NIDA Clinical Trials Network

Adverse Events (AD1)

Web Version: 1.0; 5.00; 07-26-12

Adverse Event Onset Date *(AEDATE)*:
Select Sequence Number *(AESEQNUM)*:

Record only the adverse events associated with events directly related to the collection of blood samples.

1. Adverse event name:*(A1DESCRI)*

2. Date site became aware of the event:*(A1AWARDT)* *(mm/dd/yyyy)* Click here to view calendar

3. Severity of event:*(A1SEVR2)*

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

4. Is there a reasonable possibility that the intervention caused the event?*(A1RELTIN)* ☐ No ☐ Yes

If "Unrelated" to study intervention, alternative etiology:*(A1ALTEB)*

- 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

If "Other," specify:*(A1AEBSP)*

5. Action taken with study intervention:*(A1ACTBI)*

- 0-None
- 1-Decreased intervention
- 2-Increased intervention
- 3-Temporarily stopped intervention
- 4-Permanently stopped intervention
- *Additional Options Listed Below

6. Outcome of event:*(A1OUTCM)*

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

7. Date of resolution or medically stable:*(A1RESDT)* *(mm/dd/yyyy)*

Except for "None of the following" and "Hospitalization for a medical event", 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: *(A1ASSOC2)*

0-None of the following
1-Hospitalization for a medical event
2-Death
3-Life-threatening event
4-Inpatient admission to hospital
*Additional Options Listed Below

If "Death", date of death: *(A1DTHDTE)* *(mm/dd/yyyy)*

9. If "Inpatient admission to hospital" or "Prolongation of hospitalization":

Date of hospital admission: *(A1HOSPAD)* *(mm/dd/yyyy)*

Date of hospital discharge: *(A1HOSPDC)* *(mm/dd/yyyy)*

Comments: *(A1COMM)*

MedDRA:

The following fields are auto-populated by the DSC2 based on MedDRA coding of the Adverse Event name.

Preferred Term: *(MEDRAPT)* Not Coded

System Organ Class: *(MEDRASOC)*

Additional Selection Options for AD1

Select Sequence 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
-

Action taken with study intervention:
5-Participant terminated from study

Was this event associated with:
5-Prolongation of hospitalization
6-Persistent or significant incapacity
7-Congenital anomaly or birth defect
8-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; 03-09-12

Adverse Event Onset Date *(AEDATE)*:
Select Sequence 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: *(A2SAETRT)* ☐ No ☐ Yes ☐ Unknown

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

5. Labs/Tests Performed in Conjunction with this Event: *(A2SAELAB)* ☐ No ☐ Yes ☐ Unknown

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

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

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

NIDA Clinical Trials Network

Serious Adverse Event Medical Reviewer (AD3)

Web Version: 1.0; 3.00; 03-09-12

Adverse Event Onset Date *(AEDATE)*:
Select Sequence Number *(AESEQNUM)*:

1. Was this determined to be a serious adverse event?*(A3DETER)*	☐ No ☐ Yes
2. Was this event considered associated with the study's behavioral intervention?*(A3BHINT)*	☐ 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
5. Is this an expedited/reportable event for other reasons?*(A3EXPOTH)*	☐ No ☐ Yes
6. Does the protocol need to be modified based on this event?*(A3EXPDSM)*	☐ No ☐ Yes
7. Does the consent form need to be modified based on this event?*(A3CONSEN)*	☐ No ☐ Yes
8. Is the review complete?*(A3REVDNE)*	☐ No ☐ Yes
If "No", what additional information is required:*(A3ADDINF)*	

Assessed by:*(A2ASRID)* ☐ Robert Lindblad ☐ Radhika Kondapaka

Reviewed by:*(A3REVID)* ☐ Robert Lindblad

Comments:*(A3COMM)*

Additional Selection Options for AD3

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

NIDA Clinical Trials Network

Additional Demographics (ADE)

Web Version: 1.0; 5.00; 04-05-13

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

Date of assessment: *(ADEASMDT)* _____ *(mm/dd/yyyy)* Click here for calendar

1. Is this the first time that you have been interviewed by someone on our staff to see if you are eligible to participate in this study? *(AD1STINT)*

```
0-No
1-Yes
97-Don't know
98-Refused to answer
```

a. What was the outcome of the last time you spoke to us about the study? *(ADINTOUT)*

```
1-Not eligible
2-Eligible, but not available to complete the enrollment forms at that time
98-Refuse to answer
99-Other
```

b. What happened the last time you spoke to us about the study? *(ADINTCOM)*

2. What is your gender? *(ADGENDER)*

```
1-Male
2-Female
3-Transmale (female to male)
4-Transfemale (male to female)
```

a. Some of our participants identify themselves as "transgender." Does this apply to you? *(ADTRANSG)* ☐ No ☐ Yes

b. What was your sex assigned at birth? *(ADBIRTHS)* ☐ Male ☐ Female

c. Have you had sex reassignment surgery? *(ADSEXSUR)* ☐ No ☐ Yes

3. What is the highest grade or level of school you have completed, or the highest degree you have received? *(ADEDUCAT)*

```
1-Middle school (Jr high school) or less
2-Some high school, no diploma
3-High school diploma/GED or equivalent
4-Junior (2-year) college
5-Technical/trade/vocational school
*Additional Options Listed Below
```

4. What is your marital status? *(ADMARRIE)*

```
1-Married
2-Widowed
3-Divorced
4-Separated
5-Never married
*Additional Options Listed Below
```

5. We would like to know about what you do - are you working now, looking for work, retired, keeping house, a student, or what?*(ADWORKIN)*

1-Working full-time
2-Working steady part-time
3-Working only sometimes
4-Temporarily laid off, sick leave or maternity leave
5-Unemployed, looking for work
*Additional Options Listed Below

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

a. What kind of paid work do you do?
Provide detail that describes the activity or skill required by the job, and if it involves management of others. For example, rather than "construction" we'd like "bricklayer"; rather than "metal-worker" we'd like welder; rather than "restaurant" we'd like "wait-person in a restaurant"; rather than "health care" we'd like "medical assistant" or "phlebotomist"; rather than "hair salon" we'd like "hairdresser" or "manicurist." (ADKINDWK)

b. Regardless of full-time or part-time status, how many hours per week on average do you work?*(ADWRHRWK)* Hours: *(xx)*

c. What is your current wage for this job?*(ADWAGEHR)* Hourly: *(xxx.xx)* **-or-** *(ADWAGEYR)* Annual: *(xxx,xxx)*

6. What was your total personal income in the last year from all sources?*(ADINCPER)* *(xxxxxx)* *(ADPIDKRF)* ☐ Don't know ☐ Refuse to answer

If income is greater than $999,995 enter 999,995;

Which of the following is the category that your total personal income from all sources would be in?*(ADINCPRW)*

1-$0
2-$1 to $5000
3-$5,001 to $10,000
4-$10,001 to $20,000
5-$20,001 to $30,000
*Additional Options Listed Below

7. What is your best estimate of the total income of all family members from all legal sources, before taxes, in last calendar year?*(ADINCFAM)* *(xxxxxx)* *(ADTIDKRF)* ☐ Don't know ☐ Refuse to answer

If income is greater than $999,995 enter 999,995;

Which of the following is the category that your total family income from legal sources would be in?*(ADINCFMW)*

1-$0
2-$1 to $5000
3-$5,001 to $10,000
4-$10,001 to $20,000
5-$20,001 to $30,000
*Additional Options Listed Below

Note that the participant's personal income should be included in total income.

8. Are you covered by health insurance or some other kind of health care plan?*(ADHLTINS)*

0-No
1-Yes
97-Don't know
98-Refused to answer

What kind of health insurance or health care coverage do you have?
Include those that pay for only one type of service (such as nursing home care, accidents, or dental care). Exclude private plans that only provide extra cash while hospitalized. If you have more than one kind of health insurance, tell me all plans that you have.

a. Private health insurance*(ADPRIHEA)* ☐ No ☐ Yes

b. Medicare*(ADMEDCAR)* ☐ No ☐ Yes

c. Medi-gap*(ADMEDIGA)* ☐ No ☐ Yes

d. Medicaid*(ADMEDCAD)* ☐ No ☐ Yes State plan name:*(ADMEDSTA)*

e. SCHIP (CHIP/children's health insurance program)*(ADSCHIP)* ☐ No ☐ Yes

f. Military health care (Tricare/VA/champ-VA) *(ADMILTAR)* ☐ No ☐ Yes

g. Indian health service *(ADINDIAN)* ☐ No ☐ Yes

h. State-sponsored health plan *(ADSTATES)* ☐ No ☐ Yes State plan name: *(ADSTATSP)*

i. Other government program *(ADGOVOTH)* ☐ No ☐ Yes

j. Single service plan (e.g., dental, vision, prescriptions) *(ADSINGLE)* ☐ No ☐ Yes

k. ADAP *(ADADAP)* ☐ No ☐ Yes

l. Other insurance *(ADINSOTH)* ☐ No ☐ Yes Specify "Other insurance": *(ADINOTSP)*

9. Have you ever been in jail, prison, or a correctional facility? *(ADJAIL)* ☐ No ☐ Yes

a. In the last 6 months, have you ever been in jail, prison, or a correctional facility? *(AD6MJAIL)* ☐ No ☐ Yes

b. In the past 6 months, how many days have you spent in jail, prison, or a correctional facility? *(xxx)*
If the participant provides a response in months, the number of days should be calculated with 1 month = 30 days (ADJAILDY)

10. Which of the following best describes your Hispanic ethnic background? *(ADHISBGD)*

1-Mexican, Mexican-American, Chicano
2-Puerto Rican
3-Cuban
4-Central American
5-South American
*Additional Options Listed Below

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

11. Which of the following best describes your Asian ethnic background? *(ADASIBGD)*

1-Chinese
2-Filipino
3-Japanese
4-Vietnamese
5-Korean
*Additional Options Listed Below

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

12. Which of the following best describes your Black ethnic background? *(ADBKBGD)*

1-African American
2-Dominican
3-Haitian
4-Jamaican
5-Cuban
*Additional Options Listed Below

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

13. Over the past 4 weeks, which of the following describes the amount of food you have had available to eat? *(ADFDEAT)*

1-Enough to eat
2-Sometimes not enough to eat
3-Often not enough to eat
97-Unknown
98-Refuse to answer

Number of days in the previous 4 weeks with no food or money to buy food?*(ADFDMON)*

1-0
2-1-4
3-5-9
4-10-14
5-More than 14

14. In what country were you born?*(ADCOUNTR)*

1-United States of America
2-Afghanistan
3-Africa
4-Albania
5-Algeria
*Additional Options Listed Below

Is English your second language?*(ADENG2LA)* ☐ No ☐ Yes

15. If you are enrolled in this study, will you be living in the vicinity and able to return to this site for a follow-up visit in 12-16 months from today?*(ADLIVVIC)* ☐ No ☐ Yes

16. Would you be able to understand an interviewer or counselor talking in English?*(ADUNDERS)* ☐ No ☐ Yes

Interviewer endorsement of ability to communicate in English:*(ADENDORS)* ☐ No ☐ Yes

Instruct the participant to "Think about where you were living immediately before being admitted to this hospital. How long have you lived in this area?"

17. During the past six months, where did you live or sleep most of the time?*(ADLIVSLP)*

1-Homeless (living on the street, in a park, in a bus station, etc.)
2-In a shelter
3-Transitional (time-limited) single-room occupancy hotel
4-Permanent single-room occupancy hotel
5-HIV/AIDS housing/group home
*Additional Options Listed Below

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

18. In the last 6 months, indicate all the places you have lived.

	No	Yes	Don't Know	Refuse to Answer	Not Applicable
a. Homeless (living on the street, in a park, in a bus station, etc.)	*(ADHOMELE)* ☐	☐	☐	☐	☐
b. In a shelter	*(ADSHELTE)* ☐	☐	☐	☐	☐
c. Transitional (time - limited) single - room occupancy hotel	*(ADTRANSI)* ☐	☐	☐	☐	☐
d. Permanent single - room occupancy hotel	*(ADPERMAN)* ☐	☐	☐	☐	☐
e. HIV/AIDS housing/group home	*(ADGROUP)* ☐	☐	☐	☐	☐
f. Drug treatment facility	*(ADDRUGTX)* ☐	☐	☐	☐	☐
g. Other residential facility or institution (e.g. health care facility, halfway house)	*(ADRESOTH)* ☐	☐	☐	☐	☐
h. Staying with family/friends	*(ADFAMILY)* ☐	☐	☐	☐	☐
i. Rent an apartment/house (alone or with others)	*(ADRENT)* ☐	☐	☐	☐	☐
j. Own my home	*(ADOWNHOM)* ☐	☐	☐	☐	☐

k. In Jail	*(ADLVJAIL)* ☐	☐	☐	☐	☐
l. Other, specify:*(ADLIOTSP)*	*(ADLIVEOT)* ☐	☐	☐	☐	☐

19. How long have you lived in this area (i.e., Zip Code)?*(ADLIVLGT)*

1-Less than a month
2-At least 1 month but less than 3 months
3-At least 3 months but less than 6 months
4-At least 6 months but less than 1 year
5-At least 1 year
*Additional Options Listed Below

20. Who do you live with?

	No	Yes	Refuse to Answer
a. Alone	*(ADALONE)* ☐	☐	☐
b. Partner	*(ADPARTNE)* ☐	☐	☐
c. Parents	*(ADPARENT)* ☐	☐	☐
d. Children	*(ADCHILDR)* ☐	☐	☐
e. Other Family	*(ADFAMOTH)* ☐	☐	☐
f. Friends	*(ADFRIEND)* ☐	☐	☐
g. Roommates/housemates	*(ADRMMATE)* ☐	☐	☐
h. Other, specify:*(ADLVWTSP)*	*(ADWHOOTH)* ☐	☐	☐

21. Do you live with anyone who has a current alcohol problem?*(ADLVALCH)* ☐ No ☐ Yes

22. Do you live with anyone who uses illegal drugs or marijuana?*(ADLVDRG)* ☐ No ☐ Yes

23. Do you live with anyone who abuses prescription/OTC medications or other substances?*(ADLVDRRX)* ☐ No ☐ Yes

24. Do you have any children under the age of 18?*(ADCHILD)*

0-No
1-Yes
97-Don't know
98-Refused to answer

25. How many children under 18 do you have daily care and responsibility for?*(ADRESPCA)*

(xx)

26. Which year did you get your first positive test for HIV?*(ADPOSYR)*

(xxxx) *(ADYRDKRF)* **-or-** ☐ Don't know **-or-** ☐ Refuse to answer

Which month did you get your first positive test for HIV?*(ADPOSMO)*

1-January
2-February
3-March
4-April
5-May
*Additional Options Listed Below

27. Have you ever had HIV primary care?
By HIV primary care, we mean a clinician or team of clinicians who you see in a clinic or office on a regular basis and who works with you to manage your HIV/AIDS medications, blood test results, T - cell count and viral load.(ADHIVPRI)

0-No
1-Yes
97-Don't know
98-Refused to answer

If "Yes", when was your last HIV primary care visit?*(ADLASTVS)*

1-0 to 3 months ago
2-3 to 6 months ago
3-6 months to 1 year ago
4-More than 1 year ago
97-Don't know
*Additional Options Listed Below

28. Have you taken medications specifically for your HIV?
These would be antiretrovirals or a drug cocktail to reduce your viral load.
This means medications that attack HIV, not medications for other conditions.(ADHIVME)

0-No
1-Yes
97-Don't know
98-Refused to answer

29. Are you currently taking medications specifically for HIV?*(ADTKEMED)*

0-No
1-Yes
98-Refuse to answer

If "Yes," specify:*(ADMEDSSP)*

30. How many times have you been hospitalized in the last 12 months?*(ADLSTHSP)*

(xxx)

The number of hospitalizations entered should include the current hospitalization.
Of these, how many times have you been hospitalized in the last 6 months?*(AD6MOHSP)*

(xxx)

31. Have you ever participated in alcohol or drug treatment?*(ADALDRTR)*

☐ No ☐ Yes

a. In the past 12 months have you participated in alcohol or drug treatment?*(AD12ALDR)*

☐ No ☐ Yes

b. Were any of these treatments in the past 6 months?*(AD06ALDR)*

☐ No ☐ Yes

32. In the past 12 months, which of the following types of programs have you participated in?

	No	Yes
a. Drug free outpatient drug treatment	*(AD12OUTP)* ☐	☐
b. Inpatient drug treatment	*(AD12INPT)* ☐	☐
c. Methadone maintenance	*(AD12METM)* ☐	☐
d. Buprenorphine treatment	*(AD12BUPT)* ☐	☐

e. Detoxification	*(AD12DET)* ☐	☐
f. Residential treatment program	*(AD12RES)* ☐	☐
g. Alcoholics Anonymous (AA)	*(AD12AA)* ☐	☐
h. Narcotics or Cocaine Anonymous (NA)	*(AD12NCA)* ☐	☐
i. Other, specify:*(AD12OTSP)*	*(AD12OTHE)* ☐	☐

Did you participate in any of these programs over the past 6 months?*(AD06MOPR)* ☐ No ☐ Yes

Comments:*(ADECOMM)*

Additional Selection Options for ADE

What is the highest grade or level of school you have completed, or the highest degree you have received?
6-Some college (4-year college or university)
7-College graduate (4-year college or university)
8-Graduate or professional school
98-Refused
97-Don't know

What is your marital status?
6-Living with partner
98-Refused
97-Don't know

We would like to know about what you do - are you working now, looking for work, retired, keeping house, a student, or what?
6-Unemployed, not looking for work
7-Retired
8-Disabled, permanently or temporarily
9-Unpaid child care or housework
10-Student
11-Currently incarcerated
99-Other

Which of the following is the category that your total personal income from all sources would be in?
6-$30,001 to $40,000
7-$40,001 to $50,000
8-More than $50,000

Which of the following best describes your Hispanic ethnic background?
99-Other

Which of the following best describes your Asian ethnic background?
6-Indian
7-Pakistani
99-Other

Which of the following best describes your Black ethnic background?
6-African
99-Other

In what country were you born?
6-American Samoa
7-Andora
8-Angola
9-Anguilla
10-Antarctica
11-Antigua & Barbuda
12-Antilles, Netherlands
13-Argentina
14-Armenia
15-Aruba
16-Australia
17-Austria
18-Azerbaijan
19-Bahamas, The
20-Bahrain
21-Bangladesh
22-Barbados
23-Belarus
24-Belgium
25-Belize
26-Benin
27-Bermuda
28-Bhutan
29-Bolivia
30-Bosnia & Herzegovina

31-Botswana
32-Bouvet Island
33-Brazil
34-British Indian Ocean Territory
35-British Virgin Islands
36-Brunei Darussalam
37-Bulgaria
38-Burkina Faso
39-Burundi
40-Cambodia
41-Cameroon
42-Canada
43-Cape Verde
44-Cayman Islands
45-Central African Republic
46-Chad
47-Chile
48-China
49-Christmas Island
50-Cocos (Keeling) Islands
51-Colombia
52-Comoros
53-Congo
54-Congo, Democratic Rep. of the
55-Cook Islands
56-Costa Rica
57-Cote D'Ivoire
58-Croatia
59-Cuba
60-Cyprus
61-Czech Republic
62-Denmark
63-Djibouti
64-Dominica
65-Dominican Republic
66-East Timor (Timor-Leste)
67-Ecuador
68-Egypt
69-El Salvador
70-Eritrea
71-Estonia
72-Ethiopia
73-European Union
74-Falkland Islands (Malvinas)
75-Faroe Islands
76-Fiji
77-Finland
78-France
79-French Guiana
80-French Polynesia
81-French Southern Territories - TF
82-Gabon
83-Gambia, The
84-Georgia
85-Germany
86-Ghana
87-Gibraltar
88-Greece
89-Greenland
90-Grenada
91-Guadeloupe
92-Guam
93-Guatemala
94-Guernsey & Alderney
95-Guinea

96-Guinea-Bissau
97-Guinea, Equatorial
98-Guiana, French
99-Guyana
100-Haiti
101-Heard and McDonald Islands
102-Holy See (Vatican City State)
103-Holland
104-Honduras
105-Hong Kong (China)
106-Hungary
107-Iceland
108-India
109-Indonesia
110-Iran, Islamic Republic of
111-Iraq
112-Ireland
113-Israel
114-Ivory Coast
115-Italy
116-Jamaica
117-Japan
118-Jersey
119-Jordan
120-Kazakhstan
121-Kenya
122-Kiribati
123-Korea, Demo. People's Rep. of
124-Korea, (South) Republic of
125-Kuwait
126-Kyrgyzstan
127-Lao People's Democratic Republic
128-Latvia
129-Lebanon
130-Lesotho
131-Liberia
132-Libyan Arab Jamahiriya
133-Liechtenstein
134-Lithuania
135-Luxembourg
136-Macao, (China)
137-Macedonia, TFYR
138-Madagascar
139-Malawi
140-Malaysia
141-Maldives
142-Mali
143-Malta
144-Man, Isle of
145-Marshall Islands
146-Martinique
147-Mauritania
148-Mauritius
149-Mayotte
150-Mexico
151-Micronesia, Federated States of
152-Moldova, Republic of
153-Monaco
154-Mongolia
155-Montenegro
156-Montserrat
157-Morocco
158-Mozambique
159-Myanmar (ex-Burma)
160-Namibia

161-Nauru
162-Nepal
163-Netherlands
164-Netherlands Antilles
165-New Caledonia
166-New Zealand
167-Nicaragua
168-Niger
169-Nigeria
170-Niue
171-Norfolk Island
172-Northern Mariana Islands
173-Norway
174-Oman
175-Pakistan
176-Palau
177-Palestinian Territory
178-Panama
179-Papua New Guinea
180-Paraguay
181-Peru
182-Philippines
183-Pitcairn Island
184-Poland
185-Portugal
186-Puerto Rico
187-Qatar
188-Reunion
189-Romania
190-Russia (Russian Federation)
191-Rwanda
192-Sahara
193-Saint Helena
194-Saint Kitts and Nevis
195-Saint Lucia
196-Saint Pierre and Miquelon
197-Saint Vincent and the Grenadines
198-Samoa
199-San Marino
200-Sao Tome and Principe
201-Saudi Arabia
202-Senegal
203-Serbia
204-Seychelles
205-Sierra Leone
206-Singapore
207-Slovakia
208-Slovenia
209-Soloman Islands
210-Somalia
211-South Africa
212-S. Georgia and S. Sandwich Island
213-Spain
214-Sri Lanka (ex-Ceilan)
215-Sudan
216-Suriname
217-Svalbard and Jan Mayen Islands
218-Swaziland
219-Sweden
220-Switzerland
221-Syrian Arab Republic
222-Taiwan
223-Tajikistan
224-Tanzania, United Republic of
225-Thailand

226-Timor-Leste (East Timor)
227-Togo
228-Tokelau
229-Tonga
230-Trinidad & Tobago
231-Tunisia
232-Turkey
233-Turkmenistan
234-Turks and Caicos Islands
235-Tuvalu
236-Uganda
237-Ukraine
238-United Arab Emirates
239-United Kingdom
240-Uruguay
241-Uzbekistan
242-Vanuatu
243-Vatican City State (Holy See)
244-Venezuela
245-Vietnam
246-Virgin Islands, British
247-Virgin Islands, U.S.
248-Wallis and Futuna
249-Western Sahara
250-Yemen
251-Zambia
252-Zimbabwe

During the past six months, where did you live or sleep most of the time?
6-Drug treatment facility
7-Other residential facility or institution (e.g., health care facility, halfaway house)
8-Staying with family/friends
9-Rent an apartment/house (alone or with others)
10-Own my home
11-In jail
99-Other

How long have you lived in this area (i.e., Zip Code)?
98-Refuse to answer

Which month did you get your first positive test for HIV?
6-June
7-July
8-August
9-September
10-October
11-November
12-December
97-Don't know
98-Refuse to answer

If "Yes", when was your last HIV primary care visit?
98-Refuse to answer

NIDA Clinical Trials Network

Shortened HIV Adherence Measures (ADH)

Web Version: 1.0; 1.00; 07-10-12

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

The next questions are about your current/recently prescribed anti-HIV medications.

