADCOCOM)
D9 Amphetamines:	(ADAMP30D) (xx)	(ADAMPLFT) (xx)	(ADAMPONS) (xx)	Onset: (ADAMPONA) <input type="checkbox"/> NA	(ADAMP RTE) 1-(1) Oral 2-(2) Nasal 3-(3) Smoking 4-(4) Non IV injection 5-(5) IV injection 96-(96) Not applicable 97-(97) Not answered	(ADAMP COM)
D9a Methamphetamine:	(ADMET30D) (xx)	(ADMETLFT) (xx)	(ADMETONS) (xx)	Onset: (ADMETONA) <input type="checkbox"/> NA	(ADMET RTE) 1-(1) Oral 2-(2) Nasal 3-(3) Smoking 4-(4) Non IV injection 5-(5) IV injection 96-(96) Not applicable 97-(97) Not answered	(ADMET COM)
D10 Cannabis:	(ADTHC30D) (xx)	(ADTHCLFT) (xx)	(ADTHCONS) (xx)	Onset: (ADTHCONA) <input type="checkbox"/> NA	(ADTHC RTE) 1-(1) Oral 2-(2) Nasal 3-(3) Smoking 4-(4) Non IV injection 5-(5) IV injection 96-(96) Not applicable 97-(97) Not answered	(ADTHC COM)
D11 Hallucinogens:	(ADHAL30D) (xx)	(ADHALLFT) (xx)	(ADHALONS) (xx)	Onset: (ADHALONA) <input type="checkbox"/> NA	(ADHAL RTE) 1-(1) Oral 2-(2) Nasal 3-(3) Smoking 4-(4) Non IV injection 5-(5) IV injection 96-(96) Not applicable 97-(97) Not answered	(ADHAL COM)
D12 Inhalants:	(ADINH30D) (xx)	(ADINHLFT) (xx)	(ADINHONS) (xx)	Onset: (ADINHONA) <input type="checkbox"/> NA	(ADINH RTE) 1-(1) Oral 2-(2) Nasal 3-(3) Smoking 4-(4) Non IV injection 5-(5) IV injection 96-(96) Not applicable 97-(97) Not answered	(ADINH COM)
D13 More than 1 substance per day (including alcohol, excluding nicotine):	(ADGT130D) (xx)	(ADGT1LFT) (xx)	(ADGT1ONS) (xx)	Onset: (ADGT1ONA) <input type="checkbox"/> NA	-	(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 alcohol and one or more drugs; 16 = more than one drug but no alcohol. Ask participant when not clear.

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

(ADMAJDRG)

OR

(ADMJDGNA) (97) Not answered

Comments:(ADMJDGCM)

D17 How many times have you had Alcohol DT's?

- Delirium Tremens (DT's): Occur 24-48 hours after last drink, or significant decrease in alcohol intake. Characterized by shaking, severe disorientation, fever, hallucinations; th attention.

(ADALCDT) (xx)

OR

(ADALDTNA) (97) Not answered

Comments:(ADALDTCM)

How many times in your life have you been treated for:

Include detoxification, halfway houses, in/outpatient counseling and AA or NA (if 3+ meetings within one month period).

D19 Alcohol abuse:

(ADALCTR7) (xx)

OR

(ADATR7NA) (97) Not answered

Comments:(ADATRTCM)

D20 Drug abuse:

(ADDRGTRT) (xx)

OR

(ADDTRTNA) (97) Not answered

Comments:(ADDTRTCM)

How many of these were detox only:

D21 Alcohol:

- If D19 = 00, then question D21 is Not applicable.

(ADADETOX) (xx)

OR

(ADADTXNA) (96) Not applicable (97) Not answered

Comments:(ADADTXCM)

D22 Drugs:

- If D20 = 00, then question D22 is Not applicable.

(ADDETOX) (xx)

OR

(ADDDTXNA) (96) Not applicable (97) Not answered

Comments:(ADDDTXCM)

How much money would you say you spent during the past 30 days on:
Max. = \$99999

D23 Alcohol:

- Only count actual money spent. What is the financial burden caused by alcohol?

(ADALCMNY) \$ (xxxx)

OR

(ADAMNYNA) (97) Not answered

Comments:(ADAMNYCM)

D24 Drugs:

- Only count actual money spent. What is the financial burden caused by drugs?

(ADDRGMNY) \$ (xxx.xx)

OR

(ADDMNYNA) (97) Not answered

Comments:(ADDMNYCM)

D25 How many days have you been treated in an outpatient setting for alcohol or drugs in the past 30 days?

- Include AA/NA

(ADOUPAT) (xx) days

OR

(ADOPTNA) (97) Not answered

Comments:(ADOPTCOM)

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.

(ADAP30D) (xx) days

OR

(ADAP30NA) (97) Not answered

Comments:(ADAP30CM)

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?

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

(ADAPB30D)

OR

(ADAB30NA) (97) Not answered

Comments:(ADAB30CM)

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

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

(ADAPI30D)

OR

(ADAI30NA) (97) Not answered

Comments:(ADAI30CM)

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.*

(ADDP30D) (xx) days

OR

(ADDP30NA) (97) Not answered

Comments:(ADDP30CM)

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

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

(ADDPB30D)

OR

(ADDB30NA) (97) Not answered

Comments:(ADDB30CM)

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

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

(ADDPI30D)

OR

(ADDI30NA) (97) Not answered

Comments:(ADDI30CM)

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:(ASDCOMM)



NIDA Clinical Trials Network

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

Web Version: 1.0; 1.00; 01-16-14

Segment (PROTSEG):

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, No Yes intent, plan) SI present.(CHSCIDTN)

**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 No Yes potentially self-injurious behavior associated with intent to die. Intent can be stated by patient or inferred by rater).(CHSCATMP)

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 No Yes with no intent to die.(CHSIBDIE)

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 No Yes (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)

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

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

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; 1.02; 04-09-14

Segment (PROTSEG):

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)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. I have no future. (CHNOFUTR)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. It seems as if I can do nothing right. (CHNORGH)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Everything I do turns out wrong. (CHWRONG)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. There is no one I can depend on. (CHDEPEND)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. The people I care the most for are gone. (CHPLGNE)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. I wish my suffering could just all be over. (CHSUFFER)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. I feel that there is no reason to live. (CHRSLIVE)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. I wish I could just go to sleep and not wake up. (CHSLEEP)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. I find myself saying or doing things without thinking. (CHNOTHINK)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. I often make decisions quickly or "on impulse." (CHIMPULS)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. I often feel irritable or easily angered. (CHIRRITE)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. I often overreact with anger or rage over minor things. (CHOVRCT)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. I have been having thoughts of killing myself. (CHKILLMS)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. I have thoughts about how I might kill myself. (CHHOWKIL)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. I have a plan to kill myself. (CHPLNKIL)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments: (CHPCOMM)

NIDA Clinical Trials Network

Demographics (DEM)

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

1. Date of birth:(DEBRTHDT)

(mm/dd/yyyy)

2. Gender:(DEGENDER)

Male Female Don't know Refused

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

No Yes Don't know Refused

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

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

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

(Check all that apply)

White: (DEWHITE)

Black/ African American: (DEBLACK)

Indian (American): (DEAMEIND)

Alaska native: (DEALASKA)

Native Hawaiian: (DEHAWAII)

Guamanian: (DEGUAM)

Samoa: (DESAMOAN)

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

Asian Indian: (DEASAIND)

Chinese: (DECHINA)

Filipino: (DEFILIPN)

Japanese: (DEJAPAN)

Korean: (DEKOREA)

Vietnamese: (DEVIETNM)

Other Asian: (DEASIAN) Specify:(DEASIAOT)

Some other race: (DERACEOT) Specify:(DERACESP)

-OR-

Don't know:(DERACEDK)

Refused: (DERACERF)

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

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

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

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

If "Other", specify:(DEJOBSP)

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

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

Comments:(DEM COMM)

Additional Selection Options for DEM

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

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

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

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

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

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

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

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

NIDA Clinical Trials Network

DSM - 5 - Substance Use Disorders (DSM)

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

Segment (PROTSEG):

Visit number (VISNO):

Date of assessment: (DSMASMDT)

(mm/dd/yyyy)

	Opioids	Alcohol	Amphetamines	Cannabis	Cocaine	Sedatives
Have you used in the past 12 months:	<input type="checkbox"/> No <input type="checkbox"/> Yes (DSOPI12M)	<input type="checkbox"/> No <input type="checkbox"/> Yes (DSALC12M)	<input type="checkbox"/> No <input type="checkbox"/> Yes (DSAMP12M)	<input type="checkbox"/> No <input type="checkbox"/> Yes (DSTHC12M)	<input type="checkbox"/> No <input type="checkbox"/> Yes (DSCOC12M)	<input type="checkbox"/> No <input type="checkbox"/> Yes (DSSED12M)

Answer the following for drugs used in the past 12 months

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

Criteria Opioids Alcohol Amphetamines Cannabis Cocaine Sedatives

6. The substance is often taken in larger amounts or over a longer period than was intended:

	<input type="checkbox"/> O-No <input type="checkbox"/> 1-Yes	<input type="checkbox"/> O-No <input type="checkbox"/> 1-Yes	<input type="checkbox"/> O-No <input type="checkbox"/> 1-Yes	<input type="checkbox"/> O-No <input type="checkbox"/> 1-Yes	<input type="checkbox"/> O-No <input type="checkbox"/> 1-Yes	<input type="checkbox"/> O-No <input type="checkbox"/> 1-Yes	<input type="checkbox"/> O-No <input type="checkbox"/> 1-Yes
(DSOPIDOS)		(DSALCDOS)		(DSAMPDOS)		(DSTHCDS)	

7. There is a persistent desire or unsuccessful efforts to cut down or control substance use:

	<input type="checkbox"/> O-No <input type="checkbox"/> 1-Yes	<input type="checkbox"/> O-No <input type="checkbox"/> 1-Yes	<input type="checkbox"/> O-No <input type="checkbox"/> 1-Yes	<input type="checkbox"/> O-No <input type="checkbox"/> 1-Yes	<input type="checkbox"/> O-No <input type="checkbox"/> 1-Yes	<input type="checkbox"/> O-No <input type="checkbox"/> 1-Yes	<input type="checkbox"/> O-No <input type="checkbox"/> 1-Yes
(DSOPICUT)		(DSALCCUT)		(DSAMPCUT)		(DSTHCCT)	

8. A great deal of time is spent in activities necessary to obtain the substance, use the substance, or recover from its effects:

	<input type="checkbox"/> O-No <input type="checkbox"/> 1-Yes	<input type="checkbox"/> O-No <input type="checkbox"/> 1-Yes	<input type="checkbox"/> O-No <input type="checkbox"/> 1-Yes	<input type="checkbox"/> O-No <input type="checkbox"/> 1-Yes	<input type="checkbox"/> O-No <input type="checkbox"/> 1-Yes	<input type="checkbox"/> O-No <input type="checkbox"/> 1-Yes	<input type="checkbox"/> O-No <input type="checkbox"/> 1-Yes
(DSOPITIM)		(DSALCTIM)		(DSAMPTIM)		(DSTHCTIM)	

9. Important social, occupational, or recreational activities are given up or reduced because of substance use:

	<input type="checkbox"/> O-No <input type="checkbox"/> 1-Yes	<input type="checkbox"/> O-No <input type="checkbox"/> 1-Yes	<input type="checkbox"/> O-No <input type="checkbox"/> 1-Yes	<input type="checkbox"/> O-No <input type="checkbox"/> 1-Yes	<input type="checkbox"/> O-No <input type="checkbox"/> 1-Yes	<input type="checkbox"/> O-No <input type="checkbox"/> 1-Yes	<input type="checkbox"/> O-No <input type="checkbox"/> 1-Yes
(DSOPIACT)		(DSALCACT)		(DSAMPACT)		(DSCOCACT)	

10. The substance use is continued despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance:

	<input type="checkbox"/> O-No <input type="checkbox"/> 1-Yes	<input type="checkbox"/> O-No <input type="checkbox"/> 1-Yes	<input type="checkbox"/> O-No <input type="checkbox"/> 1-Yes	<input type="checkbox"/> O-No <input type="checkbox"/> 1-Yes	<input type="checkbox"/> O-No <input type="checkbox"/> 1-Yes	<input type="checkbox"/> O-No <input type="checkbox"/> 1-Yes	<input type="checkbox"/> O-No <input type="checkbox"/> 1-Yes
(DSOPICON)		(DSALCCON)		(DSAMPCON)		(DSCOCCON)	

11. Craving or a strong desire or urge to use a specific substance:

	<input type="checkbox"/> O-No <input type="checkbox"/> 1-Yes	<input type="checkbox"/> O-No <input type="checkbox"/> 1-Yes	<input type="checkbox"/> O-No <input type="checkbox"/> 1-Yes	<input type="checkbox"/> O-No <input type="checkbox"/> 1-Yes	<input type="checkbox"/> O-No <input type="checkbox"/> 1-Yes	<input type="checkbox"/> O-No <input type="checkbox"/> 1-Yes	<input type="checkbox"/> O-No <input type="checkbox"/> 1-Yes
(DSOPICRA)		(DSALCCRA)		(DSAMPRA)		(DSTHCRA)	

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

12. Currently, which substance is the major problem?(DSMAJDRG)

Alcohol Opioids

Comments:(DSMCOMM)

NIDA Clinical Trials Network

Electrocardiogram (ECG) Results (ECG)

Web Version: 1.0; 3.00; 01-22-14

Segment (*PROTSEG*):

Visit number (*VISNO*):

Date of assessment:(*ECGASMDT*)

(mm/dd/yyyy)

1. QTc interval:(*ECQTC*)

(xxx) (ms)

2. Does the participant have any finding on the screening ECG that, in the opinion of the study medical clinician, would preclude safe participation in the study?(*ECGELIG2*)

No Yes

Comments:(*ECGCOMM*)

NIDA Clinical Trials Network

Urine Ethyl Glucuronide (ETG)

Web Version: 1.0; 1.00; 03-11-14

Segment (PROTSEG):

1. Was the screening urine ethyl glucuronide sample shipped?(ETSHIPS1)

No Yes

a. If "Yes", date of shipment:(ETS1SHDT)

(mm/dd/yyyy)

b. If "No", reason:(ETRSNS1)

- 1-Participant reported being unable to provide sample
- 2-Participant refused to provide sample
- 3-Study staff error
- 99-Other

If "Other", specify:(ETS1OTSP)

Comments:(ETGCOMM)

NIDA Clinical Trials Network

0055A (ENR)

Web Version: 1.0; 2.00; 11-24-14

Date informed consent signed:(*S7CNSTDT*)

(mm/dd/yyyy)

Pre-screening ID:(*S7SCRNID*)

(xxxx)

Comments:(*S7COMM*)

NIDA Clinical Trials Network

HIV Care Utilization (HCU)

Web Version: 1.0; 1.00; 01-28-14

Segment (*PROTSEG*):

Visit number (*VISNO*):

Date of assessment:(*HCUASMDT*)

 (mm/dd/yyyy)

1. Number of HIV primary care visits attended in previous 16 weeks:(*HCVISITS*)

 (xx)

2. Number of counseling sessions attended in HIV clinic in previous 16 weeks:
(*HCCOUNSL*)

 (xx)

Comments:(*HCUCOMM*)

NIDA Clinical Trials Network

Clinical Laboratory Tests (LAB)

Web Version: 1.0; 6.02; 02-17-15

Segment (PROTSEG):

Visit number (VISNO):

	Test	Result	Date of Collection (mm/dd/yyyy)	Abstracted from Medical Record
CBC	1. WBC	(LAWBC) (xx.x) 10 ³ /μL	(LACBCDT)	(LACBCMR) <input type="checkbox"/> Yes
	2. RBC	(LARBC) (xx.xx) 10 ⁶ /μL		
	3. Haemoglobin	(LAHEMGLB) (xx.x) g/dL		
		(LAHEMGLO) (xxx) g/L		
	4. Haematocrit	(LAHEMATO) (xx.x) %		
		(LAHEMATC) (x.xx)		
	5. Platelets	(LAPLATES) (xxx.x) 10 ³ /μL		
	6. Neutrophils	(LANEUTRO) (xx.x) 10 ³ /μL		
LFTs	7. Aspartate Aminotransferase (AST/SGOT)	(LAAST) (xxxx.x) IU/L	(LAASTDT)	(LAASTM) <input type="checkbox"/> Yes
	8. Alanine Aminotransferase (ALT/SGPT)	(LAALT) (xxxx.x) IU/L	(LAALTD)	(LAALTM) <input type="checkbox"/> Yes
	9. INR	(LAINR) (x.xx)	(LAINRDT)	(LAINRM) <input type="checkbox"/> Yes

Comments:(LABCOMM)

NIDA Clinical Trials Network

Medication Adherence (MAD)

Web Version: 1.0; 1.00; 01-29-14

Segment (PROTSEG):

Visit number (VISNO):

Date of assessment: (MADASMDT)

(mm/dd/yyyy)

This questionnaire asks about your HIV medications that you took over the last four days. Most people with HIV have many pills to take at different times during the day. Many people find it hard to always remember their pills. Some people get busy and forget to carry their pills with them. Some people find it hard to take their pills according to all the instructions, such as "with meals", "on an empty stomach", "every 8 hours", or "with plenty of fluids". Some people decide to skip doses to avoid side effects or to just not be taking pills that day.

We need to understand how people with HIV are really doing with their pills. Please tell us what you are actually doing. Don't worry about telling us that you don't take all your pills. We need to know what is really happening, not what you think we "want to hear". This questionnaire asks about the medications that you may have missed taking over the last four days. Please complete the following table by filling in the boxes below.

IF YOU TOOK ONLY A PORTION OF A DOSE ON ONE OR MORE OF THESE DAYS, PLEASE REPORT THE DOSE(S) AS BEING MISSED.

Repeat questions for each medication the respondent is prescribed.

Name of Anti-HIV Medication:	How Many Doses Did You Miss...			
	Yesterday (x) doses	Day Before Yesterday (x) doses	3 Days Ago (x) doses	4 Days Ago (x) doses
1. (MAHIVRX1) <div style="border: 1px solid black; padding: 2px; margin-top: 5px;"> 00-None 97-Don't know 99-Other/Experimental/Blinded study - OTHR 01-Apivus - TPV 02-Atripla - EFV + TDF + FTC *Additional Options Listed Below </div>	(MARX1D1) <input style="width: 50px;" type="text"/>	(MARX1D2) <input style="width: 50px;" type="text"/>	(MARX1D3) <input style="width: 50px;" type="text"/>	(MARX1D4) <input style="width: 50px;" type="text"/>
2. (MAHIVRX2) <div style="border: 1px solid black; padding: 2px; margin-top: 5px;"> 00-None 97-Don't know 99-Other/Experimental/Blinded study - OTHR 01-Apivus - TPV 02-Atripla - EFV + TDF + FTC *Additional Options Listed Below </div>	(MARX2D1) <input style="width: 50px;" type="text"/>	(MARX2D2) <input style="width: 50px;" type="text"/>	(MARX2D3) <input style="width: 50px;" type="text"/>	(MARX2D4) <input style="width: 50px;" type="text"/>
3. (MAHIVRX3) <div style="border: 1px solid black; padding: 2px; margin-top: 5px;"> 00-None 97-Don't know 99-Other/Experimental/Blinded study - OTHR 01-Apivus - TPV 02-Atripla - EFV + TDF + FTC *Additional Options Listed Below </div>	(MARX3D1) <input style="width: 50px;" type="text"/>	(MARX3D2) <input style="width: 50px;" type="text"/>	(MARX3D3) <input style="width: 50px;" type="text"/>	(MARX3D4) <input style="width: 50px;" type="text"/>
4. (MAHIVRX4) <div style="border: 1px solid black; padding: 2px; margin-top: 5px;"> 00-None 97-Don't know 99-Other/Experimental/Blinded study - OTHR 01-Apivus - TPV 02-Atripla - EFV + TDF + FTC *Additional Options Listed Below </div>	(MARX4D1) <input style="width: 50px;" type="text"/>	(MARX4D2) <input style="width: 50px;" type="text"/>	(MARX4D3) <input style="width: 50px;" type="text"/>	(MARX4D4) <input style="width: 50px;" type="text"/>
5. (MAHIVRX5) <div style="border: 1px solid black; padding: 2px; margin-top: 5px;"> 00-None 97-Don't know 99-Other/Experimental/Blinded study - OTHR 01-Apivus - TPV 02-Atripla - EFV + TDF + FTC *Additional Options Listed Below </div>	(MARX5D1) <input style="width: 50px;" type="text"/>	(MARX5D2) <input style="width: 50px;" type="text"/>	(MARX5D3) <input style="width: 50px;" type="text"/>	(MARX5D4) <input style="width: 50px;" type="text"/>

6. (MAHIVRX6) 00-None 97-Don't know 99-Other/Experimental/Blinded study - OTHR 01-Apivus - TPV 02-Atripla - EFV + TDF + FTC *Additional Options Listed Below	(MARX6D1) <input type="text"/>	(MARX6D2) <input type="text"/>	(MARX6D3) <input type="text"/>	(MARX6D4) <input type="text"/>
7. (MAHIVRX7) 00-None 97-Don't know 99-Other/Experimental/Blinded study - OTHR 01-Apivus - TPV 02-Atripla - EFV + TDF + FTC *Additional Options Listed Below	(MARX7D1) <input type="text"/>	(MARX7D2) <input type="text"/>	(MARX7D3) <input type="text"/>	(MARX7D4) <input type="text"/>

8. In the past 30 days, how often did you take your anti-HIV medications as prescribed? (MATKRX30)

0-None of the time
 1-A little of the time
 2-Some of the time
 3-A good bit of the time
 4-Most of the time
 *Additional Options Listed Below

9. About what percentage of the time would you say you take your anti-HIV medications as prescribed? (MATKRXP)

0-0%
 1-10%
 2-20%
 3-30%
 4-40%
 *Additional Options Listed Below

10. How would you rate your adherence to your anti-HIV medications? That is, how well do you follow your provider's instructions for which medications to take, how much to take, and when to take them? (MARXADHR)

1-Very poor
 2-Poor
 3-Fair
 4-Good
 5-Very good
 *Additional Options Listed Below

Comments: (MADCOMM)

Additional Selection Options for MAD

Anti-HIV medication 1

03-Combivir - ZDV + 3TC or AZT + 3TC
04-Complera - RPV + TDF + FTV
05-Crixivan - IDV
06-Edurant - RPV
07-Emtriva - FTC
08-Epivir - 3TC
09-Epizicom - ABC + 3TC
10-Fuzeon - T20
11-Intelligence - ETV
12-Invirase - SQV
13-Isentress - RAL
14-Isentress + Truvada - RAL + TDF + FTC
15-Kaletra - LPV/r
16-Lexiva - FPV
17-Norvir - RTV
18-Prezista BID - DRV
19-Prezista QD - DRV
20-Prezista + Norvir + Truvada (DRV/r twice daily) - DRV/r + TDF + FTC
21-Prezista + Norvir + Truvada (once daily) - DRV/r + TDF + FTC
22-Reyataz - ATV
23-Reyataz + Norvir + Truvada
- ATV/r + TDF + FTC
24-Rescriptor - DLV
25-Retrovir - AZT (or ZDV)
26-Selzentry - MVC
27-Selzentry + Truvada - MVC + TDF + FTC
28-Stribild - EVG + COBI + TDF + FTC
29-Sustiva - EFV
30-Tivacay (dolutegravir)
31-Trizivir - ABC + 3TC + ZDV (or AZT)
32-Truvada - TDF + FTC
33-Videx - ddI
34-Viracept - NFV
35-Viramune - NVP
36-Viramune XR (QD) - NVP
37-Viread - TDF
38-Zerit - d4T
39-Ziagen - ABC

In the past 30 days, how often did you take your anti-HIV medications as prescribed?

5- All of the time

About what percentage of the time would you say you take your anti-HIV medications as prescribed?

5- 50%

6- 60%

7- 70%

8- 80%

9- 90%

10- 100%

How would you rate your adherence to your anti-HIV medications? That is, how well do you follow your provider's instructions for which medications to take, how much to take, and when to take them?

