ARV Medication Log (Abstracted Records) (ARM)

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

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

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

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

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

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

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

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

Comments: *(ARVCOMM)*

Additional Selection Options for ARM

Drug name 01
06-Descovy - TAF + FTC
07-Edurant - RPV
08-Emtriva - FTC
09-Epivir - 3TC
10-Epzicom - ABC + 3TC
11-Evotaz - ATV/c
12-Fuzeon - T20
13-Genovya - TAF + FTC + EVG/c
14-Intelence - ETV
15-Invirase - SQV
16-Isentress - RAL
17-Kaletra - LPV/r
18-Lexiva - FPV
19-Norvir - RTV or r
20-Odefsy - TAF + FTC + RPV
21-Prezcobix - DRV/c
22-Prezista QD - DRV
23-Reyataz - ATV
24-Rescriptor - DLV
25-Retrovir - AZT (or ZDV)
26-Selzentry - MVC
28-Stribild - EVG + COBI + TDF + FTC
29-Sustiva - EFV
30-Tivicay - DTG
31-Triumeq - ABC + 3TC + DTG
32-Trizivir - ABC + 3TC + ZDV (or AZT)
33-Truvada - TDF + FTC
34-Videx - ddl
35-Viracept - NFV
36-Viramune - NVP
37-Viramune XR (QD) - NVP
38-Viread - TDF
39-Vitekta - EVG
40-Zerit - d4T
41-Ziagen - ABC
42-Biktarvy - BIC + TAF + FTC
97-Don't know
99-Other/Experimental/Blinded study - OTHR

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

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

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

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

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

Route of Administration:

1 = Oral   2 = Nasal   3 = Smoking   4 = Non-IV injection   5 = IV injection

*Note the **usual or most recent route.** For more than one route, choose the most severe. The routes are listed from least severe to most severe.*

If "Past 30" day use is zero, "Route of Administration" must be "Not applicable".

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

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

D14 Currently, which substance is the major problem?

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

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

OR

(ADMJDGNA) ☐ (97) Not answered

Comments: *(ADMJDGCM)*

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

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

(ADALCPRB) [＿＿＿＿] *days*

OR

(ADAPRBNA) ☐ (97) Not answered

Comments: *(ADAPRBCM)*

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

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

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

OR

(ADABOTNA) ☐ (97) Not answered

Comments: *(ADABOTCM)*

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

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

OR

(ADAIMPNA) ☐ (97) Not answered

Comments: *(ADAIMPCM)*

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

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

(ADDRGPRB) [＿＿＿＿] *days*

OR

(ADDPRBNA) ☐ (97) Not answered

Comments: *(ADDPRBCM)*

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

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

(ADDRGBOT)

OR

(ADDBOTNA) ☐ (97) Not answered

Comments:*(ADDBOTCM)*

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

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

(ADDRGIMP)

OR

(ADDIMPNA) ☐ (97) Not answered

Comments:*(ADDIMPCM)*

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

D34 Participant's misrepresentation?

(ADMISREP) ☐ (0) No   ☐ (1) Yes

D35 Participant's inability to understand?

(ADUNDRST) ☐ (0) No   ☐ (1) Yes

Comments:*(ASXCOMM)*

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

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

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

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

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

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

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

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

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

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

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

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

Comments: *(CHCCOMM)*

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

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

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

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

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

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

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

Comments:*(CHPCOMM)*

☐

Criminal Justice (CRJ)

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

Date of assessment:*(CRJASMDT)* [＿＿＿＿＿] *(mm/dd/yyyy)*

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

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

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

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

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

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

   If "Yes", specify what happened:*(CRMSRXSP)*

   [＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿]

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

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

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

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

Comments:*(CRJCOMM)*

[＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿＿]

Demographics (DEM)

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

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

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

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

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

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

    American Indian or Alaska Native:*(DEAMEIND)* ☐

    Asian:*(DEASIAN)* ☐

        Asian Indian:*(DEASAIND)* ☐

        Chinese:*(DECHINA)* ☐

        Filipino:*(DEFILIPN)* ☐

        Japanese:*(DEJAPAN)* ☐

        Korean:*(DEKOREA)* ☐

        Vietnamese:*(DEVIETNM)* ☐

        Specify other Asian:*(DEASIAOT)* [_____]

    Black or African American:*(DEBLACK)* ☐

    Native Hawaiian or Pacific Islander:*(DEHAWAII)* ☐

        Native Hawaiian:*(DENATHAW)* ☐

        Guamanian or Chamorro:*(DEGUAM)* ☐

        Samoan:*(DESAMOAN)* ☐

        Specify other Pacific Islander:*(DEPACISO)* [_____]

    White:*(DEWHITE)* ☐

    Some other race:*(DERACEOT)* ☐ Specify:*(DERACESP)* [_____]

    -or-

    Don't know:*(DERACEDK)* ☐

    Refused:*(DERACERF)* ☐

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

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

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

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

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

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

        Married
        Widowed
        Divorced
        Separated
        Never married
        *Additional Options Listed Below

    Comments:*(DEMCOMM)* [_____]

Additional Selection Options for DEM

If "Yes", indicate the group that represents his or her Hispanic origin or ancestry:
Central or South American
Other Latin American
Other Hispanic or Latino
Refused
Don't know

What is the highest grade or level of school the participant has completed or the highest degree they have received?
5th grade
6th grade
7th grade
8th grade
9th grade
10th grade
11th grade
12th grade, no diploma
High school graduate
GED or equivalent
Some college, no degree
Associate's degree: occupational, technical, or vocational program
Associate's degree: academic program
Bachelor's degree (e.g., BA, AB, BS, BBA)
Master's degree (e.g., MA, MS, MEng, MEd, MBA)
Professional school degree (e.g., MD, DDS, DVM, JD)
Doctoral degree (e.g., PhD, EdD)
Refused
Don't know

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

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

DSM-5 Checklist (DSM)