Date of assessment:*(ADHASMDT)* _____ *(mm/dd/yyyy)* Click here for calendar

1. Have you been prescribed any anti-HIV medications?*(ADHIVMED)* ☐ No ☐ Yes

Many patients find it difficult to take all their HIV medication exactly as prescribed.

2. How many doses of your HIV medication did you miss in the past 7 days?*(ADDOSMS)* _____ *(xx)*

3. Provide your best guess about what percentage of your prescribed HIV medication you have taken in the last month. _____ *(xxx)* %

It would be surprising if this was 100% for most people.
Examples: 0% means you have taken none of your medications in the last month, 50% means you have taken half of your medications in the last month and 100% means that you have taken every single dose of your medications.(ADDOSTKP)

4. Sometimes if you feel worse, do you stop taking your HIV medications?*(ADWORSE)* ☐ No ☐ Yes

5. Did you miss any of your HIV medications over the past weekend? ☐ No ☐ Yes
"Yes" means you missed meds
"No" means you did NOT miss meds(ADWKND)

*The following questions ask about symptoms you might have had during the **past month**. Choose the response/answer that describes how much you have been bothered by each symptom.*
RA Instruction: Provide participant with a reference card that lists all response options for his/her easy reference.

6. Fatigue or loss of energy?*(ADENERGY)*

0-I do not have this symptom
1-I have this symptom and it does n't bother me
2-I have this symptom and it bothers me a little
3-I have this symptom and it bothers me a lot
4-I have this symptom and it bothers me terribly

7. Fevers, chills or sweats?*(ADFEVER)*

0-I do not have this symptom
1-I have this symptom and it does n't bother me
2-I have this symptom and it bothers me a little
3-I have this symptom and it bothers me a lot
4-I have this symptom and it bothers me terribly

8. Feeling dizzy or lightheaded?*(ADDIZZY)*

0-I do not have this symptom
1-I have this symptom and it doesn't bother me
2-I have this symptom and it bothers me a little
3-I have this symptom and it bothers me a lot
4-I have this symptom and it bothers me terribly

9. Pain, numbness or tingling in the hands or feet?*(ADNUMB)*

0-I do not have this symptom
1-I have this symptom and it doesn't bother me
2-I have this symptom and it bothers me a little
3-I have this symptom and it bothers me a lot
4-I have this symptom and it bothers me terribly

10. Trouble remembering?*(ADRMBER)*

0-I do not have this symptom
1-I have this symptom and it doesn't bother me
2-I have this symptom and it bothers me a little
3-I have this symptom and it bothers me a lot
4-I have this symptom and it bothers me terribly

11. Nausea or vomiting?*(ADVOMIT)*

0-I do not have this symptom
1-I have this symptom and it doesn't bother me
2-I have this symptom and it bothers me a little
3-I have this symptom and it bothers me a lot
4-I have this symptom and it bothers me terribly

12. Diarrhea or loose bowel movements?*(ADBOWEL)*

0-I do not have this symptom
1-I have this symptom and it doesn't bother me
2-I have this symptom and it bothers me a little
3-I have this symptom and it bothers me a lot
4-I have this symptom and it bothers me terribly

13. Felt sad, down or depressed?*(ADSADEN)*

0-I do not have this symptom
1-I have this symptom and it doesn't bother me
2-I have this symptom and it bothers me a little
3-I have this symptom and it bothers me a lot
4-I have this symptom and it bothers me terribly

14. Felt nervous or anxious?*(ADNERVES)*

0-I do not have this symptom
1-I have this symptom and it doesn't bother me
2-I have this symptom and it bothers me a little
3-I have this symptom and it bothers me a lot
4-I have this symptom and it bothers me terribly

15. Difficulty falling or staying asleep?*(ADSLEEP)*

0-I do not have this symptom
1-I have this symptom and it doesn't bother me
2-I have this symptom and it bothers me a little
3-I have this symptom and it bothers me a lot
4-I have this symptom and it bothers me terribly

16. Skin problems, such as rash, dryness or itching? *(ADSKNPRB)*

0-I do not have this symptom
1-I have this symptom and it doesn't bother me
2-I have this symptom and it bothers me a little
3-I have this symptom and it bothers me a lot
4-I have this symptom and it bothers me terribly

17. Cough or trouble catching your breath? *(ADCOUGH)*

0-I do not have this symptom
1-I have this symptom and it doesn't bother me
2-I have this symptom and it bothers me a little
3-I have this symptom and it bothers me a lot
4-I have this symptom and it bothers me terribly

18. Headache? *(ADHEDACH)*

0-I do not have this symptom
1-I have this symptom and it doesn't bother me
2-I have this symptom and it bothers me a little
3-I have this symptom and it bothers me a lot
4-I have this symptom and it bothers me terribly

19. Loss of appetite or change in the taste of food? *(ADAPETIT)*

0-I do not have this symptom
1-I have this symptom and it doesn't bother me
2-I have this symptom and it bothers me a little
3-I have this symptom and it bothers me a lot
4-I have this symptom and it bothers me terribly

20. Bloating, pain or gas in your stomach? *(ADBLOAT)*

0-I do not have this symptom
1-I have this symptom and it doesn't bother me
2-I have this symptom and it bothers me a little
3-I have this symptom and it bothers me a lot
4-I have this symptom and it bothers me terribly

21. Muscle aches or joint pain? *(ADMSACHE)*

0-I do not have this symptom
1-I have this symptom and it doesn't bother me
2-I have this symptom and it bothers me a little
3-I have this symptom and it bothers me a lot
4-I have this symptom and it bothers me terribly

22. Problems with having sex, such as loss of interest or lack of satisfaction? *(ADSEX)*

0-I do not have this symptom
1-I have this symptom and it doesn't bother me
2-I have this symptom and it bothers me a little
3-I have this symptom and it bothers me a lot
4-I have this symptom and it bothers me terribly

23. Changes in the way your body looks, such as fat deposits or weight gain?*(ADBDYCHG)*

0-I do not have this symptom
1-I have this symptom and it doesn't bother me
2-I have this symptom and it bothers me a little
3-I have this symptom and it bothers me a lot
4-I have this symptom and it bothers me terribly

24. Problems with weight loss or wasting?*(ADWEIGHT)*

0-I do not have this symptom
1-I have this symptom and it doesn't bother me
2-I have this symptom and it bothers me a little
3-I have this symptom and it bothers me a lot
4-I have this symptom and it bothers me terribly

25. Hair loss or changes in the way your hair looks?*(ADHAIRCG)*

0-I do not have this symptom
1-I have this symptom and it doesn't bother me
2-I have this symptom and it bothers me a little
3-I have this symptom and it bothers me a lot
4-I have this symptom and it bothers me terribly

Comments:*(ADHCOMM)*

NIDA Clinical Trials Network

Medication Adherence Self Efficacy (ADS)

Web Version: 1.0; 2.00; 07-01-13

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

Date of assessment:*(ADSASMDT)* _____ *(mm/dd/yyyy)* Click here for calendar

RA Instruction: Provide participant with a reference card that lists all response options for his/her easy reference.

The next several questions are about your confidence with taking HIV medications. I will ask you to tell me in ***the past month, including today,*** *how confident you have been that you can do the following things. Please respond on a scale of 0 to 10 where 0 = you cannot do at all, 5 = moderately (somewhat) certain you can do and 10 = completely certain you can do.*

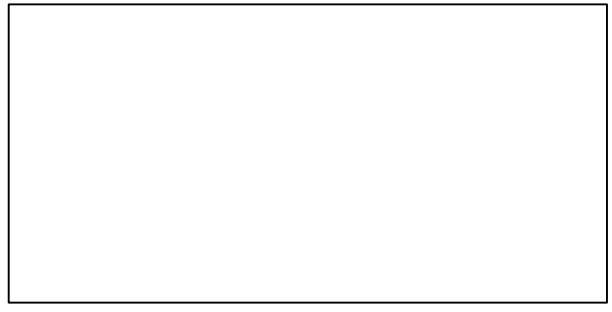
****RA reminder: If the participant previously indicated that s/he has not taken medications specifically for HIV (ADE item #26 = NO) and/or has not been prescribed any anti-HIV medications (ADH item #1 = NO), staff should still administer the ADS form. However, the above instructions should refer to "next month" instead of "past month" and the lead in statement should be re-framed as,* ***"If you were to be prescribed HIV medications in the next month, how confident are you that you can:"********

****RA reminder: If the participant previously indicated that s/he has not been prescribed any anti-HIV medications (ADH item #1 = NO), staff should still administer the ADS form. However, the above instructions should refer to "next month" instead of "past month" and the lead in statement should be re-framed as,* ***"If you were to be prescribed HIV medications in the next month, how confident are you that you can:"********

In the past month, how confident are you that you can:

	0 Cannot do at all	1	2	3	4	5 Moderately certain can do	6	7	8	9	10 Completely certain can do
1. Stick to your treatment plan even when side effects begin to interfere with daily activities?	*(ADSIDEEF)* ☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
2. Integrate your treatment into your daily routine?	*(ADROUTN)* ☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
3. Integrate your treatment into your daily routine even if it means taking medication or doing other things in front of people who don't know you are HIV-infected?	*(ADPPLSEE)* ☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
4. Stick to your treatment schedule even when your daily routine is disrupted?	*(ADDYDSRP)* ☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
5. Stick to your treatment schedule when you aren't feeling well?	*(ADNOTWEL)* ☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
6. Stick to your treatment schedule when it means changing your eating habits?	*(ADCHGEAT)* ☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
7. Continue with your treatment even if doing so interferes with your daily activities?	*(ADACTVTY)* ☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
8. Continue with the treatment plan your physician prescribed even if your T-cells/CD4 cells drop significantly in the next three months?	*(ADTCD4)* ☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
9. Continue with your treatment even when you are feeling discouraged about your health?	*(ADDISCRG)* ☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
10. Continue with your treatment even when getting to your clinic appointments is a major hassle?	*(ADCLINIC)* ☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
11. Continue with your treatment even when people close to you tell you that they don't think that it is doing any good?	*(ADNTGOOD)* ☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
12. Get something positive out of your participation in treatment, even if the medication you are taking does not improve your health?	*(ADPOS)* ☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Comments: *(ADSCOMM)*



NIDA Clinical Trials Network

Alcohol Breathalyzer (ALB)

Web Version: 1.0; 1.02; 05-10-12

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

1. Was an Alcohol Breathalyzer performed?*(ABPERFRM)* ☐ No ☐ Yes
   If "No",specify reason:*(ABREASON)* ☐ Participant refused to provide sample ☐ Study staff error ☐ Other
   If "Other", specify*(AB1OTHSP)*
2. Date of assessment:*(ABASMTDT)* *(mm/dd/yyyy)*
3. Alcohol Breathalyzer result:*(ABRESULT)* *(.xxx)* mg/mL
4. Is a repeat test required?*(ABREPTST)* ☐ No ☐ Yes
   If "Yes", complete the questions below.
   a. Was the repeat Alcohol Breathalyzer performed?*(ABREPPRF)* ☐ No ☐ Yes
   If "No", specify reason:*(ABRREASN)* ☐ Participant refused to provide sample ☐ Study staff error ☐ Other
   If "Other", specify*(AB2OTHSP)*
   b. Repeat test date:*(ABREPDT)* *(mm/dd/yyyy)*
   c. Repeat Alcohol Breathalyzer result:*(ABREPRES)* *(.xxx)* mg/mL

Comments:*(ALBCOMM)*

NIDA Clinical Trials Network

ARVs Med Log (ARV)

Web Version: 1.0; 2.02; 09-05-13

You said you had been prescribed anti-HIV medications. Are you currently taking anti-HIV medication?

If "no," RA Instructions: You may need to remind the participant that s/he answered "Yes" to item number 1 on the Shortened HIV Adherence Measures form and ask for clarification on his/her response. Even if the participant has poor adherence, if s/he has an active prescription of antiretrovirals that s/he is currently taking even SOMETIMES, enter it on the ARV log.

If "yes," ask: "What are the names of your medications? Do you have your medications or a list with you? When did you start your current regimen?"

RA Instructions: If the participant does not have a list or medication bottles, you may need to help him/her remember the medications.
Use the laminated card with pictures of the pills to help the participant identify his/her medication.
Utilize the "Common Regimens" list to suggest names; use both generic and brand names to jog his/her memory.
ONLY record antiretroviral medications on this log; other medications, even those for OI prevention, should NOT be added to the log.

	Drug Name	Start Date (mm/dd/yyyy)	Stop Date (mm/dd/yyyy)	Self-Report	Medical Record
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) Calendar	(ARSP01DT) Calendar	(ARSELF01) ☐	(ARMED01) ☐
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) Calendar	(ARSP02DT) Calendar	(ARSELF02) ☐	(ARMED02) ☐
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) Calendar	(ARSP03DT) Calendar	(ARSELF03) ☐	(ARMED03) ☐
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) Calendar	(ARSP04DT) Calendar	(ARSELF04) ☐	(ARMED04) ☐

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) Calendar	(ARSP05DT) Calendar	(ARSELF05) ☐	(ARMED05) ☐
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) Calendar	(ARSP06DT) Calendar	(ARSELF06) ☐	(ARMED06) ☐
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) Calendar	(ARSP07DT) Calendar	(ARSELF07) ☐	(ARMED07) ☐
8.	(ARDRUG08) 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	(ARST08DT) Calendar	(ARSP08DT) Calendar	(ARSELF08) ☐	(ARMED08) ☐
9.	(ARDRUG09) 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	(ARST09DT) Calendar	(ARSP09DT) Calendar	(ARSELF09) ☐	(ARMED09) ☐
10.	(ARDRUG10) 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	(ARST10DT) Calendar	(ARSP10DT) Calendar	(ARSELF10) ☐	(ARMED10) ☐
11.	(ARDRUG11) 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	(ARST11DT) Calendar	(ARSP11DT) Calendar	(ARSELF11) ☐	(ARMED11) ☐

12.	(ARDRUG12)	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	(ARST12DT) Calendar	(ARSP12DT) Calendar	(ARSELF12) ☐	(ARMED12) ☐
13.	(ARDRUG13)	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	(ARST13DT) Calendar	(ARSP13DT) Calendar	(ARSELF13) ☐	(ARMED13) ☐
14.	(ARDRUG14)	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	(ARST14DT) Calendar	(ARSP14DT) Calendar	(ARSELF14) ☐	(ARMED14) ☐
15.	(ARDRUG15)	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	(ARST15DT) Calendar	(ARSP15DT) Calendar	(ARSELF15) ☐	(ARMED15) ☐
16.	(ARDRUG16)	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	(ARST16DT) Calendar	(ARSP16DT) Calendar	(ARSELF16) ☐	(ARMED16) ☐
17.	(ARDRUG17)	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	(ARST17DT) Calendar	(ARSP17DT) Calendar	(ARSELF17) ☐	(ARMED17) ☐
18.	(ARDRUG18)	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	(ARST18DT) Calendar	(ARSP18DT) Calendar	(ARSELF18) ☐	(ARMED18) ☐

19.	(ARDRUG19)	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	(ARST19DT) Calendar	(ARSP19DT) Calendar	(ARSELF19) ☐	(ARMED19) ☐
20.	(ARDRUG20)	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	(ARST20DT) Calendar	(ARSP20DT) Calendar	(ARSELF20) ☐	(ARMED20) ☐
21.	(ARDRUG21)	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	(ARST21DT) Calendar	(ARSP21DT) Calendar	(ARSELF21) ☐	(ARMED21) ☐
22.	(ARDRUG22)	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	(ARST22DT) Calendar	(ARSP22DT) Calendar	(ARSELF22) ☐	(ARMED22) ☐
23.	(ARDRUG23)	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	(ARST23DT) Calendar	(ARSP23DT) Calendar	(ARSELF23) ☐	(ARMED23) ☐
24.	(ARDRUG24)	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	(ARST24DT) Calendar	(ARSP24DT) Calendar	(ARSELF24) ☐	(ARMED24) ☐
25.	(ARDRUG25)	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	(ARST25DT) Calendar	(ARSP25DT) Calendar	(ARSELF25) ☐	(ARMED25) ☐

26.	(ARDRUG26)	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	(ARST26DT) Calendar	(ARSP26DT) Calendar	(ARSELF26) ☐	(ARMED26) ☐
27.	(ARDRUG27)	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	(ARST27DT) Calendar	(ARSP27DT) Calendar	(ARSELF27) ☐	(ARMED27) ☐
28.	(ARDRUG28)	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	(ARST28DT) Calendar	(ARSP28DT) Calendar	(ARSELF28) ☐	(ARMED28) ☐
29.	(ARDRUG29)	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	(ARST29DT) Calendar	(ARSP29DT) Calendar	(ARSELF29) ☐	(ARMED29) ☐
30.	(ARDRUG30)	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	(ARST30DT) Calendar	(ARSP30DT) Calendar	(ARSELF30) ☐	(ARMED30) ☐
31.	(ARDRUG31)	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	(ARST31DT) Calendar	(ARSP31DT) Calendar	(ARSELF31) ☐	(ARMED31) ☐
32.	(ARDRUG32)	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	(ARST32DT) Calendar	(ARSP32DT) Calendar	(ARSELF32) ☐	(ARMED32) ☐

33.	(ARDRUG33)	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	(ARST33DT) Calendar	(ARSP33DT) Calendar	(ARSELF33) ☐	(ARMED33) ☐
34.	(ARDRUG34)	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	(ARST34DT) Calendar	(ARSP34DT) Calendar	(ARSELF34) ☐	(ARMED34) ☐
35.	(ARDRUG35)	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	(ARST35DT) Calendar	(ARSP35DT) Calendar	(ARSELF35) ☐	(ARMED35) ☐
36.	(ARDRUG36)	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	(ARST36DT) Calendar	(ARSP36DT) Calendar	(ARSELF36) ☐	(ARMED36) ☐
37.	(ARDRUG37)	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	(ARST37DT) Calendar	(ARSP37DT) Calendar	(ARSELF37) ☐	(ARMED37) ☐
38.	(ARDRUG38)	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	(ARST38DT) Calendar	(ARSP38DT) Calendar	(ARSELF38) ☐	(ARMED38) ☐
39.	(ARDRUG39)	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	(ARST39DT) Calendar	(ARSP39DT) Calendar	(ARSELF39) ☐	(ARMED39) ☐

40.	(ARDRUG40)	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	(ARST40DT) Calendar	(ARSP40DT) Calendar	(ARSELF40) ☐	(ARMED40) ☐
41.	(ARDRUG41)	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	(ARST41DT) Calendar	(ARSP41DT) Calendar	(ARSELF41) ☐	(ARMED41) ☐
42.	(ARDRUG42)	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	(ARST42DT) Calendar	(ARSP42DT) Calendar	(ARSELF42) ☐	(ARMED42) ☐
43.	(ARDRUG43)	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	(ARST43DT) Calendar	(ARSP43DT) Calendar	(ARSELF43) ☐	(ARMED43) ☐
44.	(ARDRUG44)	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	(ARST44DT) Calendar	(ARSP44DT) Calendar	(ARSELF44) ☐	(ARMED44) ☐
45.	(ARDRUG45)	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	(ARST45DT) Calendar	(ARSP45DT) Calendar	(ARSELF45) ☐	(ARMED45) ☐

Comments: *(ARVCOMM)*

Additional Selection Options for ARV

Drug name 01
06-Edurant - RPV
07-Emtriva - FTC
08-Epivir - 3TC
09-Epzicom - ABC + 3TC
10-Fuzeon - T20
11-Intelence - ETV
12-Invirase - SQV
13-Isentress - RAL
34-Isentress + Truvada - RAL + TDF + FTC
14-Kaletra - LPV/r
15-Lexiva - FPV
16-Norvir - RTV
33-Other/Experimental/Blinded study - OTHR
18-Prezista BID - DRV
17-Prezista QD - DRV
36-Prezista + Norvir +Truvada (DRV/r twice daily) - DRV/r +TDF + FTC
35-Prezista + Norvir + Truvada (once daily) - DRV/r + TDF + FTC
19-Reyataz - ATV
37-Reyataz + Norvir + Truvada
- ATV/r + TDF + FTC
20-Rescriptor - DLV
21-Retrovir - AZT (or ZDV)
22-Selzentry - MVC
38-Selzentry + Truvada - MVC + TDF + FTC
39-Stribild - EVG + COBI + TDF + FTC
23-Sustiva - EFV
40-Tivacay (dolutegravir)
24-Trizivir - ABC + 3TC + ZDV (or AZT)
25-Truvada - TDF + FTC
26-Videx - ddl
27-Viracept - NFV
28-Viramune - NVP
29-Viramune XR (QD) - NVP
30-Viread - TDF
31-Zerit - d4T
32-Ziagon - ABC

NIDA Clinical Trials Network

CTN-ASI Lite v. 1: Drug/Alcohol Use (ASA)

Web Version: 1.0; 2.00; 12-02-14

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

Date of assessment:*(ASAASMDT)* *(mm/dd/yyyy)* Click here for calendar

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):*	*(ASALA30D)* *(xx)*	-	*(ASALACOM)*
D2 Alcohol *(to intoxication):*	*(ASALI30D)* *(xx)*	-	*(ASALICOM)*
D3 Heroin	*(ASHER30D)* *(xx)*	*(ASHERRTE)* 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	*(ASHERCOM)*
D4 Methadone/LAAM *(prescribed):*	*(ASMDP30D)* *(xx)*	*(ASMDPRTE)* 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	*(ASMDPCOM)*
D4a Methadone/LAAM *(illicit):*	*(ASMLI30D)* *(xx)*	*(ASMLIRTE)* 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	*(ASMLICOM)*

D5 Other Opiates/Analgesics:	*(ASOPI30D)* *(xx)*	*(ASOPIRTE)* 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	*(ASOPICOM)*
D6 Barbiturates:	*(ASBAR30D)* *(xx)*	*(ASBARRTE)* 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	*(ASBARCOM)*
D7 Other Sedatives/ Hypnotics/Tranquilizers:	*(ASSHT30D)* *(xx)*	*(ASSHTRTE)* 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	*(ASSHTCOM)*
D8 Cocaine:	*(ASCOC30D)* *(xx)*	*(ASCOCRTE)* 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	*(ASCOCCOM)*
D9 Amphetamines:	*(ASAMP30D)* *(xx)*	*(ASAMPRTE)* 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	*(ASAMPCOM)*
D10 Cannabis:	*(ASTHC30D)* *(xx)*	*(ASTHCRTE)* 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	*(ASTHCCOM)*

D11 Hallucinogens:	*(ASHAL30D)* _____ *(xx)*	*(ASHALRTE)* 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	*(ASHALCOM)* _____
D12 Inhalants:	*(ASINH30D)* _____ *(xx)*	*(ASINHRTE)* 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	*(ASINHCOM)* _____
D13 More than 1 substance per day *(including alcohol, excluding nicotine):*	*(ASGT130D)* _____ *(xx)*	-	*(ASGT1COM)* _____

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.*

(ASMAJDRG)
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

OR

(ASMJDGNA) ☐ (97) Not Answered

Comments:*(ASMJDGCM)*

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.*

(ASALCDT) _____ *(xxx)*

OR

(ASALDTNA) ☐ (97) Not Answered

Comments:*(ASALDTCM)*

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:

(ASALCTRT) _____ *(xx)*

OR

(ASATRTNA) ☐ (97) Not Answered

Comments:*(ASATRTCM)*

D20 Drug abuse:

(ASDRGTRT) _____ *(xx)*

OR

(ASDTRTNA) ☐ (97) Not Answered

Comments:*(ASDTRTCM)*

How many of these were detox only:

D21 Alcohol:

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

(ASADETOX) _____ *(xx)*

OR

(ASADTXNA) ☐ (96) Not applicable ☐ (97) Not answered

Comments:*(ASADTXCM)*

D22 Drugs:

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

(ASDDETOX) ____ *(xx)*

OR

(ASDDTXNA) ☐ (96) Not applicable ☐ (97) Not answered

Comments:*(ASDDTXCM)*

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?*

(ASALCMNY) $ _____ *(xxxxx)*

OR

(ASAMNYNA) ☐ (97) Not Answered

Comments:*(ASAMNYCM)*

D24 Drugs:

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

(ASDRGMNY) $ _____ *(xxxxx)*

OR

(ASDMNYNA) ☐ (97) Not Answered

Comments:*(ASDMNYCM)*

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

- *Include AA/NA*

(ASOUTPAT) _____ *(xx)* days

OR

(ASOPTNA) ☐ (97) Not Answered

Comments:*(ASOPTCOM)*

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.*

(ASAP30D) _____ *(xx)* days

OR

(ASAP30NA) ☐ (97) Not Answered

Comments:*(ASAP30CM)*

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?