6- Excellent

NIDA Clinical Trials Network

Medication Assisted Treatment (MAT)

Web Version: 1.0; 2.01; 04-06-15

Segment (PROTSEG):

Visit number (VISNO):

Report Type (REPORT): Participant self-report

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

In the past 28 days, were you prescribed any of the following for addiction treatment:

1. Disulfiram (Antabuse):(MADSFRRX)

No Yes

a. If "Yes", how many days in the past 28 days did you take this medication?
(MADSFDA Y) (xx)

b. Usual daily dose:(MADSFDFSE) (xxx) mg

2. Acamprosate (Campral):(MAACMRX)

No Yes

a. If "Yes", how many days in the past 28 days did you take this medication?
(MAACMDAY) (xx)

b. Usual daily dose:(MAACMDSE) (xxxx) mg

3. Oral naltrexone (ReVia):(MANTXRX)

No Yes

a. If "Yes", how many days in the past 28 days did you take this medication?
(MANTXDAY) (xx)

b. Usual daily dose:(MANTXDSE) (xxx.xx) mg

4. Gabapentin (Neurotin):(MAGBPRX)

No Yes

a. If "Yes", how many days in the past 28 days did you take this medication?
(MAGBPDAY) (xx)

b. Usual daily dose:(MAGBPDSE) (xxxx) mg

5. Topiramate (Topamax):(MATPMRX)

No Yes

a. If "Yes", how many days in the past 28 days did you take this medication?
(MATPMDAY) (xx)

b. Usual daily dose:(MATPMDSE) (xxx) mg

6. Valproic acid (Depakote):(MAVPARX)

No Yes

a. If "Yes", how many days in the past 28 days did you take this medication?
(MAVPADAY) (xx)

b. Usual daily dose:(MAVPADSE) (xxxx) mg

7. Other medication for addiction treatment:(MAOT1RX)

No Yes

a. If "Yes", specify:(MAOT1SP)

b. How many days in the past 28 days did you take this medication?
(MAOT1DAY) (xx)

c. Usual daily dose:(MAOT1DSE) (xxxx.xx) mg

8. Other medication for addiction treatment:(MAOT2RX)

No Yes

a. If "Yes", specify:(MAOT2SP)

b. How many days in the past 28 days did you take this medication?
(MAOT2DAY) (xx)

c. Usual daily dose:(*MAOT2DSE*)

(*xxxx.xx*) mg

Comments:(*MATCOMM*)

Additional Selection Options for MAT

Report Type (*REPORT*) (key field):

- 1-Participant self-report
- 2-Medical record abstraction

NIDA Clinical Trials Network

Medication Assisted Treatment (MAT)

Web Version: 1.0; 2.01; 04-06-15

Segment (PROTSEG):

Visit number (VISNO):

Report Type (REPORT): [Medical Record Abstraction](#)

Date of assessment:(MATASMDT)

 (mm/dd/yyyy)

In the past 28 days, was the participant prescribed any of the following for addiction treatment:

1. Disulfiram (Antabuse):(MADSFRX)

 No Yes

Prescribed dose:(MADSFSE)

 (xxx) mg

2. Acamprosate (Campral):(MAACMRX)

 No Yes

Prescribed dose:(MAACMSE)

 (xxxx) mg

3. Oral naltrexone (ReVia):(MANTXRX)

 No Yes

Prescribed dose:(MANTXDSE)

 (xxx.xx) mg

4. Gabapentin (Neurontin):(MAGBPRX)

 No Yes

Prescribed dose:(MAGBPDSE)

 (xxxx) mg

5. Topiramate (Topamax):(MATPMRX)

 No Yes

Prescribed dose:(MATPMDSE)

 (xxx) mg

6. Valproic acid (Depakote):(MAVPARX)

 No Yes

Prescribed dose:(MAVPADSE)

 (xxxx)

7. Other medication for addiction treatment:(MAOT1RX)

 No Yes

a. If "Yes", specify:(MAOT1SP)

b. Prescribed dose:(MAOT1DSE)

 (xxx.xx) mg

8. Other medication for addiction treatment:(MAOT2RX)

 No Yes

a. If "Yes", specify:(MAOT2SP)

b. Prescribed dose:(MAOT2DSE)

 (xxx.xx) mg

Comments:(MATCOMM)

Additional Selection Options for MAT

Report Type (*REPORT*) (key field):

- 1-Participant self-report
- 2-Medical record abstraction

NIDA Clinical Trials Network

Medical and Psychiatric History (MHX)

Web Version: 1.0; 4.01; 09-17-14

Segment (PROTSEG):
Visit number (VISNO):

Date of assessment: (MHXASMDT)

[] (mm/dd/yyyy)

Medical History			
Condition	History of the Condition:	If "Yes", specify:	Condition Present Currently:
1. Eye disorders:	(MHEYEH) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MHEYESP) []	(MHEYEC) <input type="checkbox"/> No <input type="checkbox"/> Yes
2. Ear disorders:	(MHEARH) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MHEARSP) []	(MHEARC) <input type="checkbox"/> No <input type="checkbox"/> Yes
3. Respiratory and throat disorders:	(MHRESPH) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MHRESPSP) []	(MHRESPC) <input type="checkbox"/> No <input type="checkbox"/> Yes
4. Cardiovascular disorders:	(MHCARDH) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MHCARDSP) []	(MHCARDC) <input type="checkbox"/> No <input type="checkbox"/> Yes
5. Liver and gallbladder disorders:	(MHLIVRH) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MHLIVRSP) []	(MHLIVRC) <input type="checkbox"/> No <input type="checkbox"/> Yes
6. Other gastrointestinal disorders:	(MHGIH) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MHGISP) []	(MHGIC) <input type="checkbox"/> No <input type="checkbox"/> Yes
7. Skin disorders:	(MHSKINH) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MHSKINSP) []	(MHSKINC) <input type="checkbox"/> No <input type="checkbox"/> Yes
8. Musculoskeletal disorders:	(MHMUSCH) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MHMUSCSP) []	(MHMUSCC) <input type="checkbox"/> No <input type="checkbox"/> Yes
9. Metabolic disorders:	(MHMETAH) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MHMETASP) []	(MHMETAC) <input type="checkbox"/> No <input type="checkbox"/> Yes
10. Endocrine disorders:	(MHENDO H) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MHENDOSP) []	(MHENDOC) <input type="checkbox"/> No <input type="checkbox"/> Yes
11. Renal and urinary tract disorders:	(MHREN LH) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MHREN LSP) []	(MHREN LC) <input type="checkbox"/> No <input type="checkbox"/> Yes
12. Reproductive system and breast disorders:	(MHREPO H) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MHREPO SP) []	(MHREPO C) <input type="checkbox"/> No <input type="checkbox"/> Yes
13. Epilepsy or seizure disorder:	(MHELPHY H) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MHELPHY SP) []	(MHELPHY C) <input type="checkbox"/> No <input type="checkbox"/> Yes
14. Clinically significant neurological damage:	(MHNEUR H) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MHNEUR SP) []	(MHNEUR C) <input type="checkbox"/> No <input type="checkbox"/> Yes
15. Other nervous system disorders:	(MHNERV H) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MHNERV SP) []	(MHNERV C) <input type="checkbox"/> No <input type="checkbox"/> Yes

Psychiatric History			
Condition	History of the Condition:	If "Yes", specify:	Condition Present Currently:
16. Anxiety or panic disorder:	(MHANXH) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MHANXSP) 	(MHANXC) <input type="checkbox"/> No <input type="checkbox"/> Yes
17. Attention Deficit Hyperactivity Disorder:	(MHADHDH) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MHADHDSP) 	(MHADHC) <input type="checkbox"/> No <input type="checkbox"/> Yes
18. Bipolar Disorder:	(MHBPLRH) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MHBPLRSP) 	(MHBPLRC) <input type="checkbox"/> No <input type="checkbox"/> Yes
19. Major Depressive Disorder:	(MHMDDH) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MHMDDSP) 	(MHMDDC) <input type="checkbox"/> No <input type="checkbox"/> Yes
20. Schizophrenia:	(MHSCHZH) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MHSCHZSP) 	(MHSCHZC) <input type="checkbox"/> No <input type="checkbox"/> Yes
21. Suicidal ideation:	(MHSIDH) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MHSIDSP) 	(MHSIDC) <input type="checkbox"/> No <input type="checkbox"/> Yes
22. Suicidal behavior:	(MHSBEHH) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MHSBEHSP) 	(MHSBEHC) <input type="checkbox"/> No <input type="checkbox"/> Yes
23. Homicidal ideation:	(MHHIDH) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MHHIDSP) 	(MHHIDC) <input type="checkbox"/> No <input type="checkbox"/> Yes
24. Homicidal behavior:	(MHHBEHH) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MHHBEHSP) 	(MHHBEHC) <input type="checkbox"/> No <input type="checkbox"/> Yes
25. Violent behavior:	(MHVBEHH) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MHVBEHSP) 	(MHVBEHC) <input type="checkbox"/> No <input type="checkbox"/> Yes
26. Psychotic episodes:	(MHPSYEH) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MHPSYESP) 	(MHPSYEC) <input type="checkbox"/> No <input type="checkbox"/> Yes
27. Other psychiatric disorder:	(MHPSYOH) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MHPSYOSP) 	(MHPSYOC) <input type="checkbox"/> No <input type="checkbox"/> Yes

Other Conditions not Listed Above	Specific Details:	Condition Present Currently:
28. (MHOTHR1)	(MHOTHR1S)	(MHOTHR1C) <input type="checkbox"/> No <input type="checkbox"/> Yes

29. (MHOTHR2) <input type="text"/>		(MHOTHR2C) <input type="checkbox"/> No <input type="checkbox"/> Yes
30. (MHOTHR3) <input type="text"/>	(MHOTHR2S) <input type="text"/>	(MHOTHR3C) <input type="checkbox"/> No <input type="checkbox"/> Yes
	(MHOTHR3S) <input type="text"/>	

HIV History

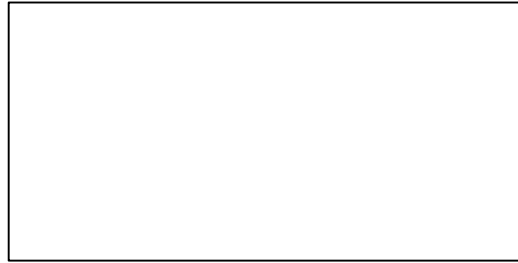
31. When did you first learn that you were HIV positive? (MHHIVDT) (mm/dd/yyyy) **OR** (MHHIVDKR) Don't know Refused
32. When did you begin receiving care for HIV at this clinic? (MHHIVCRE) Less than 3 months ago 3 or more months ago
33. Have you ever been diagnosed with an opportunistic infection? (MHHIVINF) No Yes
34. Have you taken any antiretroviral therapy in the last month? (MHHIVART) No Yes
35. How do you think that you got HIV?
- | | No | Yes |
|--|-------------------------------------|--|
| a. Same sex sexual contact: | (MHHIVHOM) <input type="checkbox"/> | <input type="checkbox"/> |
| b. Heterosexual sexual contact: | (MHHIVHTR) <input type="checkbox"/> | <input type="checkbox"/> |
| c. Injection drug use: | (MHHIVIDU) <input type="checkbox"/> | <input type="checkbox"/> |
| d. Blood transfusion, blood components, or tissue: | (MHHIVBLD) <input type="checkbox"/> | <input type="checkbox"/> |
| e. Mother-to-child transmission: | (MHHIVMTR) <input type="checkbox"/> | <input type="checkbox"/> |
| f. Other: | (MHHIVOTH) <input type="checkbox"/> | <input type="checkbox"/> Specify:(MHHIVOSP) <input type="text"/> |

-OR-

Don't know:(MHHIVDK)

Refused: (MHHIVRF)

Comments: (MHXCOMM)



NIDA Clinical Trials Network

Non-Fatal Overdose (NFO)

Web Version: 1.0; 1.00; 02-04-14

Segment (PROTSEG):

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, dilaudid, or percocet).

1. Have you ever had an opioid overdose?(NFOPIOD)

No Yes

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

 (xx)

Comments:(NFOCOMM)

NIDA Clinical Trials Network

Pregnancy and Birth Control Assessment (PBC)

Web Version: 1.0; 3.02; 12-09-14

Segment (PROTSEG):

Visit number (VISNO):

Complete this form only for females.

Date of assessment:(PBCASMDT)

 (mm/dd/yyyy)

1. Is the participant breastfeeding?(PBBSTFED)

No Yes

2. Does the participant agree to take measures to avoid becoming pregnant?
(PBUSEBC)

No Yes

If "Yes", select all that apply:

a. Oral contraceptives:(PBORALCN)

No Yes

b. Contraceptive patch:(PBPATCH)

No Yes

c. Barrier (diaphragm or condom):(PBBARRIR)

No Yes

d. Levonorgestrel implant:(PBLEVIMP)

No Yes

e. Medroxyprogesterone acetate injection:(PBMEDINJ)

No Yes

f. Complete abstinence from sexual intercourse:(PBABSTIN)

No Yes

g. Hormonal vaginal contraceptive ring:(PBRING)

No Yes

h. Surgical sterilization:(PBSURGSZ)

No Yes

i. Intrauterine contraceptive device (IUD):(PBINTDEV)

No Yes

j. Other:(PBBCOTH)

No Yes

If "Other", specify:(PBBCOSP)

3. Was a pregnancy test performed?(PBPRGTST)

No Yes

a. Date of pregnancy test:(PBP TSTDT)

 (mm/dd/yyyy)

b. Result of pregnancy test:(PBRESULT)

Negative Positive

Comments:(PBCCOMM)

NIDA Clinical Trials Network

Protocol Deviation Review (PDR)

Web Version: 1.0; 2.00; 03-24-14

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

Completed by Protocol Specialist:

1. What section of the protocol does this deviation refer to?(PDSECTN)

2. Does the report of this deviation require site staff retraining?(PDTRAIN)

No Yes

If "Yes", specify plan for retraining:(PDPLATRA)

3. Deviation was discussed with Lead Investigative Team on:(PDDISCDT)

(mm/dd/yyyy)

4. Deviation is categorized as:(PDCA TGRY)

Major Minor

5. Deviation assessment by Protocol Specialist complete:(PDPSCMP)

No Yes

Protocol Specialist reviewer:(PDPSRVID)

(initials)

Completed by Protocol Monitor:

6. Corrective action for this deviation was completed and documented on-site as described:(PDACTDOC)

No Yes

If "No", specify reason:(PDSITESP)

7. Deviation was reported to the IRB as required:(PDIRBRPT)

No Yes

If "No", specify reason:(*PDIRBSP*)

8. Preventive action plan related to this event was completed and documented on-site as described:(*PDPREVENT*)

No Yes

9. Review by Protocol Monitor is complete:(*PDPMCMP*)

No Yes

Protocol Monitor reviewer:(*PDPMRVID*)

(initials)

Comments:(*PVCOMM*)

Additional Selection Options for PDR

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

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

NIDA Clinical Trials Network

Protocol Deviation (PDV)

Web Version: 1.0; 1.00; 03-21-14

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

1. Date deviation identified: (PDVDATE)

 (mm/d/yyyy)

2. Deviation type: (PDTYPE)

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

If "Other", specify: (PDTYPSP)

3. Brief description of what occurred: (PDDESCPT)

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

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

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

No Yes

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

No Yes

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

(mm/d/yyyy)

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

(mm/d/yyyy)

Comments:(*PDVCOMM*)

Additional Selection Options for PDV

Protocol deviation number (PDSEQNUM) (key field):

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

Deviation type:

01E--- Informed consent process not properly conducted and/or documented
01Z--- Other (specify)
Z02-INCLUSION/EXCLUSION CRITERIA
02A--- Ineligible participant randomized/inclusion/exclusion criteria not met
02Z--- Other (specify)
Z04-LABORATORY ASSESSMENTS
04A--- Biologic specimen not collected/processed as per protocol
04Z--- Other (specify)
Z05-STUDY PROCEDURES/ASSESSMENTS
05A--- Protocol required visit/assessment not scheduled or conducted
05B--- Study assessments not completed/followed as per protocol
05C--- Inappropriate unblinding
05Z--- Other (specify)
Z06-ADVERSE EVENT
06A--- AE not reported
06B--- SAE not reported
06C--- AE/SAE reported out of protocol specified reporting time frame
06D--- AE/SAE not elicited, observed and/or documented as per protocol
06E--- Safety assessment (e.g. labs, ECG, clinical referral to care) not conducted per protocol
06Z--- Other (specify)
Z07-RANDOMIZATION PROCEDURES
07A--- Stratification error
07Z--- Other (specify)
Z08-STUDY MEDICATION MANAGEMENT
08A--- Medication dispensed to ineligible participant
08B--- Medication dispensed to incorrect participant
08C--- Medication dosing errors (protocol specified dose not dispensed)
08D--- Participant use of protocol prohibited medication
08Z--- Other (specify)
Z09-STUDY BEHAVIORAL INTERVENTION
09A--- Study behavioral intervention was not provided/performed as per protocol
09Z--- Other (specify)
Z99-OTHER SIGNIFICANT DEVIATIONS
99A--- Destruction of study materials without prior authorization from sponsor
99B--- Breach of Confidentiality
99Z--- Other (specify)

NIDA Clinical Trials Network

Pain Assessment (PEG)

Web Version: 1.0; 1.01; 08-12-14

Segment (PROTSEG):

Visit number (VISNO):

Date of assessment: (PEGASMDT)

(mm/dd/yyyy)

	0	1	2	3	4	5	6	7	8	9	10
1. What number best describes your average level of pain in the past week? <i>'0' represents no pain and '10' represents the worst pain you can imagine.</i>	(PEPAINAV) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. What number best describes how pain has interfered with your enjoyment of life in the past week? <i>'0' represents no interference and '10' represents complete interference.</i>	(PEENJOY) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. What number best describes how pain has interfered with your general activity in the past week? <i>'0' represents no interference and '10' represents complete interference.</i>	(PEACTVTY) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

4. How did you manage your pain?

No Yes

a. Acupuncture: (PEACUPNT)

b. Massage: (PEMASSGE)

c. Exercise: (PEEXRCSE)

d. Non-opioid medications (e.g., ibuprofen, acetaminophen, gabapentin): (PEMEDS)

e. Prescribed opioid medications: (PEOPIRX)

f. Non-prescribed opioids: (PEOPINRX)

g. Consultation with a doctor: (PEMD)

h. Did not manage pain: (PENOTMNG)

i. Other: (PEPAINOT) If "Other", specify: (PEPNOSP)

Comments: (PEG COMM)

NIDA Clinical Trials Network

Physical Examination (PEX)

Web Version: 1.0; 2.00; 11-19-13

Segment (PROTSEG):

Visit number (VISNO):

Date of assessment:(PEXASMDT)

(mm/dd/yyyy)

Comments

General appearance:

(PEGENAPP)

1-Normal
2-Abnormal, not clinically significant
3-Abnormal, clinically significant
97-Notassessed

(PEGASP)

Skin, hair, and nails:

(PESKHRNA)

1-Normal
2-Abnormal, not clinically significant
3-Abnormal, clinically significant
97-Notassessed

(PESHNSP)

Head and neck:

(PEHDNK)

1-Normal
2-Abnormal, not clinically significant
3-Abnormal, clinically significant
97-Notassessed

(PEHDNKSP)

Ears, eyes, nose, and throat

(PEEENT)

1-Normal
2-Abnormal, not clinically significant
3-Abnormal, clinically significant
97-Notassessed

(PEENTSP)

Cardiovascular:

(PECARD)

(PECARDSP)

1-Normal
2-Abnormal, not clinically significant
3-Abnormal, clinically significant
97-Not assessed

Respiratory:

(PERESP)

1-Normal
2-Abnormal, not clinically significant
3-Abnormal, clinically significant
97-Not assessed

(PERESPSP)

Gastrointestinal:

(PEGAST)

1-Normal
2-Abnormal, not clinically significant
3-Abnormal, clinically significant
97-Not assessed

(PEGASTSP)

Extremities:

(PEEXTR)

1-Normal
2-Abnormal, not clinically significant
3-Abnormal, clinically significant
97-Not assessed

(PEEXTRSP)

Lymph nodes:

(PELYMP)

1-Normal
2-Abnormal, not clinically significant
3-Abnormal, clinically significant
97-Not assessed

(PELYMPSP)

Musculoskeletal:

(PEMUSC)

1-Normal
2-Abnormal, not clinically significant
3-Abnormal, clinically significant
97-Not assessed

(PEMUSCSP)

Neurological:

(PENEUR)

1-Normal
2-Abnormal, not clinically significant
3-Abnormal, clinically significant
97-Not assessed

(PENEURSP)

Planned injection site assessment:

(PEINJS)

1-Normal
2-Abnormal, not clinically significant
3-Abnormal, clinically significant
97-Not assessed

(PEINJSSP)

Other (specify in comments):

(PEOTHER)

1-Normal
2-Abnormal, not clinically significant
3-Abnormal, clinically significant
97-Not assessed

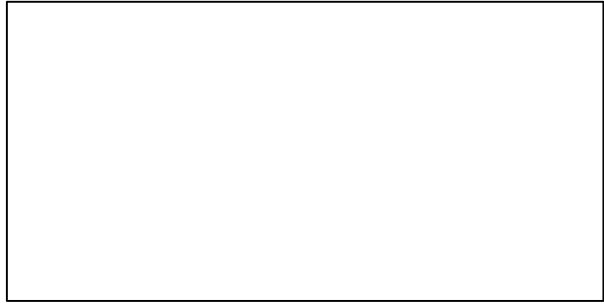
(PEOTHESP)

1. Does participant have a body habitus that precludes gluteal intramuscular injection of naltrexone with provided needle?(PEBDYHBT)

No Yes

Comments:(PEBDHBSF)

Comments:(*PEXCOMM*)



NIDA Clinical Trials Network

Pre-Screen Interview (PSI)

Web Version: 1.0; 2.02; 01-06-15

Pre-Screen ID (PRESCNID):

Date of assessment:(PSIASMDT)

(mm/dd/yyyy)

1. Do you give consent to answer pre-screening questions?(PSCNST)

No Yes

If "Yes", date of consent:(PSCNSTDT)

(mm/dd/yyyy)

2. Do you have HIV or AIDS?(PSHIVPOS)

No Yes

3. How old are you?(PSAGE)

(xx) years old

4. What is your gender?(PSGENDER)

1-Male
2-Female
3-Transgender, male-to-female
4-Transgender, female-to-male
97-Don't know
*Additional Options Listed Below

a. If female or transgender (female-to-male), are you pregnant or currently breastfeeding?(PSPREG)

No Yes

b. If female or transgender (female-to-male), are you willing to take measures to avoid becoming pregnant?(PBCUSE)

No Yes

5. Are you Hispanic/Latino?(PSHISPNC)

No Yes Don't know Refused

If "Yes", what group represents your Hispanic origin or ancestry?(PSHISPSP)

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

6. What is your race?

(Check all that apply.)

White: (PSWHITE)

Black/African American: (PSBLACK)

Indian (American): (PSAMEIND)

Alaska native: (PSALASKA)

Native Hawaiian: (PSHAWAII)

Guamanian: (PSGUAM)

Samoan: (PSSAMOAN)

Other Pacific Islander: (PSPACISL) Specify:(PSPACISO)

Asian Indian: (PSASAIND)

Chinese: (PSCHINA)

Filipino: (PSFILIPN)

Japanese: (PSJAPAN)

Korean: (PSKOREA)

Vietnamese: (PSVIETNM)

Other Asian: (PSASINOT) Specify:(PSASINSP)

Some other race: (PSRACEOT) Specify:(PSRACEESP)

-OR-

Refused: (PSRACERF)

Don't know:(PSRACEDK)

Caucasian/White: (PSWHITE)

South Asian (e.g., Indian, Pakistani): (PSSOASIA)

Chinese: (PSCHINA)

Other Asian (e.g., Vietnamese, Japanese): (PSAS/NOT) Specify:(PSAS/INSP) _____

Latin American: (PSLATNAM) Specify:(PSLAT/NSP) _____

Middle Eastern: (PSMDEAST) Specify:(PSMDE/ASP) _____

Black African: (PSAFRICA)

Black Caribbean: (PSCARBBN)

Other Black: (PSBLCKOT) Specify:(PSBLCK/SP) _____

First Nations/Aboriginal/Inuit: (PSABORIG)

Metis: (PSMETIS)

Some other race: (PSRACEOT) Specify:(PSRACE/SP) _____

-OR-

Refused: (PSRACERF)

Don't know:(PSRACEDK)

7. In the past year, have you used any opioids (such as heroin, prescription opioid medication, or opium)?(PSOPIATE) No Yes

8. Are you interested in cutting back or quitting your opioid use?(PSS TPOPI) No Yes

9. Are you currently receiving methadone or buprenorphine for treatment of opioid addiction?(PSOPRXTX) No Yes

Extended-Release Naltrexone for Opioid Addiction:

Extended-release naltrexone is a medicine used to treat opioid dependence (addiction to opioid drugs, including heroin and narcotic painkillers). It works by blocking opioid activity in a part of the brain. People who take naltrexone have less craving for opioids and do not feel the effects of opioids.

To start the medication, people first need to be opioid free for 3 days. Extended-release naltrexone is given as an injection in the buttock muscle once a month. Potential side effects include initial nausea and vomiting and muscle aches and soreness at the injection site. People who stop taking naltrexone do not experience withdrawal symptoms.

	Definitely Not	Maybe Not	Maybe Yes	Definitely Yes
10. I believe extended-release naltrexone is an effective treatment for opioid addiction.	(PSVIVOP1) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. I would consider taking extended-release naltrexone for my opioid addiction.	(PSTKVIVO) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. I would be willing to participate in a study that compared taking extended-release naltrexone versus usual treatment for opioid addiction.	(PSPTTOPI) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

13. In the past year, have you had "X" or more drinks in a day? No Yes

(X = 5 for men < 65, X = 4 for women and for men ≥ 65) (PSALCHL)

14. Are you interested in cutting back or quitting your alcohol use?(PSS TPALC) No Yes

Extended-Release Naltrexone for Alcohol Addiction:

Extended-release naltrexone is a medicine used to treat alcohol dependence. It works by blocking opioid activity in a part of the brain. People who take naltrexone have less craving for alcohol.

Extended-release naltrexone is given as an injection in the buttock muscle once a month. Potential side effects include initial nausea and vomiting and muscle aches and soreness at the injection site. Naltrexone injection should not be used to treat people who have used opiates within the past 3 days.