Segment *(PROTSEG)***:** A

Visit number *(VISNO)***:**

Date of assessment:*(DSMASMDT)*

[   ] *(mm/dd/yyyy)*

	Opioids	Alcohol	Amphetamines	Cannabis	Cocaine	Sedatives	Tobacco
1. Have you used [insert substance] in the past 12 months?	*(DSOPI12M)* 0-No 1-Yes	*(DSALC12M)* 0-No 1-Yes	*(DSAMP12M)* 0-No 1-Yes	*(DSTHC12M)* 0-No 1-Yes	*(DSCOC12M)* 0-No 1-Yes	*(DSSED12M)* 0-No 1-Yes	*(DSTOB12M)* 0-No 1-Yes
2. Have you often found that when you started using [insert substance], you ended up taking more than you intended to? For example, you planned to have a small amount of [insert substance], but you ended up having much more; or you ended up using for a longer period than intended?	*(DSOPIDOS)* 0-No 1-Yes	*(DSALCDOS)* 0-No 1-Yes	*(DSAMPDOS)* 0-No 1-Yes	*(DSTHCDOS)* 0-No 1-Yes	*(DSCOCDOS)* 0-No 1-Yes	*(DSSEDDOS)* 0-No 1-Yes	*(DSTOBDOS)* 0-No 1-Yes
3. Have you wanted to stop or cut down or control your use of [insert substance]?	*(DSOPICUT)* 0-No 1-Yes	*(DSALCCUT)* 0-No 1-Yes	*(DSAMPCUT)* 0-No 1-Yes	*(DSTHCCUT)* 0-No 1-Yes	*(DSCOCCUT)* 0-No 1-Yes	*(DSSEDCUT)* 0-No 1-Yes	*(DSTOBCUT)* 0-No 1-Yes
4. Have you spent a lot of time getting or using [insert substance]? Or has it taken a lot of time for you to get over the effect?	*(DSOPITIM)* 0-No 1-Yes	*(DSALCTIM)* 0-No 1-Yes	*(DSAMPTIM)* 0-No 1-Yes	*(DSTHCTIM)* 0-No 1-Yes	*(DSCOCTIM)* 0-No 1-Yes	*(DSSEDTIM)* 0-No 1-Yes	*(DSTOBTIM)* 0-No 1-Yes
5. Have you had a strong desire or urge to use [insert substance] in between those times when you were using? Has there been a time when you had such strong cravings or urges to use that you had trouble thinking about anything else?	*(DSOPICRA)* 0-No 1-Yes	*(DSALCCRA)* 0-No 1-Yes	*(DSAMPCRA)* 0-No 1-Yes	*(DSTHCCRA)* 0-No 1-Yes	*(DSCOCCRA)* 0-No 1-Yes	*(DSSEDCRA)* 0-No 1-Yes	*(DSTOBCRA)* 0-No 1-Yes
6. Have you missed work or school or often arrived late because you were intoxicated, high or recovering from the night before? How about not taking care of things at home because of your use?	*(DSOPIOBL)* 0-No 1-Yes	*(DSALCOBL)* 0-No 1-Yes	*(DSAMPOBL)* 0-No 1-Yes	*(DSTHCOBL)* 0-No 1-Yes	*(DSCOCOBL)* 0-No 1-Yes	*(DSSEDOBL)* 0-No 1-Yes	*(DSTOBOBL)* 0-No 1-Yes
7. Has your use of [insert substance] caused problems with other people such as with family members, friends or people at work? Do you get into arguments about your use or fights when you are using? Did you keep using despite these problems?	*(DSOPICON)* 0-No 1-Yes	*(DSALCCON)* 0-No 1-Yes	*(DSAMPCON)* 0-No 1-Yes	*(DSTHCCON)* 0-No 1-Yes	*(DSCOCCON)* 0-No 1-Yes	*(DSSEDCON)* 0-No 1-Yes	*(DSTOBCON)* 0-No 1-Yes
8. Have you had to give up or spend less time working, enjoying hobbies, or being with others because of your drug use?	*(DSOPIACT)* 0-No 1-Yes	*(DSALCACT)* 0-No 1-Yes	*(DSAMPACT)* 0-No 1-Yes	*(DSTHCACT)* 0-No 1-Yes	*(DSCOCACT)* 0-No 1-Yes	*(DSSEDACT)* 0-No 1-Yes	*(DSTOBACT)* 0-No 1-Yes
9. Have you ever gotten high before doing something that requires coordination or concentration like driving, boating, climbing a ladder, or operating heavy machinery? Would you say your use affected your coordination or concentration so that it was more likely that you or someone else could have been hurt?	*(DSOPIHAZ)* 0-No 1-Yes	*(DSALCHAZ)* 0-No 1-Yes	*(DSAMPHAZ)* 0-No 1-Yes	*(DSTHCHAZ)* 0-No 1-Yes	*(DSCOCHAZ)* 0-No 1-Yes	*(DSSEDHAZ)* 0-No 1-Yes	*(DSTOBHAZ)* 0-No 1-Yes
10. Have you continued to use even though you knew that the drug caused you problems like making you depressed, anxious, agitated or irritable? Has your use ever caused physical problems like heart palpitations, trouble breathing or constipation?	*(DSOPISOC)* 0-No 1-Yes	*(DSALCSOC)* 0-No 1-Yes	*(DSAMPSOC)* 0-No 1-Yes	*(DSTHCSOC)* 0-No 1-Yes	*(DSCOCSOC)* 0-No 1-Yes	*(DSSEDSOC)* 0-No 1-Yes	*(DSTOBSOC)* 0-No 1-Yes
11. Do you have a prescription for [insert substance]?			*(DSAMPRX)* 0-No 1-Yes			*(DSSEDRX)* 0-No 1-Yes	
12. Have you found you needed to use much more [insert substance] to get the same effect that you did when you first started taking it?	*(DSOPITOL)* 0-No 1-Yes	*(DSALCTOL)* 0-No 1-Yes	*(DSAMPTOL)* 0-No 1-Yes	*(DSTHCTOL)* 0-No 1-Yes	*(DSCOCTOL)* 0-No 1-Yes	*(DSSEDTOL)* 0-No 1-Yes	*(DSTOBTOL)* 0-No 1-Yes
13. Have you had withdrawal symptoms or felt sick when you cut down or stopped using (aches, shaking, fever, weakness, diarrhea, nausea, sweating, heart pounding, difficulty sleeping, or feel agitated, anxious, irritable, or depressed)? Did you use again to keep yourself from getting sick?	*(DSOPIWIT)* 0-No 1-Yes	*(DSALCWIT)* 0-No 1-Yes	*(DSAMPWIT)* 0-No 1-Yes	*(DSTHCWIT)* 0-No 1-Yes	*(DSCOCWIT)* 0-No 1-Yes	*(DSSEDWIT)* 0-No 1-Yes	*(DSTOBWIT)* 0-No 1-Yes
	Opioids	Alcohol	Amphetamines	Cannabis	Cocaine	Sedatives	Tobacco
Severity of Substance Use Disorder:	*(DSOPISCO)* 1-Severe 2-Moderate 3-Mild 4-None	*(DSALCSCO)* 1-Severe 2-Moderate 3-Mild 4-None	*(DSAMPSCO)* 1-Severe 2-Moderate 3-Mild 4-None	*(DSTHCSCO)* 1-Severe 2-Moderate 3-Mild 4-None	*(DSCOCSCO)* 1-Severe 2-Moderate 3-Mild 4-None	*(DSSEDSCO)* 1-Severe 2-Moderate 3-Mild 4-None	*(DSTOBSCO)* 1-Severe 2-Moderate 3-Mild 4-None