(ASAPB30D)
0-(0) Not at all
1-(1) Slightly
2-(2) Moderately
3-(3) Considerably
4-(4) Extremely

OR

(ASAB30NA) ☐ (97) Not Answered

Comments:*(ASAB30CM)*

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

(ASAPI30D)
0-(0) Not at all
1-(1) Slightly
2-(2) Moderately
3-(3) Considerably
4-(4) Extremely

OR

(ASAI30NA) ☐ (97) Not Answered

Comments:*(ASAI30CM)*

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.*

(ASDP30D) _____ *(xx)* days

OR

(ASDP30NA) ☐ (97) Not Answered

Comments:*(ASDP30CM)*

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

(ASDPB30D)

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

OR

(ASDB30NA) ☐ (97) Not Answered

Comments:*(ASDB30CM)*

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

(ASDPI30D)

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

OR

(ASDI30NA) ☐ (97) Not Answered

Comments:*(ASDI30CM)*

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

D34 Participant's misrepresentation?

(ASMISREP) ☐ (0) No ☐ (1) Yes

D35 Participant's inability to understand?

(ASUNDRST) ☐ (0) No ☐ (1) Yes

Comments:*(ASACOMM)*

List of Commonly Used Drugs

Alcohol:	Beer, wine, liquor
Methadone:	Dolophine, LAAM
Opiates:	Pain killers = Morphine, Diluaudid, Demerol, Percocet, Darvon, Talwin, Codeine, Tylenol 2, 3, 4 Syrups = Robitussin, Fentanyl
Barbiturates:	Nembutal, Seconal, Tuinol, Amytal, Pentobarbital, Secobarbital, Phenobarbital, Fiorinol
Sed/Hyp/Tranq:	Benzodiazepines = Valium, Librium, Ativan, Serax, Tranxene, Dalmane, Halcion, Xanax, Miltown, Other = Chloral Hydrate (Noctex), Quaaludes
Cocaine:	Cocaine Crystal, Free-Base Cocaine or "Crack", and "Rock Cocaine"
Amphetamines:	Monster, Crank, Benzedrine, Dexedrine, Ritalin, Preludin, Methamphetamine, Speed, Ice, Crystal
Cannabis:	Marijuana, Hashish
Hallucinogens:	LSD (Acid), Mescaline, Mushrooms (Psilocybin), Peyote, Green, PCP (Phencyclidine), Angel Dust, Ecstacy
Inhalants:	Nitrous Oxide, Amyl Nitrate (Whippits, Poppers), Glue, Solvents, Gasoline, Toluene, etc.

Just note if these are used: Antidepressants,
Ulcer Meds = Zantac, Tagamet
Asthma Meds = Ventoline Inhaler, Theodur
Other meds = Antipsychotics, Lithium

NIDA Clinical Trials Network

Access to Care Scale (ATC)

Web Version: 1.0; 1.00; 07-06-12

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

Now I'm going to read you some statements about health care that ask about the past 6 months.

RA Instruction: Provide participant with a reference card that lists all response options for his/her easy reference.

Date of assessment:*(ATCASMDT)* *(mm/dd/yyyy)* Click here for calendar

I am going to read you some statements that ask about the past 6 months.
Tell me if you strongly agree, somewhat agree, are uncertain, somewhat disagree, or strongly disagree with each statement.

In the past 6 months, would you say:	Strongly agree	Somewhat agree	Uncertain	Somewhat disagree	Strongly disagree
1. If I need hospital care, I can get admitted without trouble.	*(ATADMIT)* ☐	☐	☐	☐	☐
2. It is hard for me to get medical care in an emergency.	*(ATERCARE)* ☐	☐	☐	☐	☐
3. Sometimes I go without the medical care I need because it is too expensive.	*(ATEXPNSV)* ☐	☐	☐	☐	☐
4. I have easy access to the medical specialists that I need.	*(ATACCESS)* ☐	☐	☐	☐	☐
5. Places where I can get medical care are very conveniently located.	*(ATLOCATN)* ☐	☐	☐	☐	☐
6. I am able to get medical care whenever I need it.	*(ATMDCARE)* ☐	☐	☐	☐	☐

Comments:*(ATCCOMM)*

NIDA Clinical Trials Network

AUDIT (AUC)

Web Version: 1.0; 4.01; 10-21-13

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

The next several questions are about alcohol use over the past 1 year.
The next several questions are about alcohol use since your last visit.
RA Instruction: Provide participant with a reference card that lists all 5 response options for his/her easy reference.
RA Instruction: Provide participant with a reference card that lists all response options for his/her easy reference.

Date of assessment:*(AUCASMDT)* *(mm/dd/yyyy)* Click here for calendar

1. How often do you have a drink containing alcohol?
(AUALFREQ)

0-Never
1-Monthly or less
2-2 to 4 times a month
3-2 to 3 times a week
4-4 or more times a week

2. How often do you have a drink containing alcohol?
(AUALFREQ)

0-Never
1-Monthly or less
2-2 to 4 times a month
3-2 to 3 times a week
4-4 or more times a week

3. How many drinks containing alcohol do you have on a typical day when drinking?*(AUNUMBER)*

0-1 or 2
1-3 or 4
2-5 or 6
3-7 to 9
4-10 or more

	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
4. How often do you have six or more drinks on one occasion?	*(AU6DRINK)* ☐	☐	☐	☐	☐
5. How often during the last year have you found that you were unable to stop drinking once you started?	*(AUNOSTP)* ☐	☐	☐	☐	☐
6. How often during the last year have you failed to do what was normally expected of you because of drinking?	*(AUEXPECT)* ☐	☐	☐	☐	☐
7. How often during the last year have you needed a first drink in the morning to get yourself going after a heavy drinking session?	*(AUAMDRNK)* ☐	☐	☐	☐	☐
8. How often during the last year have you felt guilt or remorse after drinking?	*(AUGUILTY)* ☐	☐	☐	☐	☐
9. How often during the last year have you been unable to remember what happened the night before because of drinking?	*(AUREMBR)* ☐	☐	☐	☐	☐

10. Does the hospital system medical record has evidence of heavy alcohol use in the past 12 months? *(AUHVYALC)*

☐ No ☐ Yes

a. If "Yes", specify source of evidence:

Clinician notes:*(AUCLINSO)*

☐ No ☐ Yes

Toxicology report for alcohol:*(AUTOXSO)*

☐ No ☐ Yes

b. If source is "Toxicology report", specify alcohol level:*(AUALCLVL)*

_____ *(x.xx)* %

c. If source is "Toxicology report", date toxicology for alcohol obtained:*(AUTOXDT)*

_____ *(mm/dd/yyyy)* Click here for calendar

11. Have you or someone else been injured as a result of your drinking?*(AUINJURD)*

0-No
2-Yes, but not in the last year
4-Yes, during the last year

12. Has a relative, friend, doctor, or other health worker, been concerned about your drinking or suggested you cut down?*(AUCONCRN)*

0-No
2-Yes, but not in the last year
4-Yes, during the last year

Total score (include screening numbers):*(AUSCORE)*

_____ *(xx)*

Total score:*(AUSCORE)*

_____ *(xx)*

Comments:*(AUCCOMM)*

NIDA Clinical Trials Network

Brief Symptom Inventory® 18 (BSI)

Web Version: 1.0; 2.01; 06-20-13

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

Date of assessment:*(BSASMTDT)* _____ *(mm/dd/yyyy)* Click here for calendar

The next set of questions consist of a list of problems that people sometimes have. I will read each problem to you. Then you can tell me the number of the response that best describes how much that problem has distressed or bothered you during the past 7 days, including today.

Before we get started, I'll read an example: How much were you distressed (or bothered) by body aches?

0 = Not at all 1 = A little bit 2 = Moderately 3 = Quite a bit 4 = Extremely

How much were you distressed by:
Body aches*(BSEXAMPL)* ☐ 0 = Not at all ☐ 1 = A little bit ☐ 2 = Moderately ☐ 3 = Quite a bit ☐ 4 = Extremely

RA Instruction: Provide participant with a reference card that lists all response options for his/her easy reference.

How much were you distressed by:	NOT AT ALL 0	A LITTLE BIT 1	MODERATELY 2	QUITE A BIT 3	EXTREMELY 4
1. Faintness or dizziness:	*(BSFNTDIZ)* ☐	☐	☐	☐	☐
2. Feeling no interest in things:	*(BSNOINT)* ☐	☐	☐	☐	☐
3. Nervousness or shakiness inside:	*(BSNERVOS)* ☐	☐	☐	☐	☐
4. Pains in heart or chest:	*(BSPAINHR)* ☐	☐	☐	☐	☐
5. Feeling lonely:	*(BSLONELY)* ☐	☐	☐	☐	☐
6. Feeling tense or keyed up:	*(BSTENSE)* ☐	☐	☐	☐	☐
7. Nausea or upset stomach:	*(BSNAUSE)* ☐	☐	☐	☐	☐
8. Feeling blue:	*(BSBLUE)* ☐	☐	☐	☐	☐
9. Suddenly scared for no reason:	*(BSSCARED)* ☐	☐	☐	☐	☐
10. Trouble getting your breath:	*(BSBREATH)* ☐	☐	☐	☐	☐
11. Feelings of worthlessness:	*(BSWORTH)* ☐	☐	☐	☐	☐
12. Spells of terror or panic:	*(BSTERRO)* ☐	☐	☐	☐	☐
13. Numbness or tingling in parts of body:	*(BSNUMB)* ☐	☐	☐	☐	☐
14. Feeling hopeless about the future:	*(BSHOPELS)* ☐	☐	☐	☐	☐
15. Feeling so restless you couldn't sit still:	*(BSRESTLS)* ☐	☐	☐	☐	☐
16. Feeling weak in parts of your body:	*(BSWEAK)* ☐	☐	☐	☐	☐

17. Thoughts of ending your life:	*(BSENDLIF)* ☐	☐	☐	☐	☐
18. Feeling fearful:	*(BSFEARFL)* ☐	☐	☐	☐	☐

Comments:*(BSICOMM)*

NIDA Clinical Trials Network

Computer Assisted Personal Interview (CAP)

Web Version: 1.0; 1.00; 03-15-12

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

Where is this assessment being performed?*(CAPLOCTN)*

1-On site
2-Offsite
3-Telephone

Do not read these five lines of text to the participant.

Welcome!

You will be administering some questions using this computer by clicking on checkboxes like this: *(CAPBOX1)* ☐

When you're done, click on the "Save" button at the top or bottom of the screen.

Try it out!

Click this checkbox and then click on the "Save" button: *(CAPBOX2)* ☐

NIDA Clinical Trials Network

Debriefing Provider Visit with Participant - Patient Navigator and Contingency Management (CDP)

Web Version: 1.0; 1.00; 07-19-12

Segment *(PROTSEG)*:
Session Date *(PCSESDT)*:

Date of assessment:*(CDPASMDT)* _____ *(mm/dd/yyyy)* Click here for calendar

Patient navigator number:*(CPPNNUM)* _____

Session length:*(CPSESLEN)* _____ *(xxx)* minutes

To what extent did the patient navigator:	Not at all	Somewhat	Mostly	Completely	Not rated
1. **Support participant efforts:** Invite participant to articulate positive outcomes from care visit and participant efforts. Elicit from participant what the participant learned and what strengths the participant demonstrated; verbally acknowledge participant strengths; if appropriate, explore with the participant what can be done differently in future care visits to achieve a more positive outcome.	*(CPSUPPOR)* ☐	☐	☐	☐	☐
2. **Discuss outstanding business:** Ask participant to identify unanswered/unaddressed questions (see index card); identify new questions/concerns that may have come up.	*(CPOUTSTN)* ☐	☐	☐	☐	☐
3. **Discuss and prepare for next steps in self-care:** Strategize lab draw and/or medication pick-up and medication start date, assist with setting dates, rehearse preliminary steps; encourage participant to discuss taking medications with pharmacy staff; offer to call participant between patient navigator meetings to check in about taking medications.	*(CPNEXTST)* ☐	☐	☐	☐	☐
4. **Plan next patient navigator meeting:** Schedule appointment; review locator info; reinforce participant interest/effort in self-care; offer urine and breathalyzer screens, provide instructions and conduct screens; provide appropriate verbal encouragement on screen results.	*(CPMEET)* ☐	☐	☐	☐	☐
5. **Visit contingency management schedule and current and future earnings:** Offer urine and breathalyzer screens, provide instructions and conduct screens; provide appropriate verbal support on screen results and any other accomplishments (paperwork, labs, medication pick up, etc.); provide appropriate incentives; review contingency management schedule and remind participant of potential upcoming incentives that can be earned.	*(CPCMSCH)* ☐	☐	☐	☐	☐

Comments:*(CDPCOMM)*

NIDA Clinical Trials Network

Debriefing Substance Abuse Treatment Visit - Patient Navigator and Contingency Management (CDS)

Web Version: 1.0; 1.00; 07-25-12

Segment *(PROTSEG)*:
Session Date *(PCSESDT)*:

Date of assessment:*(CDSASMDT)* _____ *(mm/dd/yyyy)* Click here for calendar

Patient navigator number:*(CSPNNUM)* _____

Session length:*(CSSESLEN)* _____ *(xxx)* minutes

To what extent did the patient navigator:	Not at all	Somewhat	Mostly	Completely	Not rated
1. **Support participant's efforts:** Invite the participant to articulate the positive outcomes from the visit and participant's efforts. Elicit from participant what participant learned and what strengths participant demonstrated; verbally acknowledge participant strengths; if appropriate, explore with participant what can be done differently in future care visits to achieve a more positive outcome.	*(CSSUPPOR)* ☐	☐	☐	☐	☐
2. **Discuss outstanding business:** Ask participant to identify unanswered/unaddressed questions (see index card) and new questions/concerns that may have come up.	*(CSOUTSTN)* ☐	☐	☐	☐	☐
3. **Discuss and prepare for next steps in self-care:** Strategize follow-up to substance abuse treatment plan, assist participant in setting specific substance abuse treatment activities and rehearse preliminary steps.	*(CSNEXTST)* ☐	☐	☐	☐	☐
4. **Plan next patient navigator meeting:** Schedule appointment; review locator form; reinforce participant interest/effort in self-care.	*(CSMEET)* ☐	☐	☐	☐	☐
5. **Visit contingency management schedule and current and future earnings:** If appropriate: offer urine and breathalyzer screens, provide instructions and conduct screens; provide appropriate verbal encouragement on screen results and any other accomplishments (paperwork, labs, medication pick up, etc.); provide appropriate incentives; review contingency management schedule and remind participant of potential upcoming incentives participant can earn.	*(CSCMSCH)* ☐	☐	☐	☐	☐

Comments:*(CDSCOMM)*

NIDA Clinical Trials Network

Concise Health Risk Tracking (CHRT) Participant Rated Module (CHR)

Web Version: 1.0; 3.00; 06-27-13

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

RA Instruction: Provide participant with a reference card that lists all response options for his/her easy reference.

Date of assessment:*(CHASMTDT)* _____ *(mm/dd/yyyy)* Click here for calendar

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. *(CHNOTHRT)*	☐	☐	☐	☐	☐
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)*	☐	☐	☐	☐	☐

Comments: *(CHRCOMM)*

NIDA Clinical Trials Network

Clinical Labs Data (CLD)

Web Version: 1.0; 9.05; 01-27-14

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

Study Labs

1. Participant has a detectable (>200 copies/mL) viral load or unknown level in the past 12 months: *(CDVRLOAD)* ☐ No ☐ Yes
   a. If "Yes" or "No", specify viral load: *(CDLOADVL)* _____ *(xxxxxxx)* copies per mL **- OR -** *(CDVRUNK)* ☐ Unknown
   b. Date viral load obtained: *(CDLOADDT)* _____ *(mm/dd/yyyy)* Click here for calendar

2. Participant's most recent CD4 count <=500 cells/uL in the past 12 months: *(CDBSECD4)* ☐ No ☐ Yes ☐ Unknown
   a. If "Yes" or "No", specify CD4 count: *(CDCD4VAL)* _____ *(xxxxx)* cells/µL
   b. Date CD4 count obtained: *(CDCD4DT)* _____ *(mm/dd/yyyy)* Click here for calendar

3. It is the Site PI's discretion that the participant is likely to currently have a viral load greater than 200 copies/mL, is not currently successfully/correctly taking ART, and needs to be on ART: *(CDPI)* ☐ No ☐ Yes

4. Has the participant had an AIDS defining illness during the current hospital admission? *(CDAIDS)* ☐ No ☐ Yes
   If "Yes", specify: *(CDAIDSSP)*

   1-Candidiasis (bronchi, trachea, lungs, esophageal)
   2-Coccidiomycosis (disseminated/extrapulmonary, cryptococcosis (extrapulmonary))
   3-Cryptosporidiosis (>1 month), CMV (other than liver/spleen/lymphnodes), HIV encephalopathy
   4-Herpes simplex (lung/esophageal or chronic ulcers>1 mo)
   5-Histoplasmosis (disseminated/extrapulmonary), Kaposi's sarcoma
   *Additional Options Listed Below

5. Was a sample collected? *(CDCOLTD)* ☐ No ☐ Yes
   If "Yes," date: *(CDCOLTDT)* _____ *(mm/dd/yyyy)* Click here for calendar
6. CD4 collection method: *(CDCD4CLT)*

   0-Not collected
   1-Blood draw at research site
   2-Blood collection off site
   3-Medical record abstraction

   a. CD4 collection date: *(CDCD4CDT)* _____ *(mm/dd/yyyy)* Click here for calendar
   b. CD4: *(CDCD4C)* _____ *(xxxxx)* (cells/µL)
   c. CD4 %: *(CDCD4P)* _____ *(xxx.x)* %
7. Viral load collection method: *(CDVLCLT)*

   0-Not collected
   1-Blood draw at research site
   2-Blood collection off site
   3-Medical record abstraction

   a. Viral load collection date: *(CDVLCDT)* _____ *(mm/dd/yyyy)* Click here for calendar
   b. Is HIV viral load undetectable? *(CDHIVVLU)* ☐ No ☐ Yes

c. If "Yes," what is your lab's lower limit? *(CDLOWER)*

< _____ *(xxx)* (copies/mL)

d. If "No," how many copies? *(CDCOPIES)*

_____ *(xxxxxxx)* (copies/mL)

e. VL Assay Type: *(CDASSAY)*

_____

8. CBC collection method: *(CDCBCCLT)*

0-Not collected
1-Blood draw at research site
2-Blood collection off site
3-Medical record abstraction

a. CBC collection date: *(CDCBCCDT)*

_____ *(mm/dd/yyyy)* Click here for calendar

b. Hemoglobin: *(CDHGB)*

_____ *(xx.x)* g/dL

c. Hematocrit: *(CDHCT)*

_____ *(xx.x)* %

d. WBC: *(CDWBC)*

_____ *(xxx.x)* k/µL

e. Platelets: *(CDPLAT)*

_____ *(xxxx)* k/µL

BMI

9. Height: *(CDHGHTIN)*

_____ *(xx)* in **- OR -** *(CDHGHTCM)* _____ *(xxx)* cm

10. Weight: *(CDWGHTLB)*

_____ *(xxx.x)* lbs **- OR -** *(CDWGHTKG)* _____ *(xxx.x)* kg

Was weight measured or abstracted? *(CDWGHTMA)*

☐ Measured ☐ Abstracted

11. BMI: *(CDCALC)*

_____

Abstracted Labs

Lab values within the 6 months prior to Date of Randomization through 1 month after Date of Randomization

Lab Name	Date Collected	Date Collected	Value	Alternate Value
12. Creatinine:	*(CDCREDT)* _____ Calendar	*(CDCREDT)* _____ Calendar	*(CDCREAT)* _____ *(xx.xx)* mg/dL	
13. eGFR calculated by lab:	*(CDEGFRDT)* _____ Calendar	*(CDEGFRDT)* _____ Calendar	*(CDEGFR)* _____ *(xxx.x)* mL/min/1.73 m^2	*(CDEGFRNE)* **- OR - >** _____ *(xxx)* mL/min/1.73 m^2
14. Total bilirubin:	*(CDTBILDT)* _____ Calendar	*(CDTBILDT)* _____ Calendar	*(CDTBILI)* _____ *(xx.xx)* mg/dL	
15. Direct bilirubin:	*(CDDBILDT)* _____ Calendar	*(CDDBILDT)* _____ Calendar	*(CDDBILI)* _____ *(xx.xx)* mg/dL	
16. Total protein:	*(CDTPRODT)* _____ Calendar	*(CDTPRODT)* _____ Calendar	*(CDTPROT)* _____ *(xx.x)* g/dL	
17. Albumin:	*(CDALBDT)* _____ Calendar	*(CDALBDT)* _____ Calendar	*(CDALB)* _____ *(xx.x)* g/dL	
18. AST:	*(CDASTDT)* _____ Calendar	*(CDASTDT)* _____ Calendar	*(CDAST)* _____ *(xxxxx)* U/L	
19. ALT:	*(CDALTDT)* _____ Calendar	*(CDALTDT)* _____ Calendar	*(CDALT)* _____ *(xxxxx)* U/L	
20. ALK phos:	*(CDALKDT)* _____ Calendar	*(CDALKDT)* _____ Calendar	*(CDALK)* _____ *(xxxxx)* U/L	

-OR- no abstracted labs available: *(CDNOABST)* ☐

21. HCV antibody: *(CDHCVAB)*

☐ Negative ☐ Positive

HCV antibody collection date: *(CDHCVDT)*

_____ *(mm/dd/yyyy)* Click here for calendar

Is the HCV viral load undetectable? *(CDHCVVLU)*

☐ No ☐ Yes ☐ Unknown

HCV viral load collection date:*(CDHCVLDT)* *(mm/dd/yyyy)* Click here for calendar

If "No", how many copies?*(CDHCVVL)* *(xxxxxxxxx)* (copies/mL)

22. Does the patient have a diagnosis of an AIDS defining illness listed in the past medical history or problem list?*(CDDIAG)* ☐ No ☐ Yes