	Definitely Not	Maybe Not	Maybe Yes	Definitely Yes
15. I believe extended-release naltrexone is an effective treatment for alcohol problems.	(PSVIVALC) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. I would consider taking extended-release naltrexone for my alcohol problems.	(PSTKVIVA) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. I would be willing to participate in a study that compared taking extended-release naltrexone versus usual treatment for alcohol problems.	(PSPTTALC) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

18. Do you have chronic pain that requires ongoing treatment with opioid pain medicines?(PSPA INRX) No Yes

19. Is this person eligible to continue with in-person screening?(PSELIG) No Yes

20. If "Yes", you may be eligible to participate in the study. Are you interested in scheduling an appointment for the next step?(PSSCHED) No Yes

If "Yes", complete the prescreen contact form and set appointment date and time.

a. If "Yes", in-person screening appointment date:(PSAPTDT) (mm/d/yyyy)

b. If "No", are any of the following reasons why?

1. Declined to schedule:(PSDECSCH) No Yes

2. Not interested in study:(PSNOSTUD) No Yes

3. Doesn't want the study medication:(PSNOMED) No Yes

4. Other:(PSSCHOTH) No Yes Specify:(PSSCHSP) _____

Comments:(PSICOMM)

Additional Selection Options for PSI

What is your gender?

98 -Refused

99 -Other

If "Yes", what group represents your Hispanic origin or ancestry?

6-Cuban

7-Cuban American

8-Central or South American

9-Other Latin American

99-Other Hispanic

98 -Refused

97 -Don't know

NIDA Clinical Trials Network

Quality of Life - PhenX (QLP)

Web Version: 1.0; 1.02; 01-03-14

Segment (PROTSEG):

Visit number (VISNO):

Date of assessment:(QLPASMDT)

(mm/dd/yyyy)

1. Would you say that in general your health is:(QLHEALTH)

1-Excellent
2-Very good
3-Good
4-Fair
5-Poor
97-Don't know/Not sure
98-Refused

2. Now thinking about your physical health, which includes physical illness and injury, for how many days during the past 30 days was your physical health not good?(QLHLTNGD)

(xx) Number of days

3. Now thinking about your mental health, which includes stress, depression, and problems with emotions, for how many days during the past 30 days was your mental health not good?(QLMTLNG)

(xx) Number of days

4. During the past 30 days, for about how many days did poor physical or mental health keep you from doing your usual activities, such as self-care, work, or recreation?(QLACT)

(xx) Number of days

Comments:(QLPCOMM)

NIDA Clinical Trials Network

Risk Assessment Battery (RAB)

Web Version: 1.0; 3.00; 11-12-14

Segment (PROTSEG):

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)

0- Zero or I have not shot up in the past month
1- 1 other person
2- 2 or 3 different people
3- 4 or more different people

4. In the past month, how often have you used a needle after someone (with or without cleaning)?(RAUSOTND)

0- Never or I have not shot up or shared in the past month
1- A few times (1 or 2 times)
2- A bout once a week (3 or 4 times)
3- 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)

0- Never or I have not shot up or shared in the past month
1- A few times (1 or 2 times)
2- A bout once a week (3 or 4 times)
3- 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)

0- Never or I have not shot up or shared in the past month
1- A few times (1 or 2 times)
2- A bout once a week (3 or 4 times)
3- 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)

0- Never
1- A few times (1 or 2 times)
2- A bout once a week (3 or 4 times)
3- 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)

0- Never
1- A few times (1 or 2 times)
2- A bout once a week (3 or 4 times)
3- 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)

0- I have not shot up in the past month 1- I ALWAYS use new needles 2- I ALWAYS clean my needle just BEFORE I shoot up 3- After I shoot up, I ALWAYS clean my needle 4- SOMETIMES I clean my needle, sometimes I don't *Additional Options Listed Below
--

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) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. In the past month, how often have you shared a cooker?	(RACOKRSH) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. In the past month, how often have you shared cotton?	(RACTNSH) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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)

0-0
1-1
2-2 or 3
3-4 or more

men/man

18. With how many women have you had sex in the past month? (RASEXWMN)

0-0
1-1
2-2 or 3
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) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20. In the past month, how often have you given drugs to someone so you could have sex with them?	(RADG4SEX) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21. In the past month, how often were you paid money to have sex with someone?	(RAPOSTUT) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22. In the past month, how often did you give money to someone so you could have sex with them?	(RAPD4SEX) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

24. In the past month, how often did you use condoms when you had sex?(*RASEXSFE*)

- 0-I have not had sex in the past month
- 1-All the time
- 2-Most of the time
- 3-Some of the time
- 4-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)

Comments:(*RABCOMM*)

Additional Selection Options for RAB

Which statement best describes the way you cleaned your needles during the past month?

5-I NEVER clean my needle

NIDA Clinical Trials Network

Readiness for Substance Use Treatment (RST)

Web Version: 1.0; 2.00; 07-25-14

Segment (PROTSEG):

Visit number (VISNO):

Date of assessment (RSTASMDT)

(mm/dd/yyyy)

The following questions ask about "substances". By "substance" we mean **opioids**.

	Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree
1. Treatment could be my last chance to solve my substance use problems.	(RSCHNCEO) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. If I enter treatment, I will stay for a while.	(RSS TAYO) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Treatment could really help me.	(RSHELPO) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. I want to be in a treatment program.	(RSWNTTXO) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Most counselors in substance use treatment programs are "squares" who don't understand substance users.	(RSCNSLRO) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Substance use treatment programs have too many rules and regulations for me.	(RSRULESO) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. I don't think I could trust many of the people who work in the substance use treatment programs.	(RSTRUSTO) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. It takes too much time and effort to get into a substance use treatment program.	(RSEFFRTO) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

The following questions ask about "substances". By "substance" we mean **alcohol**.

	Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree
1. Treatment could be my last chance to solve my substance use problems.	(RSCHNCEA) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. If I enter treatment, I will stay for a while.	(RSS TAYA) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Treatment could really help me.	(RSHELPA) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. I want to be in a treatment program.	(RSWNTTXA) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Most counselors in substance use treatment programs are "squares" who don't understand substance users.	(RSCNSLRA) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Substance use treatment programs have too many rules and regulations for me.	(RSRULESA) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. I don't think I could trust many of the people who work in the substance use treatment programs.	(RSTRUSTA) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. It takes too much time and effort to get into a substance use treatment program.	(RSEFFRTA) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments: (RSTCOMM)



NIDA Clinical Trials Network

Timeline Followback (T55)

Web Version: 1.0; 1.00; 07-24-14

TFB week start date (TFWKSTDT):

Day	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Date	(TLDATE1) <input type="text"/>	(TLDATE2) <input type="text"/>	(TLDATE3) <input type="text"/>	(TLDATE4) <input type="text"/>	(TLDATE5) <input type="text"/>	(TLDATE6) <input type="text"/>	(TLDATE7) <input type="text"/>
1. Have any illicit substances or alcohol been used on this day?	(TLSUBAL1) <input type="checkbox"/> No <input type="checkbox"/> Yes	(TLSUBAL2) <input type="checkbox"/> No <input type="checkbox"/> Yes	(TLSUBAL3) <input type="checkbox"/> No <input type="checkbox"/> Yes	(TLSUBAL4) <input type="checkbox"/> No <input type="checkbox"/> Yes	(TLSUBAL5) <input type="checkbox"/> No <input type="checkbox"/> Yes	(TLSUBAL6) <input type="checkbox"/> No <input type="checkbox"/> Yes	(TLSUBAL7) <input type="checkbox"/> No <input type="checkbox"/> Yes
2. Alcohol number of standard drinks (xx):	(TLALCHL1) <input type="text"/>	(TLALCHL2) <input type="text"/>	(TLALCHL3) <input type="text"/>	(TLALCHL4) <input type="text"/>	(TLALCHL5) <input type="text"/>	(TLALCHL6) <input type="text"/>	(TLALCHL7) <input type="text"/>
3. Cannabinoids/ Marijuana:	(TLTHCR1) 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
4. 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
5. 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
6. Amphetamine-type stimulants	(TLAMPR1) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLAMPR2) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLAMPR3) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLAMPR4) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLAMPR5) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLAMPR6) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLAMPR7) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below
7. 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
8. Heroin:	(TLHERR1)	(TLHERR2)	(TLHERR3)	(TLHERR4)	(TLHERR5)	(TLHERR6)	(TLHERR7)

Comments:(755COMM)



Additional Selection Options for T55

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

NIDA Clinical Trials Network

TLFB Assessment Period (TAP)

Web Version: 1.0; 3.02; 07-11-14

Segment (PROTSEG):

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 illicit substances or alcohol been taken during this assessment period?(TASUBALC)

No Yes

Comments:(TAPCOMM)

NIDA Clinical Trials Network

Treatment Services Review (TSR)

Web Version: 1.0; 4.00; 04-29-15

Segment (*PROTSEG*):

Visit number (*VISNO*):

Date of assessment: (*TSRASMDT*)

(mm/dd/yyyy)

Beginning of assessment period: (*TSBEGDT*)

(mm/dd/yyyy)

End of assessment period: (*TSENDT*)

(mm/dd/yyyy)

Number of days in the assessment period: (*TSDAYSPD*)

(xxx)

A. HOUSING SERVICES:

1. Where did you stay for the past 28 days?

Number of Days
(xx)

a. Alone (in private house, apartment, hotel, etc.):

(*TSRESALN*)

b. With others (in private house, apartment, hotel, etc.):

(*TSRESOTH*)

c. Institution (e.g., hospital, jail, prison):

(*TSRESINT*)

Specify:

(i) Hospital/residential treatment:

(*TSRESHSP*)

(ii) Jail or prison:

(*TSRESPRN*)

d. Structured living situation (e.g., recovery house, group home, halfway house):

(*TSRESSTR*)

Specify:

(i) For alcohol or drug problems (including dual detox):

(*TSRESDRG*)

(ii) For psychological or emotional problems:

(*TSRESPSY*)

(iii) For medical problems:

(*TSRESMED*)

(iv) For criminal behavior or legal problems:

(*TSRESLGL*)

(v) For domestic violence:

(*TSRESDMV*)

e. Homeless shelter:

(*TSRESHSH*)

f. Homeless (i.e., on the street, in an abandoned building, in a car):

(*TSRESHLS*)

B. ALCOHOL AND DRUG SERVICES:

QUESTIONS ABOUT **INPATIENT** TREATMENT FOR ALCOHOL AND/OR DRUGS RECEIVED OVER PAST 28 DAYS

- | | IN
(xx) | OUT
(xx) |
|--|--|--|
| 2. How many nights did you stay at an inpatient/residential drug/alcohol treatment unit? | (<i>TSINDRGI</i>) <input type="text"/> | (<i>TSINDRGO</i>) <input type="text"/> |
| If "Out", specify location: (<i>TSINDRGL</i>) <input type="text"/> | | |
| 3. How many of those nights were detoxification only? | (<i>TSINDTXI</i>) <input type="text"/> | (<i>TSINDTXO</i>) <input type="text"/> |
| If "Out", specify location: (<i>TSINDTXL</i>) <input type="text"/> | | |
| 4. How many individual (one-on-one) sessions did you attend during which substance use was the main purpose of the discussion? | (<i>TSINIDVI</i>) <input type="text"/> | (<i>TSINIDVO</i>) <input type="text"/> |
| a. Specify the number of sessions with: | | |
| (i) Medical doctor (e.g., psychiatrist or physician): | (<i>TSIIDMDI</i>) <input type="text"/> | (<i>TSIIDMDO</i>) <input type="text"/> |

- | | | |
|--|---------------------------------|---------------------------------|
| (ii) Non-medical doctor (e.g., psychologist - Ph.D./Psy.D.): | (TSIIDNMI) <input type="text"/> | (TSIIDNMO) <input type="text"/> |
| (iii) Nurse: | (TSIIDRNI) <input type="text"/> | (TSIIDRNO) <input type="text"/> |
| (iv) Other clinician (e.g., counselor, social worker, clergy): | (TSIIDOTI) <input type="text"/> | (TSIIDOTO) <input type="text"/> |
| (v) Don't know: | (TSIIDDKI) <input type="text"/> | (TSIIDDKO) <input type="text"/> |
| b. On average, how long did each individual session last? (xx minutes) | (TSIIDTMI) <input type="text"/> | (TSIIDTMO) <input type="text"/> |
| | IN
(xx) | OUT
(xx) |
| 5. How many 12-Step/self-help group meeting for substance use (e.g., AA, NA, CA) did you attend? | (TSIN12SI) <input type="text"/> | (TSIN12SO) <input type="text"/> |
| 6. How many meetings did you have with your sponsor/mentor during which your substance problem was the main purpose of the discussion? | (TSINMTRI) <input type="text"/> | (TSINMTRO) <input type="text"/> |
| 7. How many other group therapy/counseling sessions for substance use (i.e., non-self-help groups) did you attend? | (TSINGRPI) <input type="text"/> | (TSINGRPO) <input type="text"/> |
| a. Specify the number of sessions with: | | |
| (i) Medical doctor (e.g., psychiatrist or physician): | (TSIGPMDI) <input type="text"/> | (TSIGPMDO) <input type="text"/> |
| (ii) Non-medical doctor (e.g., psychologist - Ph.D./Psy.D.): | (TSIGPNMI) <input type="text"/> | (TSIGPNMO) <input type="text"/> |
| (iii) Nurse: | (TSIGPRNI) <input type="text"/> | (TSIGPRNO) <input type="text"/> |
| (iv) Other clinician (e.g., counselor, social worker, clergy): | (TSIGPOTI) <input type="text"/> | (TSIGPOTO) <input type="text"/> |
| (v) Don't know: | (TSIGPDKI) <input type="text"/> | (TSIGPDKO) <input type="text"/> |
| b. How many of these groups focused solely on education about alcohol/drugs? | (TSIGPEDI) <input type="text"/> | (TSIGPEDO) <input type="text"/> |
| c. On average, how long did each individual session last? (xx minutes) | (TSIGPTMI) <input type="text"/> | (TSIGPTMO) <input type="text"/> |
| d. On average, how many other patients were in a group? | (TSIGPPTI) <input type="text"/> | (TSIGPPTO) <input type="text"/> |

QUESTIONS ABOUT TREATMENT FOR ALCOHOL AND/OR DRUGS RECEIVED OVER PAST 28 DAYS WHEN NOT IN INPATIENT TREATMENT

- | | | |
|---|---------------------------------|---------------------------------|
| | IN
(xx) | OUT
(xx) |
| 8. How many days did you attend any outpatient treatment for substance use problems, excluding any 12-Step or self help group meetings? | (TSOPDRGI) <input type="text"/> | (TSOPDRGO) <input type="text"/> |
| If "Out", specify location: (TSOPDRGL) <input type="text"/> | | |
| 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)? | (TSOPHSPI) <input type="text"/> | (TSOPHSPO) <input type="text"/> |
| If "Out", specify location: (TSOPHSPL) <input type="text"/> | | |
| 10. How many individual (one-on-one) sessions did you attend during which substance use was the main purpose of the discussion? | (TSOPIDVI) <input type="text"/> | (TSOPIDVO) <input type="text"/> |
| a. Specify the number of sessions with: | | |
| (i) Medical doctor (e.g., psychiatrist or physician): | (TSOIDMDI) <input type="text"/> | (TSOIDMDO) <input type="text"/> |
| (ii) Non-medical doctor (e.g., psychologist - Ph.D./Psy.D.): | (TSOIDNMI) <input type="text"/> | (TSOIDNMO) <input type="text"/> |
| (iii) Nurse: | (TSOIDRNI) <input type="text"/> | (TSOIDRNO) <input type="text"/> |
| (iv) Other clinician (e.g., counselor, social worker, clergy): | (TSOIDOTI) <input type="text"/> | (TSOIDOTO) <input type="text"/> |
| (v) Don't know: | (TSOIDDKI) <input type="text"/> | (TSOIDDKO) <input type="text"/> |
| b. On average, how long did each individual session last? (xx minutes) | (TSOIDTMI) <input type="text"/> | (TSOIDTMO) <input type="text"/> |
| | IN
(xx) | OUT
(xx) |
| 11. How many 12-Step/self-help group meeting for substance use (e.g., AA, NA, CA) did you attend? | (TSOP12SI) <input type="text"/> | (TSOP12SO) <input type="text"/> |
| 12. How many meetings did you have with your sponsor/mentor during which your substance problem was the main purpose of the discussion? | (TSOPMTRI) <input type="text"/> | (TSOPMTRO) <input type="text"/> |
| 13. How many other group therapy/counseling sessions for substance use (i.e., non-self-help groups) did you attend? | (TSOPGRPI) <input type="text"/> | (TSOPGRPO) <input type="text"/> |
| a. Specify the number of sessions with: | | |

- (i) Medical doctor (e.g., psychiatrist or physician): (TSOGPMDI) [] (TSOGPMDO) []
- (ii) Non-medical doctor (e.g., psychologist - Ph.D./Psy.D.): (TSOGPNMI) [] (TSOGPNMO) []
- (iii) Nurse: (TSOGPRNI) [] (TSOGPRNO) []
- (iv) Other clinician (e.g., counselor, social worker, clergy): (TSOGPOTI) [] (TSOGPOTO) []
- (v) Don't know: (TSOGPKI) [] (TSOGPKO) []
- b. How many of these groups focused solely on education about alcohol/drugs? (TSOGPEDI) [] (TSOGPEDO) []
- c. On average, how long did each individual session last? (xx minutes) (TSOGPTMI) [] (TSOGPTMO) []
- d. On average, how many other patients were in a group? (TSOGPPTI) [] (TSOGPPTO) []

QUESTIONS ABOUT TREATMENT RECEIVED ON ANY OF THE PAST 28 DAYS

- | | IN
(xx) | OUT
(xx) |
|---|------------|----------------|
| 14. How many times were you tested for alcohol and/or drug use? | | |
| a. Urinalysis: (TS TS TUR I) [] | | (TSTSTURO) [] |
| b. Breathalyzer: (TS TS TBR I) [] | | (TSTSTBRO) [] |
| c. Any other test for alcohol/drug use (e.g., blood, saliva, hair): (TS TS TO TI) [] | | (TSTSTOTO) [] |
| If "Other", specify: (TS TS TSP I) [] | | (TSTSTSPO) [] |

C. MEDICAL SERVICES:

QUESTIONS ABOUT ANY MEDICAL TREATMENT RECEIVED OVER THE PAST 28 DAYS

- | | IN
(xx) | OUT
(xx) |
|--|---------------|-----------------|
| 15. How many nights were you an inpatient in a medical hospital, nursing home, or medical rehabilitation facility? | (TSINPTI) [] | (TSINPTO) [] |
| a. Specify the number of nights in each facility: | | |
| (i) Medical hospital: (TSINHSP I) [] | | (TSINHSP O) [] |
| (ii) Nursing home or medical rehabilitation facility: (TSINRHBI) [] | | (TSINRHBO) [] |
| b. Diagnosis or major problem at visit 1: (TSINPDX) [] | | |
| c. Diagnosis or major problem at visit 2: (TSINPDX2) [] | | |
| d. Diagnosis or major problem at visit 3: (TSINPDX3) [] | | |
| e. Diagnosis or major problem at visit 4: (TSINPDX4) [] | | |
| f. Diagnosis or major problem at visit 5: (TSINPDX5) [] | | |
| g. Diagnoses or major problems at additional visits: (TSINPDX6) [] | | |
| h. Major procedures or evaluations: (TSINPPRC) [] | | |

QUESTIONS ABOUT MEDICAL TREATMENT RECEIVED OVER PAST 28 DAYS WHEN NOT IN A MEDICAL HOSPITAL

- | | IN
(xx) | OUT
(xx) |
|---|-------------|-------------|
| 16. How many times did you visit an emergency room? | (TSEDI) [] | (TSEDO) [] |
| a. Indicate reason for emergency room visit | | |

(i) Medical:

(TSEDMED)

(TSEDMEDO)

(ii) Psychological:

(TSEDPSYI)

(TSEDPSYO)

(iii) Substance use:

(TSEDSBSI)

(TSEDSBSO)

b. Diagnosis or major problem at visit 1: (TSEDDX)

c. Diagnosis or major problem at visit 2: (TSEDDX2)

d. Diagnosis or major problem at visit 3: (TSEDDX3)

e. Diagnosis or major problem at visit 4: (TSEDDX4)

f. Diagnosis or major problem at visit 5: (TSEDDX5)

g. Diagnoses or major problems at additional visits: (TSEDDX6)

h. Major procedures or evaluations: (TSEDPRC)

17. How many times did you visit a medical doctor (e.g., physician, psychiatrist) for testing, examination, treatment, or care of medical concerns/problems?

(TSMDI)

(TSMDO)

a. Diagnosis or major problem at visit 1: (TSMDDX)

b. Diagnosis or major problem at visit 2: (TSMDDX2)

c. Diagnosis or major problem at visit 3: (TSMDDX3)

d. Diagnosis or major problem at visit 4: (TSMDDX4)

e. Diagnosis or major problem at visit 5: (TSMDDX5)

f. Diagnoses or major problems at additional visits: (TSMDDX6)

g. Major procedures or evaluations: (TSMPPRC)

18. How many times did you visit any other medical professional (e.g., dentist, optometrists, nurse, physical therapist, X-ray or lab technician) for testing, examination, or treatment of medical concerns/problems?

(TSOMPI)

(TSOMPO)

a. Diagnosis or major problem at visit 1: (TSOMPDX)

b. Diagnosis or major problem at visit 2: (TSOMPDX2)

c. Diagnosis or major problem at visit 3: (TSOMPDX3)

d. Diagnosis or major problem at visit 4: (TSOMPDX4)

e. Diagnosis or major problem at visit 5: (TSOMPDX5)

f. Diagnoses or major problems at additional visits: (TSOMPDX6)

g. Major procedures or evaluations: (TSOMPPRC)

IN
(xx)

OUT
(xx)

19. How many individual or group counseling sessions did you attend with non-medical personnel during which medical concerns/problems were the main focus?
Exclude all previously recorded visits.
- (TSCNSLI) (TSCNSLO)
- a. Number of those with:
- (i) Non-medical doctor (e.g., psychologist - Ph.D./Psy.D.): (TSCNLNMI) (TSCNLNMO)
 - (ii) Other clinician (e.g., counselor, social worker, clergy): (TSCNLOTI) (TSCNLOTO)
 - (iii) Group member(s) (i.e., a support group not professionally led): (TSCNLGMI) (TSCNLGMO)
 - (iv) Don't know: (TSCNLDKI) (TSCNLDKO)
- b. How many of these were group sessions? (TSCNLGPI) (TSCNLGPO)
- c. On average, how long did a session last? (*xx minutes*) (TSCNLTMI) (TSCNLTMO)

Given all the services, treatments, and contacts you've had in the past 28 days, how much of all of that dealt with:

	None	A Little Bit	Some	Quite A Bit	A Lot
20. Your substance use problems and issues?	(TSSBSUSE) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21. Your physical health or medical problems?	(TSHEALTH) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22. Your mental health or psychological problems and issues?	(TSPSYCH) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23. Your family problems and issues?	(TSFAMILY) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
24. Your employment, education, finances, or housing?	(TSEMPLOY) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
25. Your legal or criminal problems and issues?	(TSLEGAL) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments:(TSRCOMM)

NIDA Clinical Trials Network

Tobacco Use History (TUH)

Web Version: 1.0; 1.02; 01-10-14

Segment (PROTSEG):

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)

1-Every day
2-Some days
3-Not at all
97-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

Section A: Every-Day Smokers

5. On the average, about how many cigarettes do you now smoke each day?(TUNUMDY)

[] (xx) Cigarettes per day

6. How old were you when you first started smoking cigarettes every day?(TUSTRTAG)

[] (xx) Years old

Section B: Some-Day Smokers

7. On how many of the past 30 days did you smoke cigarettes?(TU30DAYS)

[] (xx) Days

8. On the average, on those [answer to Q7] days, how many cigarettes did you usually smoke each day?(TU30AVG)

[] (xx) Cigarettes per day

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

10. When you last smoked fairly regularly, on average how many cigarettes did you smoke each day?(TUNUMRDY)

[] (xx) Cigarettes per day

Comments:(TUHCOMM)

[]

NIDA Clinical Trials Network

Urine Drug Screen (UDS)

Web Version: 1.0; 4.00; 03-06-14

Segment (PROTSEG):

Visit number (VISNO):

1. Was a urine drug screen performed?(UDTEST1)

If "No", reason:(UDNORSN)

If "Other", specify:(UDNOSP1)

No Yes

1-Participant reported being unable to provide sample
 2-Participant refused to provide sample
 3-Study staff error
 99-Other

1st Urine Drug Screen

2. Date 1st urine specimen collected:(UDCOLDT1)

3. Time 1st urine specimen collected (24-hour format):(UDCOLTM1)

4. Was the 1st urine temperature within range? (90 - 100 °F)(UDETEMP1)

5. Was the 1st urine specimen determined to be adulterated?(UDADULT1)

6. 1st Urine Drug Screen Result(s):

(mm/d d/yyyy)

(hh:mm)