Comments:*(DSMCOMM)*

[   ]

EQ-5D-3L (EQD)

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

Health Questionnaire

English version for the USA

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

Mobility
(EQ5MBTLY)

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

Self-Care
(EQ5SLFCR)

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

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

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

Pain / Discomfort
(EQ5PAIND)

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

Anxiety / Depression
(EQ5ANXDE)

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

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

(xxx)

The best health
you can imagine
The worst health
you can imagine

YOUR
HEALTH
TODAY *(EQ5HLTTD)*

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

Yes

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NIDA Clinical Trials Network

0067A (ENR)

Date informed consent signed:*(STARTDT)* ☐ *(mm/dd/yyyy)*

Comments:*(S7COMM)* ☐

Main Study Consent
    Original main consent
      IRB approval date of ICF:*(S7IRBDT)* ☐ *(mm/dd/yyyy)*

    Main study re-consent
      IRB approval date of ICF:*(S7IRB2DT)* ☐ *(mm/dd/yyyy)*
      Date informed consent signed:*(S7CST2DT)* ☐ *(mm/dd/yyyy)*

    Main study re-consent
      IRB approval date of ICF:*(S7IRB3DT)* ☐ *(mm/dd/yyyy)*
      Date informed consent signed:*(S7CST3DT)* ☐ *(mm/dd/yyyy)*

    Main study re-consent
      IRB approval date of ICF:*(S7IRB4DT)* ☐ *(mm/dd/yyyy)*
      Date informed consent signed:*(S7CST4DT)* ☐ *(mm/dd/yyyy)*

Other Consents
    Other consent 1
      Type of consent:*(S7CST5TY)*
        3-HIPAA
        4-Medical Release
        99-Other

      If "Other", specify:*(S7CST5SP)* ☐
      IRB approval date of ICF:*(S7IRB5DT)* ☐ *(mm/dd/yyyy)*
      Date informed consent signed:*(S7CST5DT)* ☐ *(mm/dd/yyyy)*

    Other 1 re-consent
      IRB approval date of ICF:*(S7IRB6DT)* ☐ *(mm/dd/yyyy)*
      Date informed consent signed:*(S7CST6DT)* ☐ *(mm/dd/yyyy)*

    Other consent 2
      Type of consent:*(S7CST7TY)*
        3-HIPAA
        4-Medical Release
        99-Other

      If "Other", specify:*(S7CST7SP)* ☐
      IRB approval date of ICF:*(S7IRB7DT)* ☐ *(mm/dd/yyyy)*
      Date informed consent signed:*(S7CST7DT)* ☐ *(mm/dd/yyyy)*

    Other 2 re-consent
      IRB approval date of ICF:*(S7IRB8DT)* ☐ *(mm/dd/yyyy)*
      Date informed consent signed:*(S7CST8DT)* ☐ *(mm/dd/yyyy)*

Fatal Opioid Overdose (FOO)

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

1. Date of suspected or confirmed opioid overdose:*(FOODDT)* *(mm/dd/yyyy)*

2. Date site became aware of fatal overdose:*(FOAWARDT)* *(mm/dd/yyyy)*

3. Source of information:*(FOSOURCE)*

Medical record
Locator form inquiry
Other

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

Comments:*(FOOCOMM)*

HIV Care Utilization (Abstracted Records) (HCU)

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

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

This form collects abstracted medical record data only.

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

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

Comments:*(HCUCOMM)*

Clinical Laboratory Tests (LAB)

Date of lab collection: | MM/DD/YYYY

1 HIV-1 RNA PCR:

xxxxxxxx

copies/mL **- or -** ☐ Undetectable

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

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

If "Yes":

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

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

Comments:
(LABCOMM)

Medication Adherence (MAD)

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

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

HIV Antiretroviral Medications

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

1. Are you currently prescribed any anti-HIV medications?*(MAART)*   No   Yes

2. Thinking about the **past 4 weeks**, on average, how would you rate your ability to take all of your HIV antiretroviral medications as your doctor prescribed?*(MATKART)*

   | Very poor |
   | Poor |
   | Fair |
   | Good |
   | Very good |
   | Excellent |

3. Think about your HIV medications over the **past month**. Click on the line below or click and drag the blue circle to the spot that most closely reflects the percentage of HIV medications that have been taken in the **past month**.*(MAARTPRC)*   *(xxx)*