AIDS defining illnesses include: candidiasis (bronchi, trachea, lungs, esophageal); coccidiomycosis (disseminated/extrapulmonary, cryptococcosis (extrapulmonary); cryptosporidiosis (>1 month), CMV (other than liver/spleen /lymphnodes), HIV encephalopathy; Herpes simplex (lung/esophageal or chronic ulcers>1 mo); histoplasmosis (disseminated/extrapulmonary), Kaposi's sarcoma; burkitt's lymphoma; immunoblastic lymphoma; primary CNS lymphoma; Mycobacterium avium complex or Mycobacterium kansasii; Other mycobacterium (disseminated, extrapulm); M. Tuberculosis (any site); pneumocystis jirovecii pneumonia; isosporiasis; progressive multifocal leukoencephalopathy; recurrent salmonella septicemia; toxoplasmosis of the brain; wasting syndrome due to HIV; invasive cervical cancer; recurrent pneumonia)

Ancillary Labs

Lab values within the 48-hours post Initial Hospital Admission Date

Lab Name	Date Collected	Value
23. PaO_2:	*(CDPAO2DT)* Calendar	*(CDPAO2)* *(xxx)* mmHg
24. Sodium (Na):	*(CDSODIDT)* Calendar	*(CDSODIUM)* *(xxx)* mEq/L
25. Chloride (Cl):	*(CDCHLDT)* Calendar	*(CDCHLOR)* *(xxx)* mmol/L
26. Bicarbonate (CO_2):	*(CDBICADT)* Calendar	*(CDBICARB)* *(xx)* mmol

-OR- no ancillary labs available:*(CDNOANCL)* ☐

27. Absolute lymphocyte count:*(CDALYMPH)* *(xx.xx)* x 10^9/L Date collected:*(CDALYMDT)* *(mm/dd/yyyy)* Calendar

- OR -

28. WBC:*(CDWBCAN)* *(xx.xx)* x 10^9/L Date collected:*(CDWBCADT)* *(mm/dd/yyyy)* Calendar

29. Percentage lymphocytes:*(CDLYMPCT)* *(xxx)* % Date collected:*(CDLYMPDT)* *(mm/dd/yyyy)* Calendar

Comments:*(CLDCOMM)*

Additional Selection Options for CLD

If "Yes", specify:
6-Burkitt's lymphoma
7-Immunoblastic lymphoma
8-Primary CNS lymphoma
9-Mycobacterium avium complex or Mycobacterium kansasii
10-Other mycobacterium (disseminated, extrapulm)
11-M. Tuberculosis (any site)
12-Pneumocystis jirovecii pneumonia
13-Isosporiasis
14-Progressive multifocal leukoencephalopathy
15-Recurrent salmonella septicemia
16-Toxoplasmosis of the brain
17-Wasting syndrome due to HIV
18-Invasive cervical cancer
19-Recurrent pneumonia

NIDA Clinical Trials Network

Preparing for Initial Substance Abuse Treatment Visit - Patient Navigator and Contingency Management (CMA)

Web Version: 1.0; 1.00; 07-23-12

Segment *(PROTSEG)*:
Session Date *(PCSESDT)*:

Date of assessment:*(CMAASMDT)* _____ *(mm/dd/yyyy)* Click here for calendar

Patient navigator number:*(CAPNNUM)* _____

Session length:*(CASESLEN)* _____ *(xxx)* minutes

To what extent did the patient navigator:	Not at all	Somewhat	Mostly	Completely	Not rated
1. **Familiarize participant with the specifics of substance abuse treatment agency:** Review names and basic info about provider/agency staff; review pictures (if appropriate); discuss any clinic consideration for HIV+ clients; discuss typical visit flow; review visit requirements (ID, paperwork), discuss transportation to clinic.	*(CATXAG)* ☐	☐	☐	☐	☐
2. **Prepare participant for meeting with substance abuse treatment provider:** Assist participant with questions to ask provider; write down questions/concerns/points on two index cards; rehearse communication with provider, discuss solutions to potential barriers.	*(CATXPR)* ☐	☐	☐	☐	☐
3. **Prepare for patient navigator-participant meeting prior to substance abuse treatment visit:** Choose time and clear/specific place to meet; discuss reminder phone call/email; resolve transportation issues.	*(CAPNPPT)* ☐	☐	☐	☐	☐
4. **Provide clear expectations of roles during substance abuse treatment visit:** Clarify clinic policy regarding patient navigator's presence; discuss participant's expectation around patient navigator's presence; discuss nature of support/facilitation provided by patient navigator. Note: If participant is ambivalent, roll with resistance (validate/discuss concerns of substance abuse, explore trial run visit, revisiting topic at future patient navigator/participant meeting, etc.	*(CAROLES)* ☐	☐	☐	☐	☐
5. **Prepare for next patient navigator meeting:** Schedule next appointment; review locator information; reinforce participant interest in self-care.	*(CAMEET)* ☐	☐	☐	☐	☐
6. **Visit contingency management schedule and current and future earnings:** If appropriate: offer urine and breathalyzer screens, provide instructions and conduct screens; provide appropriate verbal support on screen results and any other accomplishments (paperwork, labs, medication pick up, etc.); provide appropriate incentives; review contingency management schedule and remind participant of potential upcoming incentives that participant can earn.	*(CACMSCH)* ☐	☐	☐	☐	☐

Comments:*(CMACOMM)*

NIDA Clinical Trials Network

Preparing to Meet Care Provider - Patient Navigator and Contingency Management (CMC)

Web Version: 1.0; 1.00; 07-19-12

Segment *(PROTSEG)*:
Session Date *(PCSESDT)*:

Date of assessment:*(CMCASMDT)* _____ *(mm/dd/yyyy)* Click here for calendar

Patient navigator number:*(CCPNNUM)* _____

Session length:*(CCSESLEN)* _____ *(xxx)* minutes

To what extent did the patient navigator:	Not at all	Somewhat	Mostly	Completely	Not rated
1. **Familiarize the participant with the care agency:** Review names and basic information about provider/agency staff; review pictures (if appropriate); review agency address; discuss typical visit flow; review visit requirements (ID, paperwork); discuss transportation to clinic.	*(CCFAMILR)* ☐	☐	☐	☐	☐
2. **Prepare the participant for meeting with care provider:** Assist participant with questions to ask provider; write down questions/concerns/points on two index cards; rehearse provider interaction; discuss solutions to potential barriers.	*(CCPROVID)* ☐	☐	☐	☐	☐
3. **Prepare for navigator-participant meeting prior to care visit:** Choose time and clear/specific place for patient navigator and participant to meet; discuss reminder phone call/email; resolve transportation issues.	*(CCNAVPPT)* ☐	☐	☐	☐	☐
4. **Discuss expectations of patient navigator/participant roles at care visit:** Clarify clinic policy on patient navigator presence; discuss participant's expectation around patient navigator presence; discuss nature of support/facilitation provided by patient navigator. Note: If participant is ambivalent, roll with resistance (validate/discuss concerns of treatment, explore trial run visit, revisiting topic at another patient navigator/participant meeting, etc.).	*(CCROLES)* ☐	☐	☐	☐	☐
5. **Prepare for next patient navigator meeting:** Schedule appointment; review locator info; reinforce participant interest in self-care.	*(CCMEET)* ☐	☐	☐	☐	☐
6. **Visit contingency management schedule and current and future earnings:** If appropriate: offer urine and breathalyzer screens, provide instructions and conduct screens; provide appropriate verbal support on screen results and any other accomplishments (paperwork, labs, medication pick up, etc.); provide appropriate incentives and verbal encouragement; review contingency management schedule and remind participant of potential upcoming incentives that participant can earn.	*(CCCMSCH)* ☐	☐	☐	☐	☐

Comments:*(CMCCOMM)*

NIDA Clinical Trials Network

Final Patient Navigator Meeting - Patient Navigator and Contingency Management (CMF)

Web Version: 1.0; 1.00; 07-19-12

Segment *(PROTSEG)*:
Session Date *(PCSESDT)*:

Date of assessment:*(CMFASMDT)* _____ *(mm/dd/yyyy)* Click here for calendar

Patient navigator number:*(CFPNNUM)* _____

Session length:*(CFSESLEN)* _____ *(xxx)* minutes

To what extent did the patient navigator:	Not at all	Somewhat	Mostly	Completely	Not rated
1. **Review self-care progress since initial patient navigator meeting:** Invite/help participant to acknowledge ways that participant demonstrated self-care in last 6 months (related to HIV, substance abuse, housing, accessing services, employment, social/physical health); If appropriate, refer to patient navigator tracking program in order to outline self-care progress; acknowledge/support attempts at self-care and small successes (getting ID, etc.).	*(CFREVIEW)* ☐	☐	☐	☐	☐
2. **Examine challenges to self-care efforts and goals:** Invite participant to identify current challenges to self-care; focus on ways participant overcame barriers in participant past; reinforce strengths participant demonstrated.	*(CFCHALL)* ☐	☐	☐	☐	☐
3. **Discuss ways to continue self-care efforts post-study:** Explore support options to maintain self-care goals (identify agencies and individuals); discuss/strategize possible realistic next steps.	*(CFCONTIN)* ☐	☐	☐	☐	☐
4. **Explore the experience of working together:** Encourage participant to share participant benefits and challenges of working together. Navigator shares patient navigator experience, focusing on positive and successful resolutions of challenges.	*(CFEXPLOR)* ☐	☐	☐	☐	☐
5. **Discuss upcoming HOPE study (non-patient navigator) follow-up visit:** Review date/activities for 6 month follow-up visit (provide appointment card), remind participant of reimbursement and express appreciation for participant study involvement; review locator information; reinforce participant interest/effort in self-care.	*(CFUPCOM)* ☐	☐	☐	☐	☐
6. **Visit contingency management schedule and current and total earnings:** Offer urine and breathalyzer screens, provide instructions and conduct screens; provide appropriate verbal support on screen results; provide appropriate incentives and verbal encouragement; review contingency management schedule and share total incentives earned for self-care behaviors completed; discuss continued self-care without incentives; discuss current and future benefits of continued self-care.	*(CFCMSCH)* ☐	☐	☐	☐	☐

Comments:*(CMFCOMM)*

NIDA Clinical Trials Network

Initial Patient Navigator Meeting - Patient Navigator and Contingency Management (CMI)

Web Version: 1.0; 1.00; 07-19-12

Segment *(PROTSEG)*:
Session Date *(PCSESDT)*:

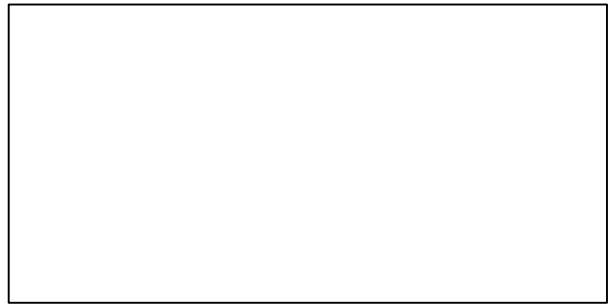
Date of assessment:*(CMIASMDT)* _____ *(mm/dd/yyyy)* Click here for calendar

Patient navigator number:*(CIPNNUM)* _____

Session length:*(CISESLEN)* _____ *(xxx)* minutes

To what extent did the patient navigator:	Not at all	Somewhat	Mostly	Completely	Not rated
1. **Provide introductions and patient navigator overview:** Greet participant; introduce each to the other, describe professional background; provide verbal overview of HOPE patient navigation and offer HOPE question and answer handout.	*(CIINTRO)* ☐	☐	☐	☐	☐
2. **Provide contingency management concepts:** Share overview of contingency management; provide contingency management Q&A handout; introduce contingency management tracking program.	*(CICONCPT)* ☐	☐	☐	☐	☐
3. **Build rapport and understanding of participant's HIV history:** Explore participant's experience with HIV, hospitalizations, medications, care providers; answer knowledge-based HIV questions.	*(CIHIVHX)* ☐	☐	☐	☐	☐
4. **Elicit motivation for taking control of HIV:** Show video; explore participant's reaction and highlight relevant themes, reinforce benefits of HIV treatment.	*(CIMOTIV)* ☐	☐	☐	☐	☐
5. **Evoke optimism about HIV treatment:** Briefly share information and encouragement around newer/more effective treatment regiments; offer support with accessing primary HIV care and/or support to improve relationship with existing provider.	*(CIOPTIM)* ☐	☐	☐	☐	☐
6. **Provide care agency information:** Share photo album; share knowledge of the clinic, staff, services and other participant's positive experiences; discuss participant's interest, expectations and concerns about linkage.	*(CICARE)* ☐	☐	☐	☐	☐
7. **Assess readiness to change substance use:** Conduct brief assessment of substance abuse and treatment histories; explore interests, expectations and concerns regarding linkage.	*(CIASSESS)* ☐	☐	☐	☐	☐
8. **Assess external barriers to linkage to treatment:** Explore identified barriers (food, clothing and/or housing insecurities, identification, insurance, transportation); share commitment to help participant meet needs.	*(CIEXBAR)* ☐	☐	☐	☐	☐
9. **Provide initial preparation for primary care visit:** If agrees to visit: review/help schedule appointment, discuss prerequisite paperwork, labs; discuss and schedule reminder call, meeting time/location; identify/address barriers to appointment. If decides against linkage: empathetically and collaboratively discuss decision, explore/normalize ambivalence, remind participant of continuation of patient navigator meetings for other linkages.	*(CIPRIMRY)* ☐	☐	☐	☐	☐
10. **Prepare for next patient navigator meeting:** Schedule appointment, provide folder, review locator info, reinforce participant interest in self-care.	*(CIMEET)* ☐	☐	☐	☐	☐
11. **Reinforce targeted HOPE behaviors:** Offer urine and breathalyzer screens, provide instructions and conduct screens; provide appropriate verbal support on screen results and any other accomplishments (paperwork, labs, medication pick up, etc.); provide appropriate incentives; review contingency management schedule and remind participant of potential upcoming incentives that participant can earn.	*(CITARGET)* ☐	☐	☐	☐	☐

Comments: *(CMICOMM)*



NIDA Clinical Trials Network

Unscripted Patient Navigator/Participant Visit - Patient Navigator and Contingency Management (CMU)

Web Version: 1.0; 1.00; 07-19-12

Segment *(PROTSEG)*:
Session Date *(PCSESDT)*:

Date of assessment:*(CMUASMDT)* _____ *(mm/dd/yyyy)* Click here for calendar

Patient navigator number:*(CUPNNUM)* _____

Session length:*(CUSESLEN)* _____ *(xxx)* minutes

To what extent did the patient navigator:	Not at all	Somewhat	Mostly	Completely	Not rated
1. **Support participant's recent self-care efforts:** Invite the participant to articulate any self-care efforts attempted and/or accomplished since last patient navigator meeting; elicit from participant what participant learned and what strengths participant demonstrated; verbally acknowledge/affirm participant strengths; if appropriate, explore with participant what can be done differently in the future to achieve more positive outcomes; continue to build/maintain rapport.	*(CUSUPPOR)* ☐	☐	☐	☐	☐
2. **Assist participant in addressing ambivalence re: self-care:** Using motivational interviewing techniques (OARS) and manual tools, address ambivalence: ask participant to identify pros/cons of status quo; pros/cons of change (self-care behaviors); ask what participant sees for self in 3 or 5 years if no change occurs; what hopes participant has for future; what is important for participant; what needs to happen for participant to be more ready to make change, etc.	*(CUAMBIV)* ☐	☐	☐	☐	☐
3. **Discuss and prepare for any next steps in any self-care:** Strategize what participant may want to accomplish between now and next patient navigator/participant visit related to self-care (housing, food, support, HIV care, substance abuse treatment, dental, clothing, etc.); assist participant in setting specific steps and target dates for goal; discuss ways to overcome potential barriers.	*(CUNEXTST)* ☐	☐	☐	☐	☐
4. **Plan next patient navigator meeting:** Schedule appointment; discuss any appropriate agenda for next meeting; review locator form; reinforce participant interest/effort in self-care.	*(CUMEET)* ☐	☐	☐	☐	☐
5. **Visit contingency management schedule and current and future earnings:** If appropriate, offer urine and breathalyzer screens, provide instructions and conduct screens; provide appropriate verbal encouragement on screen results and any other accomplishments (paper work, labs, medication pick up, etc.); provide appropriate incentives; review contingency management schedule and remind participant of upcoming incentives that participant can earn.	*(CUCMSCH)* ☐	☐	☐	☐	☐

Comments:*(CMUCOMM)*

NIDA Clinical Trials Network

Cognitive Screening (COG)

Web Version: 1.0; 1.00; 03-09-12

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

Date of assessment:*(COASMTDT)* *(mm/dd/yyyy)* Click here for calendar

Memory-Registration *- Give four words to recall (dog, hat, bean, red) - 1 second to say each. Then ask the patient all four words after you have said them. Repeat words if the patient does not recall them all immediately. Tell the patient you will ask for recall of the words again a bit later.*

1. Motor Speed: Have the patient tap the thumb and forefinger of the non-dominant hand as widely and as quickly as possible.*(COMOTSPD)*

0-0 to 2 in 5 seconds
1-3 to 6 in 5 seconds
2-7 to 10 in 5 seconds
3-11 to 14 in 5 seconds
4-15 in 5 seconds

2. Psychomotor Speed: Have the patient perform the following movements with the non-dominant hand as quickly as possible:

   1) Clench hand in fist on flat surface.
   2) Put hand flat on surface with palm down.
   3) Put hand perpendicular to flat surface on the side of the 5th digit.

   Demonstrate and have patient perform twice for practice.*(COPSYSPD)*

0-Unable to perform
1-1 sequence in 10 seconds
2-2 sequences in 10 seconds
3-3 sequences in 10 seconds
4-4 sequences in 10 seconds

Memory-Recall *- Ask the patient to recall the four words. For words not recalled, prompt with a semantic clue as follows: animal (dog); piece of clothing (hat); vegetable (bean); color (red).*

1. Recall: dog*(COMEDOG)*

0-Unable to recall
1-Recalled after prompting
2-Spontaneously recalled

2. Recall: hat*(COMEHAT)*

0-Unable to recall
1-Recalled after prompting
2-Spontaneously recalled

3. Recall: bean*(COMEBEAN)*

0-Unable to recall
1-Recalled after prompting
2-Spontaneously recalled

4. Recall: red*(COMERED)*

0-Unable to recall
1-Recalled after prompting
2-Spontaneously recalled

Comments: *(COGCOMM)*

NIDA Clinical Trials Network

Demographics (DEM)

Web Version: 1.0; 1.00; 06-03-11

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

2. Sex:*(DEGENDER)* ☐ Male ☐ Female ☐ Participant chooses not to answer

3. Ethnicity:*(DEETHNIC)* ☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Participant chooses not to answer

4. Race:

American Indian or Alaska Native*(DEAMEIND)*	☐ No ☐ Yes
Asian*(DEASIAN)*	☐ No ☐ Yes
Black or African American*(DEBLACK)*	☐ No ☐ Yes
Native Hawaiian or Pacific Islander*(DEHAWAII)*	☐ No ☐ Yes
White*(DEWHITE)*	☐ No ☐ Yes
Other*(DEOTHER)*	☐ No ☐ Yes
If "Yes", specify:*(DEOTHRSP)*	_____

OR

Unknown*(DEUNKNOW)*	☐ Yes
Participant chooses not to provide their race*(DENORACE)*	☐ Yes

Comments:*(DEMCOMM)* _____

NIDA Clinical Trials Network

DAST-10 (DST)

Web Version: 1.0; 1.00; 07-06-12

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

The next several questions are about drug use. Please answer No or Yes.

Date of assessment:*(DSTASMDT)* *(mm/dd/yyyy)* Click here to view calendar

1. Have you used drugs other than those required for medical reasons?*(DSREASON)* ☐ No ☐ Yes
2. Do you use more than one drug at a time?*(DSABUSEM)* ☐ No ☐ Yes
3. Are you always able to stop using drugs when you want to?*(DSABLES)* ☐ No ☐ Yes
4. Have you had "blackouts" or "flashbacks" as a result of drug use?*(DSFBLACK)* ☐ No ☐ Yes
5. Do you ever feel bad or guilty about your drug use?*(DSFEELB)* ☐ No ☐ Yes
6. Does your spouse/partner (or parents) ever complain about your involvement with drugs?*(DSSPOUSE)* ☐ No ☐ Yes
7. Have you neglected your family because of your use of drugs?*(DSNEGLEC)* ☐ No ☐ Yes
8. Have you engaged in illegal activities in order to obtain drugs?*(DSILLEGA)* ☐ No ☐ Yes
9. Have you ever experienced withdrawal symptoms (felt sick) when you stopped taking drugs? *(DSWITHDR)* ☐ No ☐ Yes
10. Have you had medical problems as a result of your drug use (e.g., memory loss, hepatitis, convulsions, bleeding, etc.)?*(DSPROBLE)* ☐ No ☐ Yes

Comments:*(DSTCOMM)*

NIDA Clinical Trials Network

Death Form (DTH)

Web Version: 1.0; 1.03; 08-07-14

Date of death *(DTDTHDT)*:

1. Time of death (24-hour format):*(DTDTHTM)* *(hh:mm)*
2. Date staff notified of death:*(DTNOFYDT)* *(mm/dd/yyyy)* Click here for calendar
3. Date of last contact with participant:*(DTCNTCDT)* *(mm/dd/yyyy)* Click here for calendar
4. Date of participant's last primary care visit:*(DTPRIMDT)* *(mm/dd/yyyy)* Click here for calendar

5. Primary cause of death:*(DTCAUSE)*

1-Cardiovascular
2-Cerebrovascular
3-Infection
4-Malignancy
5-Trauma/accidental
*Additional Options Listed Below

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

6. Secondary cause of death:*(DT2COD)*

1-Tuberculosis
2-Serious liver disease (cirrhosis, varices, hepatic failure, encephalopathy)
3-Cardiovascular discuses (MI, CAD, CHF)
4-ESRD
5-Cerebral vascular disease
*Additional Options Listed Below

If "Other", specify:*(DT2CODSP)*

7. Source:*(DTSOURCE)*

1-Medical chart
2-Death certificate
3-Autopsy report
99-Other

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

8. Was an autopsy performed?*(DTAUTPSY)* ☐ No ☐ Yes ☐ Unknown

Can a copy of the autopsy report be obtained?*(DTAUTCPY)* ☐ No ☐ Yes ☐ Unknown

9. Did death occur while the participant was hospitalized?*(DTHOSPTZ)* ☐ No ☐ Yes ☐ Unknown

If "No", where did the death occur?*(DTPLACE)*

10. Was participant seen in the emergency department within one week prior to death?*(DTEDVIST)* ☐ No ☐ Yes ☐ Unknown

If "Yes", date of ED visit:*(DTEDDT)* *(mm/dd/yyyy)* Click here for calendar

11. Was participant hospitalized within one week prior to death?*(DTHSVIST)* ☐ No ☐ Yes ☐ Unknown

If "Yes", admit date:*(DTHSDT)* *(mm/dd/yyyy)* Click here for calendar

12. Was the participant discharged prior to death?*(DTDISCHG)* ☐ No ☐ Yes ☐ Unknown

If "Yes", discharge date:*(DTDSCHDT)* *(mm/dd/yyyy)* Click here for calendar

13. Was drug use a contributing factor in the death?*(DTDRUG)* ☐ No ☐ Yes ☐ Unknown

14. Was alcohol a contributing factor in the death?*(DTALCOHL)* ☐ No ☐ Yes ☐ Unknown

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

Comments:*(DTHCOMM)*

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

Additional Selection Options for DTH

Primary cause of death:
6-Not obtainable
97-Unknown
99-Other

Secondary cause of death:
6-Malignancy (excluding skin cancer)
7-Diabetes
99-Other

NIDA Clinical Trials Network

0049B (ENR)