No Yes

No Yes

Drug Name (Abbreviation)	Negative	Positive	Invalid
Benzodiazepines (BZO):	(UDBZO1) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Amphetamine (AMP):	(UDAMP1) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Marijuana (THC):	(UDTHC1) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Methamphetamine (MET):	(UDMET1) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Opiates (2000 ng)(OPI):	(UDOPI1) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cocaine (COC):	(UDCOC1) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ecstasy (MDMA):	(UDMDA1) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Oxycodone (OXY):	(UDOXY1) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Methadone (MTD):	(UDMTD1) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Barbiturate (BAR):	(UDBAR1) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Opiates (300ng)(OPI):(UDOP1300)

Buprenorphine (BUP):(UDBUP1)

Negative Positive Invalid

Negative Positive Invalid

2nd Urine Drug Screen

7. If the 1st urine specimen was determined to be adulterated, was a second specimen collected?(UDTEST2)

If "No", reason:(UDNORSN2)

If "Other", specify:(UDNOSP2)

8. Time 2nd urine specimen collected (24 hour format):(UDCOLTM2)

9. Was the 2nd urine temperature within range? (90 - 100 °F)(UDETEMP2)

10. Was the 2nd urine specimen determined to be adulterated?(UDADULT2)

11. 2nd Urine Drug Screen Result(s):

No Yes

1-Participant reported being unable to provide sample
 2-Participant refused to provide sample
 3-Study staff error
 99-Other

(hh:mm)

No Yes

No Yes

Drug Name (Abbreviation)	Negative	Positive	Invalid
Benzodiazepines (BZO):	(UDBZO2) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Amphetamine (AMP):	(UDAMP2) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Marijuana (THC):	(UDTHC2) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Methamphetamine (MET):	(UDMET2) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Opiates (2000 ng) (OPI):	(UDOPI2) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cocaine (COC):	(UDCOC2) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ecstasy (MDMA):	(UDMDA2) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Oxycodone (OXY):	(UDOXY2) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Methadone (MTD):	(UDMTD2) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Barbiturate (BAR):	(UDBAR2) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Opiates (300ng)(OPI):(UDOP2300)

Buprenorphine (BUP):(UDBUP2)

Negative Positive Invalid
 Negative Positive Invalid

Comments:(UDSCOMM)

NIDA Clinical Trials Network

Visual Analog Scale (VAS)

Web Version: 1.0; 2.01; 07-08-14

Segment (*PROTSEG*):

Visit number (*VISNO*):

Date of assessment:(*VASASMDT*)

(mm/dd/yyyy)

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

(xxx)

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

(xxx)

Comments:(*VASCOMM*)

NIDA Clinical Trials Network

Vital Signs (VIS)

Web Version: 1.0; 3.02; 01-09-15

Segment (PROTSEG):

Visit number (VISNO):

Date of assessment:(VISASMDT)

(mm/dd/yyyy)

Body Mass Index

1. Standing height:(VIHGTIN)

(xx.x) inches (VIHGTCM) (xxx) cm

2. Measured weight:(VIWTLBS)

(xxx.x) lbs (VIWTKGS) (xxx.x) kgs

3. BMI:(VIBMI)

Vital Signs

4. Temperature:(VITEMPF)

(xxx.x) °F or (VITEMPC) (xx.x) °C

5. Heart rate:(VIPULSE)

(xxx) BPM

6. Blood pressure:(VIBPSYS1)

/ (VIBPDIS1) Systolic/Diastolic (mmHg)

Comments:(VISCOMM)

NIDA Clinical Trials Network

Adverse Events (AD1)

Web Version: 1.0; 4.00; 10-02-15

Adverse event onset date (AEDATE):

Event number (AESEQNUM):

1. Adverse event name: (A1DESCPT)

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

3. Severity of event: (A1SEVRTY)

4. Is there a reasonable possibility that the extended-release naltrexone caused the event? (A1RDRUG1)

If "Yes", action taken with extended-release naltrexone: (A1ADRUG1)

5. If "Unrelated" to the study drug, alternative etiology: (A1ALTESD)

If "Other," specify: (A1AEPSP)

6. Outcome of event: (A1OUTCM)

7. Date of resolution or medically stable: (A1RESDT)

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)

a. If "Death", date of death: (A1DTHDT)

b. If "Inpatient admission to hospital or prolongation of hospitalization":

Date of hospital admission: (A1HOSPAD)

Date of hospital discharge: (A1HOSPDC)

(mm/dd/yyyy)

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

No Yes

0-None
1-Decreased drug
2-Increased drug
3-Temporarily stopped drug
4-Permanently stopped drug

0-None apparent
1-Study disease
2-Concomitant medication
3-Other pre-existing disease or condition
4-Accident, trauma, or external factors
*Additional Options Listed Below

1-Ongoing
2-Resolved without sequelae
3-Resolved with sequelae
4-Resolved by convention
5-Death

(mm/dd/yyyy)

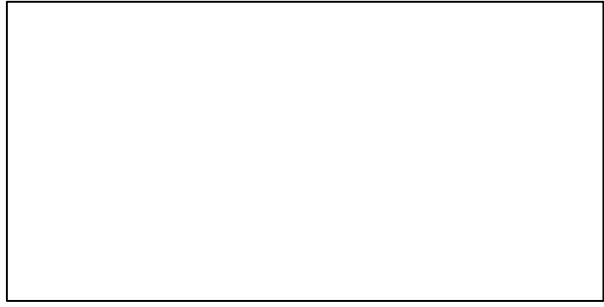
0-None of the following
1-Death
2-Life-threatening event
3-Inpatient admission to hospital or prolongation of existing hospitalization
4-Persistent or significant incapacity
*Additional Options Listed Below

(mm/dd/yyyy)

(mm/dd/yyyy)

(mm/dd/yyyy)

Comments:(AD1 COMM)



Additional Selection Options for AD1

Event number (AESEQNUM) (key field):

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

Was this event associated with:

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

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Serious Adverse Event Summary (AD2)

Web Version: 1.0; 1.00; 02-25-15

Adverse event onset date (AEDATE):

Event number (AESEQNUM):

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) <input type="text"/>	(A2_01DIN) <input type="text"/>
(A2_02DNM) <input type="text"/>	(A2_02DIN) <input type="text"/>
(A2_03DNM) <input type="text"/>	(A2_03DIN) <input type="text"/>
(A2_04DNM) <input type="text"/>	(A2_04DIN) <input type="text"/>
(A2_05DNM) <input type="text"/>	(A2_05DIN) <input type="text"/>
(A2_06DNM) <input type="text"/>	(A2_06DIN) <input type="text"/>
(A2_07DNM) <input type="text"/>	(A2_07DIN) <input type="text"/>
(A2_08DNM) <input type="text"/>	(A2_08DIN) <input type="text"/>
(A2_09DNM) <input type="text"/>	(A2_09DIN) <input type="text"/>
(A2_10DNM) <input type="text"/>	(A2_10DIN) <input type="text"/>

4. Treatments for the event: (A2SAETR7) No Yes Unknown

Treatment	Indication	Date Treated (mm/dd/yyyy)
(A2_1TNME) <input type="text"/>	(A2_1TIND) <input type="text"/>	(A2_1LTD7) <input type="text"/>

(A2_2TNME)	(A2_2TIND)	(A2_2LTD T)
(A2_3TNME)	(A2_3TIND)	(A2_3LTD T)
(A2_4TNME)	(A2_4TIND)	(A2_4LTD T)
(A2_5TNME)	(A2_5TIND)	(A2_5LTD T)

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:

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

(A2FOLLUP)

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 (*AESQNUM*) (key field):

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

NIDA Clinical Trials Network

Serious Adverse Event Medical Reviewer (AD3)

Web Version: 1.0; 3.00; 08-19-14

Adverse event onset date (AEDATE):

Event number (AESEQNUM):

- 1. Was this determined to be a serious adverse event?(A3SAE) No Yes
- 2. Was this event considered associated with extended-release naltrexone?
(A3RXRNTX) 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 (*AESQNUM*) (key field):

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

NIDA Clinical Trials Network

ARV Medication Log (ARV)

Web Version: 1.0; 2.00; 03-10-14

	Drug Name	Start Date (mm/dd/yyyy)	Estimated Start Date	Stop Date (mm/dd/yyyy)	Estimated Stop Date	Ongoing at Study Termination
1.	(ARDRUG01) 01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below	(ARST01DT)	(ARETST01) <input type="checkbox"/>	(ARSP01DT)	(ARETSP01) <input type="checkbox"/>	(ARONG01) <input type="checkbox"/>
2.	(ARDRUG02) 01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below	(ARST02DT)	(ARETST02) <input type="checkbox"/>	(ARSP02DT)	(ARETSP02) <input type="checkbox"/>	(ARONG02) <input type="checkbox"/>
3.	(ARDRUG03) 01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below	(ARST03DT)	(ARETST03) <input type="checkbox"/>	(ARSP03DT)	(ARETSP03) <input type="checkbox"/>	(ARONG03) <input type="checkbox"/>
4.	(ARDRUG04) 01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below	(ARST04DT)	(ARETST04) <input type="checkbox"/>	(ARSP04DT)	(ARETSP04) <input type="checkbox"/>	(ARONG04) <input type="checkbox"/>
5.	(ARDRUG05) 01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below	(ARST05DT)	(ARETST05) <input type="checkbox"/>	(ARSP05DT)	(ARETSP05) <input type="checkbox"/>	(ARONG05) <input type="checkbox"/>
6.	(ARDRUG06) 01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below	(ARST06DT)	(ARETST06) <input type="checkbox"/>	(ARSP06DT)	(ARETSP06) <input type="checkbox"/>	(ARONG06) <input type="checkbox"/>
7.	(ARDRUG07) 01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below	(ARST07DT)	(ARETST07) <input type="checkbox"/>	(ARSP07DT)	(ARETSP07) <input type="checkbox"/>	(ARONG07) <input type="checkbox"/>
8.	(ARDRUG08)	(ARST08DT)	(ARETST08) <input type="checkbox"/>	(ARSP08DT)	(ARETSP08) <input type="checkbox"/>	(ARONG08) <input type="checkbox"/>

	<p>01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below</p>					
9.	<p>(ARDRUG09)</p> <p>01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below</p>	(ARST09DT)	(ARETST09)	(ARSP09DT)	(ARETSP09)	(ARONG09)
10.	<p>(ARDRUG10)</p> <p>01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below</p>	(ARST10DT)	(ARETST10)	(ARSP10DT)	(ARETSP10)	(ARONG10)
11.	<p>(ARDRUG11)</p> <p>01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below</p>	(ARST11DT)	(ARETST11)	(ARSP11DT)	(ARETSP11)	(ARONG11)
12.	<p>(ARDRUG12)</p> <p>01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below</p>	(ARST12DT)	(ARETST12)	(ARSP12DT)	(ARETSP12)	(ARONG12)
13.	<p>(ARDRUG13)</p> <p>01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below</p>	(ARST13DT)	(ARETST13)	(ARSP13DT)	(ARETSP13)	(ARONG13)
14.	<p>(ARDRUG14)</p> <p>01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below</p>	(ARST14DT)	(ARETST14)	(ARSP14DT)	(ARETSP14)	(ARONG14)
15.	<p>(ARDRUG15)</p> <p>01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below</p>	(ARST15DT)	(ARETST15)	(ARSP15DT)	(ARETSP15)	(ARONG15)
16.	<p>(ARDRUG16)</p> <p>01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below</p>	(ARST16DT)	(ARETST16)	(ARSP16DT)	(ARETSP16)	(ARONG16)
17.	<p>(ARDRUG17)</p>	(ARST17DT)	(ARETST17)	(ARSP17DT)	(ARETSP17)	(ARONG17)

	<p>01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below</p>					
18.	<p>(ARDRUG18)</p> <p>01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below</p>	(ARST18DT)	(ARETST18)	(ARSP18DT)	(ARETSP18)	(ARONG18)
		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
19.	<p>(ARDRUG19)</p> <p>01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below</p>	(ARST19DT)	(ARETST19)	(ARSP19DT)	(ARETSP19)	(ARONG19)
		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
20.	<p>(ARDRUG20)</p> <p>01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below</p>	(ARST20DT)	(ARETST20)	(ARSP20DT)	(ARETSP20)	(ARONG20)
		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
21.	<p>(ARDRUG21)</p> <p>01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below</p>	(ARST21DT)	(ARETST21)	(ARSP21DT)	(ARETSP21)	(ARONG21)
		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
22.	<p>(ARDRUG22)</p> <p>01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below</p>	(ARST22DT)	(ARETST22)	(ARSP22DT)	(ARETSP22)	(ARONG22)
		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
23.	<p>(ARDRUG23)</p> <p>01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below</p>	(ARST23DT)	(ARETST23)	(ARSP23DT)	(ARETSP23)	(ARONG23)
		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
24.	<p>(ARDRUG24)</p> <p>01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below</p>	(ARST24DT)	(ARETST24)	(ARSP24DT)	(ARETSP24)	(ARONG24)
		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
25.	<p>(ARDRUG25)</p> <p>01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below</p>	(ARST25DT)	(ARETST25)	(ARSP25DT)	(ARETSP25)	(ARONG25)
		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
26.	<p>(ARDRUG26)</p>	(ARST26DT)	(ARETST26)	(ARSP26DT)	(ARETSP26)	(ARONG26)
		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>

	<p>01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below</p>					
27.	<p>(ARDRUG27)</p> <p>01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below</p>	(ARST27DT)	(ARETST27)	(ARSP27DT)	(ARETSP27)	(ARONG27)
28.	<p>(ARDRUG28)</p> <p>01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below</p>	(ARST28DT)	(ARETST28)	(ARSP28DT)	(ARETSP28)	(ARONG28)
29.	<p>(ARDRUG29)</p> <p>01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below</p>	(ARST29DT)	(ARETST29)	(ARSP29DT)	(ARETSP29)	(ARONG29)
30.	<p>(ARDRUG30)</p> <p>01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below</p>	(ARST30DT)	(ARETST30)	(ARSP30DT)	(ARETSP30)	(ARONG30)
31.	<p>(ARDRUG31)</p> <p>01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below</p>	(ARST31DT)	(ARETST31)	(ARSP31DT)	(ARETSP31)	(ARONG31)
32.	<p>(ARDRUG32)</p> <p>01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below</p>	(ARST32DT)	(ARETST32)	(ARSP32DT)	(ARETSP32)	(ARONG32)
33.	<p>(ARDRUG33)</p> <p>01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below</p>	(ARST33DT)	(ARETST33)	(ARSP33DT)	(ARETSP33)	(ARONG33)
34.	<p>(ARDRUG34)</p> <p>01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below</p>	(ARST34DT)	(ARETST34)	(ARSP34DT)	(ARETSP34)	(ARONG34)
35.	(ARDRUG35)	(ARST35DT)	(ARETST35)	(ARSP35DT)	(ARETSP35)	(ARONG35)

	01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below						
--	--	--	--	--	--	--	--

Comments:(ARVCOMM)

Additional Selection Options for ARV

Drug name 01

06-Edurant - RPV
07-Emtriva - FTC
08-Epivir - 3TC
09-Epizcom - ABC + 3TC
10-Fuzeon - T20
11-Intencele - ETV
12-Invirase - SQV
13-Isentress - RAL
14-Isentress + Truvada - RAL + TDF + FTC
15-Kaletra - LPV/r
16-Lexiva - FPV
17-Norvir - RTV
99-Other/Experimental/Blinded study - OTHR
18-Prezista BID - DRV
19-Prezista QD - DRV
20-Prezista + Norvir + Truvada (DRV/r twice daily) - DRV/r + TDF + FTC
21-Prezista + Norvir + Truvada (once daily) - DRV/r + TDF + FTC
22-Reyataz - ATV
23-Reyataz + Norvir + Truvada
- ATV/r + TDF + FTC
24-Rescriptor - DLV
25-Retrovir - AZT (or ZDV)
26-Selzentry - MVC
27-Selzentry + Truvada - MVC + TDF + FTC
28-Stribild - EVG + COBI + TDF + FTC
29-Sustiva - EFV
30-Tivacay (dolutegravir)
31-Trizivir - ABC + 3TC + ZDV (or AZT)
32-Truvada - TDF + FTC
33-Videx - ddI
34-Viracept - NFV
35-Viramune - NVP
36-Viramune XR (QD) - NVP
37-Viread - TDF
38-Zerit - d4T
39-Ziagen - ABC

NIDA Clinical Trials Network

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

Web Version: 1.0; 2.00; 03-10-14

Segment (PROTSEG):

Visit number (VISNO):

CTN-ASI Lite v. 1 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 Days is zero, route should be "Not applicable".

Substance	A Past 30 (Days)	D Route of Administration	Comments
D1 Alcohol (any use at all):	(ADALA30D) _____ (xx)	-	(ADALACOM) _____
D2 Alcohol (to intoxication):	(ADALI30D) _____ (xx)	-	(ADALICOM) _____
D3 Heroin	(ADHER30D) _____ (xx)	(ADHERRTE) 1-(1) Oral 2-(2) Nasal 3-(3) Smoking 4-(4) Non IV injection 5-(5) IV injection 96-(96) Not applicable 97-(97) Not answered	(ADHERCOM) _____
D4 Methadone/LAAM (prescribed):	(ADM DP30D) _____ (xx)	(ADM DP RTE) 1-(1) Oral 2-(2) Nasal 3-(3) Smoking 4-(4) Non IV injection 5-(5) IV injection 96-(96) Not applicable 97-(97) Not answered	(ADM DP COM) _____
D4a Methadone/LAAM (illicit):	(ADM DI30D) _____ (xx)	(ADM DI RTE) 1-(1) Oral 2-(2) Nasal 3-(3) Smoking 4-(4) Non IV injection 5-(5) IV injection 96-(96) Not applicable 97-(97) Not answered	(ADM DI COM) _____
D5 Other Opiates/Analgesics :	(ADOPI30D) _____ (xx)	(ADOPI RTE) 1-(1) Oral 2-(2) Nasal 3-(3) Smoking 4-(4) Non IV injection 5-(5) IV injection 96-(96) Not applicable 97-(97) Not answered	(ADOPI COM) _____
D6 Barbiturate s:	(ADBAR30D) _____ (xx)	(ADBARRTE)	(ADBARCOM) _____

		1-(1) Oral 2-(2) Nasal 3-(3) Smoking 4-(4) Non IV injection 5-(5) IV injection 96-(96) Not applicable 97-(97) Not answered	
D7 Other Sedatives/ Hypnotics/Tranquilizers:	(ADSHT30D) (xx)	(ADSHTRTE) 1-(1) Oral 2-(2) Nasal 3-(3) Smoking 4-(4) Non IV injection 5-(5) IV injection 96-(96) Not applicable 97-(97) Not answered	(ADSHTCOM) _____
D8 Cocaine:	(ADCOC30D) (xx)	(ADCOCRTE) 1-(1) Oral 2-(2) Nasal 3-(3) Smoking 4-(4) Non IV injection 5-(5) IV injection 96-(96) Not applicable 97-(97) Not answered	(ADCOCOM) _____
D9 Amphetamines:	(ADAMP30D) (xx)	(ADAMP RTE) 1-(1) Oral 2-(2) Nasal 3-(3) Smoking 4-(4) Non IV injection 5-(5) IV injection 96-(96) Not applicable 97-(97) Not answered	(ADAMP COM) _____
D9a Methamphetamine:	(ADMET30D) (xx)	(ADMETRTE) 1-(1) Oral 2-(2) Nasal 3-(3) Smoking 4-(4) Non IV injection 5-(5) IV injection 96-(96) Not applicable 97-(97) Not answered	(ADMETCOM) _____
D10 Cannabis:	(ADTHC30D) (xx)	(ADTHCRTE) 1-(1) Oral 2-(2) Nasal 3-(3) Smoking 4-(4) Non IV injection 5-(5) IV injection 96-(96) Not applicable 97-(97) Not answered	(ADTHCCOM) _____
D11 Hallucinogens:	(ADHAL30D) (xx)	(ADHALRTE) 1-(1) Oral 2-(2) Nasal 3-(3) Smoking 4-(4) Non IV injection 5-(5) IV injection 96-(96) Not applicable 97-(97) Not answered	(ADHALCOM) _____
D12 Inhalants:	(ADINH30D) (xx)	(ADINHRTE) 1-(1) Oral 2-(2) Nasal 3-(3) Smoking 4-(4) Non IV injection 5-(5) IV injection 96-(96) Not applicable 97-(97) Not answered	(ADINHCOM) _____

		1-(1) Oral 2-(2) Nasal 3-(3) Smoking 4-(4) Non IV injection 5-(5) IV injection 96-(96) Not applicable 97-(97) Not answered	
D13 More than 1 substance per day <i>(including alcohol, excluding nicotine):</i>	(ADGT130D) _____ (xx)	-	(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.

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

(ADMAJDRG)

OR

(ADMJDGNA) (97) Not answered

Comments:(ADMJDGCM)

D17 How many times since your last ASI have you had Alcohol DTs?

- Delirium Tremens (DT's): Occur 24-48 hours after last drink, or significant decrease in alcohol intake. Characterized by shaking, severe disorientation, fever, hallucinations; they usually require medical attention.

(ADALCDT) _____ (xx)

OR

(ADALDTNA) (97) Not answered

Comments:(ADALDTCM)

How many times since your last ASI have you been treated for:

Include detoxification, halfway houses, in/outpatient counseling and AA or NA (if 3+ meetings within one month period).

D19 Alcohol abuse:

(ADALCTRT) (xx)

OR

(ADATRANA) (97) Not answered

Comments:(ADATRANCM)

D20 Drug abuse:

(ADDRGTRT) (xx)

OR

(ADDTRANA) (97) Not answered

Comments:(ADDTRANCM)

How many of these were detox only:

D21 Alcohol:

- If D19 = 00, then question D21 is Not applicable.

(ADADETOX) (xx)

OR

(ADADTXNA) (96) Not applicable (97) Not answered

Comments:(ADADTXCM)

D22 Drugs:

- If D20 = 00, then question D22 is Not applicable.

(ADDETOX) (xx)

OR

(ADDDTXNA) (96) Not applicable (97) Not answered

Comments:(ADDDTXCM)

How much money would you say you spent during the past 30 days on:
Max. = \$99999

D23 Alcohol:

- *Only count actual money spent. What is the financial burden caused by alcohol?*

(ADALCMNY) \$ (xxxx)

OR

(ADAMNYNA) (97) Not answered

Comments:(ADAMNYCM)

D24 Drugs:

- *Only count actual money spent. What is the financial burden caused by drugs?*

(ADDRGMNY) \$ (xxxx)

OR

(ADDMNYNA) (97) Not answered

Comments:(ADDMNYCM)

D25 How many days have you been treated in an outpatient setting for alcohol or drugs in the past 30 days?

- *Include AA/NA*

(ADOPTA) (xx) days

OR

(ADOPTNA) (97) Not answered

Comments:(ADOPTCOM)

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.

(ADAP30D) (xx) days

OR

(ADAP30NA) (97) Not answered

Comments:(ADAP30CM)

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?

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

(ADAPB30D)

OR

(ADAB30NA) (97) Not answered

Comments:(ADAB30CM)

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

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

(ADAPI30D)

OR

(ADAI30NA) (97) Not answered

Comments:(ADA130CM)

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.

(ADDP30D) (xx) days

OR

(ADDP30NA) (97) Not answered

Comments:(ADDP30CM)

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

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

(ADDPB30D)

OR

(ADDB30NA) (97) Not answered

Comments:(ADDB30CM)

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

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

(ADDP130D)

OR

(ADDI30NA) (97) Not answered

Comments:(ADDI30CM)

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:(ASDCOMM)

NIDA Clinical Trials Network

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

Web Version: 1.0; 1.00; 01-16-14

Segment (PROTSEG):

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, [] No [] Yes intent, plan) SI present.(CHSCIDTN)

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 [] No [] Yes potentially self-injurious behavior associated with intent to die. Intent can be stated by patient or inferred by rater).(CHSCATMP)

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 [] No [] Yes with no intent to die.(CHSIBDIE)

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 [] No [] Yes (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)

5. Completed Suicide - Confirmed (i.e. Coroner's report, suicide note, other [] No [] Yes collateral information).(CHSCMPL)

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

7. Death (not enough information to classify as suicide)(CHDEATH) [] No [] Yes

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

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; 1.02; 04-09-14

Segment (PROTSEG):

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) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. I have no future.	(CHNOFUTR) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. It seems as if I can do nothing right.	(CHNORGH) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Everything I do turns out wrong.	(CHWRONG) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. There is no one I can depend on.	(CHDEPEND) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. The people I care the most for are gone.	(CHPLGNE) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. I wish my suffering could just all be over.	(CHSUFFER) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. I feel that there is no reason to live.	(CHRSLIVE) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. I wish I could just go to sleep and not wake up.	(CHSLEEP) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. I find myself saying or doing things without thinking.	(CHNOTHINK) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. I often make decisions quickly or "on impulse."	(CHIMPULS) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. I often feel irritable or easily angered.	(CHIRRITE) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. I often overreact with anger or rage over minor things.	(CHOVRCT) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. I have been having thoughts of killing myself.	(CHKILLMS) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. I have thoughts about how I might kill myself.	(CHHOWKIL) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. I have a plan to kill myself.	(CHPLNKIL) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments: (CHPCOMM)

NIDA Clinical Trials Network

Demographics (DEM)

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

1. Date of birth:(DEBRTHDT)

(mm/dd/yyyy)

2. Gender:(DEGENDER)

Male Female Don't know Refused

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

No Yes Don't know Refused

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

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

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

(Check all that apply)

White: (DEWHITE)

Black/ African American: (DEBLACK)

Indian (American): (DEAMEIND)

Alaska native: (DEALASKA)

Native Hawaiian: (DEHAWAII)

Guamanian: (DEGUAM)

Samoa: (DESAMOAN)

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

Asian Indian: (DEASAIN)

Chinese: (DECHINA)

Filipino: (DEFILIPN)

Japanese: (DEJAPAN)

Korean: (DEKOREA)

Vietnamese: (DEVIETNM)

Other Asian: (DEASIAN) Specify:(DEASIAOT)

Some other race: (DERACEOT) Specify:(DERACESP)

-OR-

Don't know:(DERACEDK)

Refused: (DERACERF)

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

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

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

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

If "Other", specify:(DEJOBSP)

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

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

Comments:(DEM COMM)

Additional Selection Options for DEM

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

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

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

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

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

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

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

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

NIDA Clinical Trials Network

Detoxification (DTX)

Web Version: 1.0; 1.01; 03-19-14

Segment (PROTSEG):

Visit number (VISNO):

Date of assessment:(DTXASMDT)

(mm/dd/yyyy)

1. Did the participant initiate opioid detoxification?

(DTDTXOP) No Yes

a. In what setting was opioid detoxification conducted?