4. How many doses of your medications did you miss in the **past 7 days**?*(MAMISART)*

   | 0 |
   | 1 |
   | 2 |
   | 3 |
   | 4 |
   | More than 4 |

5. When was the last time you missed any of your anti-HIV medications?*(MALSTART)*

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

Opioid Use Disorder Medications

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

6. Are you currently receiving methadone treatment?*(MAMTD)*   No   Yes

   What is your current daily methadone dose?*(MAMTDDOS)*   *(xxx)* mg

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

   | Very poor |
   | Poor |
   | Fair |
   | Good |
   | Very good |
   | Excellent |

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

9. How many doses of your methadone did you miss in the **past 7 days**?*(MAMISMTD)*

   | 0 |
   | 1 |
   | 2 |
   | 3 |
   | 4 |
   | More than 4 |

10. How many days in the **past 28 days** did you take at least 1 dose of methadone?*(MATAKMTD)*   *(xx)* days

11. When was the last time you missed any of your methadone doses?*(MALSTMTD)*

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

12. Are you currently prescribed buprenorphine?*(MABUP)*   No   Yes

    What is your current daily buprenorphine dose?*(MABUPDOS)*   *(xx.x)* mg

/

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

| Very poor ▲ |
| Poor |
| Fair |
| Good |
| Very good |
| Excellent |
| ▼ |

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

(xxx)

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

| 0 ▲ |
| 1 |
| 2 |
| 3 |
| 4 |
| More than 4 |
| ▼ |

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

(xx) days

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

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

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

No   Yes

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

Yes

Comments: *(MADCOMM)*

NIDA Clinical Trials Network

Concomitant Medications (MED)

Segment *(PROTSEG)*: A
Drug start date *(MEDSTRDT)*:
Sequence of medication *(MEDSEQ)*:

This form should capture prescribed medications you are currently taking. By current we mean you have an active prescription.
The following prescriptions should <u>not</u> be reported in this form:

- *Antiretroviral (also called "ART") medicine for HIV treatment*
- *Medications used for the treatment of opioid use disorder*

1. Name of medication: *(MDNAME)*

2. Start date of medication: *(MDSTRTDT)*
   ☐ 1-Estimated   ☐ 2-Actual

3. Indication: *(MDIND)*

A99-GASTROINTESTINAL
01A---Acid related
02A---Antiemetics
03A---Constipation
04A---Antidiarrheal
*Additional Options Listed Below

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

4. Dose: *(MDDOSE)*   *(xxxxxx.xxx)*

5. Dose units: *(MDUNITS)*

01-Applications
02-Tablets
03-Capsules
04-Drops
05-Metered puffs
*Additional Options Listed Below

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

6. Route: *(MDROUTE)*

01-Oral
06-Intravenous
07-Subcutaneous
08-Intramuscular
09-Sublingual
*Additional Options Listed Below

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

7. Frequency: *(MDFREQ)*

01-QD - Once daily
02-BID - Twice daily
03-TID - Three times a day
04-QID - Four times a day
05-PRN - As needed
*Additional Options Listed Below

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

Comments: *(MEDCOMM)*

Additional Selection Options for MED

Sequence of medication *(MEDSEQ)* **(key field):**
01-1st medication
02-2nd medication
03-3rd medication
04-4th medication
05-5th medication
06-6th medication
07-7th medication
08-8th medication
09-9th medication
10-10th medication
11-11th medication
12-12th medication
13-13th medication
14-14th medication
15-15th medication
16-16th medication
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18-18th medication
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31-31st medication
32-32nd medication
33-33rd medication
34-34th medication
35-35th medication
36-36th medication
37-37th medication
38-38th medication
39-39th medication
40-40th medication
41-41st medication
42-42nd medication
43-43rd medication
44-44th medication
45-45th medication
46-46th medication
47-47th medication
48-48th medication
49-49th medication
50-50th medication

Indication:
05A---Diabetes
06A---Vitamins
07A---Mineral
99A---Other gastrointestinal
B99-BLOOD AND BLOOD FORMING ORGANS
01B---Aspirin/coumadin/heparin
02B---Antianemic
03B---Blood products/IV fluids
99B---Other blood and blood forming organs
C99-CARDIOVASCULAR SYSTEM
01C---Antihypertensives
02C---Diuretics
03C---Beta blocking
04C---Calcium Channel
05C---Lipid modifying agents
99C---Other cardiovascular system
D99-ALL SKIN CREAMS
01D---All skin creams
G99-CONTRACEPTIVES/ED/SEX HORMONES
01G---Contraceptives/ED/Sex hormones
H99-STEROIDS/THYROID HORMONES
01H---Steroids/Thyroid hormones
J99-ANTIBACTERIAL/ANTIVIRAL/ANTIFUNGAL/TB/VACCINES
01J---Antibacterial/Antiviral/Antifungal/TB/Vaccines
M99-MUSCULOSKELETAL SYSTEM
01M---Antiinflammatory and antirheumatic
02M---Muscle relaxants
03M---Antigout
99M---Other musculoskeletal system
N99-NERVOUS SYSTEM
01N---Analgesics including antipyretics
02N---Antiepileptics
03N---Anxiety/Depression/Sleep
99N---Other nervous system
R99-RESPIRATORY SYSTEM
01R---Nasal
02R---Throat
03R---Obstructive airway
04R---Cough and cold
05R---Antihistamines
99R---Other respiratory system
S99-EYE AND EAR DROPS
01S---Eye and ear drops
Z01-VARIOUS
01V---Allergens
02V---All other therapeutic products
03V---Diagnostic agents
04V---General nutrients
05V---All other non-therapeutic products

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Medical and Psychiatric History (MHX)