Web Version: 1.0; 4.03; 09-16-13

Date of assessment:*(R6ASMDT)* _____ *(mm/dd/yyyy)* Click here for calendar

Inclusion Criteria

In order to meet eligibility ALL **Inclusion answers must be "Yes".**

1. Participant is at least 18 years old:*(R6PTAGE)* ☐ No ☐ Yes ☐ Unknown
2. Participant signed HIPAA and/or ROI to abstract hospital records to verify CD4 and VL eligibility criteria: *(R6HIPAA)* ☐ No ☐ Yes ☐ Unknown
3. Participant reports living in the vicinity and is able to return for follow-up visits:*(R6LIVRET)* ☐ No ☐ Yes ☐ Unknown
4. Participant is able to communicate in English:*(R6ENGLSH)* ☐ No ☐ Yes ☐ Unknown
5. Participant was admitted to a hospital and was HIV-infected at the time of recruitment:*(R6ADMIT)* ☐ No ☐ Yes ☐ Unknown
6. Participant has a Karnofsky performance scale index score of greater than or equal to 60:*(R6KARNOF)* ☐ No ☐ Yes ☐ Unknown
7. Participant reports any opioid and/or stimulant and/or heavy alcohol use within the past year:*(R6DRGUSE)* ☐ No ☐ Yes ☐ Unknown
8. Participant has an indication of any opioid and/or stimulant and/or heavy alcohol use within the past 12 months:*(R6DRGUSE)* ☐ No ☐ Yes ☐ Unknown
   a. If female, the AUDIT-C score is greater than or equal to 3 or if male, the AUDIT-C score is greater than or equal to 4:*(R6AUC)* ☐ No ☐ Yes ☐ Unknown
   b. In the past year, participant has used one of the following for non-medical reasons: Ecstasy, Heroin, Methamphetamine, Powdered Cocaine, Rock Cocaine, or Recreational use of prescription drugs or pain killers to get high:*(R6SUB)* ☐ No ☐ Yes ☐ Unknown
   c. The hospital system medical record for this participant has evidence of opioid or stimulant use in the past 12 months:*(R6SUBHR)* ☐ No ☐ Yes ☐ Unknown
   d. The hospital system medical record for this participant has evidence of heavy alcohol use in the past 12 months:*(R6AUCHR)* ☐ No ☐ Yes ☐ Unknown
9. Participant has a detectable (>200 copies/mL) viral load or unknown level in the past 6 months: *(R6VRLOAD)* ☐ No ☐ Yes ☐ Unknown
   a. If "Yes" or "No", specify viral load:*(R6LOADVL)* _____ *(xxxxxxxx)* copies/mL **-or-** *(R6VRUNK)* ☐ Unknown
   b. Date viral load obtained:*(R6LOADDT)* _____ *(mm/dd/yyyy)*
10. Participant has a baseline CD4 count <350 cells/uL in the past 6 months:*(R6BSECD4)* ☐ No ☐ Yes ☐ Unknown
    a. If "Yes" or "No", specify CD4 count:*(R6CD4VAL)* _____ *(xxxxx)* cells/uL
    b. Date CD4 count obtained:*(R6CD4DT)* _____ *(mm/dd/yyyy)*
11. Participant meets one or more of the following:*(R6VLCD4)* ☐ No ☐ Yes
    a. Participant has an AIDS-defining illness during the current hospital admission:*(R6AIDS)* ☐ No ☐ Yes ☐ Unknown
    b. Within the past 6 months, participant's most recent CD4 count performed is less than 350 cells/uL and viral load is greater than 200 copies/mL:*(R6VLCD6)* ☐ No ☐ Yes ☐ Unknown
    c. Within the past 12 months, participant's most recent CD4 count performed is less than or equal to 500 cells/uL and viral load is greater than 200 copies/mL or unknown **AND** the Site PI's discretion indicates that the participant is likely to currently have a viral load greater than 200 copies/mL, is not currently successfully/correctly taking ART, and needs to be on ART:*(R6VLCD12)* ☐ No ☐ Yes ☐ Unknown

If the above criteria are "Yes," the patient is eligible to enroll in the study (proceed with main consent and locator information form).

12. Participant provided informed consent for baseline assessments: *(R6INFORM)* ☐ No ☐ Yes
    a. Date informed consent signed for baseline assessment: *(R6CNSTDT)* *(mm/dd/yyyy)* Click here for calendar
    b. If "No", specify: *(R6CNSNO)*
    1-Ineligible due to screening criteria
    2-Participant's decision/changed mind
    3-Judgment of study personnel
    4-Failed to return to complete ICF
    99-Other
    If "Judgment of study personnel", specify: *(R6CNSJUD)*
    If "Other", specify: *(R6CNSOSP)*
    c. Provided consent for audio recording: *(R6INFAUD)* ☐ No ☐ Yes
    d. Provided consent to be contacted for optional future studies: *(R6INFFUT)* ☐ No ☐ Yes
13. Participant provides sufficient locator information: *(R6LCATOR)* ☐ No ☐ Yes ☐ Unknown
14. A baseline blood draw has been completed for this participant: *(R6BLOOD)* ☐ No ☐ Yes ☐ Unknown
15. Participant has completed the baseline CAPI assessments: *(R6CAPI)* ☐ No ☐ Yes

Exclusion Criteria

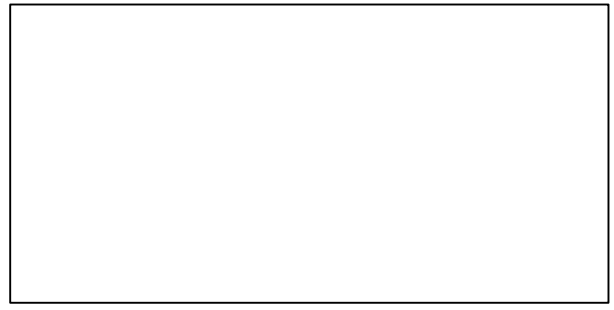
In order to meet eligibility ALL **Exclusion answers must be "No".**

1. Participant has a significant cognitive or developmental impairment to the extent that they are unable to provide informed consent: *(R6SIGCOG)* ☐ No ☐ Yes ☐ Unknown
2. Participant is terminated via site PI decision with agreement from study LI: *(R6TERM)* ☐ No ☐ Yes ☐ Unknown
   If "Yes", specify: *(R6TERMSP)*

Eligibility for Randomization

1. Is the participant eligible for the study? *(R6PTELIG)* ☐ No ☐ Yes
2. Is the participant eligible for randomization? *(R6PTRAND)* ☐ No ☐ Yes
   a. If "No", specify: *(R6NORASP)*
   1-Failed to return to clinic
   2-Declined study participation
   3-Death
   4-Judgment of CTP/research staff
   5-Other
   b. If "Judgment of CTP/research staff", specify: *(R6JUDGSP)*
   c. If "Other", specify: *(R6OTHRSP)*

Comments:*(R6COMM)*



NIDA Clinical Trials Network

Fagerstrom Test for Nicotine Dependence (FTA)

Web Version: 1.0; 1.00; 07-06-12

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

The next few questions are about smoking habits.

Date of assessment:*(FAASMTDT)* _____ *(mm/dd/yyyy)* Click here for calendar

Do you currently smoke cigarettes?*(FASMOKE)* ☐ No ☐ Yes

Please read each question below. For each question enter the answer choice which best describes your responses.

1. How soon after you wake up do you smoke your first cigarette?*(FAFSTCIG)*

3-(3) Within 5 minutes
2-(2) 6 - 30 minutes
1-(1) 31 - 60 minutes
0-(0) After 60 minutes

2. Do you find it difficult to refrain from smoking in places where it is forbidden, e.g., in church, at the library, in cinema, etc.?*(FAFORBID)*

1-(1) Yes
0-(0) No

3. Which cigarette would you hate most to give up?*(FAGIVEUP)*

1-(1) The first one in the morning
0-(0) All others

4. How many cigarettes/day do you smoke?*(FAPERDAY)*

0-(0) 10 or less
1-(1) 11-20
2-(2) 21-30
3-(3) 31 or more

5. Do you smoke more frequently during the first hours after waking than during the rest of the day?*(FAFREQ)*

1-(1) Yes
0-(0) No

6. Do you smoke if you are so ill that you are in bed most of the day?*(FAILL)*

1-(1) Yes
0-(0) No

Comments:*(FTACOMM)*

Heatherton TF; Kozlowski LT; Frecker RC; The Fagerström Test for Nicotine Dependence: a revision of the Fagerström Tolerance Questionnaire. *Br J Addict* (1991), 86, 119-1127.

NIDA Clinical Trials Network

Global Assessment of Functioning - Karnofsky (GAF)

Web Version: 1.0; 1.01; 06-20-13

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

Now I'm going to ask you a few questions about your functional status (your ability to care for yourself and perform activities on your own). Please think about your status immediately BEFORE you were admitted to this hospital.
Now I'm going to ask you a few questions about your functional status (your ability to care for yourself and perform activities on your own). Please think about your status in the past week.

Date of assessment:*(GAFASMDT)* _____ *(mm/dd/yyyy)* Click here for calendar

How would you rate this participant on the Karnofsky Performance Scale Index? The scale is below. *(GARATING)* _____ *(xxx)* %

Karnofsky Performance Status Scale

	Condition	Performance Status %	Comments
A.	Able to carry on normal activity and to work. No special care is needed.	100	Normal. No complaints. No evidence of disease.
		90	Able to carry on normal activity. Minor signs of symptoms or disease.
		80	Normal activity with effort. Some signs or symptoms of disease.
B.	Unable to work. Able to live at home, care for most personal needs. A varying degree of assistance is needed.	70	Cares for self. Unable to carry on normal activity or to do active work.
		60	Requires occasional assistance, but is able to care for most of his needs.
		50	Requires considerable assistance and frequent medical care.
C.	Unable to care for self. Requires equivalent of institutional or hospital care. Disease may be progressing rapidly.	40	Disabled. Requires special care and assistance.
		30	Severely disabled. Hospitalization is indicated although death not imminent.
		20	Hospitalization necessary, very sick active supportive treatment necessary.
		10	Moribund. Fatal processes progressing rapidly.
		0	Dead.

Comments:*(GAFCOMM)*

NIDA Clinical Trials Network

Gain Risk Behaviors - Modified (GRB)

Web Version: 1.0; 1.00; 10-25-12

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

Date of assessment:*(GRBASMDT)* _____ *(mm/dd/yyyy)* Click here for calendar

*We would like to ask a few personal questions about behaviors that may have affected your risk of getting or spreading infectious diseases. Remember that all of your answers are strictly confidential. The first questions are about the use of a needle to inject you with drugs or medication. Do **not** include shots given by a doctor or nurse, but **do** include if you were injected by someone besides a doctor or nurse **or** if you injected prescribed medication.*

1. When was the **last** time, if ever, that you used a **needle to inject drugs or medication**?
   Include medication prescribed by a doctor.(GRLSTNDL)

   6-Within the past 2 days
   5-3 to 7 days ago
   4-1 to 4 weeks ago
   3-1 to 3 months ago
   2-4 to 12 months ago
   1-More than 12 months ago
   0-Never

2. **During the past 12 months**, did you...
   a. Use a needle to shoot up drugs?*(GRNDSTUP)* ☐ No ☐ Yes
   b. Reuse a needle that **you** had used before?*(GRNDREUS)* ☐ No ☐ Yes
   c. Reuse a needle **without** cleaning it with bleach or boiling water first?*(GRNDNOCL)* ☐ No ☐ Yes
   d. Use a needle that you knew or suspected **someone else** had used before?*(GRNDELSE)* ☐ No ☐ Yes
   e. Use someone else's **rinse water, cooker, or cotton** after they did?*(GRNDH20)* ☐ No ☐ Yes
   f. Ever **skip** cleaning your needle with bleach or boiling water **after** you were done?*(GRNDSKIP)* ☐ No ☐ Yes
   g. Let someone else use a needle **after** you used it?*(GRNDAFTR)* ☐ No ☐ Yes
   h. Let someone else use the **rinse water, cooker, or cotton** after you did?*(GRNDH20A)* ☐ No ☐ Yes
   i. Allow someone else to inject you with drugs?*(GRNDINJT)* ☐ No ☐ Yes

3. **During the past 90 days:**
   a. On how many **days** did you use a needle to inject any kind of drug or medication?*(GR90DUN)* _____ *(xx Days)*
   b. With how many **people** have you given needles/works/rinse water or cotton to use after you?*(GR90DPG)* _____ *(xx People)*
      1. How many of these people were HIV negative or you did not know their HIV status?*(GR90DPGH)* _____ *(xx People)*
      2. On how many **days** did you give needles/works/rinse water or cotton to be used after you?*(GR90DDG)* _____ *(xx Days)*
   c. From how many **people** have you taken needles/works/rinse water or cotton to use after them?*(GR90DPT)* _____ *(xx People)*
      1. How many of these people were HIV negative or you did not know their HIV status*(GR90DPTH)* _____ *(xx People)*
      2. On how many **days** did you take needles/works/rinse water or cotton from someone to use after them?*(GR90DDTK)* _____ *(xx Days)*

The next questions are about having sex. When we refer to sex it includes vaginal, oral and anal sex with anyone. (Vaginal sex is when a man puts his penis into a woman's vagina. Oral sex is when one person puts his or her mouth onto the other person's penis or vagina. Anal sex is when a man puts his penis into another person's anus or butt.)

4. When was the **last** time, if ever, that you **had any kind of vaginal, oral, or anal sex** with another person?*(GRLASTSX)*

6-Within the past 2 days
5-3 to 7 days ago
4-1 to 4 weeks ago
3-1 to 3 months ago
2-4 to 12 months ago
1-More than 12 months ago
0-Never

5. **During the past 12 months**, did you…
   a. Have sex while you **were high on alcohol or on other drugs**?*(GRSEXHGH)* ☐ No ☐ Yes
   b. Have sex with someone who was an **injection drug user**?*(GRSEXINJ)* ☐ No ☐ Yes
   c. Have sex involving **anal intercourse** (penis to butt)?*(GRSEXANL)* ☐ No ☐ Yes
   d. Have sex against your will (you were forced or coerced)?*(GRSEXAGS)* ☐ No ☐ Yes
   e. **Trade** sex to get drugs, gifts or money?*(GRSEXTRD)* ☐ No ☐ Yes
   f. Use drugs, gifts, or money to **purchase** or get sex?*(GRSEXDRG)* ☐ No ☐ Yes
   g. Have sex with someone who you thought was **HIV negative** or you did not know their HIV status? *(GRSEXNEG)* ☐ No ☐ Yes
   h. Have **two or more** different sex partners (not necessarily at the same time)?*(GRSEX2PP)* ☐ No ☐ Yes
   i. Have sex with a **male partner**?*(GRSEXMAL)* ☐ No ☐ Yes
   j. Have sex with a **female partner**?*(GRSEXFEM)* ☐ No ☐ Yes
   k. Have sex **without** using any any kind of condom to protect you and your partner from diseases or pregnancy?*(GRSEXCND)* ☐ No ☐ Yes
   l. Have a lot of **pain** during sex or after having had sex?*(GRSEXPAN)* ☐ No ☐ Yes
   m. Use alcohol or other drugs to make sex **last longer or hurt less**?*(GRSEXLST)* ☐ No ☐ Yes

We want to ask you some questions about your sexual partners.

6. ***During the past 90 days…***
   a. How many sex partners did you have who were male?*(GR9SXMAL)* ☐ *(xxx Partners)*
      How many of your male sex partners were HIV negative or you did not know their HIV status? *(GR9SXMHV)* ☐ *(xxx Partners)*
   b. How many sex partners did you have who were female?*(GR9SXFEM)* ☐ *(xxx Partners)*
      How many of your female sex partners were HIV negative or you did not know their HIV status? *(GR9SXFHV)* ☐ *(xxx Partners)*
   c. With how many of your male or female partners have you been high on alcohol or drugs when having sex at least once in the past 90 days?*(GR9SXHGH)* ☐ *(xxx Partners)*
   d. Have you had a partner that you consider a primary partner? ☐ No ☐ Yes
      (By primary we mean someone with whom you felt a special emotional commitment, someone you have dated or would call your boyfriend, girlfriend, spouse, significant other or lifetime partner.)
      (GRPRIMPT)
      1. Your primary partner's gender is:*(GRPRIMGN)* ☐ Male ☐ Female

2. How long have the two of you been seeing each other?*(GRRELTLT)*

1-Less than 2 months
2-2 - 4 months
3-4 - 6 months
4-6 - 12 months
5-1 - 2 years
6-Over 2 years

3. What is your primary partner's HIV status?*(GRPRIMHS)* ☐ Positive ☐ Negative ☐ Unknown

4. Do you believe this relationship to be exclusive or monogamous (i.e., that neither of you have sex with other partners)?*(GRPRIMEX)* ☐ No ☐ Yes

5. How many times in the last 12 months did you have any kind of vaginal or anal sex with your primary partner?*(GRPRIMSX)* _____ *(xxx)*

6. How many times when you had any kind of vaginal or anal sex with your primary partner, did you use a condom from start to finish?*(GRPRIMCN)* _____ *(xxx)*

7. How many times when you had anal or vaginal sex with your primary partner, were you high on alcohol or drugs?*(GRPRIMHG)* _____ *(xxx)*

7. **During the past 90 days,** when you had sex with your male and/or female partners (excluding your primary partner, if you had one), how many times…

a. Did you have vaginal or anal sex with HIV positive partners?*(GRSEXHVP)* _____ *(xxx Times)*

b. Did you have vaginal or anal sex with HIV negative or unknown status partners?*(GRSEXHVN)* _____ *(xxx Times)*

Of these, how many times was a condom worn from start to finish?*(GRCONDOM)* _____ *(xxx Times)*

c. Did you have sex while you were **high on alcohol or other drugs**?*(GRNPMHGH)* _____ *(xxx Times)*

d. Did you **trade sex** for drugs, gifts, or money?*(GRNPMTRD)* _____ *(xxx Times)*

e. Use drugs, gifts, or money to purchase or get sex?*(GRNPMDRG)* _____ *(xxx Times)*

Comments:*(GRBCOMM)*

NIDA Clinical Trials Network

Household Food Survey (HFS)

Web Version: 1.0; 1.00; 07-19-12

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

I will now ask you some questions about your access to food.
RA Instruction: Provide participant with a reference card that lists all response options for his/her easy reference.

Date of assessment:*(HFSASMDT)* _____ *(mm/dd/yyyy)* Click here for calendar

1. In the past four weeks, did you worry that you would not have enough food?*(HFNFOOD)* ☐ No ☐ Yes
   How often did this happen?*(HFHOFTEN)*
   1-Rarely (once or twice in the past four weeks)
   2-Sometimes (three to ten times in the past four weeks)
   3-Often (more than ten times in the past four weeks)

2. In the past four weeks, were you not able to eat the kinds of foods you preferred because of a lack of resources? ☐ No ☐ Yes
   "Yes" means you were NOT able to eat.
   "No" means you were able to eat.(HSPREFER)
   How often did this happen?*(HSPREOFT)*
   1-Rarely (once or twice in the past four weeks)
   2-Sometimes (three to ten times in the past four weeks)
   3-Often (more than ten times in the past four weeks)

3. In the past four weeks, did you have to eat a limited variety of foods due to a lack of resources? ☐ No ☐ Yes
   (HSVARIET)
   How often did this happen?*(HSVAROFT)*
   1-Rarely (once or twice in the past four weeks)
   2-Sometimes (three to ten times in the past four weeks)
   3-Often (more than ten times in the past four weeks)

4. In the past four weeks, did you have to eat some foods that you really did not want to eat because of lack of resources to obtain other types of food?*(HSNOTEAT)* ☐ No ☐ Yes
   How often did this happen?*(HSNOTOFT)*
   1-Rarely (once or twice in the past four weeks)
   2-Sometimes (three to ten times in the past four weeks)
   3-Often (more than ten times in the past four weeks)

5. In the past four weeks, did you have to eat a smaller meal than you felt you needed because there was not enough food?*(HSSMALLE)* ☐ No ☐ Yes
   How often did this happen?*(HSSMAOFT)*
   1-Rarely (once or twice in the past four weeks)
   2-Sometimes (three to ten times in the past four weeks)
   3-Often (more than ten times in the past four weeks)

6. In the past four weeks, did you have to eat fewer meals in a day because there was not enough food?*(HSFFEWER)* ☐ No ☐ Yes

How often did this happen?*(HSFEWOFT)*

1-Rarely (once or twice in the past four weeks)
2-Sometimes (three to ten times in the past four weeks)
3-Often (more than ten times in the past four weeks)

7. In the past four weeks, was there ever no food to eat of any kind in your household because of lack of resources to get food?
"Yes" means there was a time when there was NO food.
"No" means there was NEVER a time without food.(HSLACKRE)

☐ No ☐ Yes

How often did this happen?*(HSLACKOF)*

1-Rarely (once or twice in the past four weeks)
2-Sometimes (three to ten times in the past four weeks)
3-Often (more than ten times in the past four weeks)

8. In the past four weeks, did you go to sleep at night hungry because there was not enough food?*(HSNOTFOO)*

☐ No ☐ Yes

How often did this happen?*(HSNIGOFT)*

1-Rarely (once or twice in the past four weeks)
2-Sometimes (three to ten times in the past four weeks)
3-Often (more than ten times in the past four weeks)

9. In the past four weeks, did you go a whole day and night without eating anything because there was not enough food?*(HFWHOLED)*

☐ No ☐ Yes

How often did this happen?*(HFWHOOFT)*

1-Rarely (once or twice in the past four weeks)
2-Sometimes (three to ten times in the past four weeks)
3-Often (more than ten times in the past four weeks)

Comments:*(HFSCOMM)*

NIDA Clinical Trials Network

Modified Illegal Activities (MIA)

Web Version: 1.0; 3.01; 11-26-13

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

Date of assessment:*(MIASMTDT)* _____ *(mm/dd/yyyy)* Click here for calendar

Have you been arrested in the last 6 months?*(MIARST6M)* ☐ No ☐ Yes

Have you been incarcerated in the last 6 months?*(MIINCA6M)* ☐ No ☐ Yes

How many days have you been incarcerated in the past 6 months?*(MIIN6MDY)* _____ *(xxx)*

The next several questions are about illegal activities.