1-Inpatient
2-Outpatient
99-Other

(DTLOCOP)

If "Other", specify:

(DTLOCOSP)

b. What medications were used during treatment of opioid detoxification?

Drug 1:

00-- None
97-- Don't know
01-- BUP-NX Sublingual
02-- BUP only Sublingual
03-- Methadone PO
*Additional Options Listed Below

(DTRXOP01)

Drug 2:

00-- None
97-- Don't know
01-- BUP-NX Sublingual
02-- BUP only Sublingual
03-- Methadone PO
*Additional Options Listed Below

(DTRXOP02)

Drug 3:

00-- None
97-- Don't know
01-- BUP-NX Sublingual
02-- BUP only Sublingual
03-- Methadone PO
*Additional Options Listed Below

(DTRXOP03)

Drug 4:

00-- None
97-- Don't know
01-- BUP-NX Sublingual
02-- BUP only Sublingual
03-- Methadone PO
*Additional Options Listed Below

(DTRXOP04)

Drug 5:

00-- None
97-- Don't know
01-- BUP-NX Sublingual
02-- BUP only Sublingual
03-- Methadone PO
*Additional Options Listed Below

(DTRXOP05)

Drug 6:

00-- None
97-- Don't know
01-- BUP-NX Sublingual
02-- BUP only Sublingual
03-- Methadone PO
*Additional Options Listed Below

(DTRXOP06)

Drug 7:

00-- None
 97-- Don't know
 01-- BUP-NX Sublingual
 02-- BUP only Sublingual
 03-- Methadone PO
 *Additional Options Listed Below

(DTRXOP07)

Drug 8:

00-- None
 97-- Don't know
 01-- BUP-NX Sublingual
 02-- BUP only Sublingual
 03-- Methadone PO
 *Additional Options Listed Below

(DTRXOP08)

Drug 9:

00-- None
 97-- Don't know
 01-- BUP-NX Sublingual
 02-- BUP only Sublingual
 03-- Methadone PO
 *Additional Options Listed Below

(DTRXOP09)

Drug 10:

00-- None
 97-- Don't know
 01-- BUP-NX Sublingual
 02-- BUP only Sublingual
 03-- Methadone PO
 *Additional Options Listed Below

(DTRXOP10)

c. Was opioid detoxification completed?

(DTCMPOPI) No Yes

2. Did the participant initiate alcohol detoxification?

(DTDTXALC) No Yes

a. In what setting was alcohol detoxification conducted?

1-Inpatient
 2-Outpatient
 99-Other

(DTLOCALC)

If "Other", specify:

(DTLOCA SP)

b. What medications were used during treatment of alcohol detoxification?

Drug 1:

00-- None
 97-- Don't know
 Z01-BENZODIAZEPINES
 01A-- Chlordiazepoxide
 02A-- Clonazepam
 *Additional Options Listed Below

(DTRXAL01)

Drug 2:

00-- None
 97-- Don't know
 Z01-BENZODIAZEPINES
 01A-- Chlordiazepoxide
 02A-- Clonazepam
 *Additional Options Listed Below

(DTRXAL02)

Drug 3:

00-- None
 97-- Don't know
 Z01-BENZODIAZEPINES
 01A-- Chlordiazepoxide
 02A-- Clonazepam
 *Additional Options Listed Below

(DTRXAL03)

Drug 4:

00-- None
 97-- Don't know
 Z01-BENZODIAZEPINES
 01A-- Chlordiazepoxide
 02A-- Clonazepam
 *Additional Options Listed Below

(DTRXAL04)

Drug 5:

00--- None
97--- Don't know
Z 01 -BENZ ODIAZEPINES
O1A--- Chlordiazepoxide
O2A--- Clonazepam
*A dditional Options Listed Below

(DTRXAL 05)

Drug 6:

00--- None
97--- Don't know
Z 01 -BENZ ODIAZEPINES
O1A--- Chlordiazepoxide
O2A--- Clonazepam
*A dditional Options Listed Below

(DTRXAL 06)

Drug 7:

00--- None
97--- Don't know
Z 01 -BENZ ODIAZEPINES
O1A--- Chlordiazepoxide
O2A--- Clonazepam
*A dditional Options Listed Below

(DTRXAL 07)

Drug 8:

00--- None
97--- Don't know
Z 01 -BENZ ODIAZEPINES
O1A--- Chlordiazepoxide
O2A--- Clonazepam
*A dditional Options Listed Below

(DTRXAL 08)

Drug 9:

00--- None
97--- Don't know
Z 01 -BENZ ODIAZEPINES
O1A--- Chlordiazepoxide
O2A--- Clonazepam
*A dditional Options Listed Below

(DTRXAL 09)

Drug 10:

00--- None
97--- Don't know
Z 01 -BENZ ODIAZEPINES
O1A--- Chlordiazepoxide
O2A--- Clonazepam
*A dditional Options Listed Below

(DTRXAL 10)

c. Was alcohol detoxification completed?

(DTCMPALC) No Yes

Comments:(DTXCOMM)

Additional Selection Options for DTX

Detox meds - opioids 01

04--- Methadone IM

05--- Clonidine

Z01-BENZODIAZEPINES

01A-- Chlordiazepoxide

02A-- Clonazepam

03A-- Diazepam

04A-- Lorazepam

05A-- Oxazepam

99A-- Other

Z02-GABA AGENTS/MUSCLE RELAXANTS

01B--- Gabapentin

02B--- Baclofen

03B--- Cyclobenzaprine

99B--- Other

Z03-SLEEP/ANXIETY/ANTI-HISTAMINE AGENTS

01C--- Trazodone

02C--- Diphenhydramine

03C--- Hydroxyzine

04C--- Zolpidem

05C--- Mirtazapine

99C--- Other

Z04-GI AGENTS

01D--- Anti-acid agent

02D--- Anti-diarrheal agent

03D--- Laxative agent

99D--- Other

Z05-NON-STEROIDAL ANTI-INFLAMMATORY AGENTS

01E--- Ibuprofen

02E--- Naproxen

03E--- Acetaminophen

04E--- Aspirin

99E--- Other

Detox meds - alcohol 01

03A-- Diazepam

04A-- Lorazepam

05A-- Oxazepam

99A-- Other

Z06-ANTICONVULSANTS/SEDATIVES

01F--- Carbamazepine

02F--- Valproic acid

03F--- Gabapentin

04F--- Quetiapine

05F--- Phenobarbital

99F--- Other

Z07-SUPPLEMENTS

01G--- Thiamine

02G--- Folate

99G--- Other

NIDA Clinical Trials Network

End of Medication (EOM)

Web Version: 1.0; 4.00; 08-05-15

Segment (PROTSEG):

1. Did the participant discontinue study medication early?(EOEARLY)

No Yes

Primary reason for not completing study medication:(EOSTOP55)

- 1-Participant became pregnant
- 2-Participant unable to tolerate side effects
- 4-Contraindicated concomitant medication
- 5-Participant refused, non-specific
- 6-Participant left study and never returned
- *Additional Options Listed Below

If "Other", specify:(EOSTOPSP)

Comments:(EOMCOMM)

Additional Selection Options for EOM

Primary reason for not completing study medication:

- 7-Clinical deterioration: new onset of psychiatric or medical condition
- 8-Physical illness or condition that precludes taking study medication
- 9-Participant feels study treatment no longer necessary, cured
- 10-Participant feels study treatment no longer necessary, not working
- 11-Participant became incarcerated
- 12-Participant withdrew consent
- 13-Participant moved from area
- 14-Participant deceased
- 99-Other

NIDA Clinical Trials Network

End of Treatment (EOT)

Web Version: 1.0; 1.00; 01-27-14

Segment (PROTSEG):

1. Did the participant discontinue study treatment early? No Yes
(EOTEARLY)

Primary reason for not completing study treatment:
(EOREASON)

- 1-Participant became pregnant
- 2-Participant unable to tolerate side effects
- 4-Contraindicated concomitant medication
- 5-Participant refused, non-specific
- 6-Participant left study and never returned
- *Additional Options Listed Below

If "Other", specify:(EORSNSP)

2. Date of last dose of medication or last attended meeting:(EOTRDT)

(mm/dd/yyyy)

Comments:(EOTCOMM)

Additional Selection Options for EOT

Primary reason for not completing study treatment:

- 7-Clinical deterioration: new onset of psychiatric or medical condition
- 8-Physical illness or condition that precludes treatment
- 9-Participant feels study treatment no longer necessary, cured
- 10-Participant feel study treatment no longer necessary, not working
- 11-Participant became incarcerated
- 12-Participant withdrew consent
- 13-Participant moved from area
- 14-Participant deceased
- 99-Other

NIDA Clinical Trials Network

Urine Ethyl Glucuronide (ETG)

Web Version: 1.0; 1.00; 03-11-14

Segment (PROTSEG):

Indicate whether the following urine ethyl glucuronide samples were shipped:

Visit	No	Yes	If "Yes", shipment date: (mm/dd/yyyy)	If "No", reason:	If "Other", specify:
Week 01:	(ETSHIP01) <input type="checkbox"/>	<input type="checkbox"/>	(ET01SHDT) <input type="text"/>	1-Participant reported being unable to provide sample 2-Participant refused to provide sample 3-Study staff error 99-Other (ETRSN01)	(ET01OTSP) <input type="text"/>
Week 04:	(ETSHIP04) <input type="checkbox"/>	<input type="checkbox"/>	(ET04SHDT) <input type="text"/>	1-Participant reported being unable to provide sample 2-Participant refused to provide sample 3-Study staff error 99-Other (ETRSN04)	(ET04OTSP) <input type="text"/>
Week 08:	(ETSHIP08) <input type="checkbox"/>	<input type="checkbox"/>	(ET08SHDT) <input type="text"/>	1-Participant reported being unable to provide sample 2-Participant refused to provide sample 3-Study staff error 99-Other (ETRSN08)	(ET08OTSP) <input type="text"/>
Week 12:	(ETSHIP12) <input type="checkbox"/>	<input type="checkbox"/>	(ET12SHDT) <input type="text"/>	1-Participant reported being unable to provide sample 2-Participant refused to provide sample 3-Study staff error 99-Other (ETRSN12)	(ET12OTSP) <input type="text"/>
Week 16:	(ETSHIP16) <input type="checkbox"/>	<input type="checkbox"/>	(ET16SHDT) <input type="text"/>	1-Participant reported being unable to provide sample 2-Participant refused to provide sample 3-Study staff error 99-Other (ETRSN16)	(ET16OTSP) <input type="text"/>

Comments: (ETGCOMM)



NIDA Clinical Trials Network

0055B (ENR)

Web Version: 1.0; 1.00; 02-14-14

Date of assessment: (R7ASMDT)

(mm/dd/yyyy)

Inclusion Criteria

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

- Participant meets DSM-5 criteria for moderate or severe opioid use disorder and/or alcohol use disorder: (R7DRGDEP) No Yes Unknown
- Participant is willing to be randomized to antagonist-based therapy or TAU for treatment of opioid and/or alcohol use disorders: (R7SEEKTX) No Yes Unknown
- Participant is HIV-infected as defined by history of positive HIV serology or HIV RNA pcr >10,000 copies/mL: (R7HIVPOS) No Yes Unknown
- Participant is willing to establish ongoing HIV care at CTP, if not already receiving ongoing care: (R7HIVTX) No Yes Unknown
- Participant is willing to initiate ART, if not already prescribed ART, regardless of CD4 count: (R7ARTRX) No Yes Unknown
- Participant is at least 18 years old: (R7PTAGE) No Yes
- Participant has provided written informed consent and HIPAA for medical record abstraction: (R7INFORM) No Yes
- Participant is able to communicate in English: (R7ENGLISH) No Yes
- If female, participant is willing to take measures 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".

- Participant has a serious medical, psychiatric, or substance use disorder that, in the opinion of the study physician, would make study participation hazardous to the participant, compromise study findings, or prevent the participant from completing the study.
Examples include:
(a) Disabling or terminal medical illness (e.g., active opportunistic infection, uncompensated heart failure, cirrhosis or end-stage liver disease, acute hepatitis and moderate to severe renal impairment) as assessed by medical history, review of systems, physical exam and/or laboratory assessments;
(b) Severe, untreated, or inadequately treated mental health disorder (e.g., active psychosis, uncontrolled manic-depressive illness) as assessed by history and/or clinical interview;
(c) Current severe benzodiazepine or other depressant or sedative hypnotic use requiring medical detoxification;
(d) Suicidal or homicidal ideation requiring immediate attention. (R7PSYCH) No Yes Unknown
- Participant has aspartate aminotransferase (AST) or alanine aminotransferase (ALT) liver enzymes greater than five times the upper limit of normal on screening phlebotomy: (R7LFTS) No Yes Unknown
- Participant has INR > 1.50 or platelet count < 100,000 mm³: (R7INR) No Yes Unknown
- Participant has a known allergy or sensitivity to naloxone, naltrexone, polylactide-co-glycolide, carboxymethylcellulose, or other components of the Vivitrol[®] diluent: (R7ALERGY) No Yes Unknown
- Participant anticipates undergoing surgery during study participation: (R7SURGRY) No Yes Unknown
- Participant has chronic pain requiring ongoing pain management with opioid analgesics: (R7PAIN) No Yes Unknown
- Participant is pending legal action or other reasons that might prevent an individual from completing the study: (R7LEGAL) No Yes Unknown
- Participant is currently pregnant or breastfeeding: (R7PREGNT) No Yes Unknown Not applicable
- Participant has a 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): (R7HABTUS) No Yes Unknown
- Participant received methadone or buprenorphine maintenance therapy for treatment of opioid dependence in the 4 weeks prior to screening: (R7MTDMNT) No Yes Unknown
- Participant has taken an investigational drug in another study within 30 days of study consent: (R7OTSTDY) No Yes Unknown
- Participant has ECG findings that, in the opinion of the study medical clinician, would preclude safe participation in the study: (R7BLOCK) No Yes Unknown
- Participant has had treatment with XR-NTX for opioid or alcohol dependence in the 3 months prior to screening: (R7XRNTX) No Yes Unknown

Eligibility for Randomization

1. Is the participant eligible for the study?(R7ELGSTY)

No Yes

2. Will the participant be randomized?(R7ELGRDM)

No Yes

If "No", specify:(R7NORSP)

2-Declined study participation
3-Death
4-Judgment of site/research staff
5-Failed to return to clinic prior to randomization
99-Other

If "Judgment of research staff", specify:(R7JGOTSP)

If "Other", specify:(R7OTHRSP)

Comments:(R7COMM)

NIDA Clinical Trials Network

Fatal Overdose (FOD)

Web Version: 1.0; 1.00; 02-13-14

Segment (PROTSEG):

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)

0-Medical record
1-Locator form inquiry
99-Other

If "Other", specify:(FOSRCESP)

Comments:(FODCOMM)

NIDA Clinical Trials Network

HIV Care Utilization (HCU)

Web Version: 1.0; 1.00; 01-28-14

Segment (PROTSEG):

Visit number (VISNO):

Date of assessment:(*HCUASMDT*)

 (mm/dd/yyyy)

1. Number of HIV primary care visits attended between baseline and week 16:(*HCVISITS*)

 (xx)

2. Number of counseling sessions attended in HIV clinic between baseline and week 16:(*HCCOUNSL*)

 (xx)

Comments:(*HCUCOMM*)

NIDA Clinical Trials Network

Injection Site Abnormality (INA)

Web Version: 1.0; 1.00; 10-04-13

Segment (PROTSEG):

Note: If abnormality results in a SAE, complete SAE CRFs.

Abnormal Event If "Other", specify in comments	Event Start Date (mm/dd/yyyy)	Severity	Treatment	Event Resolution Date (mm/dd/yyyy)	Comments
1. (INETYP1) 1-Pain 2-Tenderness 3-Induration 4-Swelling 5-Erythema (redness) *Additional Options Listed Below	(INESDT1)	(INESVR1) <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	(INETRT1)	(INERDT1)	(INECOM1)
2. (INETYP2) 1-Pain 2-Tenderness 3-Induration 4-Swelling 5-Erythema (redness) *Additional Options Listed Below	(INESDT2)	(INESVR2) <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	(INETRT2)	(INERDT2)	(INECOM2)
3. (INETYP3) 1-Pain 2-Tenderness 3-Induration 4-Swelling 5-Erythema (redness) *Additional Options Listed Below	(INESDT3)	(INESVR3) <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	(INETRT3)	(INERDT3)	(INECOM3)
4. (INETYP4) 1-Pain 2-Tenderness 3-Induration 4-Swelling 5-Erythema (redness) *Additional Options Listed Below	(INESDT4)	(INESVR4) <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	(INETRT4)	(INERDT4)	(INECOM4)
5. (INETYP5)	(INESDT5)	(INESVR5) <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	(INETRT5)	(INERDT5)	(INECOM5)

<p>1-Pain 2-Tenderness 3-Induration 4-Swelling 5-Erythema (redness) *Additional Options Listed Below</p>		Severe			
<p>6. (INETY6) 1-Pain 2-Tenderness 3-Induration 4-Swelling 5-Erythema (redness) *Additional Options Listed Below</p>	(INESDT6) <input type="text"/>	(INESVR6) <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	(INETRT6) <input type="text"/>	(INERDT6) <input type="text"/>	(INECOM6) <input type="text"/>
<p>7. (INETY7) 1-Pain 2-Tenderness 3-Induration 4-Swelling 5-Erythema (redness) *Additional Options Listed Below</p>	(INESDT7) <input type="text"/>	(INESVR7) <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	(INETRT7) <input type="text"/>	(INERDT7) <input type="text"/>	(INECOM7) <input type="text"/>
<p>8. (INETY8) 1-Pain 2-Tenderness 3-Induration 4-Swelling 5-Erythema (redness) *Additional Options Listed Below</p>	(INESDT8) <input type="text"/>	(INESVR8) <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	(INETRT8) <input type="text"/>	(INERDT8) <input type="text"/>	(INECOM8) <input type="text"/>
<p>9. (INETY9) 1-Pain 2-Tenderness 3-Induration 4-Swelling 5-Erythema (redness) *Additional Options Listed Below</p>	(INESDT9) <input type="text"/>	(INESVR9) <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	(INETRT9) <input type="text"/>	(INERDT9) <input type="text"/>	(INECOM9) <input type="text"/>
<p>10. (INETY10) 1-Pain 2-Tenderness 3-Induration 4-Swelling 5-Erythema (redness) *Additional Options Listed Below</p>	(INESDT10) <input type="text"/>	(INESVR10) <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	(INETRT10) <input type="text"/>	(INERDT10) <input type="text"/>	(INECOM10) <input type="text"/>
<p>11. (INETY11)</p>	(INESDT11) <input type="text"/>	(INESVR11) <input type="checkbox"/> Mild <input type="checkbox"/> Moderate	(INETRT11) <input type="text"/>	(INERDT11) <input type="text"/>	(INECOM11) <input type="text"/>

1-Pain 2-Tenderness 3-Induration 4-Swelling 5-Erythema (redness) *Additional Options Listed Below		<input type="checkbox"/> Severe			
12. (INETYP12) 1-Pain 2-Tenderness 3-Induration 4-Swelling 5-Erythema (redness) *Additional Options Listed Below	(INESDT12) <input type="text"/>	(INESV12) <input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe	(INETRT12) <input type="text"/>	(INERDT12) <input type="text"/>	(INECOM12) <input type="text"/>

Comments: (INACOMM)

Additional Selection Options for INA

Event 1 type

6-Bruising

7-Pruritus

8-Nodule

9-Hematoma

10-Abscess

11-Sterile abscess

12-Necrosis

13-Cellulitis

99-Other

NIDA Clinical Trials Network

XR-NTX Administration (INJ)

Web Version: 1.0; 2.00; 12-30-13

Segment (PROTSEG):
Injection number (INJNUM):

Date of injection: (INJINJDT)

(mm/dd/yyyy)

1. Location of previous injection: (INPREV)

Right buttock Left buttock

2. Injection location: (INJLOC)

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):

1-1

2-2

3-3

4-4

NIDA Clinical Trials Network

Injection Site Examination (INX)

Web Version: 1.0; 1.01; 10-30-13

Segment (PROTSEG):
Injection number (INJNUM):

Date of examination:(INXASMDT)

(mm/dd/yyyy)

Location of previous injection:(INJPREV)

Right buttock Left buttock

1. Location of injection:(INJLOC)

Right buttock Left buttock

2. Is this injection site normal?(INJOK)

No Yes

If the injection site is "abnormal", complete the Injection Site Abnormality Log.

Note: If this event is an SAE, you must complete the AE forms.

Comments:(INXCOMM)

Additional Selection Options for INX

Injection number (*INJNUM*) (key field):

1-1

2-2

3-3

4-4

NIDA Clinical Trials Network

Clinical Laboratory Tests (LAB)

Web Version: 1.0; 6.02; 02-17-15

Segment (PROTSEG):

Visit number (VISNO): 00 (Randomization)

	Test	Result	Date of Collection (mm/dd/yyyy)	Abstracted from Medical Record
Hepatitis	1. Hep B surface antigen (HBsAG)	(LAHBSAG) <input type="checkbox"/> Negative <input type="checkbox"/> Positive	(LAHBAGDT) <input type="text"/>	(LAHBAGMR) <input type="checkbox"/> Yes
	2. Hep C antibody	(LAHEPC) <input type="checkbox"/> Negative <input type="checkbox"/> Positive	(LAHEPCDT) <input type="text"/>	(LAHEPCMR) <input type="checkbox"/> Yes
	3. Hep C PCR confirmation	(LAHPCPCR) <input type="checkbox"/> Negative <input type="checkbox"/> Positive	(LACPCRDT) <input type="text"/>	(LACPCMR) <input type="checkbox"/> Yes
HIV Measures	4. CD4 Count	(LACD4CNT) <input type="text"/> (xxxxx) cells/μL	(LACD4DT) <input type="text"/>	N/A
	5. HIV viral load is undetectable:	(LAHIVUND) <input type="checkbox"/> No <input type="checkbox"/> Yes		
	a. If "Yes", lab's lower limit:	(LAHIVLOW) < <input type="text"/> (xxx) copies/mL		
b. If "No", HIV-1 RNA PCR:	(LAHIVPCR) <input type="text"/> (xxxxxxxx) copies/mL	(LAHPCRDT) <input type="text"/>	N/A	

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

a. If "Yes", date PBMC sample was drawn:(LAPBMC DT) (mm/dd/yyyy)

b. If "Yes", date PBMC sample was shipped:(LAPBMSDT) (mm/dd/yyyy)

Comments:(LABCOMM)

NIDA Clinical Trials Network

Clinical Laboratory Tests (LAB)

Web Version: 1.0; 6.02; 02-17-15

Segment (PROTSEG):

Visit number (VISNO): 01 (Week 01)

Lab collection date:(LABDATE)

(mm/dd/yyyy)

	Test	Result
LFTs	1. Aspartate Aminotransferase (AST/SGOT)	(LAAST) <input type="text"/> (xxxx.x) IU/L
	2. Alanine Aminotransferase (ALT/SGPT)	(LAAALT) <input type="text"/> (xxxx.x) IU/L
	3. INR	(LAINR) <input type="text"/> (x.xx)

Comments:(LABCOMM)

NIDA Clinical Trials Network

Clinical Laboratory Tests (LAB)

Web Version: 1.0; 6.02; 02-17-15

Segment (PROTSEG):

Visit number (VISNO): 04 (Week 04)

Lab collection date:(LABDATE)

[] (mm/dd/yyyy)

	Test	Result
LFTs	1. Aspartate Aminotransferase (AST/SGOT)	(LAAST) [] (xxxx.x) IU/L
	2. Alanine Aminotransferase (ALT/SGPT)	(LAALT) [] (xxxx.x) IU/L
	3. INR	(LAINR) [] (x.xx)
HIV Measures	4. CD4 Count	(LACD4CNT) [] (xxxxx) cells/μL
	5. HIV viral load is undetectable:	(LAHIVUND) <input type="checkbox"/> No <input type="checkbox"/> Yes
	a. If "Yes", lab's lower limit:	(LAHIVLOW) < [] (xxx) copies/mL
b. If "No", HIV-1 RNA PCR:	(LAHIVPCR) [] (xxxxxxxx) copies/mL	

6. Was a sample submitted for PBMCs (peripheral blood mononuclear cells)? (LAPBMC)

No Yes

a. If "Yes", date PBMC sample was drawn:(LAPBMCDT)

[] (mm/dd/yyyy)

b. If "Yes", date PBMC sample was shipped:(LAPBMSDT)

[] (mm/dd/yyyy)

Comments:(LABCOMM)

NIDA Clinical Trials Network

Clinical Laboratory Tests (LAB)

Web Version: 1.0; 6.02; 02-17-15

Segment (PROTSEG):

Visit number (VISNO): 08 (Week 08) / 12 (Week 12) / 16 (Week 16)

Lab collection date:(LABDATE)

[] (mm/dd/yyyy)

	Test	Result
LFTs	1. Aspartate Aminotransferase (AST/SGOT)	(LAAST) [] (xxxx.x) IU/L
	2. Alanine Aminotransferase (ALT/SGPT)	(LAALT) [] (xxxx.x) IU/L
	3. INR	(LAINR) [] (x.xx)
HIV Measures	4. CD4 Count	(LACD4CNT) [] (xxxxx) cells/μL
	5. HIV viral load is undetectable:	(LAHIVUND) <input type="checkbox"/> No <input type="checkbox"/> Yes
	a. If "Yes", lab's lower limit:	(LAHIVLOW) < [] (xxx) copies/mL
b. If "No", HIV-1 RNA PCR:	(LAHIVPCR) [] (xxxxxxxx) copies/mL	

Comments:(LABCOMM)

NIDA Clinical Trials Network

Medication Adherence (MAD)

Web Version: 1.0; 1.00; 01-29-14

Segment (PROTSEG):

Visit number (VISNO):

Date of assessment: (MADASMDT)

(mm/dd/yyyy)

This questionnaire asks about your HIV medications that you took over the last four days. Most people with HIV have many pills to take at different times during the day. Many people find it hard to always remember their pills. Some people get busy and forget to carry their pills with them. Some people find it hard to take their pills according to all the instructions, such as "with meals", "on an empty stomach", "every 8 hours", or "with plenty of fluids". Some people decide to skip doses to avoid side effects or to just not be taking pills that day.