Web Version: 1.0; 6.00; 02-20-19

Segment *(PROTSEG):* A

Visit number *(VISNO):*

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

Medical and Psychiatric History

Medical Condition	History of the Condition	If "Yes", specify:	Condition Present Currently
1. Eye disorders:	*(MHEYEH)* ☐ 0-No ☐ 1-Yes	*(MHEYESP)*	*(MHEYEC)* ☐ 0-No ☐ 1-Yes
2. Ear disorders:	*(MHEARH)* ☐ 0-No ☐ 1-Yes	*(MHEARSP)*	*(MHEARC)* ☐ 0-No ☐ 1-Yes
3. Respiratory and throat disorders:	*(MHRESPH)* ☐ 0-No ☐ 1-Yes	*(MHRESPSP)*	*(MHRESPC)* ☐ 0-No ☐ 1-Yes
4. Cardiovascular disorders:	*(MHCARDH)* ☐ 0-No ☐ 1-Yes	*(MHCARDSP)*	*(MHCARDC)* ☐ 0-No ☐ 1-Yes
5. Liver and gallbladder disorders:	*(MHLIVRH)* ☐ 0-No ☐ 1-Yes	*(MHLIVRSP)*	*(MHLIVRC)* ☐ 0-No ☐ 1-Yes
6. Other gastrointestinal disorders:	*(MHGIH)* ☐ 0-No ☐ 1-Yes	*(MHGISP)*	*(MHGIC)* ☐ 0-No ☐ 1-Yes
7. Skin disorders:	*(MHSKINH)* ☐ 0-No ☐ 1-Yes	*(MHSKINSP)*	*(MHSKINC)* ☐ 0-No ☐ 1-Yes
8. Musculoskeletal disorders:	*(MHMUSCH)* ☐ 0-No ☐ 1-Yes	*(MHMUSCSP)*	*(MHMUSCC)* ☐ 0-No ☐ 1-Yes

9. Metabolic disorders:	*(MHMETAH)* ☐ 0-No ☐ 1-Yes	*(MHMETASP)*	*(MHMETAC)* ☐ 0-No ☐ 1-Yes
10. Endocrine disorders:	*(MHENDOH)* ☐ 0-No ☐ 1-Yes	*(MHENDOSP)*	*(MHENDOC)* ☐ 0-No ☐ 1-Yes
11. Renal and urinary tract disorders:	*(MHRENLH)* ☐ 0-No ☐ 1-Yes	*(MHRENLSP)*	*(MHRENLC)* ☐ 0-No ☐ 1-Yes
12. Reproductive system and breast disorders:	*(MHREPOH)* ☐ 0-No ☐ 1-Yes	*(MHREPOSP)*	*(MHREPOC)* ☐ 0-No ☐ 1-Yes
13. Epilepsy or seizure disorder:	*(MHELPYH)* ☐ 0-No ☐ 1-Yes	*(MHELPYSP)*	*(MHELPYC)* ☐ 0-No ☐ 1-Yes
14. Clinically significant neurological damage:	*(MHNEURH)* ☐ 0-No ☐ 1-Yes	*(MHNEURSP)*	*(MHNEURC)* ☐ 0-No ☐ 1-Yes
15. Other nervous system disorders:	*(MHNERVH)* ☐ 0-No ☐ 1-Yes	*(MHNERVSP)*	*(MHNERVC)* ☐ 0-No ☐ 1-Yes

Psychiatric Condition	**History of the Condition**	**If "Yes", specify:**	**Condition Present Currently**
16. Anxiety or panic disorder:	*(MHANXH)* ☐ 0-No ☐ 1-Yes	*(MHANXSP)*	*(MHANXC)* ☐ 0-No ☐ 1-Yes
17. Attention Deficit Hyperactivity Disorder:	*(MHADHDH)* ☐ 0-No ☐ 1-Yes	*(MHADHDSP)*	*(MHADHDC)* ☐ 0-No ☐ 1-Yes
18. Bipolar Disorder:	*(MHBPLRH)* ☐ 0-No ☐ 1-Yes	*(MHBPLRSP)*	*(MHBPLRC)* ☐ 0-No ☐ 1-Yes
19. Eating Disorder:	*(MHEATH)* ☐ 0-No ☐ 1-Yes	*(MHEATSP)*	*(MHEATC)* ☐ 0-No ☐ 1-Yes
20. Major Depressive Disorder:	*(MHMDDH)* ☐ 0-No ☐ 1-Yes	*(MHMDDSP)*	*(MHMDDC)* ☐ 0-No ☐ 1-Yes
21. Schizophrenia:	*(MHSCHZH)* ☐ 0-No ☐ 1-Yes	*(MHSCHZSP)*	*(MHSCHZC)* ☐ 0-No ☐ 1-Yes
22. Suicidal ideation:	*(MHSIDH)* ☐ 0-No ☐	*(MHSIDSP)*	*(MHSIDC)* ☐ 0-No

	1-Yes		☐ 1-Yes
23. Suicidal behavior:	(MHSBEHH) ☐ 0-No ☐ 1-Yes	(MHSBEHSP)	(MHSBEHC) ☐ 0-No ☐ 1-Yes
24. Homicidal ideation:	(MHHIDH) ☐ 0-No ☐ 1-Yes	(MHHIDSP)	(MHHIDC) ☐ 0-No ☐ 1-Yes
25. Homicidal behavior:	(MHHBEHH) ☐ 0-No ☐ 1-Yes	(MHHBEHSP)	(MHHBEHC) ☐ 0-No ☐ 1-Yes
26. Violent behavior:	(MHVBEHH) ☐ 0-No ☐ 1-Yes	(MHVBEHSP)	(MHVBEHC) ☐ 0-No ☐ 1-Yes
27. Psychotic episodes not specified above:	(MHPSYEH) ☐ 0-No ☐ 1-Yes	(MHPSYESP)	(MHPSYEC) ☐ 0-No ☐ 1-Yes
28. Other psychiatric disorder:	(MHPSYOH) ☐ 0-No ☐ 1-Yes	(MHPSYOSP)	(MHPSYOC) ☐ 0-No ☐ 1-Yes