Illegal Activities

1. Have you been intoxicated (high or drunk) from alcohol or drugs in public since the last visit?*(MIIAPUB)* ☐ No ☐ Yes
   a. How many times in the past 6 months have you been intoxicated (high or drunk) from alcohol or drugs in public?*(MIITXI6M)* _____ *(xxx)*
   b. How many times in the past 6 months have you been arrested for being intoxicated from alcohol or drugs in public?*(MIITXA6M)* _____ *(xxx)*

2. Have you driven under influence of alcohol or drugs since the last visit?*(MIIADUI)* ☐ No ☐ Yes
   a. How many times in the past 6 months have you driven under the influence of alcohol or drugs? *(MIDUII6M)* _____ *(xxx)*
   b. How many times in the past 6 months have you been arrested for driving under the influence of alcohol or drugs?*(MIDUIA6M)* _____ *(xxx)*

3. Have you used or possessed illegal drugs since the last visit?*(MIIAPOS)* ☐ No ☐ Yes
   a. How many times in the past 6 months have you used or possessed illegal drugs?*(MIPOSI6M)* _____ *(xxx)*
   b. How many times in the past 6 months have you been arrested for using or possessing illegal drugs? *(MIPOSA6M)* _____ *(xxx)*

4. Have you had possession with intent to distribute since the last visit?*(MIIADST)* ☐ No ☐ Yes
   a. How many times in the past 6 months have you possessed illegal drugs with the intent to distribute? *(MIDSTI6M)* _____ *(xxx)*
   b. How many times in in the past 6 months have you been arrested for possession of illegal drugs with the intent to distribute?*(MIDSTA6M)* _____ *(xxx)*

5. Have you had possession of drug paraphernalia since the last visit?*(MIIAPAR)* ☐ No ☐ Yes
   a. How many times in the past 6 months have you possessed drug paraphernalia?*(MIPARI6M)* _____ *(xxx)*
   b. How many times in the past 6 months have you been arrested for possession of drug paraphernalia? *(MIPARA6M)* _____ *(xxx)*

6. Have you manufactured or grown drugs since the last visit?*(MIIAGRW)* ☐ No ☐ Yes
   a. How many times in the past 6 months have you manufactured or grown drugs?*(MIGRWI6M)* _____ *(xxx)*
   b. How many times in the past 6 months have you been arrested for manufacturing or growing drugs? *(MIGRWA6M)* _____ *(xxx)*

7. Have you sold or distributed drugs since the last visit?*(MIIASAL)* ☐ No ☐ Yes
   a. How many times in the past 6 months have you been involved in the sale or distribution of drugs? *(MISALI6M)* _____ *(xxx)*
   b. How many times in the past 6 months have you been arrested for selling or distributing drugs? *(MISALA6M)* _____ *(xxx)*

8. Have you been involved in forgery or fraud (bad checks, credit card fraud, etc.) since the last visit? *(MIIAFRD)* ☐ No ☐ Yes
   a. How many times in the past 6 months have you been involved in forgery/fraud (bad checks, credit card fraud, etc.)?*(MIFRDI6M)* _____ *(xxx)*
   b. How many times in the past 6 months have you been arrested for forgery/fraud (bad checks, credit card fraud, etc.)?*(MIFRDA6M)* _____ *(xxx)*

9. Have you been involved in fencing (buying or selling stolen property) since the last visit?*(MIIAFEN)* ☐ No ☐ Yes
   a. How many times in the past 6 months have you been involved in fencing (buying or selling stolen property)?*(MIFENI6M)* _____ *(xxx)*
   b. How many times in the past 6 months have you been arrested for fencing (buying or selling stolen property)?*(MIFENA6M)* _____ *(xxx)*

10. Have you been involved in illegal gambling (running numbers) since the last visit?*(MIIAGAM)* ☐ No ☐ Yes
    a. How many times in the past 6 months have you been involved in illegal gambling (running numbers)? *(MIGAMI6M)* _____ *(xxx)*
    b. How many times in the past 6 months have you been arrested for illegal gambling (running numbers)? *(MIGAMA6M)* _____ *(xxx)*

11. Have you been involved in prostitution or pimping since the last visit?*(MIIAPRS)* ☐ No ☐ Yes
    a. How many times in the past 6 months have you been involved in prostitution or pimping?*(MIPRSI6M)* _____ *(xxx)*
    b. How many times in the past 6 months have you been arrested for prostitution or pimping? *(MIPRSA6M)* _____ *(xxx)*

12. Have you been involved in burglary/attempted burglary/breaking and entering (home, auto, business) since the last visit?*(MIIABAE)* ☐ No ☐ Yes
    a. How many times in the past 6 months have you been involved in burglary/attempted burglary/breaking and entering (home, auto, business)?*(MIBAEI6M)* _____ *(xxx)*
    b. How many times in the past 6 months have you been arrested for being involved in burglary/attempted burglary/breaking and entering (home, auto, business)?*(MIBAEA6M)* _____ *(xxx)*

13. Have you been involved in shoplifting/larceny/embezzlement since the last visit?*(MIIALAR)* ☐ No ☐ Yes
    a. How many times in the past 6 months have you been involved in shoplifting/larceny/embezzlement? *(MILARI6M)* _____ *(xxx)*
    b. How many times in the past 6 months have you been arrested for shoplifting/larceny/embezzlement? *(MILARA6M)* _____ *(xxx)*

14. Have you been involved in auto theft/carjacking since the last visit?*(MIIACAR)* ☐ No ☐ Yes
    a. How many times in the past 6 months have you been involved in auto theft/carjacking?*(MICARI6M)* _____ *(xxx)*
    b. How many times in the past 6 months have you been arrested for auto theft/carjacking?*(MICARA6M)* _____ *(xxx)*

15. Have you been involved in robbery/attempted robbery/mugging since the last visit?*(MIIAROB)* ☐ No ☐ Yes
    a. How many times in the past 6 months have you been involved in robbery/attempted robbery/mugging? *(MIROBI6M)* _____ *(xxx)*
    b. How many times in the past 6 months have you been arrested for robbery/attempted robbery/mugging?*(MIROBA6M)* _____ *(xxx)*

16. Have you been involved in assault/aggravated assault/battery (does not include rape or sexual assault) since the last visit?*(MIIAAAB)* ☐ No ☐ Yes

a. How many times in the past 6 months have you been involved in assault/aggravated assault/battery (does not include rape or sexual assault)?*(MIAABI6M)* ☐ *(xxx)*

b. How many times in the past 6 months have you been arrested for assault/aggravated assault/battery (does not include rape or sexual assault)?*(MIAABA6M)* ☐ *(xxx)*

17. Have you been involved in kidnapping/hostage taking since the last visit?*(MIIAKID)* ☐ No ☐ Yes

a. How many times in the past 6 months have you been involved in kidnapping/hostage taking? *(MIKIDI6M)* ☐ *(xxx)*

b. How many times in the past 6 months have you been arrested for kidnapping/hostage taking? *(MIKIDA6M)* ☐ *(xxx)*

18. Have you been involved in terrorist threats/acts since the last visit?*(MIIATER)* ☐ No ☐ Yes

a. How many times in the past 6 months have you been involved in terrorist threats/acts?*(MITERI6M)* ☐ *(xxx)*

b. How many times in the past 6 months have you been arrested for terrorist threats/acts?*(MITERA6M)* ☐ *(xxx)*

19. Have you been involved in homicide/manslaughter/attempted homicide since the last visit?*(MIIAHOM)* ☐ No ☐ Yes

a. How many times in the past 6 months have you been involved in homicide/manslaughter/attempted homicide?*(MIHOMI6M)* ☐ *(xxx)*

b. How many times in the past 6 months have you been arrested for homicide/manslaughter/attempted homicide?*(MIHOMA6M)* ☐ *(xxx)*

20. Have you been involved in arson offenses since the last visit?*(MIIAARS)* ☐ No ☐ Yes

a. How many times in the past 6 months have you been involved in arson offenses?*(MIARSI6M)* ☐ *(xxx)*

b. How many times in the past 6 months have you been arrested for arson offenses?*(MIARSA6M)* ☐ *(xxx)*

21. Have you been involved in weapons offenses since the last visit?*(MIIAWEP)* ☐ No ☐ Yes

a. How many times in the past 6 months have you been involved in weapons offenses?*(MIWEPI6M)* ☐ *(xxx)*

b. How many times in the past 6 months have you been arrested for weapons offenses?*(MIWEPA6M)* ☐ *(xxx)*

22. Have you been involved in vandalism/property damage/tagging since the last visit?*(MIIAVAN)* ☐ No ☐ Yes

a. How many times in the past 6 months have you been involved with vandalism/property damage/tagging?*(MIVANI6M)* ☐ *(xxx)*

b. How many times in the past 6 months have you been arrested for vandalism/property damage/tagging?*(MIVANA6M)* ☐ *(xxx)*

23. Have you been involved in sex offenses (rape/aggravated assault/sex with a minor) since the last visit? *(MIIASEX)* ☐ No ☐ Yes

a. How many times in the past 6 months have you been involved in a sex offense (rape/aggravated assault/sex with a minor)?*(MISEXI6M)* ☐ *(xxx)*

b. How many times in the past 6 months have you been arrested for a sex offense (rape/aggravated assault/sex with a minor)?*(MISEXA6M)* ☐ *(xxx)*

24. Have you been involved in probation/parole violations since the last visit?*(MIIAPRB)* ☐ No ☐ Yes

a. How many times in the past 6 months have you been involved in probation/parole violations? *(MIPRBI6M)* ☐ *(xxx)*

b. How many times in the past 6 months have you been arrested for probation/parole violations? *(MIPRBA6M)* ☐ *(xxx)*

25. Have you been involved in other crimes not listed above since the last visit? ☐ No ☐ Yes
If "Yes", specify in comments(MIIAOTH)

a. How many times in the past 6 months have you been involved in this crime?*(MIOTHI6M)* ☐ *(xxx)*

b. How many times in the past 6 months have you been arrested for this crime?*(MIOTHA6M)* ☐ *(xxx)*

Comments:*(MIACOMM)*

NIDA Clinical Trials Network

History of Abuse and Interpersonal Violence (MIV)

Web Version: 1.0; 2.00; 06-20-13

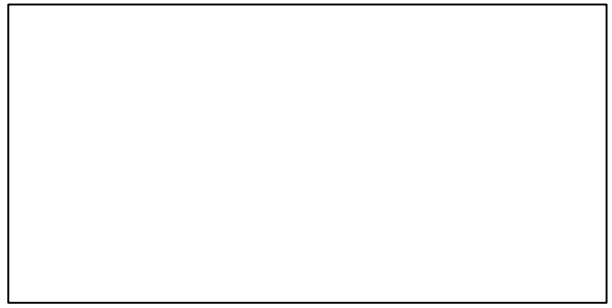
Segment *(PROTSEG)*:
Visit Number *(VISNO)*:

The next questions are about abuse and interpersonal violence. Please let me know if you would like to stop at any point. As a study interviewer, I am not permitted to discuss any specific incidents of abuse with you, but there is someone on hand who can talk with you if you'd like to do so.

Date of assessment:*(MIVASMDT)* _____ *(mm/dd/yyyy)* Click here for calendar

1. As a child, were you ever beaten, physically attacked, or physically abused?*(MICHATCK)*	☐ No	☐ Yes	☐ Refuse to answer
2. As a child, were you ever sexually attacked, raped, or sexually abused?*(MICHABUS)*	☐ No	☐ Yes	☐ Refuse to answer
3. As an adult, have you ever been beaten, physically attacked, or physically abused?*(MIADATCK)*	☐ No	☐ Yes	☐ Refuse to answer
4. Have you been beaten, physically attacked, or physically abused since your last visit?*(MIADATCK)*	☐ No	☐ Yes	☐ Refuse to answer
Were you ever in a relationship where a sexual partner did this to you?*(MIPRTATK)*	☐ No	☐ Yes	☐ Refuse to answer
Were you in a relationship where a sexual partner did this to you?*(MIPRTATK)*	☐ No	☐ Yes	☐ Refuse to answer
5. As an adult, have you ever been sexually attacked, raped, or sexually abused?*(MIADABUS)*	☐ No	☐ Yes	☐ Refuse to answer
6. Have you been sexually attacked, raped, or sexually abused since your last visit?*(MIADABUS)*	☐ No	☐ Yes	☐ Refuse to answer
Were you ever in a relationship where a sexual partner did this to you?*(MIPRTABU)*	☐ No	☐ Yes	☐ Refuse to answer
Were you in a relationship where a sexual partner did this to you?*(MIPRTABU)*	☐ No	☐ Yes	☐ Refuse to answer
7. Have you ever been in a relationship where a sexual partner threatened you with violence? *(MITHREAT)*	☐ No	☐ Yes	☐ Refuse to answer
8. Have you been in a relationship where a sexual partner threatened you with violence since your last visit?*(MITHREAT)*	☐ No	☐ Yes	☐ Refuse to answer
9. Have you ever been in a relationship where a sexual partner threw, broke, or punched things? *(MIPUNCHD)*	☐ No	☐ Yes	☐ Refuse to answer
10. Have you been in a relationship where a sexual partner threw, broke, or punched things since your last visit?*(MIPUNCHD)*	☐ No	☐ Yes	☐ Refuse to answer
11. Have you ever been in a relationship where you felt controlled by a sexual partner?*(MICONTRL)*	☐ No	☐ Yes	☐ Refuse to answer
12. Have you been in a relationship where you felt controlled by a sexual partner since your last visit? *(MICONTRL)*	☐ No	☐ Yes	☐ Refuse to answer

Comments:*(MIVCOMM)*



NIDA Clinical Trials Network

Medical Mistrust (MMT)

Web Version: 1.0; 1.00; 07-23-12

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

Now I'm going to read a series of statements to you about health care and the experiences of people of your racial/ethnic group with the health care system.
*Please tell me how much you agree or dis*agree *with each statement on a scale of 1 to 5 where 1= strongly disagree...and 5= strongly agree.*
RA Instruction: Provide participant with a reference card that lists all 5 response options for his/her easy reference.

Date of assessment:*(MMTASMDT)* *(mm/dd/yyyy)* Click here for calendar

	Strongly Disagree	Disagree	Neither	Agree	Strongly Agree
1. Doctors and health care workers sometimes hide information from patients who belong to my ethnic group.	*(MMHIDE)* ☐	☐	☐	☐	☐
2. Doctors have the best interests of people of my ethnic group in mind.	*(MMBEST)* ☐	☐	☐	☐	☐
3. People of my ethnic group should not confide in doctors and health care workers because it will be used against them.	*(MMCONFI)* ☐	☐	☐	☐	☐
4. People of my ethnic group should be suspicious of information from doctors and health care workers.	*(MMSUSPI)* ☐	☐	☐	☐	☐
5. People of my ethnic group cannot trust doctors and health care workers.	*(MMTRUST)* ☐	☐	☐	☐	☐
6. People of my ethnic group should be suspicious of modern medicine.	*(MMMEDIC)* ☐	☐	☐	☐	☐
7. Doctors and health care workers treat people of my ethnic group like "guinea pigs".	*(MMGUINE)* ☐	☐	☐	☐	☐
8. People of my ethnic group receive the same medical care from doctors and health care workers as people from other groups.	*(MMSAME)* ☐	☐	☐	☐	☐
9. Doctors and health care workers do not take the medical complaints of people of my ethnic group seriously.	*(MMCOMPL)* ☐	☐	☐	☐	☐
10. People of my ethnic group are treated the same as people of other groups by doctors and health care workers.	*(MMTREAT)* ☐	☐	☐	☐	☐
11. In most hospitals, people of different ethnic groups receive the same kind of care.	*(MMHOSP)* ☐	☐	☐	☐	☐
12. I have personally been treated poorly or unfairly by doctors or health care workers because of my ethnicity.	*(MMPERSO)* ☐	☐	☐	☐	☐

In a health care setting have you ever experienced discrimination, been prevented from doing something, or been hassled or made to feel inferior because of your:

	No	Yes	Don't Know	Refuse to Answer
1. HIV status?	*(MMHIV)* ☐	☐	☐	☐
2. Gender?	*(MMGENDE)* ☐	☐	☐	☐

3. Sexual orientation or practices?	*(MMORIEN)* ☐	☐	☐	☐
4. Race or ethnicity?	*(MMRACE)* ☐	☐	☐	☐
5. Drug use?	*(MMDRUG)* ☐	☐	☐	☐

Comments:*(MMTCOMM)*

NIDA Clinical Trials Network

Readiness for Substance Use Treatment (MTT)

Web Version: 1.0; 1.00; 03-21-12

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

Date of assessment:*(MTTASMDT)* *(mm/dd/yyyy)* Click here for calendar

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

1. Treatment could be your last chance to solve your substance use problems.*(MTLASTC)*
2. If you enter treatment, you will stay for a while.*(MTSTAY)*
3. Treatment could really help you.*(MTCOULDH)*
4. You want to be in a treatment program.*(MTWANTIN)*
5. Most counselors in substance use treatment programs are "squares" who don't understand substance users.*(MTCOUNS)*
6. Substance use treatment programs have too many rules and regulations for me.*(MTTOORUL)*

1-Strongly disagree
2-Disagree
3-Undecided
4-Agree
5-Strongly agree

7. I don't think I could trust many of the people who work in the substance use treatment programs. *(MTTRUST)*

1-Strongly disagree
2-Disagree
3-Undecided
4-Agree
5-Strongly agree

8. It takes too much time and effort to get into a substance use treatment program. *(MTTOOTIM)*

1-Strongly disagree
2-Disagree
3-Undecided
4-Agree
5-Strongly agree

Comments: *(MTTCOMM)*

NIDA Clinical Trials Network

Missed Visit Form (MVF)

Web Version: 1.0; 3.01; 05-31-13

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

Reason for missed visit:*(MVREASON)*

8-Participant failed to return to clinic and unable to contact
10-Participant unable to attend visit (e.g. no childcare, transportation, schedule conflict)
11-Participant on vacation
12-Participant in hospital, in-patient or residential treatment
13-Participant moved from area
*Additional Options Listed Below

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

Additional Selection Options for MVF

Reason for missed visit:
14-Participant incarcerated
15-CTP closed
16-Participant withdrew consent
17-Participant deceased
99-Other

NIDA Clinical Trials Network

Non-Intervention Tracking and Contact (NIT)

Web Version: 1.0; 3.01; 09-11-13

Segment *(PROTSEG)*:
Tracking log number *(NITLOGNM)*:

Tracking Log

Record each tracking activity separately. Tracking activities include any non-intervention-related contact (whether staff or participant initiated), attempt to contact, or effort to find contact information with the intention of scheduling the partici

Date (mm/dd/yyyy)	Day (of Week)	Start Time (hh:mm)	End Time (hh:mm)	Length of Time (Minutes) (xxx)	Activity
(NIAC01DT) Calendar	*(NIDAY01)*	*(NISTM01)*	*(NIETM01)*	*(NILENG01)*	*(NIDESC01)*
(NIAC02DT) Calendar	*(NIDAY02)*	*(NISTM02)*	*(NIETM02)*	*(NILENG02)*	*(NIDESC02)*
(NIAC03DT) Calendar	*(NIDAY03)*	*(NISTM03)*	*(NIETM03)*	*(NILENG03)*	*(NIDESC03)*
(NIAC04DT) Calendar	*(NIDAY04)*	*(NISTM04)*	*(NIETM04)*	*(NILENG04)*	*(NIDESC04)*
(NIAC05DT) Calendar	*(NIDAY05)*	*(NISTM05)*	*(NIETM05)*	*(NILENG05)*	*(NIDESC05)*
(NIAC06DT) Calendar	*(NIDAY06)*	*(NISTM06)*	*(NIETM06)*	*(NILENG06)*	*(NIDESC06)*
(NIAC07DT) Calendar	*(NIDAY07)*	*(NISTM07)*	*(NIETM07)*	*(NILENG07)*	*(NIDESC07)*
(NIAC08DT) Calendar	*(NIDAY08)*	*(NISTM08)*	*(NIETM08)*	*(NILENG08)*	*(NIDESC08)*
(NIAC09DT) Calendar	*(NIDAY09)*	*(NISTM09)*	*(NIETM09)*	*(NILENG09)*	*(NIDESC09)*
(NIAC10DT)	*(NIDAY10)*	*(NISTM10)*	*(NIETM10)*	*(NILENG10)*	*(NIDESC10)*

Calendar					

Comments:*(NITCOMM)*

Additional Selection Options for NIT

Tracking log number *(NITLOGNM)* (key field):
01-1st log
02-2nd log
03-3rd log
04-4th log
05-5th log
06-6th log
07-7th log
08-8th log
09-9th log
10-10th log
11-11th log
12-12th log
13-13th log
14-14th log
15-15th log
16-16th log
17-17th log
18-18th log
19-19th log
20-20th log
21-21st log
22-22nd log
23-23rd log
24-24th log
25-25th log
26-26th log
27-27th log
28-28th log
29-29th log
30-30th log

NIDA Clinical Trials Network

Debriefing Provider Visit with Participant - Patient Navigator (PDP)

Web Version: 1.0; 1.00; 07-19-12

Segment *(PROTSEG)*:
Session Date *(PCSESDT)*:

Date of assessment:*(PDPASMDT)* _____ *(mm/dd/yyyy)* Click here for calendar

Patient navigator number:*(PPPNNUM)* _____

Session length:*(PPSESLEN)* _____ *(xxx)* minutes

To what extent did the patient navigator:	Not at all	Somewhat	Mostly	Completely	Not rated
1. **Support participant efforts:** Invite participant to articulate positive outcomes from care visit and participant efforts. Elicit from participant what the participant learned and what strengths the participant demonstrated; verbally acknowledge participant strengths; if appropriate, explore with the participant what can be done differently in future care visits to achieve a more positive outcome.	*(PPSUPPOR)* ☐	☐	☐	☐	☐
2. **Discuss outstanding business:** Ask participant to identify unanswered/unaddressed questions (see index card); identify new questions/concerns that may have come up.	*(PPOUTSTN)* ☐	☐	☐	☐	☐
3. **Discuss and prepare for next steps in self-care:** Strategize lab draw and/or medication pick-up and medication start date, assist with setting dates, rehearse preliminary steps; encourage participant to discuss taking medications with pharmacy staff; offer to call participant between patient navigator meetings to check in about taking medications.	*(PPNEXTST)* ☐	☐	☐	☐	☐
4. **Plan next patient navigator meeting:** Schedule appointment; review locator info; reinforce participant interest/effort in self-care; offer urine and breathalyzer screens, provide instructions and conduct screens; provide appropriate verbal encouragement on screen results.	*(PPMEET)* ☐	☐	☐	☐	☐

Comments:*(PDPCOMM)*

NIDA Clinical Trials Network

Debriefing Substance Abuse Treatment Visit - Patient Navigator (PDS)

Web Version: 1.0; 1.00; 07-19-12

Segment *(PROTSEG)*:
Session Date *(PCSESDT)*:

Date of assessment:*(PDSASMDT)* _____ *(mm/dd/yyyy)* Click here for calendar

Patient navigator number:*(PSPNNUM)* _____

Session length:*(PSSESLEN)* _____ *(xxx)* minutes

To what extent did the patient navigator:	Not at all	Somewhat	Mostly	Completely	Not rated
1. **Support participant's efforts:** Invite the participant to articulate the positive outcomes from the visit and participant's efforts. Elicit from participant what participant learned and what strengths participant demonstrated; verbally acknowledge participant strengths; if appropriate, explore with participant what can be done differently in future care visits to achieve a more positive outcome.	*(PSSUPPOR)* ☐	☐	☐	☐	☐
2. **Discuss outstanding business:** Ask participant to identify unanswered/unaddressed questions (see index card) and new questions/concerns that may have come up.	*(PSOUTSTN)* ☐	☐	☐	☐	☐
3. **Discuss and prepare for next steps in self-care:** Strategize follow-up to substance abuse treatment plan, assist participant in setting specific substance abuse treatment activities and rehearse preliminary steps.	*(PSNEXTST)* ☐	☐	☐	☐	☐
4. **Plan next patient navigator meeting:** Schedule appointment; review locator form; reinforce participant interest/effort in self-care; offer urine and breathalyzer screens, provide instructions and conduct screens; provide appropriate verbal encouragement on screen results and any other accomplishments (paperwork, labs, medication pick-up, etc.).	*(PSMEET)* ☐	☐	☐	☐	☐

Comments:*(PDSCOMM)*

NIDA Clinical Trials Network

Perceived Health Status SF-12 (PHS)

Web Version: 1.0; 1.00; 07-10-12

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

Date of assessment: *(PHSASMDT)* *(mm/dd/yyyy)* Click here for calendar

RA Instruction: Provide participant with reference cards for each question that list all response options for his/her easy reference.

This survey asks for your views about your health. Please select the response that best describes your answer. This information will help keep track of how you feel and how well you are able to do your usual activities. Thank you for completing this survey!

For each of the following questions, please check the box that best describes your answer.