We need to understand how people with HIV are really doing with their pills. Please tell us what you are actually doing. Don't worry about telling us that you don't take all your pills. We need to know what is really happening, not what you think we "want to hear". This questionnaire asks about the medications that you may have missed taking over the last four days. Please complete the following table by filling in the boxes below.

IF YOU TOOK ONLY A PORTION OF A DOSE ON ONE OR MORE OF THESE DAYS, PLEASE REPORT THE DOSE(S) AS BEING MISSED.

Repeat questions for each medication the respondent is prescribed.

Name of Anti-HIV Medication:	How Many Doses Did You Miss...			
	Yesterday (x) doses	Day Before Yesterday (x) doses	3 Days Ago (x) doses	4 Days Ago (x) doses
1. (MAHIVRX1) <div style="border: 1px solid black; padding: 2px; margin-top: 5px;"> 00-None 97-Don't know 99-Other/Experimental/Blinded study - OTHR 01-Apivus - TPV 02-Atripla - EFV + TDF + FTC *Additional Options Listed Below </div>	(MARX1D1) <input style="width: 40px;" type="text"/>	(MARX1D2) <input style="width: 40px;" type="text"/>	(MARX1D3) <input style="width: 40px;" type="text"/>	(MARX1D4) <input style="width: 40px;" type="text"/>
2. (MAHIVRX2) <div style="border: 1px solid black; padding: 2px; margin-top: 5px;"> 00-None 97-Don't know 99-Other/Experimental/Blinded study - OTHR 01-Apivus - TPV 02-Atripla - EFV + TDF + FTC *Additional Options Listed Below </div>	(MARX2D1) <input style="width: 40px;" type="text"/>	(MARX2D2) <input style="width: 40px;" type="text"/>	(MARX2D3) <input style="width: 40px;" type="text"/>	(MARX2D4) <input style="width: 40px;" type="text"/>
3. (MAHIVRX3) <div style="border: 1px solid black; padding: 2px; margin-top: 5px;"> 00-None 97-Don't know 99-Other/Experimental/Blinded study - OTHR 01-Apivus - TPV 02-Atripla - EFV + TDF + FTC *Additional Options Listed Below </div>	(MARX3D1) <input style="width: 40px;" type="text"/>	(MARX3D2) <input style="width: 40px;" type="text"/>	(MARX3D3) <input style="width: 40px;" type="text"/>	(MARX3D4) <input style="width: 40px;" type="text"/>
4. (MAHIVRX4) <div style="border: 1px solid black; padding: 2px; margin-top: 5px;"> 00-None 97-Don't know 99-Other/Experimental/Blinded study - OTHR 01-Apivus - TPV 02-Atripla - EFV + TDF + FTC *Additional Options Listed Below </div>	(MARX4D1) <input style="width: 40px;" type="text"/>	(MARX4D2) <input style="width: 40px;" type="text"/>	(MARX4D3) <input style="width: 40px;" type="text"/>	(MARX4D4) <input style="width: 40px;" type="text"/>
5. (MAHIVRX5) <div style="border: 1px solid black; padding: 2px; margin-top: 5px;"> 00-None 97-Don't know 99-Other/Experimental/Blinded study - OTHR 01-Apivus - TPV 02-Atripla - EFV + TDF + FTC *Additional Options Listed Below </div>	(MARX5D1) <input style="width: 40px;" type="text"/>	(MARX5D2) <input style="width: 40px;" type="text"/>	(MARX5D3) <input style="width: 40px;" type="text"/>	(MARX5D4) <input style="width: 40px;" type="text"/>

6. (MAHIVRX6) 00-None 97-Don't know 99-Other/Experimental/Blinded study - OTHR 01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC *Additional Options Listed Below	(MARX6D1) <input type="text"/>	(MARX6D2) <input type="text"/>	(MARX6D3) <input type="text"/>	(MARX6D4) <input type="text"/>
7. (MAHIVRX7) 00-None 97-Don't know 99-Other/Experimental/Blinded study - OTHR 01-Aptivus - TPV 02-Atripla - EFV + TDF + FTC *Additional Options Listed Below	(MARX7D1) <input type="text"/>	(MARX7D2) <input type="text"/>	(MARX7D3) <input type="text"/>	(MARX7D4) <input type="text"/>

8. In the past 30 days, how often did you take your anti-HIV medications as prescribed? (MATKRX30)

- 0-None of the time
- 1-A little of the time
- 2-Some of the time
- 3-A good bit of the time
- 4-Most of the time
- *Additional Options Listed Below

9. About what percentage of the time would you say you take your anti-HIV medications as prescribed? (MATKRXP)

- 0-0%
- 1-10%
- 2-20%
- 3-30%
- 4-40%
- *Additional Options Listed Below

10. How would you rate your adherence to your anti-HIV medications? That is, how well do you follow your provider's instructions for which medications to take, how much to take, and when to take them? (MARXADHR)

- 1-Very poor
- 2-Poor
- 3-Fair
- 4-Good
- 5-Very good
- *Additional Options Listed Below

Comments: (MADCOMM)

Additional Selection Options for MAD

Anti-HIV medication 1

03-Combivir - ZDV + 3TC or AZT + 3TC
04-Complera - RPV + TDF + FTV
05-Crixivan - IDV
06-Edurant - RPV
07-Emtriva - FTC
08-Epivir - 3TC
09-Epizicom - ABC + 3TC
10-Fuzeon - T20
11-Intelligence - ETV
12-Invirase - SQV
13-Isentress - RAL
14-Isentress + Truvada - RAL + TDF + FTC
15-Kaletra - LPV/r
16-Lexiva - FPV
17-Norvir - RTV
18-Prezista BID - DRV
19-Prezista QD - DRV
20-Prezista + Norvir + Truvada (DRV/r twice daily) - DRV/r + TDF + FTC
21-Prezista + Norvir + Truvada (once daily) - DRV/r + TDF + FTC
22-Reyataz - ATV
23-Reyataz + Norvir + Truvada
- ATV/r + TDF + FTC
24-Rescriptor - DLV
25-Retrovir - AZT (or ZDV)
26-Selzentry - MVC
27-Selzentry + Truvada - MVC + TDF + FTC
28-Stribild - EVG + COBI + TDF + FTC
29-Sustiva - EFV
30-Tivacay (dolutegravir)
31-Trizivir - ABC + 3TC + ZDV (or AZT)
32-Truvada - TDF + FTC
33-Videx - ddI
34-Viracept - NFV
35-Viramune - NVP
36-Viramune XR (QD) - NVP
37-Viread - TDF
38-Zerit - d4T
39-Ziagen - ABC

In the past 30 days, how often did you take your anti-HIV medications as prescribed?

5- All of the time

About what percentage of the time would you say you take your anti-HIV medications as prescribed?

5- 50%

6- 60%

7- 70%

8- 80%

9- 90%

10- 100%

How would you rate your adherence to your anti-HIV medications? That is, how well do you follow your provider's instructions for which medications to take, how much to take, and when to take them?

6- Excellent

NIDA Clinical Trials Network

Medication Assisted Treatment (MAT)

Web Version: 1.0; 2.01; 04-06-15

Segment (**PROTSEG**):

Visit number (**VISNO**):

Report Type (**REPORT**): Participant self-report

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

In the past 28 days, were you prescribed any of the following for addiction treatment:

1. Methadone (Dolophine, Methadose, Methadose Oral Concentrate, Westadone): (**MAMTDRX**) No Yes
a. If "Yes", how many days in the past 28 days did you take this medication? (xx)
(**MAMTDDAY**)
b. Usual daily dose: (**MAMTDDSE**) (xxx) mg

2. Buprenorphine (Suboxone, Subutex, Zubsolv): (**MABUPRX**) No Yes
a. If "Yes", how many days in the past 28 days did you take this medication? (xx)
(**MABUPDAY**)
b. Usual daily dose: (**MABUPDSE**) (xx) mg

3. Disulfiram (Antabuse): (**MADSFrx**) No Yes
a. If "Yes", how many days in the past 28 days did you take this medication? (xx)
(**MADSFDAY**)
b. Usual daily dose: (**MADSFSE**) (xxx) mg

4. Acamprosate (Campral): (**MAACMRX**) No Yes
a. If "Yes", how many days in the past 28 days did you take this medication? (xx)
(**MAACMDAY**)
b. Usual daily dose: (**MAACMDSE**) (xxxx) mg

5. Oral naltrexone (ReVia): (**MANTXRX**) No Yes
a. If "Yes", how many days in the past 28 days did you take this medication? (xx)
(**MANTXDAY**)
b. Usual daily dose: (**MANTXDSE**) (xxx.xx) mg

6. Gabapentin (Neurotin): (**MAGBPRX**) No Yes
a. If "Yes", how many days in the past 28 days did you take this medication? (xx)
(**MAGBPDAY**)
b. Usual daily dose: (**MAGBPDSE**) (xxxx) mg

7. Topiramate (Topamax): (**MATPMRX**) No Yes
a. If "Yes", how many days in the past 28 days did you take this medication? (xx)
(**MATPMDAY**)
b. Usual daily dose: (**MATPMDSE**) (xxx) mg

8. Valproic acid (Depakote): (**MAVPARX**) No Yes
a. If "Yes", how many days in the past 28 days did you take this medication? (xx)
(**MAVPADAY**)
b. Usual daily dose: (**MAVPADSE**) (xxxx) mg

9. Other medication for addiction treatment:(*MAOT1RX*)

No Yes

a. If "Yes", specify:(*MAOT1SP*)

b. How many days in the past 28 days did you take this medication?
(*MAOT1DAY*)

 (xx)

c. Usual daily dose:(*MAOT1DSE*)

 (xxxx.xx) mg

10. Other medication for addiction treatment:(*MAOT2RX*)

No Yes

a. If "Yes", specify:(*MAOT2SP*)

b. How many days in the past 28 days did you take this medication?
(*MAOT2DAY*)

 (xx)

c. Usual daily dose:(*MAOT2DSE*)

 (xxxx.xx) mg

Comments:(*MATCOMM*)

Additional Selection Options for MAT

Report Type (*REPORT*) (key field):

- 1-Participant self-report
- 2-Medical record abstraction

NIDA Clinical Trials Network

Medication Assisted Treatment (MAT)

Web Version: 1.0; 2.01; 04-06-15

Segment (PROTSEG):
Visit number (VISNO):
Report Type (REPORT): [Medical record abstraction](#)

Date of assessment:(MATASMDT) (mm/d/d/yyyy)

In the past 28 days, was the participant prescribed any of the following for addiction treatment:

- 1. Methadone (Dolophine, Methadose, Methadose Oral Concentrate, Westadone):(MAMTDRX)
Prescribed dose:(MAMTDDSE) No Yes
 (xxx) mg
- 2. Buprenorphine (Suboxone, Subutex, Zubsolv):(MABUPRX)
Prescribed dose:(MABUPDSE) No Yes
 (xx) mg
- 3. Disulfiram (Antabuse):(MADSFrx)
Prescribed dose:(MADSFdSE) No Yes
 (xxx) mg
- 4. Acamprosate (Campral):(MAACMRX)
Prescribed dose:(MAACMDSE) No Yes
 (xxxx) mg
- 5. Oral naltrexone (ReVia):(MANTXRX)
Prescribed dose:(MANTXDSE) No Yes
 (xxx.xx) mg
- 6. Gabapentin (Neurotin):(MAGBPRX)
Prescribed dose:(MAGBPdSE) No Yes
 (xxxx) mg
- 7. Topiramate (Topamax):(MATPMRX)
Prescribed dose:(MATPMdSE) No Yes
 (xxx) mg
- 8. Valproic acid (Depakote):(MAVPARX)
Prescribed dose:(MAVPADSE) No Yes
 (xxxx) mg
- 9. Other medication for addiction treatment:(MAOT1RX)
a. If "Yes", specify:(MAOT1SP) No Yes
b. Prescribed dose:(MAOT1DSE) (xxxx.xx) mg
- 10. Other medication for addiction treatment:(MAOT2RX)
a. If "Yes", specify:(MAOT2SP) No Yes
b. Prescribed dose:(MAOT2DSE) (xxxx.xx) mg

Comments:(MATCOMM)

Additional Selection Options for MAT

Report Type (*REPORT*) (key field):

- 1-Participant self-report
- 2-Medical record abstraction

NIDA Clinical Trials Network

Missed Visit Form (MVF)

Web Version: 1.0; 1.00; 12-06-13

Segment (*PROTSEG*):

Visit number (*VISNO*):

Reason for missed visit:(*MVREASON*)

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

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

Comments:(*MVFCOMM*)

Additional Selection Options for MVF

Reason for missed visit:

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

NIDA Clinical Trials Network

Non-Fatal Overdose (NFO)

Web Version: 1.0; 1.00; 02-04-14

Segment (PROTSEG):

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, dilaudid, or percocet).

1. Have you had an opioid overdose since the baseline visit date? (NFOP/OD) No Yes

If "Yes", number of times:

(NFODNUM) (xx)

Comments:(NFOCOMM)

NIDA Clinical Trials Network

Naloxone Challenge (NXC)

Web Version: 1.0; 2.00; 01-03-14

Segment (PROTSEG):

Visit number (VISNO):

Challenge number (NXC_CHNO):

Date of naloxone administration: (NXDOSED1)

(mm/dd/yyyy)

First Dose

1. Time of administration: (NXDOSTM1)

(hh:mm) (24-hour clock)

2. Total dose: (NXDOSE1)

(x.xx) mg

3. Route of administration: (NXROUTE1)

1-I.V. (Intravenous)
2-I.M. (Intramuscular injection)
3-S.C. (Subcutaneous injection)
4-Intranasal

Second Dose (if applicable)

Note: If a second dose was administered within 5 minutes, the total quantity should be entered above as a single first dose.

4. Time of administration: (NXDOSTM2)

(hh:mm) (24-hour clock)

5. Total dose: (NXDOSE2)

(x.xx) mg

6. Route of administration: (NXROUTE2)

1-I.V. (Intravenous)
2-I.M. (Intramuscular injection)
3-S.C. (Subcutaneous injection)
4-Intranasal

Results

7. Precipitated withdrawal: (NXWTHDRW)

No Yes

8. Will the participant proceed with administration of study medication?
(NXADMED)

No Yes

Comments: (NXCCOMM)

Additional Selection Options for NXC

Challenge number (*NXC_CHNO*) (key field):

1-1

2-2

3-3

4-4

NIDA Clinical Trials Network

Oral Naltrexone Dose Log (ONX)

Web Version: 1.0; 1.00; 01-16-14

Segment (PROTSEG):

Visit number (VISNO):

First Oral Naltrexone Induction

Dose Number	Date Dose Taken (mm/dd/yyyy)	Time 24-hour (00:00)	Dose of Tablet (xx mg)	Number of Tablets Dispensed (x.xx)	Total Dose (xx.xx mg)	Administered for
1.	(ONA1DSDT) _ _ / _ _ / _ _ _	(ONA1DSTM) _ _	(ONA1DOSE) _ _	(ONA1TABS) _ _	(ONA1DSL) _ _	(ONA1DSLCL) 1-In clinic 2-Take home
2.	(ONA2DSDT) _ _ / _ _ / _ _ _	(ONA2DSTM) _ _	(ONA2DOSE) _ _	(ONA2TABS) _ _	(ONA2DSL) _ _	(ONA2DSLCL) 1-In clinic 2-Take home
3.	(ONA3DSDT) _ _ / _ _ / _ _ _	(ONA3DSTM) _ _	(ONA3DOSE) _ _	(ONA3TABS) _ _	(ONA3DSL) _ _	(ONA3DSLCL) 1-In clinic 2-Take home
4.	(ONA4DSDT) _ _ / _ _ / _ _ _	(ONA4DSTM) _ _	(ONA4DOSE) _ _	(ONA4TABS) _ _	(ONA4DSL) _ _	(ONA4DSLCL) 1-In clinic 2-Take home
5.	(ONA5DSDT) _ _ / _ _ / _ _ _	(ONA5DSTM) _ _	(ONA5DOSE) _ _	(ONA5TABS) _ _	(ONA5DSL) _ _	(ONA5DSLCL) 1-In clinic 2-Take home
6.	(ONA6DSDT) _ _ / _ _ / _ _ _	(ONA6DSTM) _ _	(ONA6DOSE) _ _	(ONA6TABS) _ _	(ONA6DSL) _ _	(ONA6DSLCL) 1-In clinic 2-Take home
7.	(ONA7DSDT) _ _ / _ _ / _ _ _	(ONA7DSTM) _ _	(ONA7DOSE) _ _	(ONA7TABS) _ _	(ONA7DSL) _ _	(ONA7DSLCL) 1-In clinic 2-Take home
8.	(ONA8DSDT) _ _ / _ _ / _ _ _	(ONA8DSTM) _ _	(ONA8DOSE) _ _	(ONA8TABS) _ _	(ONA8DSL) _ _	(ONA8DSLCL) 1-In clinic 2-Take home
9.	(ONA9DSDT) _ _ / _ _ / _ _ _	(ONA9DSTM) _ _	(ONA9DOSE) _ _	(ONA9TABS) _ _	(ONA9DSL) _ _	(ONA9DSLCL) 1-In clinic 2-Take home

Second Oral Naltrexone Induction

Dose Number	Date Dose Taken (mm/dd/yyyy)	Time 24-hour (00:00)	Dose of Tablet (xx mg)	Number of Tablets Dispensed (x.xx)	Total Dose (xx.xx mg)	Administered for
1.	(ONB1DSDT) _ _ / _ _ / _ _ _	(ONB1DSTM) _ _	(ONB1DOSE) _ _	(ONB1TABS) _ _	(ONB1DSL) _ _	(ONB1DSLCL) 1-In clinic 2-Take home

2.	(ONB2DSDT) ┌ └	(ONB2DSTM) ┌ └	(ONB2DOSE) ┌ └	(ONB2TABS) ┌ └	(ONB2DSL) ┌ └	(ONB2DSLCL) 1-In clinic 2-Take home
3.	(ONB3DSDT) ┌ └	(ONB3DSTM) ┌ └	(ONB3DOSE) ┌ └	(ONB3TABS) ┌ └	(ONB3DSL) ┌ └	(ONB3DSLCL) 1-In clinic 2-Take home
4.	(ONB4DSDT) ┌ └	(ONB4DSTM) ┌ └	(ONB4DOSE) ┌ └	(ONB4TABS) ┌ └	(ONB4DSL) ┌ └	(ONB4DSLCL) 1-In clinic 2-Take home
5.	(ONB5DSDT) ┌ └	(ONB5DSTM) ┌ └	(ONB5DOSE) ┌ └	(ONB5TABS) ┌ └	(ONB5DSL) ┌ └	(ONB5DSLCL) 1-In clinic 2-Take home
6.	(ONB6DSDT) ┌ └	(ONB6DSTM) ┌ └	(ONB6DOSE) ┌ └	(ONB6TABS) ┌ └	(ONB6DSL) ┌ └	(ONB6DSLCL) 1-In clinic 2-Take home

Comments:(ONXCOMM)

NIDA Clinical Trials Network

Pregnancy and Birth Control Assessment (PBC)

Web Version: 1.0; 3.02; 12-09-14

Segment (PROTSEG):

Visit number (VISNO):

Complete this form only for females.