Other Conditions Not Listed Above	Specific Details	Condition Present Currently
29. (MHOTHR1)	(MHOTH1SP)	(MHOTHR1C) ☐ 0-No ☐ 1-Yes
30. (MHOTHR2)	(MHOTH2SP)	(MHOTHR2C) ☐ 0-No ☐ 1-Yes
31. (MHOTHR3)	(MHOTH3SP)	(MHOTHR3C) ☐ 0-No ☐ 1-Yes

☐

HIV History

32. When did you first learn that you were HIV positive?*(MHHIVDT)*

_____ *(mm/dd/yyyy)* *(MHHIVDKR)* ☐ 97-Don't know ☐
98-Refused to answer

33. When did you begin receiving care for HIV at this clinic? *(MHHIVCRE)* ☐ 1-Less than 3 months ago   ☐ 2-3 or more months ago

34. Have you ever been diagnosed with an opportunistic infection? *(MHHIVINF)* ☐ 0-No   ☐ 1-Yes

35. How do you think that you got HIV?

    a. Same sex sexual contact: *(MHHIVHOM)* ☐ 0-No   ☐ 1-Yes

    b. Heterosexual sexual contact: *(MHHIVHTR)* ☐ 0-No   ☐ 1-Yes

    c. Injection drug use: *(MHHIVIDU)* ☐ 0-No   ☐ 1-Yes

    d. Blood transfusion, blood components, or tissue: *(MHHIVBLD)* ☐ 0-No   ☐ 1-Yes

    e. Mother-to-child transmission: *(MHHIVMTR)* ☐ 0-No   ☐ 1-Yes

    f. Other: *(MHHIVOTH)* ☐ 0-No   ☐ 1-Yes   Specify: *(MHHIVOSP)*

        -OR-

        Don't know: *(MHHIVDK)* ☐ 1-Yes

        Refused *(MHHIVRF)* ☐ 1-Yes

Specific Study Eligibility Criteria

36. Does the participant have suicidal or homicidal ideation that requires immediate attention? *(MHCIDE)* ☐ 0-No   ☐ 1-Yes

37. Does the participant have a known allergy or sensitivity to naloxone, naltrexone, polyactide-co-glycolide, carboxymethylcellulose or any other component of the Vivitrol® diluents? *(MHALGDRG)* ☐ 0-No   ☐ 1-Yes

38. Does the participant have chronic pain requiring ongoing pain management with opioid analgesics during the study period? *(MHOPIMED)* ☐ 0-No   ☐ 1-Yes

39. Does the participant have a surgery planned or scheduled during the study period? *(MHSRGSCH)* ☐ 0-No   ☐ 1-Yes

Comments: *(MHXCOMM)*

06V---Contrast media
07V---Diagnostic radiopharmaceuticals
08V---Therapeutic radiopharmaceuticals
99-OTHER

Dose units:
06-Grams
07-µg
08-mg
09-mL
10-Units
11-IU
12-mEq
13-Ounces
14-Teaspoons
15-Spray
97-Unknown
99-Other

Route:
10-Topical
11-Transdermal
12-Inhalation
02-Intranasal
13-Intravitreal
14-Subtenon
15-Subconjunctival
16-Per vaginum
17-Per rectum
99-Other

Frequency:
06-QHS - Every night at bedtime
07-QAM - Every day before noon
08-Single dose
09-QOD - Every other day
10-QWK - Once a week
11-QMO - Once a month
99-Other

NIDA Clinical Trials Network

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

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

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

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

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

1. Have you ever had an opioid overdose?*(NFOPIOD)*　　　　　0-No　　　1-Yes

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

Comments:*(NFOCOMM)*

Pain Assessment (PAA)

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

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

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

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

  ^2Did it work to relieve the pain:

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

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

Comments:*(PAACOMM)*

Pregnancy and Birth Control Assessment (PBC)

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

Complete this form only for females.

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

1. Is the participant continuing to use an effective method of birth control?*(PBUSEBC)*   No   Yes

2. Date of the first day of the participant's last menstrual period:*(PBMNTDT)*   *(mm/dd/yyyy)*

3. Was a pregnancy test performed?*(PBPRGTST)*   No   Yes

    a. Date of pregnancy test:*(PBPTSTDT)*   *(mm/dd/yyyy)*

    b. Result of pregnancy test:*(PBRESULT)*   Negative   Positive

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

Comments:*(PBCCOMM)*

/

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Physical Examination (PEX)

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

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

Comments

1. General appearance:

   1-Normal
   2-Abnormal, not clinically significant
   3-Abnormal, clinically significant
   97-Not assessed
   (PEGASP)
   (PEGENAPP)

2. Skin, hair, and nails:

   1-Normal
   2-Abnormal, not clinically significant
   3-Abnormal, clinically significant
   97-Not assessed
   (PESHNSP)
   (PESKHRNA)

3. Head and neck:

   1-Normal
   2-Abnormal, not clinically significant
   3-Abnormal, clinically significant
   97-Not assessed
   (PEHDNKSP)
   (PEHDNK)

4. Ears, eyes, nose, and throat:

   1-Normal
   2-Abnormal, not clinically significant
   3-Abnormal, clinically significant
   97-Not assessed
   (PEENTSP)
   (PEEENT)

5. Cardiovascular:

   1-Normal
   2-Abnormal, not clinically significant
   3-Abnormal, clinically significant
   97-Not assessed
   (PECARDSP)
   (PECARD)

6. Respiratory:

   1-Normal
   2-Abnormal, not clinically significant
   3-Abnormal, clinically significant
   97-Not assessed
   (PERESPSP)
   (PERESP)

7. Gastrointestinal:

   1-Normal
   2-Abnormal, not clinically significant
   3-Abnormal, clinically significant
   97-Not assessed
   (PEGASTSP)
   (PEGAST)

8. Extremities:

   1-Normal
   2-Abnormal, not clinically significant
   3-Abnormal, clinically significant
   97-Not assessed
   (PEEXTRSP)
   (PEEXTR)

9. Lymph nodes:

   1-Normal
   2-Abnormal, not clinically significant
   3-Abnormal, clinically significant
   97-Not assessed
   (PELYMPSP)
   (PELYMP)