1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
▼	▼	▼	▼	▼
(PHHEALTH) ☐	☐	☐	☐	☐

2. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
	▼	▼	▼
a. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf:	*(PHMODACT)* ☐	☐	☐
b. Climbing several flights of stairs:	*(PHSTAIRS)* ☐	☐	☐

3. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
	▼	▼	▼	▼	▼
a. Accomplished less than you would like:	*(PHPACCMP)* ☐	☐	☐	☐	☐
b. Were limited in the kind of work or other activities:	*(PHPKDWRK)* ☐	☐	☐	☐	☐

4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	All of	Most of	Some of	A little	None of

	the time	the time	the time	of the time	the time
	▼	▼	▼	▼	▼
a. Accomplished less than you would like:	*(PHEACCMP)* ☐	☐	☐	☐	☐
b. Did work or other activities less carefully than usual:	*(PHEWORK)* ☐	☐	☐	☐	☐

5. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
▼	▼	▼	▼	▼
(PHNRMWRK) ☐	☐	☐	☐	☐

6. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks...

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
	▼	▼	▼	▼	▼
a. Have you felt calm and peaceful?	*(PHCALM)* ☐	☐	☐	☐	☐
b. Did you have a lot of energy?	*(PHENERGY)* ☐	☐	☐	☐	☐
c. Have you felt downhearted and depressed?	*(PHDEPRSS)* ☐	☐	☐	☐	☐

7. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
▼	▼	▼	▼	▼
(PHSOCIAL) ☐	☐	☐	☐	☐

THANK YOU FOR COMPLETING THESE QUESTIONS!

NIDA Clinical Trials Network

Preparing for Initial Substance Abuse Treatment Visit - Patient Navigator (PNA)

Web Version: 1.0; 1.00; 07-19-12

Segment *(PROTSEG)*:
Session Date *(PCSESDT)*:

Date of assessment:*(PNAASMDT)* _____ *(mm/dd/yyyy)* Click here for calendar

Patient navigator number:*(PAPNNUM)* _____

Session length:*(PASESLEN)* _____ *(xxx)* minutes

To what extent did the patient navigator:	Not at all	Somewhat	Mostly	Completely	Not rated
1. **Familiarize participant with the specifics of substance abuse treatment agency:** Review names and basic info about provider/agency staff; review pictures (if appropriate); discuss any clinic consideration for HIV positive clients; discuss typical visit flow; review visit requirements (ID, paperwork), discuss transportation to clinic.	*(PATXAG)* ☐	☐	☐	☐	☐
2. **Prepare participant for meeting with substance abuse treatment provider:** Assist participant with questions to ask provider; write down questions/concerns/points on two index cards; rehearse communication with provider, discuss solutions to potential barriers.	*(PATXPR)* ☐	☐	☐	☐	☐
3. **Prepare for patient navigator-participant meeting prior to substance abuse treatment visit:** Choose time and clear/specific place to meet; discuss reminder phone call/email; resolve transportation issues.	*(PAPNPPT)* ☐	☐	☐	☐	☐
4. **Provide clear expectations of roles during substance abuse treatment visit:** Clarify clinic policy regarding patient navigator's presence; discuss participant's expectation around patient navigator's presence; discuss nature of support/facilitation provided by patient navigator. Note: If participant is ambivalent, roll with resistance (validate/discuss concerns of substance abuse, explore trial run visit, revisiting topic at future patient navigator/participant meeting, etc.).	*(PAROLES)* ☐	☐	☐	☐	☐
5. **Prepare for next patient navigator meeting:** Schedule next appointment; review locator information; reinforce participant interest in self-care; offer urine and breathalyzer screens, provide instructions and conduct screens; provide appropriate verbal support on screen results and any other accomplishments (paper work, labs, medication pick up, etc.).	*(PAMEET)* ☐	☐	☐	☐	☐

Comments:*(PNACOMM)*

NIDA Clinical Trials Network

Preparing to Meet Care Provider - Patient Navigator (PNC)

Web Version: 1.0; 1.00; 07-19-12

Segment *(PROTSEG)*:
Session Date *(PCSESDT)*:

Date of assessment:*(PNCASMDT)* _____ *(mm/dd/yyyy)* Click here for calendar

Patient navigator number:*(PCPNNUM)* _____

Session length:*(PCSESLEN)* _____ *(xxx)* minutes

To what extent did the patient navigator:	Not at all	Somewhat	Mostly	Completely	Not rated
1. **Familiarize the participant with the care agency:** Review names and basic information about provider/agency staff; review pictures (if appropriate); review agency address; discuss typical visit flow; review visit requirements (ID, paperwork); discuss transportation to clinic.	*(PCFAMILR)* ☐	☐	☐	☐	☐
2. **Prepare the participant for meeting with care provider:** Assist participant with questions to ask provider; write down questions/concerns/points on two index cards; rehearse provider interaction; discuss solutions to potential barriers.	*(PCPROVID)* ☐	☐	☐	☐	☐
3. **Prepare for navigator-participant meeting prior to care visit:** Choose time and clear/specific place for patient navigator and participant to meet; discuss reminder phone call/email; resolve transportation issues.	*(PCNAVPPT)* ☐	☐	☐	☐	☐
4. **Discuss expectations of patient navigator/participant roles at care visit:** Clarify clinic policy on patient navigator presence; discuss participant expectation around patient navigator presence; discuss nature of support/facilitation provided by patient navigator. Note: If participant is ambivalent, roll with resistance (validate/discuss concerns of treatment, explore trial run visit, revisiting topic at another patient navigator/participant meeting, etc.).	*(PCROLES)* ☐	☐	☐	☐	☐
5. **Prepare for next patient navigator meeting:** Schedule appointment; review locator information; reinforce participant interest in self-care; If appropriate: offer urine and breathalyzer screens, provide instructions and conduct screens; provide appropriate verbal support on screen results and any other accomplishments (paperwork, labs, medication pick up, etc.).	*(PCMEET)* ☐	☐	☐	☐	☐

Comments:*(PNCCOMM)*

NIDA Clinical Trials Network

Final Patient Navigator Meeting - Patient Navigator (PNF)

Web Version: 1.0; 1.00; 07-19-12

Segment *(PROTSEG)*:
Session Date *(PCSESDT)*:

Date of assessment:*(PNFASMDT)* _____ *(mm/dd/yyyy)* Click here for calendar

Patient navigator number:*(PFPNNUM)* _____

Session length:*(PFSESLEN)* _____ *(xxx)* minutes

To what extent did the patient navigator:	Not at all	Somewhat	Mostly	Completely	Not rated
1. **Review self-care progress since initial patient navigator meeting:** Invite/help participant to acknowledge ways that participant demonstrated self-care in last 6 months (related to HIV, substance abuse, housing, accessing services, employment, social/physical health); If appropriate, refer to patient navigator tracking program in order to outline self-care progress; acknowledge/support attempts at self-care and small successes (getting ID, etc.).	*(PFREVIEW)* ☐	☐	☐	☐	☐
2. **Examine challenges to self-care efforts and goals:** Invite participant to identify current challenges to self-care; focus on ways participant overcame barriers in participant past; reinforce strengths participant demonstrated.	*(PFCHALL)* ☐	☐	☐	☐	☐
3. **Discuss ways to continue self-care efforts post-study:** Explore support options to maintain self-care goals (identify agencies and individuals); discuss/strategize possible realistic next steps.	*(PFCONTIN)* ☐	☐	☐	☐	☐
4. **Explore the experience of working together:** Encourage participant to share participant's benefits and challenges of working together. Navigator shares patient navigator experience, focusing on positive and successful resolutions of challenges.	*(PFEXPLOR)* ☐	☐	☐	☐	☐
5. **Discuss upcoming HOPE study (non-patient navigator) follow up visit:** Review date/activities for 6 month follow-up visit (provide appointment card), remind participant of reimbursement and express appreciation for the participant study involvement; review locator information; reinforce participant interest/effort in self-care; offer urine and breathalyzer screens, provide instructions and conduct screens; provide appropriate verbal encouragement on screen results.	*(PFUPCOM)* ☐	☐	☐	☐	☐

Comments:*(PNFCOMM)*

NIDA Clinical Trials Network

Initial Patient Navigator Meeting - Patient Navigator (PNI)

Web Version: 1.0; 1.00; 07-19-12

Segment *(PROTSEG)*:
Session Date *(PCSESDT)*:

Date of assessment:*(PNIASMDT)* _____ *(mm/dd/yyyy)* Click here for calendar

Patient navigator number:*(PIPNNUM)* _____

Session length:*(PISESLEN)* _____ *(xxx)* minutes

To what extent did the patient navigator:	Not at all	Somewhat	Mostly	Completely	Not rated
1. **Provide introductions and patient navigator overview:** Greet participant; introduce each to the other, describe professional background; provide verbal overview of HOPE patient navigation and offer HOPE question and answer handout.	*(PIINTRO)* ☐	☐	☐	☐	☐
2. **Build rapport and understanding of participant HIV history:** Explore participant experience with HIV, hospitalizations, medications, care providers; answer knowledge-based HIV questions.	*(PIHIVHX)* ☐	☐	☐	☐	☐
3. **Elicit motivation for taking control of HIV:** Show video; explore participant reaction and highlight relevant themes, reinforce benefits of HIV treatment.	*(PIMOTIV)* ☐	☐	☐	☐	☐
4. **Evoke optimism about HIV treatment:** Briefly share information and encouragement around newer/more effective treatment regiments; offer support with accessing primary HIV care and/or support to improve relationship with existing provider.	*(PIOPTIM)* ☐	☐	☐	☐	☐
5. **Provide care agency information:** Share photo album; share knowledge of the clinic, staff, services and other participant positive experiences; discuss participant interest, expectations and concerns about linkage.	*(PICARE)* ☐	☐	☐	☐	☐
6. **Assess readiness to change substance use:** Conduct brief assessment of substance abuse and treatment histories; explore interests, expectations and concerns regarding linkage.	*(PIASSESS)* ☐	☐	☐	☐	☐
7. **Assess external barriers to linkage to treatment:** Explore identified barriers (food, clothing and/or housing insecurities, identification, insurance, transportation); share commitment to help participant meet needs.	*(PIEXBAR)* ☐	☐	☐	☐	☐
8. **Provide initial preparation for primary care visit:** If agrees to visit: review/help schedule appointment, discuss prerequisite paperwork, labs; discuss and schedule reminder call, meeting time/location; identify/address barriers to appointment. If decides against linkage: empathetically and collaboratively discuss decision, explore/normalize ambivalence, remind participant of continuation of patient navigator meetings for other linkages.	*(PIPRIMRY)* ☐	☐	☐	☐	☐
9. **Prepare for next patient navigator meeting:** Schedule appointment; provide folder, review locator info, reinforce participant interest in self-care; offer urine and breathalyzer screen; provide instructions; conduct screens; provide appropriate verbal support on screen results.	*(PIMEET)* ☐	☐	☐	☐	☐

Comments: *(PNICOMM)*

NIDA Clinical Trials Network

Patient Navigator Satisfaction (PNS)

Web Version: 1.0; 1.00; 02-15-12

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

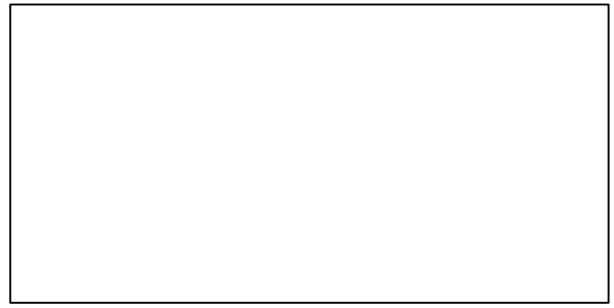
Please answer the following questions about your time working with your patient navigator.

Date of assessment:*(PNSASMDT)* _____ *(mm/dd/yyyy)* Click here for calendar

	Strongly Disagree	Disagree	Slightly Disagree	Slightly Agree	Agree	Strongly Agree
1. I feel my patient navigator understood me.	*(PNUNDERS)* ☐	☐	☐	☐	☐	☐
2. I believe my patient navigator cared about me.	*(PNCARED)* ☐	☐	☐	☐	☐	☐
3. I think I had a good relationship with my patient navigator.	*(PNRELATI)* ☐	☐	☐	☐	☐	☐
4. I liked my patient navigator as a person.	*(PNLIKED)* ☐	☐	☐	☐	☐	☐
5. When I wanted or needed to talk with my patient navigator he or she made time to talk with me.	*(PNTALKTI)* ☐	☐	☐	☐	☐	☐
6. My patient navigator repeatedly offered me help with my health care needs.	*(PNHECANE)* ☐	☐	☐	☐	☐	☐
7. My patient navigator really knows how to work with the HIV health care system.	*(PNHIVSYS)* ☐	☐	☐	☐	☐	☐
8. My patient navigator repeatedly offered me help with my substance use treatment needs.	*(PNSUBTXN)* ☐	☐	☐	☐	☐	☐
9. My patient navigator really knows how to work with the substance use treatment system.	*(PNSUTXSY)* ☐	☐	☐	☐	☐	☐
10. My patient navigator clearly explained the money I could earn by completing certain tasks.	*(PNMONEYE)* ☐	☐	☐	☐	☐	☐
11. After I completed certain tasks, my patient navigator paid me my incentive promptly (after verifying the completion of the task).	*(PNINCENT)* ☐	☐	☐	☐	☐	☐

12. Is there anything else you would like to say about your patient navigator?*(PNANYTHI)*

Comments:*(PNSCOMM)*



NIDA Clinical Trials Network

Unscripted Patient Navigator/Participant Visit - Patient Navigator (PNU)

Web Version: 1.0; 1.00; 07-19-12

Segment *(PROTSEG)*:
Session Date *(PCSESDT)*:

Date of assessment:*(PNUASMDT)* _____ *(mm/dd/yyyy)* Click here for calendar

Patient navigator number:*(PUPNNUM)* _____

Session length:*(PUSESLEN)* _____ *(xxx)* minutes

To what extent did the patient navigator:	Not at all	Somewhat	Mostly	Completely	Not rated
1. **Support participant recent self-care efforts:** Invite the participant to articulate any self-care efforts attempted and/or accomplished since last patient navigator meeting; elicit from participant what participant learned and what strengths participant demonstrated; verbally acknowledge/affirm participant strengths; if appropriate, explore with participant what can be done differently in the future to achieve more positive outcomes; continue to build/maintain rapport.	*(PUSUPPOR)* ☐	☐	☐	☐	☐
2. **Assist participant in addressing ambivalence re: self-care:** Using motivational interviewing techniques (OARS) and manual tools, address ambivalence: ask participant to identify pros/cons of status quo; pros/cons of change (self-care behaviors); ask what participant sees for self in 3 or 5 yrs if no change occurs; what hopes participant has for future; what is important for participant; what needs to happen for participant to be more ready to make change, etc.	*(PUAMBIV)* ☐	☐	☐	☐	☐
3. **Discuss and prepare for any next steps in any self-care:** Strategize what participant may want to accomplish between now and next patient navigator/participant visit related to self-care (housing, food, support, HIV care, substance abuse treatment, dental, clothing, etc.); assist participant in setting specific steps and target dates for goal; discuss ways to overcome potential barriers.	*(PUNEXTST)* ☐	☐	☐	☐	☐
4. **Plan next patient navigator meeting:** Schedule appointment; discuss any appropriate agenda for next meeting; review locator form; reinforce participant interest/effort in self-care; offer urine and breathalyzer screens, provide instructions and conduct screens; provide appropriate verbal encouragement on screen results and any other accomplishments (paperwork, labs, medication pick up, etc.).	*(PUMEET)* ☐	☐	☐	☐	☐

Comments:*(PNUCOMM)*

NIDA Clinical Trials Network

Physician Patient Relationship (PPR)

Web Version: 1.0; 2.01; 10-21-13

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

Date of assessment:*(PPRASMDT)* _____ *(mm/dd/yyyy)* Click here for calendar

The following questions ask about the healthcare provider (doctor/nurse practitioner/physician's assistant) who takes care of your HIV.
RA Instruction: Provide participant with a reference card that lists all response options for his/her easy reference.

1. Does the participant have a healthcare provider (doctor/nurse practitioner/physician's assistant) who takes care of their HIV?*(PPHIVDR)* ☐ No ☐ Yes

Overall communication

Please rate the health care provider who takes care of your HIV in each of the following things.
How is the health care provider who takes care of your HIV at:

	Excellent	Very good	Good	Fair	Poor
2. Explaining the results of tests in a way that you understand?	*(PPRESULT)* ☐	☐	☐	☐	☐
3. Giving you facts about the benefits and risks of treatment?	*(PPFACTS)* ☐	☐	☐	☐	☐
4. Telling you what to do if certain problems or symptoms occur?	*(PPTELL)* ☐	☐	☐	☐	☐
5. Demonstrating caring, compassion, and understanding?	*(PPDEMON)* ☐	☐	☐	☐	☐
6. Understanding your health worries and concerns?	*(PPUNDER)* ☐	☐	☐	☐	☐

HIV - specific information

How is the health care provider who takes care of your HIV at:

	Excellent	Very good	Good	Fair	Poor
7. Talking with you about your sex life?	*(PPSEX)* ☐	☐	☐	☐	☐
8. Asking you about stresses in your life that may affect your health?	*(PPSTRESS)* ☐	☐	☐	☐	☐
9. Asking about problems with alcohol?	*(PPALCOH)* ☐	☐	☐	☐	☐
10. Asking about problems with street drugs like heroin and cocaine?	*(PPSTREET)* ☐	☐	☐	☐	☐

Adherence dialogue

How is the health care provider who takes care of your HIV at:

	Excellent	Very good	Good	Fair	Poor
11. Giving you information about the right way to take your antiretroviral medicines?	*(PPARINFO)* ☐	☐	☐	☐	☐

12. Understanding the problems you have taking your antiretroviral medicines?	*(PPARPRBM)* ☐	☐	☐	☐	☐	
13. Helping you solve problems you have taking your antiretroviral medicines right away?	*(PPARSOLV)* ☐	☐	☐	☐	☐	

Participatory decision-making

RA Instruction: Provide participant with reference cards for subsequent items (as those items are read to the participant) that list all response options for his/her easy reference.

	Very often	Often	Sometimes	Rarely	Never
14. How often does the health care provider who takes care of your HIV infection ask you to take some of the responsibility for your treatment?	*(PPRSPTRT)* ☐	☐	☐	☐	☐

	Definitely yes	Probably yes	Uncertain	Probably not	Definitely not
15. If there was a choice between treatments, would the health care provider who takes care of your HIV infection ask you to help make the decision?	*(PPHELPDE)* ☐	☐	☐	☐	☐

	Very often	Often	Sometimes	Rarely	Never
16. How often does the health care provider who takes care of your HIV infection make an effort to give you some control over treatment decisions?	*(PPTREAT)* ☐	☐	☐	☐	☐

How often does the health care provider who takes care of your HIV infection do the following things:

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
17. Offer choices in your medical care?	*(PPOFFER)* ☐	☐	☐	☐	☐
18. Discuss the pros and cons of each choice with you?	*(PPPROCON)* ☐	☐	☐	☐	☐
19. Get you to state which choice or option you would prefer?	*(PPSTATE)* ☐	☐	☐	☐	☐
20. Take your preferences into account when making treatment decisions?	*(PPPREFER)* ☐	☐	☐	☐	☐

Overall satisfaction with health care provider

How would you rate the health care provider who takes care of your HIV infection in each of the following:

	Excellent	Very good	Good	Fair	Poor
21. Personal manner - courtesy, respect, sensitivity, friendliness:	*(PPPERSON)* ☐	☐	☐	☐	☐
22. Communication skills - listening carefully, answering questions, giving clear explanations:	*(PPCOMMU)* ☐	☐	☐	☐	☐
23. Technical skills - thoroughness, carefulness, competence:	*(PPTECHN)* ☐	☐	☐	☐	☐
24. Your health care provider's overall care:	*(PPOVERAL)* ☐	☐	☐	☐	☐

Willingness to recommend

	Definitely will not	Probably will not	Not sure	Probably will	Definitely will
25. Do you plan to continue to see the health care provider who takes care of your HIV infection in the future?	*(PPCTNSEE)* ☐	☐	☐	☐	☐
26. Do you plan to recommend the health care provider who takes care of your HIV infection to others?	*(PPRECOMM)* ☐	☐	☐	☐	☐

Trust in health care provider

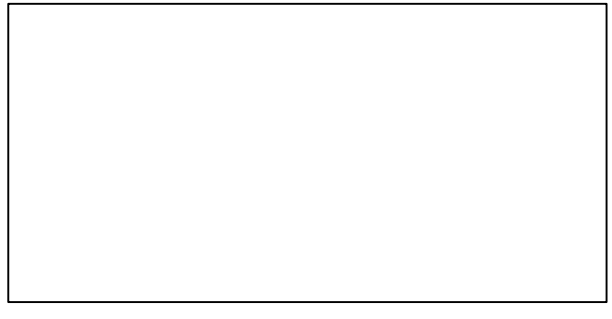
Thinking about how much you trust your health care provider, how strongly do you agree or disagree with the following statements?

	Strongly agree	Agree	Not sure	Disagree	Strongly disagree
27. I can tell my health care provider anything, even things that I might not tell anyone else.	*(PPTELLDR)* ☐	☐	☐	☐	☐
28. My health care provider cares more about holding down costs than about doing what is needed for my health.	*(PPDRCOST)* ☐	☐	☐	☐	☐
29. My health care provider cares as much as I do about my health.	*(PPDRHLTH)* ☐	☐	☐	☐	☐
30. If a mistake was made in my treatment, my health care provider would try to hide it from me.	*(PPTXMIS)* ☐	☐	☐	☐	☐

31. All things considered, how much do you trust your health care provider?

Least trust possible									**Most trust possible**
1	2	3	4	5	6	7	8	9	10
(PPTRUST) ☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Comments: *(PPRCOMM)*



NIDA Clinical Trials Network

Protocol Violation Log (PVL)

Web Version: 1.0; 3.04; 10-04-12

Date of Violation *(PVDATE)*:
Protocol Violation Number *(PVSEQNUM)*:

To be filled in by person(s) reporting this protocol violation:

1. Violation type:*(PVTYPE49)*

Z01-INFORMED CONSENT PROCEDURES
01A-No consent/assent obtained
01B-Proxy (participant representative), if appropriate, was not obtained
01C-Invalid/incomplete informed consent
01D-Unauthorized assessments and/or procedures conducted prior to obtaining informed consent
*Additional Options Listed Below

If "Other" is indicated, provide the specification:*(PVTPSP49)*

2. Description of violation:*(PVDESC)*

3. Has this protocol violation been resolved?*(PVRESOL)*

☐ No ☐ Yes

Protocol violation resolution and corrective action: *(PVRSCASP)*

4. Does this protocol violation require IRB reporting? *(PVIRB)* ☐ No ☐ Yes

If "Yes", provide date reported: *(PVIRBDT)* *(mm/dd/yyyy)* Click here for calendar

Comments: *(PVLCOMM)*

Additional Selection Options for PVL

Protocol Violation Number *(PVSEQNUM)* (key field):
01-1st Protocol Violation of the day
02-2nd Protocol Violation of the day
03-3rd Protocol Violation of the day
04-4th Protocol Violation of the day
05-5th Protocol Violation of the day
06-6th Protocol Violation of the day
07-7th Protocol Violation of the day
08-8th Protocol Violation of the day
09-9th Protocol Violation of the day
10-10th Protocol Violation of the day

Violation type:
01Z-Other (specify)
02-INCLUSION / EXCLUSION CRITERIA
03-CONCOMITANT MEDICATION/ THERAPY
Z04-LABORATORY ASSESSMENT/PROCEDURES
04A-Required testing not obtained
04B-Testing completed outside window
04C-Testing not completed as per protocol
04D-Unauthorized test/procedure obtained
04Z-Other (specify)
Z05-OTHER PROCEDURES / ASSESSMENTS
05A-Protocol required procedures not obtained
05B-Procedures / assessments not completed as per protocol
05C-Procedures / assessmentsobtained outside the visit timeframe
05Z-Other (specify)
Z07-RANDOMIZATION PROCEDURES
07A-Randomization procedures not followed (e.g. outside window, out of sequence, etc.)
07B-Ineligible participatn randomized
07E-Incorrect treatment assignment
07Z-Other (specify)
Z09-BEHAVIORAL INTERVENTION
09A-Intervention not provided per protocol schedule or visit window timeframe
09B-Incorrect intervention assignment
09Z-Other (specify)
Z10-VISIT SCHEDULE / INTERVAL
10A-Visit conducted outside of window
10Z-Other (specify)
Z99-OTHER SIGNIFICANT VIOLATIONS
99A-Destroying study materials proior to authorization from Lead Node and other appropriate parties
99B-Participating site starting the study prior to obtaining appropriate IRB(s) and/or CTM approvals
99C-Using advertising materials or brochures without prior IRB approval
99Z-Other (specify)

NIDA Clinical Trials Network

Protocol Violation Review (PVR)

Web Version: 1.0; 1.02; 01-18-13

Date of Violation *(PVDATE)*:
Protocol Violation Number *(PVSEQNUM)*:

1. Is this event considered to be:*(PVSEVER)*	☐ Major ☐ Minor
2. What section of the protocol does this event refer to?*(PVSECTN)*	
3. Does this event require retraining?*(PVTRAIN)*	☐ No ☐ Yes
4. Does the protocol need to be modified based on this event?*(PVPRTMOD)*	☐ No ☐ Yes
5. Does the consent need to be modified based on this event?*(PVCNTMOD)*	☐ No ☐ Yes
6. Is the review of this event complete?*(PVREVCMP)*	☐ No ☐ Yes
If "No", what additional information is requested?*(PVADTINF)*	

Assessed by:*(PVREVBY)*

2-RoShaunaRothwell
3-Dika(Dee)Blumberg
5-MariaCampanella
6-MatthewWright

Comments:*(PVCOMM)*

Additional Selection Options for PVR

Protocol Violation Number *(PVSEQNUM)* (key field):
01-1st Protocol Violation of the day
02-2nd Protocol Violation of the day
03-3rd Protocol Violation of the day
04-4th Protocol Violation of the day
05-5th Protocol Violation of the day
06-6th Protocol Violation of the day
07-7th Protocol Violation of the day
08-8th Protocol Violation of the day
09-9th Protocol Violation of the day
10-10th Protocol Violation of the day

NIDA Clinical Trials Network

SUD - Cost Information (SCI)

Web Version: 1.0; 3.00; 04-14-14

Segment *(PROTSEG)*:
Visit Number *(VISNO)*:
SUD Module *(SUD_MOD)*:

The next questions will ask about costs/expenses associated with your most recent visit at the _____ facility that we just discussed.