Date of assessment:(PBCASMDT)

 (mm/dd/yyyy)

1. Is participant continuing to take measures to avoid becoming pregnant?
(PBUSEBC)

 No Yes

2. 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)

NIDA Clinical Trials Network

Protocol Deviation Review (PDR)

Web Version: 1.0; 2.00; 03-24-14

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

Completed by Protocol Specialist:

1. What section of the protocol does this deviation refer to?(PDSECTN)

2. Does the report of this deviation require site staff retraining?(PDTRAIN)

No Yes

If "Yes", specify plan for retraining:(PDPLATRA)

3. Deviation was discussed with Lead Investigative Team on:(PDDISCDT)

(mm/dd/yyyy)

4. Deviation is categorized as:(PDCA TGRY)

Major Minor

5. Deviation assessment by Protocol Specialist complete:(PDPSCMP)

No Yes

Protocol Specialist reviewer:(PDPSRVID)

(initials)

Completed by Protocol Monitor:

6. Corrective action for this deviation was completed and documented on-site as described:(PDACTDOC)

No Yes

If "No", specify reason:(PDSITESP)

7. Deviation was reported to the IRB as required:(PDIRBRPT)

No Yes

If "No", specify reason:(*PDIRBSP*)

8. Preventive action plan related to this event was completed and documented on-site as described:(*PDPREVENT*)

No Yes

9. Review by Protocol Monitor is complete:(*PDPMCMP*)

No Yes

Protocol Monitor reviewer:(*PDPMRVID*)

(initials)

Comments:(*PVCOMM*)

Additional Selection Options for PDR

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

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

NIDA Clinical Trials Network

Protocol Deviation (PDV)

Web Version: 1.0; 1.00; 03-21-14

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

1. Date deviation identified: (PDVDATE)

 (mm/d/yyyy)

2. Deviation type: (PDTYPE)

Z01-INFORMED CONSENT PROCEDURES
O1A--- No consent/assent obtained
O1B--- Invalid/incomplete informed consent form
O1C--- Unauthorized assessments and/or procedures conducted prior to obtaining informed consent
O1D--- Non IRB approved/outdated/obsolete informed consent documents used
*Additional Options Listed Below

If "Other", specify: (PDYSP)

3. Brief description of what occurred: (PDESCPT)

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

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

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

No Yes

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

No Yes

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

(mm/d/yyyy)

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

(mm/d/yyyy)

Comments:(*PDVCOMM*)

Additional Selection Options for PDV

Protocol deviation number (PDSEQNUM) (key field):

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

Deviation type:

01E--- Informed consent process not properly conducted and/or documented
01Z--- Other (specify)
Z02-INCLUSION/EXCLUSION CRITERIA
02A--- Ineligible participant randomized/inclusion/exclusion criteria not met
02Z--- Other (specify)
Z04-LABORATORY ASSESSMENTS
04A--- Biologic specimen not collected/processed as per protocol
04Z--- Other (specify)
Z05-STUDY PROCEDURES/ASSESSMENTS
05A--- Protocol required visit/assessment not scheduled or conducted
05B--- Study assessments not completed/followed as per protocol
05C--- Inappropriate unblinding
05Z--- Other (specify)
Z06-ADVERSE EVENT
06A--- AE not reported
06B--- SAE not reported
06C--- AE/SAE reported out of protocol specified reporting time frame
06D--- AE/SAE not elicited, observed and/or documented as per protocol
06E--- Safety assessment (e.g. labs, ECG, clinical referral to care) not conducted per protocol
06Z--- Other (specify)
Z07-RANDOMIZATION PROCEDURES
07A--- Stratification error
07Z--- Other (specify)
Z08-STUDY MEDICATION MANAGEMENT
08A--- Medication dispensed to ineligible participant
08B--- Medication dispensed to incorrect participant
08C--- Medication dosing errors (protocol specified dose not dispensed)
08D--- Participant use of protocol prohibited medication
08Z--- Other (specify)
Z09-STUDY BEHAVIORAL INTERVENTION
09A--- Study behavioral intervention was not provided/performed as per protocol
09Z--- Other (specify)
Z99-OTHER SIGNIFICANT DEVIATIONS
99A--- Destruction of study materials without prior authorization from sponsor
99B--- Breach of Confidentiality
99Z--- Other (specify)

NIDA Clinical Trials Network

Pain Assessment (PEG)

Web Version: 1.0; 1.01; 08-12-14

Segment (PROTSEG):

Visit number (VISNO):

Date of assessment: (PEGASMDT)

(mm/dd/yyyy)

	0	1	2	3	4	5	6	7	8	9	10
1. What number best describes your average level of pain in the past week? <i>'0' represents no pain and '10' represents the worst pain you can imagine.</i>	(PEPAINAV) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. What number best describes how pain has interfered with your enjoyment of life in the past week? <i>'0' represents no interference and '10' represents complete interference.</i>	(PEENJOY) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. What number best describes how pain has interfered with your general activity in the past week? <i>'0' represents no interference and '10' represents complete interference.</i>	(PEACTVTY) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

4. How did you manage your pain?

No Yes

a. Acupuncture: (PEACUPNT)

b. Massage: (PEMASSGE)

c. Exercise: (PEEXRCSE)

d. Non-opioid medications (e.g., ibuprofen, acetaminophen, gabapentin): (PEMEDS)

e. Prescribed opioid medications: (PEOPIRX)

f. Non-prescribed opioids: (PEOPINRX)

g. Consultation with a doctor: (PEMD)

h. Did not manage pain: (PENOTMNG)

i. Other: (PEPAINOT) If "Other", specify: (PEPNOSP)

Comments: (PEGCOMM)

NIDA Clinical Trials Network

Quality of Life - PhenX (QLP)

Web Version: 1.0; 1.02; 01-03-14

Segment (PROTSEG):

Visit number (VISNO):

Date of assessment:(QLPASMDT)

(mm/dd/yyyy)

1. Would you say that in general your health is:(QLHEALTH)

- 1-Excellent
- 2-Very good
- 3-Good
- 4-Fair
- 5-Poor
- 97-Don'tknow/Not sure
- 98-Refused

2. Now thinking about your physical health, which includes physical illness and injury, for how many days during the past 30 days was your physical health not good?(QLHLTNGD)

(xx) Number of days

3. Now thinking about your mental health, which includes stress, depression, and problems with emotions, for how many days during the past 30 days was your mental health not good?(QLMTLNG)

(xx) Number of days

4. During the past 30 days, for about how many days did poor physical or mental health keep you from doing your usual activities, such as self-care, work, or recreation?(QLACT)

(xx) Number of days

Comments:(QLPCOMM)

NIDA Clinical Trials Network

Risk Assessment Battery (RAB)

Web Version: 1.0; 3.00; 11-12-14

Segment (PROTSEG):

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)

0- Zero or I have not shot up in the past month
1- 1 other person
2- 2 or 3 different people
3- 4 or more different people

4. In the past month, how often have you used a needle after someone (with or without cleaning)?(RAUSOTND)

0- Never or I have not shot up or shared in the past month
1- A few times (1 or 2 times)
2- A bout once a week (3 or 4 times)
3- 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)

0- Never or I have not shot up or shared in the past month
1- A few times (1 or 2 times)
2- A bout once a week (3 or 4 times)
3- 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)

0- Never or I have not shot up or shared in the past month
1- A few times (1 or 2 times)
2- A bout once a week (3 or 4 times)
3- 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)

0- Never
1- A few times (1 or 2 times)
2- A bout once a week (3 or 4 times)
3- 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)

0- Never
1- A few times (1 or 2 times)
2- A bout once a week (3 or 4 times)
3- 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)

0- I have not shot up in the past month 1- I ALWAYS use new needles 2- I ALWAYS clean my needle just BEFORE I shoot up 3- After I shoot up, I ALWAYS clean my needle 4- SOMETIMES I clean my needle, sometimes I don't *Additional Options Listed Below
--

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) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. In the past month, how often have you shared a cooker?	(RACOKRSH) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. In the past month, how often have you shared cotton?	(RACTNSH) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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)

0-0 1-1 2-2 or 3 3-4 or more

men/man

18. With how many women have you had sex in the past month? (RASEXWMN)

0-0 1-1 2-2 or 3 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) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20. In the past month, how often have you given drugs to someone so you could have sex with them?	(RADG4SEX) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21. In the past month, how often were you paid money to have sex with someone?	(RAPOSTUT) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22. In the past month, how often did you give money to someone so you could have sex with them?	(RAPD4SEX) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

24. In the past month, how often did you use condoms when you had sex?(RASEXSFE)

- 0-I have not had sex in the past month
- 1-All the time
- 2-Most of the time
- 3-Some of the time
- 4-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)

Comments:(RABCOMM)

Additional Selection Options for RAB

Which statement best describes the way you cleaned your needles during the past month?

5-I NEVER clean my needle

NIDA Clinical Trials Network

Readiness for Substance Use Treatment (RST)

Web Version: 1.0; 2.00; 07-25-14

Segment (PROTSEG):

Visit number (VISNO):

Date of assessment (RSTASMDT)

(mm/dd/yyyy)

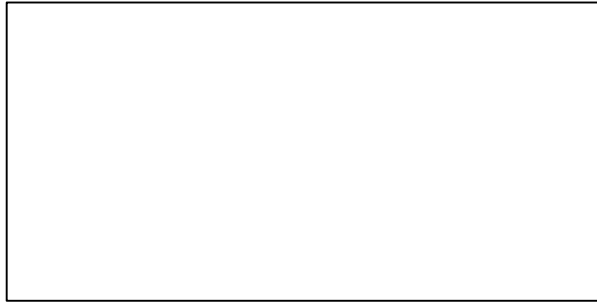
The following questions ask about "substances". By "substance" we mean **opioids**.

	Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree
1. Treatment could be my last chance to solve my substance use problems.	(RSCHNCEO) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. If I enter treatment, I will stay for a while.	(RSSTAYO) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Treatment could really help me.	(RSHELPO) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. I want to be in a treatment program.	(RSWNTTXO) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Most counselors in substance use treatment programs are "squares" who don't understand substance users.	(RSCNSLRO) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Substance use treatment programs have too many rules and regulations for me.	(RSRULESO) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. I don't think I could trust many of the people who work in the substance use treatment programs.	(RSTRUSTO) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. It takes too much time and effort to get into a substance use treatment program.	(RSEFFRTO) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

The following questions ask about "substances". By "substance" we mean **alcohol**.

	Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree
1. Treatment could be my last chance to solve my substance use problems.	(RSCHNCEA) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. If I enter treatment, I will stay for a while.	(RSSTAYA) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Treatment could really help me.	(RSHELPA) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. I want to be in a treatment program.	(RSWNTTXA) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Most counselors in substance use treatment programs are "squares" who don't understand substance users.	(RSCNSLRA) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Substance use treatment programs have too many rules and regulations for me.	(RSRULESA) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. I don't think I could trust many of the people who work in the substance use treatment programs.	(RSTRUSTA) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. It takes too much time and effort to get into a substance use treatment program.	(RSEFFRTA) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments: (RSTCOMM)



NIDA Clinical Trials Network

Study Termination (STT)

Web Version: 1.0; 2.03; 09-16-14

Segment (PROTSEG):

1. Date of study completion, early termination, or last attended study visit:
(STTRMDT) (mm/dd/yyyy)

2. Did the participant complete the study (attend the week 16 visit)? (STCOMPLT) No Yes

If "No", select primary reason for not completing the study:(STTRMRES)

- 1-Participant failed to return to clinic and unable to contact
- 2-Participant terminated due to practical problems (no childcare, transportation, other)
- 3-Participant moved from area
- 4-Participant incarcerated
- 5-Participant terminated due to AE/SAE
- *Additional Options Listed Below

If "Participant terminated for other clinical reasons", or "Participant terminated for other reason", specify:(STTRMOSP)

Comments:(STTCOMM)

Investigator's Signature

I have reviewed all the data recorded on all CRF pages and certify that they are accurate and complete to the best of my knowledge.

Principal Investigator:(STPISIGN)

Date:(STPISGDT)

 (mm/dd/yyyy)

Additional Selection Options for STT

If "No", select primary reason for not completing the study:

- 6-Participant terminated for other clinical reasons
- 7-Participant had a significant psychiatric risk (suicidal, homicidal, psychotic)
- 8-Participant withdrew consent
- 9-Participant deceased
- 19-Participant terminated due to protocol deviation
- 99-Participant terminated for other reason

NIDA Clinical Trials Network

Timeline Followback (T55)

Web Version: 1.0; 1.00; 07-24-14

TFB week start date (TFWKSTDT):

Day	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Date	(TLDATE1) <input type="text"/>	(TLDATE2) <input type="text"/>	(TLDATE3) <input type="text"/>	(TLDATE4) <input type="text"/>	(TLDATE5) <input type="text"/>	(TLDATE6) <input type="text"/>	(TLDATE7) <input type="text"/>
1. Have any illicit substances or alcohol been used on this day?	(TLSUBAL1) <input type="checkbox"/> No <input type="checkbox"/> Yes	(TLSUBAL2) <input type="checkbox"/> No <input type="checkbox"/> Yes	(TLSUBAL3) <input type="checkbox"/> No <input type="checkbox"/> Yes	(TLSUBAL4) <input type="checkbox"/> No <input type="checkbox"/> Yes	(TLSUBAL5) <input type="checkbox"/> No <input type="checkbox"/> Yes	(TLSUBAL6) <input type="checkbox"/> No <input type="checkbox"/> Yes	(TLSUBAL7) <input type="checkbox"/> No <input type="checkbox"/> Yes
2. Alcohol number of standard drinks (xx):	(TLALCHL1) <input type="text"/>	(TLALCHL2) <input type="text"/>	(TLALCHL3) <input type="text"/>	(TLALCHL4) <input type="text"/>	(TLALCHL5) <input type="text"/>	(TLALCHL6) <input type="text"/>	(TLALCHL7) <input type="text"/>
3. Cannabinoids/ Marijuana:	(TLTHCR1) 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
4. 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
5. 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
6. Amphetamine-type stimulants	(TLAMPR1) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLAMPR2) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLAMPR3) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLAMPR4) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLAMPR5) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLAMPR6) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below	(TLAMPR7) 0-00-No use 1-01-Oral 2-02-Nasal 3-03-Smoking 4-04-Non-IV Injection *Additional Options Listed Below
7. 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
8. Heroin:	(TLHERR1)	(TLHERR2)	(TLHERR3)	(TLHERR4)	(TLHERR5)	(TLHERR6)	(TLHERR7)

Comments:(755COMM)



Additional Selection Options for T55

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

NIDA Clinical Trials Network

TLFB Assessment Period (TAP)

Web Version: 1.0; 3.02; 07-11-14

Segment (*PROTSEG*):

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 illicit substances or alcohol been taken during this assessment period? (*TASUBALC*)

No Yes

Comments: (*TAPCOMM*)

NIDA Clinical Trials Network

Treatment Services Review (TSR)

Web Version: 1.0; 4.00; 04-29-15

Segment (*PROTSEG*):

Visit number (*VISNO*):

Date of assessment: (*TSRASMDT*)

(mm/dd/yyyy)

Beginning of assessment period: (*TSBEGDT*)

(mm/dd/yyyy)

End of assessment period: (*TSENDT*)

(mm/dd/yyyy)

Number of days in the assessment period: (*TSDAYSPD*)

(xxx)

A. HOUSING SERVICES:

1. Where did you stay for the past 28 days?

Number of Days
(xx)

a. Alone (in private house, apartment, hotel, etc.):

(*TSRESALN*)

b. With others (in private house, apartment, hotel, etc.):

(*TSRESOTH*)

c. Institution (e.g., hospital, jail, prison):

(*TSRESINT*)

Specify:

(i) Hospital/residential treatment:

(*TSRESHSP*)

(ii) Jail or prison:

(*TSRESPRN*)

d. Structured living situation (e.g., recovery house, group home, halfway house):

(*TSRESSTR*)

Specify:

(i) For alcohol or drug problems (including dual detox):

(*TSRESDRG*)

(ii) For psychological or emotional problems:

(*TSRESPSY*)

(iii) For medical problems:

(*TSRESMED*)

(iv) For criminal behavior or legal problems:

(*TSRESLGL*)

(v) For domestic violence:

(*TSRESDMV*)

e. Homeless shelter:

(*TSRESHSH*)

f. Homeless (i.e., on the street, in an abandoned building, in a car):

(*TSRESHLS*)

B. ALCOHOL AND DRUG SERVICES:

QUESTIONS ABOUT **INPATIENT** TREATMENT FOR ALCOHOL AND/OR DRUGS RECEIVED OVER PAST 28 DAYS

- | | IN
(xx) | OUT
(xx) |
|--|--|--|
| 2. How many nights did you stay at an inpatient/residential drug/alcohol treatment unit? | (<i>TSINDRGI</i>) <input type="text"/> | (<i>TSINDRGO</i>) <input type="text"/> |
| If "Out", specify location: (<i>TSINDRGL</i>) <input type="text"/> | | |
| 3. How many of those nights were detoxification only? | (<i>TSINDTXI</i>) <input type="text"/> | (<i>TSINDTXO</i>) <input type="text"/> |
| If "Out", specify location: (<i>TSINDTXL</i>) <input type="text"/> | | |
| 4. How many individual (one-on-one) sessions did you attend during which substance use was the main purpose of the discussion? | (<i>TSINIDVI</i>) <input type="text"/> | (<i>TSINIDVO</i>) <input type="text"/> |
| a. Specify the number of sessions with: | | |
| (i) Medical doctor (e.g., psychiatrist or physician): | (<i>TSIIDMDI</i>) <input type="text"/> | (<i>TSIIDMDO</i>) <input type="text"/> |

- | | | |
|--|---------------------------------|---------------------------------|
| (ii) Non-medical doctor (e.g., psychologist - Ph.D./Psy.D.): | (TSIIDNMI) <input type="text"/> | (TSIIDNMO) <input type="text"/> |
| (iii) Nurse: | (TSIIDRNI) <input type="text"/> | (TSIIDRNO) <input type="text"/> |
| (iv) Other clinician (e.g., counselor, social worker, clergy): | (TSIIDOTI) <input type="text"/> | (TSIIDOTO) <input type="text"/> |
| (v) Don't know: | (TSIIDDKI) <input type="text"/> | (TSIIDDKO) <input type="text"/> |
| b. On average, how long did each individual session last? (xx minutes) | (TSIIDTMI) <input type="text"/> | (TSIIDTMO) <input type="text"/> |
| | IN
(xx) | OUT
(xx) |
| 5. How many 12-Step/self-help group meeting for substance use (e.g., AA, NA, CA) did you attend? | (TSIN12SI) <input type="text"/> | (TSIN12SO) <input type="text"/> |
| 6. How many meetings did you have with your sponsor/mentor during which your substance problem was the main purpose of the discussion? | (TSINMTRI) <input type="text"/> | (TSINMTRO) <input type="text"/> |
| 7. How many other group therapy/counseling sessions for substance use (i.e., non-self-help groups) did you attend? | (TSINGRPI) <input type="text"/> | (TSINGRPO) <input type="text"/> |
| a. Specify the number of sessions with: | | |
| (i) Medical doctor (e.g., psychiatrist or physician): | (TSIGPMDI) <input type="text"/> | (TSIGPMDO) <input type="text"/> |
| (ii) Non-medical doctor (e.g., psychologist - Ph.D./Psy.D.): | (TSIGPNMI) <input type="text"/> | (TSIGPNMO) <input type="text"/> |
| (iii) Nurse: | (TSIGPRNI) <input type="text"/> | (TSIGPRNO) <input type="text"/> |
| (iv) Other clinician (e.g., counselor, social worker, clergy): | (TSIGPOTI) <input type="text"/> | (TSIGPOTO) <input type="text"/> |
| (v) Don't know: | (TSIGPDKI) <input type="text"/> | (TSIGPDKO) <input type="text"/> |
| b. How many of these groups focused solely on education about alcohol/drugs? | (TSIGPEDI) <input type="text"/> | (TSIGPEDO) <input type="text"/> |
| c. On average, how long did each individual session last? (xx minutes) | (TSIGPTMI) <input type="text"/> | (TSIGPTMO) <input type="text"/> |
| d. On average, how many other patients were in a group? | (TSIGPPTI) <input type="text"/> | (TSIGPPTO) <input type="text"/> |

QUESTIONS ABOUT TREATMENT FOR ALCOHOL AND/OR DRUGS RECEIVED OVER PAST 28 DAYS WHEN NOT IN INPATIENT TREATMENT

- | | | |
|---|---------------------------------|---------------------------------|
| | IN
(xx) | OUT
(xx) |
| 8. How many days did you attend any outpatient treatment for substance use problems, excluding any 12-Step or self help group meetings? | (TSOPDRGI) <input type="text"/> | (TSOPDRGO) <input type="text"/> |
| If "Out", specify location: (TSOPDRGL) <input type="text"/> | | |
| 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)? | (TSOPHSPI) <input type="text"/> | (TSOPHSPO) <input type="text"/> |
| If "Out", specify location: (TSOPHSPL) <input type="text"/> | | |
| 10. How many individual (one-on-one) sessions did you attend during which substance use was the main purpose of the discussion? | (TSOPIDVI) <input type="text"/> | (TSOPIDVO) <input type="text"/> |
| a. Specify the number of sessions with: | | |
| (i) Medical doctor (e.g., psychiatrist or physician): | (TSOIDMDI) <input type="text"/> | (TSOIDMDO) <input type="text"/> |
| (ii) Non-medical doctor (e.g., psychologist - Ph.D./Psy.D.): | (TSOIDNMI) <input type="text"/> | (TSOIDNMO) <input type="text"/> |
| (iii) Nurse: | (TSOIDRNI) <input type="text"/> | (TSOIDRNO) <input type="text"/> |
| (iv) Other clinician (e.g., counselor, social worker, clergy): | (TSOIDOTI) <input type="text"/> | (TSOIDOTO) <input type="text"/> |
| (v) Don't know: | (TSOIDDKI) <input type="text"/> | (TSOIDDKO) <input type="text"/> |
| b. On average, how long did each individual session last? (xx minutes) | (TSOIDTMI) <input type="text"/> | (TSOIDTMO) <input type="text"/> |
| | IN
(xx) | OUT
(xx) |
| 11. How many 12-Step/self-help group meeting for substance use (e.g., AA, NA, CA) did you attend? | (TSOP12SI) <input type="text"/> | (TSOP12SO) <input type="text"/> |
| 12. How many meetings did you have with your sponsor/mentor during which your substance problem was the main purpose of the discussion? | (TSOPMTRI) <input type="text"/> | (TSOPMTRO) <input type="text"/> |
| 13. How many other group therapy/counseling sessions for substance use (i.e., non-self-help groups) did you attend? | (TSOPGRPI) <input type="text"/> | (TSOPGRPO) <input type="text"/> |
| a. Specify the number of sessions with: | | |

- (i) Medical doctor (e.g., psychiatrist or physician): (TSOGPMDI) [] (TSOGPMDO) []
- (ii) Non-medical doctor (e.g., psychologist - Ph.D./Psy.D.): (TSOGPNMI) [] (TSOGPNMO) []
- (iii) Nurse: (TSOGPRNI) [] (TSOGPRNO) []
- (iv) Other clinician (e.g., counselor, social worker, clergy): (TSOGPOTI) [] (TSOGPOTO) []
- (v) Don't know: (TSOGPKI) [] (TSOGPKO) []
- b. How many of these groups focused solely on education about alcohol/drugs? (TSOGPEDI) [] (TSOGPEDO) []
- c. On average, how long did each individual session last? (xx minutes) (TSOGPTMI) [] (TSOGPTMO) []
- d. On average, how many other patients were in a group? (TSOGPPTI) [] (TSOGPPTO) []

QUESTIONS ABOUT TREATMENT RECEIVED ON ANY OF THE PAST 28 DAYS

- | | IN
(xx) | OUT
(xx) |
|---|------------|----------------|
| 14. How many times were you tested for alcohol and/or drug use? | | |
| a. Urinalysis: (TS TS TUR I) [] | | (TSTSTURO) [] |
| b. Breathalyzer: (TS TS TBR I) [] | | (TSTSTBRO) [] |
| c. Any other test for alcohol/drug use (e.g., blood, saliva, hair): (TS TS TO TI) [] | | (TSTSTOTO) [] |
| If "Other", specify: (TS TS TSP I) [] | | (TSTSTSPO) [] |

C. MEDICAL SERVICES:

QUESTIONS ABOUT ANY MEDICAL TREATMENT RECEIVED OVER THE PAST 28 DAYS

- | | IN
(xx) | OUT
(xx) |
|--|---------------|-----------------|
| 15. How many nights were you an inpatient in a medical hospital, nursing home, or medical rehabilitation facility? | (TSINPTI) [] | (TSINPTO) [] |
| a. Specify the number of nights in each facility: | | |
| (i) Medical hospital: (TSINHSP I) [] | | (TSINHSP O) [] |
| (ii) Nursing home or medical rehabilitation facility: (TSINRHBI) [] | | (TSINRHBO) [] |
| b. Diagnosis or major problem at visit 1: (TSINPDX) [] | | |
| c. Diagnosis or major problem at visit 2: (TSINPDX2) [] | | |
| d. Diagnosis or major problem at visit 3: (TSINPDX3) [] | | |
| e. Diagnosis or major problem at visit 4: (TSINPDX4) [] | | |
| f. Diagnosis or major problem at visit 5: (TSINPDX5) [] | | |
| g. Diagnoses or major problems at additional visits: (TSINPDX6) [] | | |
| h. Major procedures or evaluations: (TSINPPRC) [] | | |

QUESTIONS ABOUT MEDICAL TREATMENT RECEIVED OVER PAST 28 DAYS WHEN NOT IN A MEDICAL HOSPITAL

- | | IN
(xx) | OUT
(xx) |
|---|-------------|-------------|
| 16. How many times did you visit an emergency room? | (TSEDI) [] | (TSEDO) [] |
| a. Indicate reason for emergency room visit | | |

(i) Medical:

(TSEDMED)

(TSEDMEDO)

(ii) Psychological:

(TSEDPSYI)

(TSEDPSYO)

(iii) Substance use:

(TSEDSBSI)

(TSEDSBSO)

b. Diagnosis or major problem at visit 1: (TSEDDX)

c. Diagnosis or major problem at visit 2: (TSEDDX2)

d. Diagnosis or major problem at visit 3: (TSEDDX3)

e. Diagnosis or major problem at visit 4: (TSEDDX4)

f. Diagnosis or major problem at visit 5: (TSEDDX5)

g. Diagnoses or major problems at additional visits: (TSEDDX6)

h. Major procedures or evaluations: (TSEDPRC)

17. How many times did you visit a medical doctor (e.g., physician, psychiatrist) for testing, examination, treatment, or care of medical concerns/problems?

(TSMDI)

(TSMDO)

a. Diagnosis or major problem at visit 1: (TSMDDX)

b. Diagnosis or major problem at visit 2: (TSMDDX2)

c. Diagnosis or major problem at visit 3: (TSMDDX3)

d. Diagnosis or major problem at visit 4: (TSMDDX4)

e. Diagnosis or major problem at visit 5: (TSMDDX5)

f. Diagnoses or major problems at additional visits: (TSMDDX6)

g. Major procedures or evaluations: (TSMPPRC)

18. How many times did you visit any other medical professional (e.g., dentist, optometrists, nurse, physical therapist, X-ray or lab technician) for testing, examination, or treatment of medical concerns/problems?

(TSOMPI)

(TSOMPO)

a. Diagnosis or major problem at visit 1: (TSOMPDX)

b. Diagnosis or major problem at visit 2: (TSOMPDX2)

c. Diagnosis or major problem at visit 3: (TSOMPDX3)

d. Diagnosis or major problem at visit 4: (TSOMPDX4)

e. Diagnosis or major problem at visit 5: (TSOMPDX5)

f. Diagnoses or major problems at additional visits: (TSOMPDX6)

g. Major procedures or evaluations: (TSOMPPRC)

IN
(xx)

OUT
(xx)

19. How many individual or group counseling sessions did you attend with non-medical personnel during which medical concerns/problems were the main focus?
 Exclude all previously recorded visits.

(TSCNSLI)

(TSCNSLO)

a. Number of those with:

(i) Non-medical doctor (e.g., psychologist - Ph.D./Psy.D.):

(TSCNLNMI)

(TSCNLNMO)

(ii) Other clinician (e.g., counselor, social worker, clergy):

(TSCNLOTI)

(TSCNLOTO)

(iii) Group member(s) (i.e., a support group not professionally led):

(TSCNLGMI)

(TSCNLGMO)

(iv) Don't know:

(TSCNLDKI)

(TSCNLDKO)

b. How many of these were group sessions?