10. Musculoskeletal:

    1-Normal
    2-Abnormal, not clinically significant
    3-Abnormal, clinically significant
    97-Not assessed
    (PEMUSCSP)
    (PEMUSC)

11. Neurological:

    1-Normal
    2-Abnormal, not clinically significant
    3-Abnormal, clinically significant
    97-Not assessed
    (PENEURSP)
    (PENEUR)

12. Gluteal injection site:

```
1-Normal
2-Abnormal, not clinically significant
3-Abnormal, clinically significant          (PEINJSSP)
97-Not assessed
```
(PEINJSIT)

13. Other: *(specify in comments)*

```
1-Normal
2-Abnormal, not clinically significant
3-Abnormal, clinically significant          (PEOTHESP)
97-Not assessed
```
(PEOTHER)

14. Does participant have a body habitus that precludes gluteal intramuscular injection of XR-NTX in accordance with the administration equipment (needle) and procedures?*(PEBDYHBT)*   0-No   1-Yes   97-Not assessed

Comments:*(PEXCOMM)*

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

Patient Health Questionnaire (PHQ-9) (PHQ)

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

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

Please answer the following to the best of your ability.

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

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

Comments: *(PHQCOMM)*

NIDA Clinical Trials Network

Participant Treatment Preference (PTP)

Web Version: 1.0; 1.00; 05-25-18

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

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

1. What best describes your preference for medication-based treatment:*(PTPREFSC)*   *(xx)*

   Click on the line below or click and drag the circle to the spot that indicates your preference for medication-based treatment. You can leave your circle anywhere on the line.

Participant required research staff assistance in reading the questions in this assessment: 1-Yes
*Note: this includes if participant could not see well enough to read the questions or if the
participant was unable to read well enough to read the questions.(PTHELP)*
Comments:*(PTPCOMM)*

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Quality of Life (QLP)

Web Version: 1.0; 3.00; 02-23-18

Segment *(PROTSEG)*: A
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?*(QLPHYNGD)*   *(xx)* 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)* 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)* days

Participant required research staff assistance in reading the questions in this assessment:
Note: this includes if participant could not see well enough to read the questions or if the participant was unable to read well enough to read the questions.(QLHELP)   1-Yes

Comments:*(QLPCOMM)*

Risk Assessment Battery (RAB)

Segment *(PROTSEG)*: B

Visit number *(VISNO)*:

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

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

A. Needle Use

1. In the past month, have you injected drugs? *(RADRGINJ)*   No   Yes

2. In the past month, have you shared needles or works? *(RASHNDLE)*   No or I have not shot up in the past month   Yes

3. With how many different people did you share needles in the past month? *(RANDLWNO)*

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

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

   Never or I have not shot up or shared in the past month
   A few times (1 or 2 times)
   About once a week (3 or 4 times)
   More than once a week (5 or more times)

5. In the past month, how often have others used after you (with or without cleaning)? *(RANDLEOT)*

   Never or I have not shot up or shared in the past month
   A few times (1 or 2 times)
   About once a week (3 or 4 times)
   More than once a week (5 or more times)

6. In the past month, how often have you shared needles with someone you knew (or later found out) was negative for HIV, the AIDS virus? *(RAAIDSND)*

   Never or I have not shot up or shared in the past month
   A few times (1 or 2 times)
   About once a week (3 or 4 times)
   More than once a week (5 or more times)

7. In the past month, did you get your needles from any of the following:

   a. I have not shot up in the past month   *(RANDLNOT)*   No   Yes

   b. From a diabetic   *(RANDLDBT)*   No   Yes

   c. On the street   *(RANDLSRT)*   No   Yes

   d. Drugstore   *(RANDLDST)*   No   Yes

   e. Shooting gallery or other place where users go to shoot up   *(RANDLSGY)*   No   Yes

   f. Needle Exchange Program   *(RANDLEXC)*   No   Yes

   g. Other, specify: *(RANDLOSP)*   *(RANDLOTH)*   No   Yes

8. In the past month, how often have you been to a shooting gallery/house or other place where users go to shoot up? *(RASHTGLY)*

   Never
   A few times (1 or 2 times)
   About once a week (3 or 4 times)
   More than once a week (5 or more times)

9. In the past month, how often have you been to a Crack House or other place where people go to smoke crack? *(RACRCKHS)*

   Never
   A few times (1 or 2 times)
   About once a week (3 or 4 times)
   More than once a week (5 or more times)

10. Which statement best describes the way you cleaned your needles during the past month? *(RANDLCLN)*

    I have not shot up in the past month
    I ALWAYS use new needles
    I ALWAYS clean my needle just BEFORE I shoot up
    After I shoot up, I ALWAYS clean my needle
    SOMETIMES I clean my needle, sometimes I don't
    I NEVER clean my needle

11. If you cleaned your needles and works in the past month, how did you clean them?

    a. I have not shot up in the past month   /

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

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

B. Sexual Practices

16. How would you describe yourself?(RASEXPRF)

Straight or heterosexual   Gay or homosexual   Bisexual

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

17. With how many men have you had sex in the past month?(RASEXMEN)

```
0
1
2 or 3
4 or more
```
men/man

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

```
0
1
2 or 3
4 or more
```
women/woman

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

24. In the past month, how often did you use condoms when you had sex?
This also includes female condoms and dental dams.(RASEXSFE)

```
I have not had sex in the past month
All the time
Most of the time
Some of the time
None of the time
```

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

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

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

Comments:(RABCOMM)

Suicidal Risk (SUR)

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

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

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

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

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

NIDA Clinical Trials Network

Timeline Followback (T67)

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

TFB week start date *(TFWKSTDT)*:

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

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

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

Comments:(TFBCOMM)

Additional Selection Options for T67

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

file:///C:/Users/zhubbard/AppData/Local/Chrome/Downloads/0067_A___field_names__20190917_1554270442_1568750067442_973093_60990.cmb.htm

4/5

TLFB Assessment Period (TAP)