(TSCNLGPI)

(TSCNLGPO)

c. On average, how long did a session last? (xx minutes)

(TSCNLTMI)

(TSCNLTMO)

Given all the services, treatments, and contacts you've had in the past 28 days, how much of all of that dealt with:

	None	A Little Bit	Some	Quite A Bit	A Lot
20. Your substance use problems and issues?	(TSSBSUSE) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21. Your physical health or medical problems?	(TSHEALTH) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22. Your mental health or psychological problems and issues?	(TSPSYCH) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23. Your family problems and issues?	(TSFAMILY) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
24. Your employment, education, finances, or housing?	(TSEMPLOY) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
25. Your legal or criminal problems and issues?	(TSLEGAL) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments:(TSRCOMM)

NIDA Clinical Trials Network

Treatment Satisfaction (TTS)

Web Version: 1.0; 1.00; 02-14-14

Segment (PROTSEG):

Visit number (VISNO):

Date of assessment:(TTSASMDT)

(mm/dd/yyyy)

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

0-Not helpful
1-A little bit helpful
2-Somewhat helpful
3-Quite helpful
4-Very helpful

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

0-Not helpful
1-A little bit helpful
2-Somewhat helpful
3-Quite helpful
4-Very helpful

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

1-Inpatient detoxification
2-Outpatient detoxification
3-Residential rehabilitation
4-Outpatient rehabilitation
5-Group therapy sessions
6-12-step groups (NA/AA)
7-One-on-one addiction counseling
8-Methadone maintenance therapy
9-Buprenorphine maintenance therapy
10-Extended-release naltrexone (Vivitrol)
11-Oral naltrexone for alcohol dependence
12-Disulfiram
13-Accamprosate
14-Topiramate
99-Other

If "Other", specify:(TTBSTOSP)

4. Which part of the treatment do you think was most helpful in reducing your **alcohol** use?(TTBSTXA)

1-Inpatient detoxification
2-Outpatient detoxification
3-Residential rehabilitation
4-Outpatient rehabilitation
5-Group therapy sessions
6-12-step groups (NA/AA)
7-One-on-one addiction counseling
8-Methadone maintenance therapy
9-Buprenorphine maintenance therapy
10-Extended-release naltrexone (Vivitrol)
11-Oral naltrexone for alcohol dependence
12-Disulfiram
13-Accamprosate
14-Topiramate
99-Other

If "Other", specify:(TTBSTASP)

5. How satisfied are you with receiving treatment for opioid and/or alcohol dependence in the same clinic in which you receive HIV care?(TTSFYTX)

1-Very dissatisfied
2-Dissatisfied
3-Neither satisfied nor dissatisfied
4-Satisfied
5-Very satisfied

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

- 1-Very dissatisfied
- 2-Dissatisfied
- 3-Neither satisfied nor dissatisfied
- 4-Satisfied
- 5-Very satisfied

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

- 4-Definitely participate
- 3-Probably participate
- 2-Probably not participate
- 1-Definitely not participate

8. Please answer yes or no as to why you would choose to participate again:

- a. I liked the compensation/cash or gift cards(*TTCASHGD*)
- b. I liked the counseling(*TTCNSLGD*)
- c. I liked how the medication made me feel(*TTMEDSGD*)
- d. I didn't have to pay to participate in the study(*TTNOPAY*)
- e. The study/treatment helped me(*TTHELPEd*)
- f. I was able to get into the study quickly(*TTQUICK*)
- g. There aren't many other treatment options available to me(*TTNOOPT*)
- h. My participation may help others/contribute to science(*TTS CIENC*)
- i. The staff treated me well(*TTSTAFGD*)
- j. Desirable location/easy to get to clinic(*TTLOCGD*)
- k. Convenient clinic hours/days(*TTHRSGD*)
- l. Other(*TTOTHRGD*)

- No Yes
- No Yes
- No Yes Not applicable
- No Yes
- No Yes
- No Yes
- No Yes
- No Yes
- No Yes
- No Yes
- No Yes
- No Yes
- No Yes

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

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

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

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

12. Please answer yes or no as to why you would choose not to participate again:

- a. There was not enough compensation/cash or gift cards(*TTBDCASH*)
- b. I didn't like the counseling(*TTBDCNSL*)
- c. I didn't like how the medication made me feel(*TTBDMEDS*)
- d. The medication caused undesirable side effects(*TTSDEFFC*)
- e. The study/treatment didn't help me(*TTNOHELP*)
- f. There were too many visits(*TTVISITS*)
- g. There were too many procedures/visits that lasted too long(*TTLNGVST*)
- h. There wasn't enough counseling(*TTMRCNSL*)
- i. I would rather enroll in a usual treatment program(*TTTAUBTR*)
- j. The staff didn't treat me well(*TTSTAFBD*)
- k. Undesirable location/difficult to get to clinic(*TTLOCBD*)
- l. Inconvenient clinic hours/days(*TTHRSD*)
- m. Other(*TTOTHRBD*)

- No Yes
- No Yes
- No Yes Not applicable
- No Yes Not applicable
- No Yes
- No Yes
- No Yes
- No Yes
- No Yes
- No Yes
- No Yes
- No Yes
- No Yes

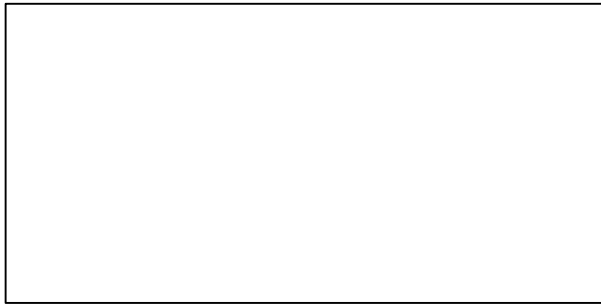
If "Other", specify:(*TTOTBDSP*)

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

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

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

Comments:(TTSCOMM)



Additional Selection Options for TTS

What is the primary reason you would choose to participate again?

- 6-I was able to get into the study quickly
- 7-There aren't many other treatment options available to me
- 8-My participation may help others/contribute to science
- 9-The staff treated me well
- 10-Desirable location/easy to get to clinic
- 11-Convenient clinic hours/days
- 99-Other

13. What is the primary reason you would choose to not participate again?

- 7-There were too many visits
- 8-There were too many procedures/visits lasted too long
- 9-There wasn't enough counseling
- 10-I would rather enroll in a usual treatment program
- 11-The staff didn't treat me well
- 12-Undesirable location/difficult to get to clinic
- 13-Inconvenient clinic hours/days
- 99-Other

NIDA Clinical Trials Network

Tobacco Use History (TUH)

Web Version: 1.0; 1.02; 01-10-14

Segment (PROTSEG):

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)

1-Every day
2-Some days
3-Not at all
97-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

Section A: Every-Day Smokers

5. On the average, about how many cigarettes do you now smoke each day?(TUNUMDY)

[] (xx) Cigarettes per day

6. How old were you when you first started smoking cigarettes every day?(TUSTRTAG)

[] (xx) Years old

Section B: Some-Day Smokers

7. On how many of the past 30 days did you smoke cigarettes?(TU30DAYS)

[] (xx) Days

8. On the average, on those [answer to Q7] days, how many cigarettes did you usually smoke each day?(TU30AVG)

[] (xx) Cigarettes per day

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

10. When you last smoked fairly regularly, on average how many cigarettes did you smoke each day?(TUNUMRDY)

[] (xx) Cigarettes per day

Comments:(TUHCOMM)

[]

NIDA Clinical Trials Network

Treatment Completion (TXC)

Web Version: 1.0; 2.00; 03-20-14

Segment (PROTSEG):

Visit number (VISNO):

Date of assessment:(TXCASMDT)

 (mm/dd/yyyy)

1. Is the participant continuing to receive substance abuse treatment as planned?

	Planned	Percentage of Treatment Completed (xxx)
a. Inpatient detoxification:	(TXDTXIN) <input type="checkbox"/>	(TXDTXINC) <input style="width: 50px;" type="text"/>
b. Outpatient detoxification:	(TXDTXOUT) <input type="checkbox"/>	(TXDTXOTC) <input style="width: 50px;" type="text"/>
c. Residential rehabilitation:	(TXRHBIN) <input type="checkbox"/>	(TXRHBINC) <input style="width: 50px;" type="text"/>
d. Outpatient rehabilitation:	(TXRHBOU) <input type="checkbox"/>	(TXRHBOTC) <input style="width: 50px;" type="text"/>
e. Group therapy sessions:	(TXGROUP) <input type="checkbox"/>	(TXGROU) <input style="width: 50px;" type="text"/>
f. 12-step groups (NA/AA):	(TX12STEP) <input type="checkbox"/>	(TX12STPC) <input style="width: 50px;" type="text"/>
g. One-on-one addiction counseling:	(TXCOUNSL) <input type="checkbox"/>	(TXCN) <input style="width: 50px;" type="text"/>
h. Medication-assisted treatment:	(TXMAT) <input type="checkbox"/>	(TXMATC) <input style="width: 50px;" type="text"/>
i. (TXTX1OSP) <input style="width: 300px;" type="text"/>		(TXX1OTC) <input style="width: 50px;" type="text"/>
j. (TXTX2OSP) <input style="width: 300px;" type="text"/>		(TXX2OTC) <input style="width: 50px;" type="text"/>

2. Is the participant continuing to receive medication-assisted treatment for substance abuse as planned?

	Planned	Percentage of Treatment Completed (xxx)
a. Methadone maintenance therapy:	(TXRXMTD) <input type="checkbox"/>	(TXRXMDC) <input style="width: 50px;" type="text"/>
b. Buprenorphine maintenance therapy:	(TXRXBUP) <input type="checkbox"/>	(TXRXBUPC) <input style="width: 50px;" type="text"/>
c. Disulfiram:	(TXRXDSFM) <input type="checkbox"/>	(TXRXDSFC) <input style="width: 50px;" type="text"/>
d. Acamprosate:	(TXRXACMP) <input type="checkbox"/>	(TXRXACMC) <input style="width: 50px;" type="text"/>
e. Oral naltrexone:	(TXRXONX) <input type="checkbox"/>	(TXRXONXC) <input style="width: 50px;" type="text"/>
f. Gabapentin:	(TXCRXGBP) <input type="checkbox"/>	(TXRXGBP) <input style="width: 50px;" type="text"/>
g. Topiramate:	(TXRXTOPM) <input type="checkbox"/>	(TXRXTOPC) <input style="width: 50px;" type="text"/>
h. Valproic acid:	(TXCRXVPA) <input type="checkbox"/>	(TXRXVPAC) <input style="width: 50px;" type="text"/>
i. (TXRX1OSP) <input style="width: 300px;" type="text"/>		(TXRX1OTC) <input style="width: 50px;" type="text"/>
j. (TXRX2OSP) <input style="width: 300px;" type="text"/>		(TXRX2OTC) <input style="width: 50px;" type="text"/>

3. Did the participant receive any other treatment that was not planned?

(TXUNPLAN)

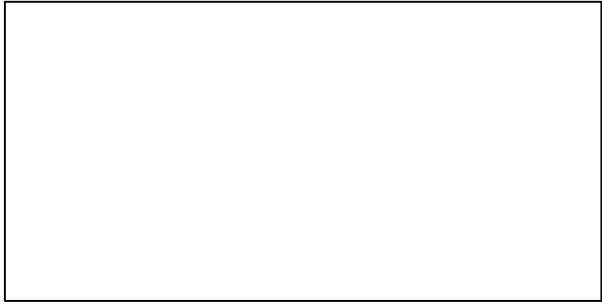
No Yes

a. If "Yes", specify treatment 1:(TXUNP1SP)

b. If "Yes", specify treatment 2:(TXUNP2SP)

c. If "Yes", specify treatment 3:(TXUNP3SP)

Comments:(TXCCOMM)



NIDA Clinical Trials Network

Treatment Initiation Status (TXI)

Web Version: 1.0; 2.00; 08-05-14

Segment (PROTSEG):

Date of assessment:(TXIASMDT)

 (mm/dd/yyyy)

1. Was treatment initiated?(TXSTATUS)

 No Yes

a. If "Yes", date of first dose of medication or first attended meeting:(TXINTDT)

 (mm/dd/yyyy)

b. If "No", why was treatment not initiated?(TXINTRSN)

- 0-Participant could not tolerate detoxification
- 1-Participant failed naloxone challenge
- 2-Participant failed to provide a negative UDS
- 3-Participant left prior to treatment initiation
- 4-Participant did not attend assigned treatment
- *Additional Options Listed Below

Comments:(TXICOMM)

Additional Selection Options for TXI

If "No", why was treatment not initiated?

- 5-Participant left study and never returned
- 6-Clinical deterioration: new onset of psychiatric or medical condition
- 7-Physical illness or condition that precludes taking study medication
- 8-Participant feels study treatment no longer necessary
- 9-Participant became incarcerated
- 10-Participant withdrew consent
- 11-Participant moved from area
- 12-Participant deceased

NIDA Clinical Trials Network

Treatment Plan (TXP)

Web Version: 1.0; 2.00; 03-10-14

Segment (PROTSEG):

Visit number (VISNO):

Date of assessment:(TXPASMDT)

(mm/dd/yyyy)

1. What form of treatment was recommended?

- | | No | Yes | |
|-------------------------------------|-------------------------------------|--------------------------|---|
| a. Inpatient detoxification: | (TXDTXIN) <input type="checkbox"/> | <input type="checkbox"/> | |
| b. Outpatient detoxification: | (TXDTXOUT) <input type="checkbox"/> | <input type="checkbox"/> | |
| c. Residential rehabilitation: | (TXRHBIN) <input type="checkbox"/> | <input type="checkbox"/> | |
| d. Outpatient rehabilitation: | (TXRHBOUT) <input type="checkbox"/> | <input type="checkbox"/> | |
| e. Group therapy sessions: | (TXGROUP) <input type="checkbox"/> | <input type="checkbox"/> | |
| f. 12-step groups (NA/AA): | (TX12STEP) <input type="checkbox"/> | <input type="checkbox"/> | |
| g. One-on-one addiction counseling: | (TXCOUNSL) <input type="checkbox"/> | <input type="checkbox"/> | |
| h. Medication-assisted treatment: | (TXMAT) <input type="checkbox"/> | <input type="checkbox"/> | |
| i. Other treatment 1: | (TXTX1OT) <input type="checkbox"/> | <input type="checkbox"/> | If "Other", specify:(TXTX1OSP) <input type="text"/> |
| j. Other treatment 2: | (TXTX2OT) <input type="checkbox"/> | <input type="checkbox"/> | If "Other", specify:(TXTX2OSP) <input type="text"/> |

2. If medication-assisted treatment was recommended, what type of medication-assisted treatment was recommended?

- | | No | Yes | |
|---------------------------------------|-------------------------------------|--------------------------|---|
| a. Methadone maintenance therapy: | (TXRXMTD) <input type="checkbox"/> | <input type="checkbox"/> | |
| b. Buprenorphine maintenance therapy: | (TXRXBUP) <input type="checkbox"/> | <input type="checkbox"/> | |
| c. Disulfiram: | (TXRXDSFM) <input type="checkbox"/> | <input type="checkbox"/> | |
| d. Acamprosate: | (TXRXACMP) <input type="checkbox"/> | <input type="checkbox"/> | |
| e. Oral naltrexone: | (TXRXONX) <input type="checkbox"/> | <input type="checkbox"/> | |
| f. Gabapentin: | (TXRXGBP) <input type="checkbox"/> | <input type="checkbox"/> | |
| g. Topiramate: | (TXRXTPM) <input type="checkbox"/> | <input type="checkbox"/> | |
| h. Valproic acid: | (TXRXVPA) <input type="checkbox"/> | <input type="checkbox"/> | |
| i. Other medication 1: | (TXRX1OT) <input type="checkbox"/> | <input type="checkbox"/> | If "Other", specify:(TXRX1OSP) <input type="text"/> |
| j. Other medication 2: | (TXRX2OT) <input type="checkbox"/> | <input type="checkbox"/> | If "Other", specify:(TXRX2OSP) <input type="text"/> |

Comments:(TXPCOMM)

NIDA Clinical Trials Network

Urine Drug Screen (UDS)

Web Version: 1.0; 4.00; 03-06-14

Segment (PROTSEG):

Visit number (VISNO):

1. Was a urine drug screen performed?(UDTEST1)

If "No", reason:(UDNORSN)

If "Other", specify:(UDNOSP1)

No Yes

1-Participant reported being unable to provide sample
 2-Participant refused to provide sample
 3-Study staff error
 99-Other

1st Urine Drug Screen

2. Date 1st urine specimen collected:(UDCOLDT1)

3. Time 1st urine specimen collected (24-hour format):(UDCOLTM1)

4. Was the 1st urine temperature within range? (90 - 100 °F)(UDETEMP1)

5. Was the 1st urine specimen determined to be adulterated?(UDADULT1)

6. 1st Urine Drug Screen Result(s):

(mm/d d/yyyy)

(hh:mm)

No Yes

No Yes

Drug Name (Abbreviation)	Negative	Positive	Invalid
Benzodiazepines (BZO):	(UDBZO1) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Amphetamine (AMP):	(UDAMP1) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Marijuana (THC):	(UDTHC1) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Methamphetamine (MET):	(UDMET1) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Opiates (2000 ng)(OPI):	(UDOPI1) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cocaine (COC):	(UDCOC1) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ecstasy (MDMA):	(UDMDA1) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Oxycodone (OXY):	(UDOXY1) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Methadone (MTD):	(UDMTD1) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Barbiturate (BAR):	(UDBAR1) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Opiates (300ng)(OPI):(UDOP1300)

Buprenorphine (BUP):(UDBUP1)

Negative Positive Invalid

Negative Positive Invalid

2nd Urine Drug Screen

7. If the 1st urine specimen was determined to be adulterated, was a second specimen collected?(UDTEST2)

If "No", reason:(UDNORSN2)

If "Other", specify:(UDNOSP2)

8. Time 2nd urine specimen collected (24 hour format):(UDCOLTM2)

9. Was the 2nd urine temperature within range? (90 - 100 °F)(UDETEMP2)

10. Was the 2nd urine specimen determined to be adulterated?(UDADULT2)

11. 2nd Urine Drug Screen Result(s):

No Yes

1-Participant reported being unable to provide sample
 2-Participant refused to provide sample
 3-Study staff error
 99-Other

(hh:mm)

No Yes

No Yes

Drug Name (Abbreviation)	Negative	Positive	Invalid
Benzodiazepines (BZO):	(UDBZO2) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Amphetamine (AMP):	(UDAMP2) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Marijuana (THC):	(UDTHC2) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Methamphetamine (MET):	(UDMET2) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Opiates (2000 ng) (OPI):	(UDOPI2) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cocaine (COC):	(UDCOC2) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ecstasy (MDMA):	(UDMDA2) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Oxycodone (OXY):	(UDOXY2) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Methadone (MTD):	(UDMTD2) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Barbiturate (BAR):	(UDBAR2) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Opiates (300ng)(OPI):(UDOP2300)

Buprenorphine (BUP):(UDBUP2)

Negative Positive Invalid
 Negative Positive Invalid

Comments:(UDSCOMM)

NIDA Clinical Trials Network

Visual Analog Scale (VAS)

Web Version: 1.0; 2.01; 07-08-14

Segment (PROTSEG):

Visit number (VISNO):

Date of assessment:(VASASMDT)

(mm/dd/yyyy)

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

(xxx)

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

(xxx)

Comments:(VASCOMM)

NIDA Clinical Trials Network

Vital Signs (VIS)

Web Version: 1.0; 3.02; 01-09-15

Segment (PROTSEG):

Visit number (VISNO):

Date of assessment:(VISASMDT)

(mm/dd/yyyy)

Body Mass Index

1. Standing height:(VIHGTIN)

(xx.x) inches (VIHGTCM) (xxx) cm

2. Measured weight:(VIWTLBS)

(xxx.x) lbs (VIWTKGS) (xxx.x) kgs

3. BMI:(VIBMI)

Vital Signs

4. Temperature:(VITEMPF)

(xxx.x) °F or (VITEMPC) (xx.x) °C

5. Heart rate:(VIPULSE)

(xxx) BPM

6. Blood pressure:(VIBPSYS1)

/ (VIBPDIS1) Systolic/Diastolic (mmHg)

Comments:(VISCOMM)

NIDA Clinical Trials Network

Demographics (DEM)

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

1. Date of birth:(DEBRTHDT)

(mm/dd/yyyy)

2. Gender:(DEGENDER)

Male Female Don't know Refused

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

No Yes Don't know Refused

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

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

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

(Check all that apply)

White: (DEWHITE)

Black/ African American: (DEBLACK)

Indian (American): (DEAMEIND)

Alaska native: (DEALASKA)

Native Hawaiian: (DEHAWAII)

Guamanian: (DEGUAM)

Samoa: (DESAMOAN)

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

Asian Indian: (DEASAIND)

Chinese: (DECHINA)

Filipino: (DEFILIPN)

Japanese: (DEJAPAN)

Korean: (DEKOREA)

Vietnamese: (DEVIETNM)

Other Asian: (DEASIAN) Specify:(DEASIAOT)

Some other race: (DERACEOT) Specify:(DERACESP)

-OR-

Don't know:(DERACEDK)

Refused: (DERACERF)

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

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

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

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

If "Other", specify:(DEJOBSP)

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

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

Comments:(DEM COMM)

Additional Selection Options for DEM

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

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

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

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

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

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

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

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

NIDA Clinical Trials Network

0055B (ENR)

Web Version: 1.0; 1.00; 02-14-14

Date of assessment: (R7ASMDT)

(mm/dd/yyyy)

Inclusion Criteria

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

- Participant meets DSM-5 criteria for moderate or severe opioid use disorder and/or alcohol use disorder: (R7DRGDEP) No Yes Unknown
- Participant is willing to be randomized to antagonist-based therapy or TAU for treatment of opioid and/or alcohol use disorders: (R7SEEKTX) No Yes Unknown
- Participant is HIV-infected as defined by history of positive HIV serology or HIV RNA pcr >10,000 copies/mL: (R7HIVPOS) No Yes Unknown
- Participant is willing to establish ongoing HIV care at CTP, if not already receiving ongoing care: (R7HIVTX) No Yes Unknown
- Participant is willing to initiate ART, if not already prescribed ART, regardless of CD4 count: (R7ARTRX) No Yes Unknown
- Participant is at least 18 years old: (R7PTAGE) No Yes
- Participant has provided written informed consent and HIPAA for medical record abstraction: (R7INFORM) No Yes
- Participant is able to communicate in English: (R7ENGLISH) No Yes
- If female, participant is willing to take measures 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".

- Participant has a serious medical, psychiatric, or substance use disorder that, in the opinion of the study physician, would make study participation hazardous to the participant, compromise study findings, or prevent the participant from completing the study.
Examples include:
(a) Disabling or terminal medical illness (e.g., active opportunistic infection, uncompensated heart failure, cirrhosis or end-stage liver disease, acute hepatitis and moderate to severe renal impairment) as assessed by medical history, review of systems, physical exam and/or laboratory assessments;
(b) Severe, untreated, or inadequately treated mental health disorder (e.g., active psychosis, uncontrolled manic-depressive illness) as assessed by history and/or clinical interview;
(c) Current severe benzodiazepine or other depressant or sedative hypnotic use requiring medical detoxification;
(d) Suicidal or homicidal ideation requiring immediate attention. (R7PSYCH) No Yes Unknown
- Participant has aspartate aminotransferase (AST) or alanine aminotransferase (ALT) liver enzymes greater than five times the upper limit of normal on screening phlebotomy: (R7LFTS) No Yes Unknown
- Participant has INR > 1.50 or platelet count < 100,000 mm³: (R7INR) No Yes Unknown
- Participant has a known allergy or sensitivity to naloxone, naltrexone, polylactide-co-glycolide, carboxymethylcellulose, or other components of the Vivitrol[®] diluent: (R7ALERGY) No Yes Unknown
- Participant anticipates undergoing surgery during study participation: (R7SURGRY) No Yes Unknown
- Participant has chronic pain requiring ongoing pain management with opioid analgesics: (R7PAIN) No Yes Unknown
- Participant is pending legal action or other reasons that might prevent an individual from completing the study: (R7LEGAL) No Yes Unknown
- Participant is currently pregnant or breastfeeding: (R7PREGNT) No Yes Unknown Not applicable
- Participant has a 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): (R7HABTUS) No Yes Unknown
- Participant received methadone or buprenorphine maintenance therapy for treatment of opioid dependence in the 4 weeks prior to screening: (R7MTDMNT) No Yes Unknown
- Participant has taken an investigational drug in another study within 30 days of study consent: (R7OTSTDY) No Yes Unknown
- Participant has ECG findings that, in the opinion of the study medical clinician, would preclude safe participation in the study: (R7BLOCK) No Yes Unknown
- Participant has had treatment with XR-NTX for opioid or alcohol dependence in the 3 months prior to screening: (R7XRNTX) No Yes Unknown

Eligibility for Randomization

1. Is the participant eligible for the study?(R7ELGSTY)

No Yes

2. Will the participant be randomized?(R7ELGRDM)

No Yes

If "No", specify:(R7NORSP)

2-Declined study participation
3-Death
4-Judgment of site/research staff
5-Failed to return to clinic prior to randomization
99-Other

If "Judgment of research staff", specify:(R7JGOTSP)

If "Other", specify:(R7OTHRSP)

Comments:(R7COMM)