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

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

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

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

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

Comments:*(TAPCOMM)*

Translated Form Documentation (TFD)

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

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

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

1. Was the translated informed consent used for this participant? *(TFICF)*   No   Yes

2. Was the translated re-consent used for this participant? *(TFRECONS)*   No   Yes   N/A

3. Did the participant use the translated ePRO system or paper ePRO forms at this visit? *(TFEPRO)*   No   Yes

4. Were the translated paper eClinical CRFs used for this participant at this visit? *(TFPAPER)*   No   Yes

Comments: *(TFDCOMM)*

Tobacco Use History (TUH)

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

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

1. Have you smoked at least 100 cigarettes in your entire life?*(TUSMK100)*   No   Yes   Don't know/refused

2. Do you now smoke cigarettes every day, some days, or not at all?*(TUSMFREQ)*

| Every day |
| Some days |
| Not at all |
| Don't know/refused |

3. Have you EVER smoked cigarettes EVERY DAY for at least 6 months?*(TUEVERY)*   No   Yes   Don't know/refused

4. How old were you when you first started smoking cigarettes FAIRLY REGULARLY?*(TUSTRTRG)*   *(xx)* years old *(TUSTRGDR)*   Don't know/refused

Section A: Every-Day Smokers

5. On the average, about how many cigarettes do you now smoke each day?*(TUNUMDY)*   *(xx)* cigarettes per day *(TUNMDYDR)*   Don't know/refused

6. How old were you when you first started smoking cigarettes every day?*(TUSTRTAG)*   *(xx)* years old *(TUSTAGDR)*   Don't know/refused

Section B: Some-Day Smokers

7. On how many of the past 30 days did you smoke cigarettes?*(TU30DAYS)*   *(xx)* days *(TU30DDR)*   Don't know/refused

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

Section C: Former Smokers

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

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

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

/

Treatment Services Review (TXR)

Date of assessment:*(TXRASMDT)*	*(mm/dd/yyyy)*
Beginning of assessment period:*(TXBEGDT)*	*(mm/dd/yyyy)*
End of assessment period:*(TXENDDT)*	*(mm/dd/yyyy)*
Number of days in the assessment period:*(TXDAYSPD)*	*(xxx)*

A. HOUSING SERVICES:

1.   **Number of Days**
(xx)

2. Where did you stay since the last assessment?

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

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

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

     Specify:

       (i) Hospital/residential treatment: *(TXRESHSP)*

       (ii) Jail or prison: *(TXRESPRN)*

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

     Specify:

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

       (ii) For psychological or emotional problems: *(TXRESPSY)*

       (iii) For medical problems: *(TXRESMED)*

       (iv) For criminal behavior or legal problems: *(TXRESLGL)*

       (v) For domestic violence: *(TXRESDMV)*

    e. Homeless shelter: *(TXRESHSH)*

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

B. ALCOHOL AND DRUG SERVICES:

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

           NUMBER
(xx)

3. How many nights did you stay at an inpatient/residential drug/alcohol treatment unit?   *(TXINDRGI)*

4. How many of those nights were detoxification only?   *(TXINDTXI)*

5. How many 12-Step/self-help group meeting for substance use (e.g., AA, NA, CA) did you attend?   *(TXIN12SI)*

6. How many meetings did you have with your sponsor/mentor during which your substance problem was the main purpose of the discussion?   *(TXINMTRI)*

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

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

           NUMBER
(xx)

8. How many days did you attend any outpatient treatment for substance use problems, excluding any 12-Step or self help group meetings?   *(TXOPDRGI)*

9. How many of these were at a day hospital or intensive outpatient program (i.e., several days per week, for several hours each day)?   *(TXOPHSP)*

10. How many individual (one-on-one) sessions did you attend during which substance use was the main purpose of the discussion?   *(TXOPIDVI)*

11. How many 12-Step/self-help group meeting for substance use (e.g., AA, NA, CA) did you attend?   *(TXOP12SI)*

12. How many meetings did you have with your sponsor/mentor during which   /

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

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

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

NUMBER
(xx)

14. How many times were you tested for alcohol and/or drug use?

    a. Urinalysis: *(TXTSTURI)*

    b. Breathalyzer: *(TXTSTBRI)*

    c. Any other test for alcohol/drug use (e.g., blood, saliva, hair): *(TXTSTOT)*

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

C. MEDICAL SERVICES:

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

NUMBER
(xx)

15. How many nights were you an inpatient in a medical hospital, nursing home, or *(TXINPTI)*
medical rehabilitation facility?

    Specify the number of nights in each facility:

      (i) Medical hospital: *(TXINHSP)*

      (ii) Nursing home or medical rehabilitation facility: *(TXINRHBI)*

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

NUMBER
(xx)

16. How many times did you visit an emergency room? *(TXEDI)*

    Indicate reason for emergency room visit:

      (i) Medical: *(TXEDMEDI)*

      (ii) Psychological: *(TXEDPSYI)*

      (iii) Substance use: *(TXEDSBSI)*

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

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

Comments: *(TXRCOMM)*

/

Urine Drug Screen (UDS)

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

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

| | No | Yes |

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

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

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

1st Urine Drug Screen

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

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

2nd Urine Drug Screen

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

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

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

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

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

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

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

Cocaine (COC):   (UDCOC2)

Ecstasy (MDMA):   (UDMDA2)

Oxycodone (OXY):   (UDOXY2)

Methadone (MTD):   (UDMTD2)

Barbiturate (BAR):   (UDBAR2)

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

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

Fentanyl (FEN):   (UDFEN2)

EtG: (UDETG2)

Comments:(UDSCOMM)

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

Cocaine (COC):   (UDCOC2)

Ecstasy (MDMA):   (UDMDA2)

Oxycodone (OXY):   (UDOXY2)

Methadone (MTD):   (UDMTD2)

Visual Analog Craving Scale (VAS)

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

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

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

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

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

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

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

Vital Signs (VIT)

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

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

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

Comments:*(VITCOMM)*