Cost Information for Most Recent Outpatient or Community Clinic
Fill Out only for most recent outpatient or community clinic visit that was HIV related. If none were HIV related fill out for most recent visit.

Cost Information for Most Recent Doctor's Office Visit
Fill out only for most recent doctor's office appointment that was HIV-related. If no doctor's office visit was HIV-related, fill out for most recent Dr. office visit (for whatever reason).

Cost Information for Residential Substance Use Treatment Visit #1
Fill Out only for Most Recent Residential Substance Use Treatment visit

Cost Information for Outpatient Substance Use Treatment Visit #1
Fill Out only for Most Recent Outpatient Substance Use Treatment visit

1. How long did this session (visit to facility) take? Be sure to include any time you were waiting to be seen, the time it took to get to and from the session and the time for the session itself?
   a. Waiting time:*(SCWAITHR)* *(xx)* Hour(s) *(SCWAITMN)* *(xx)* Minute(s)
   b. Session time:*(SCSESNHR)* *(xxx)* Hour(s) *(SCSESNMN)* *(xx)* Minute(s)
   c. Round-trip travel time:*(SCTRVLHR)* *(xx)* Hour(s) *(SCTRVLMN)* *(xx)* Minute(s)

2. How did you get to this facility?*(SCTRNSTO)*
   1-Drove myself
   2-Was driven by a friend
   3-Took train or bus
   4-Took cab or shuttle
   5-Walked
   *Additional Options Listed Below
   If "Other", specify:*(SCTRNTSP)*

3. Did you get home the same way?*(SCTRNSSM)* ☐ No ☐ Yes
   If "No", how did you get back home?*(SCTRNSHM)*
   1-Drove myself
   2-Was driven by a friend
   3-Took train or bus
   4-Took cab or shuttle
   5-Walked
   *Additional Options Listed Below
   If "Other", specify:*(SCTRNHSP)*

4. If you "Drove yourself" or were "driven by a friend", how many miles did you drive (round-trip if drove both ways)?*(SCMILE)* *(xxx)*

5. If you "Drove yourself" or were "driven by a friend", did you have to pay for parking?*(SCPARK)* ☐ No ☐ Yes
   If "Yes", what was the amount?*(SCPARKCS)* *(xxx.xx)*

6. Did you have to arrange child care to go to this session (visit to facility)?*(SCCHILD)* ☐ No ☐ Yes

If "Yes", what child care arrangements did you make?*(SCCHLDTP)*

1-Family or a friend watch children without pay
2-Paid a baby sitter, paid child care, or other paid child care
3-Other unpaid arrangement (eg. after-school program)

If you "paid a baby sitter or other paid child care", how much did you pay for the child care for the time that you needed for this session (visit to the facility)?*(SCCHLDCS)*

(xxx.xx)

7. Did you receive any vouchers or reimbursement for travel, parking or child care?*(SCVOUCHR)*

☐ No ☐ Yes

If "Yes", what was the total value of your vouchers/reimbursements?*(SCVCHRVL)*

(xxx.xx)

8. Did you take time off from work to attend this session (visit to facility)?*(SCWORK)*

☐ No ☐ Yes

a. If "Yes", how much time did you take off from paid work to attend this session (visit to facility)? *(SCWRKHR)*

(xx) Hour(s) *(SCWRKMN)* *(xx)* Minute(s)

b. If "Yes", will you lose pay because of this?*(SCWRKPAY)*

☐ No ☐ Yes

9. Did you take time off from unpaid child care or other household duties to attend this session (visit to facility)?*(SEUNPD)*

☐ No ☐ Yes

How much time did you take off from unpaid child care or other household duities to attend this session (visit to facility)?*(SCUNPDHR)*

(xxx) Hour(s) *(SCUNPDMN)* *(xx)* Minute(s)

Comments:*(SCICOMM)*

Additional Selection Options for SCI

SUD Module *(SUD_MOD)* (key field):
1-Module E. Hospital Clinic/Outpatient Department and Doctors Office
2-Module G. Doctors Office
3-Module I. Residential Treatment for Substance Abuse
4-Question 8b: Outpatient Substance Abuse Treatment

How did you get to this facility?
6-Ambulance
9-Other

NIDA Clinical Trials Network

SUD - Module B. Inpatient Hospital (SDB)

Web Version: 1.0; 3.03; 09-08-14

Segment *(PROTSEG)*:
Report Type *(REPORT)*:
Hospital Visit Date *(SDBIH)*:

Was the visit date exact or an approximation:*(SBDTEXAP)* ☐ Exact ☐ Approximation

Now I'm going to ask you to tell me about each of the hospitalizations that you mentioned having over the past 6 months.
Secure an appropriate medical release to facilitate medical record abstraction.

1. Hospital name:*(SBHSPNAM)*

2. How many nights were you in the hospital for this stay?*(SBNIGHT)* *(xxx)*
3. How many nights was the participant in the hospital for this stay?*(SBNIGHT)* *(xxx)*

4. During this hospitalization, did the participant spend any nights in the following types of special units?
   a. Intensive care unit (ICU/Coronary care unit (CCU):*(SBSPCICU)*
   0-No
   1-Yes
   97-Don't know
   98-Refused to answer
   Nights:*(SBNGTICU)* *(xxx)*
   b. Psychiatric unit:*(SBSPCPSY)*
   0-No
   1-Yes
   97-Don't know
   98-Refused to answer
   Nights:*(SBNGTPSY)* *(xxx)*
   c. Drug/alcohol unit:*(SBSPCDRG)*
   0-No
   1-Yes
   97-Don't know
   98-Refused to answer
   Nights:*(SBNGTDRG)* *(xxx)*

5. What were the first three discharge diagnoses for this hospitalization?
   a. *(SBDISDX)*
   b. *(SBDISDX2)*
   c. *(SBDISDX3)*

6. Did the participant sign appropriate release form to collect medical records?*(SBPTSIGN)* ☐ No ☐ Yes

Comments: *(SDBCOMM)*

Additional Selection Options for SDB

Report Type *(REPORT)* (key field):
1-Self-report only
2-Abstracted medical record only
3-Combined self-report/abstracted medical record

NIDA Clinical Trials Network

SUD - Module D. Day Hospital/Partial Hospitalization Program (SDD)

Web Version: 1.0; 2.02; 09-08-14

Segment *(PROTSEG)*:
Visit Number *(VISNO)*:
Facility Name *(PROGRMNM)*:
Report Type *(REPORT)*:

Now I'm going to ask you to tell me about each of the Day Hospital/Partial Hospitalization Programs that you mentioned visiting in each hospital/program over the past 6 months. Secure an appropriate medical record release to facilitate medical record abstraction.

1. How many days did you attend this program during the past 6 months?*(SDDAYS)* ☐ *(xxx)*
2. How many days did the participant attend this program during the past 6 months?*(SDDAYS)* ☐ *(xxx)*
3. What type of services did you get in this program?
4. What type of services did the participant get in this program?

		No	Yes	Don't Know	Refused
a.	Medical care: *(SDMEDCAR)*	☐	☐	☐	☐
b.	Mental health care: *(SDMNTLHT)*	☐	☐	☐	☐
c.	Housing assistance: *(SDHOUSNG)*	☐	☐	☐	☐
d.	Other:*(SDOTHSP)* _____ *(SDOTHER)*	☐	☐	☐	☐

5. Did the the participant sign an appropriate release form to collect medical records?*(SDPTSIGN)* ☐ No ☐ Yes

Comments:*(SDDCOMM)*

Additional Selection Options for SDD

Report Type *(REPORT)* (key field):
1-Self-report only
2-Abstracted medical record only
3-Combined self-report/abstracted medical record

NIDA Clinical Trials Network

SUD - Module E. Hospital Clinic/Outpatient Department & Doctor's Office (SDE)

Web Version: 1.0; 5.01; 06-24-14

Segment *(PROTSEG)*:
Visit Number *(VISNO)*:
Facility Name *(PROGRMNM)*:
Report Type *(REPORT)*:

Now I'm going to ask you to tell me about each of the Hospital Clinic/Outpatient Departments that you mentioned visiting over the past 6 months.
Secure an appropriate medical release to facilitate medical record abstraction

Date of assessment:*(SDEASMDT)* _____ *(mm/dd/yyyy)* Click here for calendar

1. Was the visit to a "clinic/outpatient" or "doctor's office"?*(SEVSTYPE)* ☐ Clinical/outpatient department ☐ Doctor's office
2. How many times did you visit this hospital clinic or outpatient department during the past 6 months? *(SEVISIT)* _____ *(xx)*
3. How many times did you visit this facility during the past 6 months?

Month *(mmm)*	Year *(yyyy)*	Number of Visits *(xx)*
(SEMOV1)	*(SEYRV1)*	*(SENUMV1)*
(SEMOV2)	*(SEYRV2)*	*(SENUMV2)*
(SEMOV3)	*(SEYRV3)*	*(SENUMV3)*
(SEMOV4)	*(SEYRV4)*	*(SENUMV4)*
(SEMOV5)	*(SEYRV5)*	*(SENUMV5)*
(SEMOV6)	*(SEYRV6)*	*(SENUMV6)*
(SEMOV7)	*(SEYRV7)*	*(SENUMV7)*

4. Date of first visit:*(SEPRGDT)* _____ *(mm/dd/yyyy)* Click here for calendar
5. Date of last (most recent) visit:*(SELASTDT)* _____ *(mm/dd/yyyy)* Click here for calendar
6. If the facility is a hospital, what is the name of the clinic or outpatient department within the hospital? *(SEDEPT)* _____ **- OR -** *(SEDEPUNK)* ☐ Unknown
7. If the facility is a "Doctor's office", what is the name of your doctor?*(SEDRNAME)* _____ **- OR -** *(SEDRUNK)* ☐ Unknown
8. Did the participant sign an appropriate release form to collect medical records?*(SEPTSIGN)* ☐ No ☐ Yes

Comments: *(SDECOMM)*

Additional Selection Options for SDE

Report Type *(REPORT)* (key field):
1-Self-report only
2-Abstracted medical record only
3-Combined self-report/abstracted medical record

NIDA Clinical Trials Network

SUD - Module I. Residential Treatment for Substance Abuse (SDI)

Web Version: 1.0; 2.01; 06-25-13

Segment *(PROTSEG)*:
Report Type *(REPORT)*:
Residential Visit Date *(SDIRES)*:

Was the visit date exact or an approximation?*(SIDATE)* ☐ Exact ☐ Approximation

Now I'm going to ask you to tell me about each of the Residential Treatment visits that you mentioned having over the past 6 months.

1. Name of the residential treatment facility or detox hospital:*(SITRTNAM)*
2. How many nights were you in the treatment facility/detox hospital for this stay?*(SINIGHTS)* *(xxx)*
3. During this stay, what did you receive treatment for?*(SIRCVTRT)*

1-Alcoholabuse
2-Drug abuse
3-Both alcoholand drug abuse
4-Refused
5-Don'tknow

If treated for "Drug abuse", did you receive methadone or Buprenorphine maintenance? *(SIMTHBUP)*

0-No
1-Yes
7-Refused
8-Don'tknow

Comments:*(SDICOMM)*

Additional Selection Options for SDI

Report Type *(REPORT)* (key field):
1-Self-report only
2-Abstracted medical record only
3-Combined self-report/abstracted medical record

NIDA Clinical Trials Network

SUD - Module A. Emergency Room (SMA)

Web Version: 1.0; 2.01; 06-10-13

Segment *(PROTSEG)*:
Visit Number *(VISNO)*:
Hospital Name *(SDHSPNM)*:
Report Type *(REPORT)*:

Now I'm going to ask you to tell me about the ER visits that you mentioned having in each hospital over the past 6 months.
Secure an appropriate medical release to facilitate medical record abstraction.

Date of assessment:*(SMAASMDT)* *(mm/dd/yyyy)* Click here for calendar

1. How many ER visits did you have in this hospital in the past 6 months?

Month *(mmm)*	Year *(yyyy)*	Number of Visits *(xx)*
(SAMOV1)	*(SAYRV1)*	*(SANUMV1)*
(SAMOV2)	*(SAYRV2)*	*(SANUMV2)*
(SAMOV3)	*(SAYRV3)*	*(SANUMV3)*
(SAMOV4)	*(SAYRV4)*	*(SANUMV4)*
(SAMOV5)	*(SAYRV5)*	*(SANUMV5)*
(SAMOV6)	*(SAYRV6)*	*(SANUMV6)*
(SAMOV7)	*(SAYRV7)*	*(SANUMV7)*

2. Did the participant sign an appropriate release form to collect medical records?*(SAPTSIGN)* ☐ No ☐ Yes

Comments:*(SMACOMM)*

Additional Selection Options for SMA

Report Type *(REPORT)* (key field):
1-Self-report only
2-Abstracted medical record only
3-Combined self-report/abstracted medical record

NIDA Clinical Trials Network

SUD - Module C. Nursing Home, Respite Care, Personal Care Home rehabilitation And Hospice Facility (SMC)

Web Version: 1.0; 1.02; 07-01-13

Segment *(PROTSEG)*:
Visit Number *(VISNO)*:
Facility name *(SDCNAME)*:
Report Type *(REPORT)*:

Now I'm going to ask you to tell me about the nursing home, respite care, personal care home rehabilitation and hospice visits that you mentioned having in each facility over the past 6 months.

Date of assessment:*(SMCASMDT)* *(mm/dd/yyyy)* Click here for calendar

1. What type of facility was this:*(SCFACTYP)*

1-Nursing home
2-Hospice
3-Rehabilitation Center
97-Don't know
98-Refused

2. How many nights were you in the facility for each month in the past 6 months?

Month *(mmm)*:	**Year *(yyyy)*:**	**Number of Nights *(xx)*:**
(SCMOV1)	*(SCYRV1)*	*(SCNUMV1)*
(SCMOV2)	*(SCYRV2)*	*(SCNUMV2)*
(SCMOV3)	*(SCYRV3)*	*(SCNUMV3)*
(SCMOV4)	*(SCYRV4)*	*(SCNUMV4)*
(SCMOV5)	*(SCYRV5)*	*(SCNUMV5)*
(SCMOV6)	*(SCYRV6)*	*(SCNUMV6)*
(SCMOV7)	*(SCYRV7)*	*(SCNUMV7)*

3. Did the participant sign appropriate release form to collect medical records?*(SCPTSIGN)* ☐ No ☐ Yes

Comments:*(SMCCOMM)*

Additional Selection Options for SMC

Report Type *(REPORT)* (key field):
1-Self-report only
2-Abstracted medical record only
3-Combined self-report/abstracted medical record

NIDA Clinical Trials Network

Conflictual Social Interaction Scale (STS)

Web Version: 1.0; 1.00; 07-19-12

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

Date of assessment:*(STSASMDT)* _____ *(mm/dd/yyyy)* Click here for calendar

RA Instruction: Provide participant with a reference card that lists all response options for his/her easy reference.
The next questions are about your interactions with others. During the past four weeks, how much of the time have you (insert question). Would you say none of the time, a little of the time, some of the time, most of the time, or all of the time?

	None of the time	A little of the time	Some of the time	Most of the time	All of the time
1. Had serious disagreements with your family about things that were important to you?	*(STDISFAM)* ☐	☐	☐	☐	☐
2. Had serious disagreements with your friends about things that were important to you?	*(STDISFR)* ☐	☐	☐	☐	☐
3. Felt that others were trying to make changes in you that you did not want to make?	*(STCHANGE)* ☐	☐	☐	☐	☐

People sometimes look to others for companionship, assistance, or other types of support. How often was each of the following kinds of support available to you (during the past 4 weeks) if you needed it?

How often do you have:	None of the time	A little of the time	Some of the time	Most of the time	All of the time
1. Someone to love and make you feel wanted?	*(STWANTED)* ☐	☐	☐	☐	☐
2. Someone to help with daily chores (child care, buying food, preparing meals) if you were sick?	*(STCHORES)* ☐	☐	☐	☐	☐
3. Someone to help you buy medicines?	*(STMED)* ☐	☐	☐	☐	☐
4. Someone to help with transportation?	*(STTRAN)* ☐	☐	☐	☐	☐
5. Someone to give you money if you need it?	*(STMONEY)* ☐	☐	☐	☐	☐

Comments:*(STSCOMM)*

NIDA Clinical Trials Network

Study Termination (STT)

Web Version: 1.0; 3.02; 12-13-13

1. Date of study completion, early termination, or last attended study visit:*(TRTRMDT)* *(mm/dd/yyyy)* Click here for calendar

2. Did the participant complete the study?*(TRCOMPLT)* ☐ No ☐ Yes

If "No", select the primary reason for study termination:*(TRTRMRES)*

1-Participant incarcerated for duration of study
2-Participant terminated for clinical reasons
3-Participant terminated due to AE/SAE
4-Participant withdrew consent
5-Participant died
*Additional Options Listed Below

If "Participant terminated for other reason", provide other reason:*(TRTRMOSP)*

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 or designee:*(TRPISIGN)*

Date:*(TRPISGDT)* *(mm/dd/yyyy)* Click here for calendar

Additional Selection Options for STT

If "No", select the primary reason for study termination:
6-Participant terminated due to protocol violation
7-Participant lost to followup
8-Participant moved
99-Participant terminated for other reason

NIDA Clinical Trials Network

Service Utilization Detail (SUD)

Web Version: 1.0; 3.04; 08-07-14

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

The next questions ask about your use of medical and social services in the past 6 months.

RA Instruction: Provide participant with a reference card that lists all response options for his/her easy reference.

Date of assessment:*(SUDASMDT)* _____ *(mm/dd/yyyy)* Click here for calendar

1. During the past 6 months, did you go to a hospital emergency room for emergency care?
   Include any visits to the emergency room, even if you were admitted to the hospital from there. Include emergency rooms of psychiatric hospitals. Please include your current hospital stay when responding to this question.(SUER)

   0-No
   1-Yes (Follow-up with applicable module)
   97-Don't know
   98-Refused

   a. If "Yes," how many different times did you go to a hospital emergency room for emergency care during the past 6 months, including psychiatric hospitals?*(SUERVS)* _____ *(xxx)* visits
   b. During the past 6 months how many emergency departments have you attended?*(SUERDEPT)* _____ *(xx)* departments

2. During the past 6 months, were you a patient in any hospital overnight or longer?
   Include psychiatric hospitals. Please include your current hospital stay when responding to this question.(SUOVHS)

   0-No
   1-Yes (Follow-up with applicable module)
   97-Don't know
   98-Refused

   a. If "Yes," how many separate overnight hospital stays did you have during the past 6 months, including psychiatric hospital stays?*(SUOVHSVS)* _____ *(xxx)* stays

3. During the past 6 months, did you spend one or more nights in a respite care facility, personal care home, nursing home, rehabilitation center, or hospice facility?*(SUCARE)*

   0-No
   1-Yes (Follow-up with applicable module)
   97-Don't know
   98-Refused

   a. If "Yes," how many separate stays in a nursing home or hospice facility did you have during the past 6 months?*(SUCAREVS)* _____ *(xxx)* stays

4. During the past 6 months, did you attend any medical program where you spent the day there but went home at night? *Include day hospitals, partial hospitalizations, or intensive outpatient programs for reasons other than substance abuse. (SUDAYH)*

   0-No
   1-Yes (Follow-up with applicable module)
   97-Don't know
   98-Refused

   a. If "Yes," how many different programs like this did you go to during the past 6 months?*(SUDAYHVS)* _____ *(xx)* programs

5. During the past 6 months, did you go to any hospital clinic, hospital outpatient department, community clinic or neighborhood health center for medical care, for example, to care for your HIV/AIDS or other physical problems?
Include visits for urgent care. (SUOUTP)

0-No
1-Yes (Follow-up with applicable module)
97-Don't know
98-Refused

a. If "Yes," how many different hospital clinics, outpatient departments, community clinics or neighborhood health centers did you visit for medical care during the past 6 months?*(SUOUTPVS)* _____ *(xx)* clinics, departments, and/or centers

b. If "Yes," were any of these HIV primary care visits?*(SUPRMCRE)*

0-No
1-Yes
97-Don't know
98-Refused to answer

1. What was the date of the first HIV primary care visit to one of these clinics in the last 6 months? *(SUOUT1DT)* _____ *(mm/dd/yyyy)* Click here for calendar
2. What was the date of the last HIV primary care visit to one of these clinics in the last 6 months? *(SUOUT2DT)* _____ *(mm/dd/yyyy)* Click here for calendar

6. During the past 6 months, did you get medical care in any private doctor's office?*(SUDR)*

0-No
1-Yes (Follow-up with applicable module)
97-Don't know
98-Refused

a. If "Yes," how many different private doctor's offices did you visit for medical care during the past 6 months?*(SUDRVS)* _____ *(xx)* different doctor's offices

1. What was the date of the first HIV-related visit to one of these doctor's offices in the last 6 months? *(SUDR1DT)* _____ *(mm/dd/yyyy)* Click here for calendar
2. What was the date of the last HIV-related visit to one of these doctor's offices in the last 6 months? *(SUDR2DT)* _____ *(mm/dd/yyyy)* Click here for calendar

7. During the past 6 months, did you see any professional for the primary purpose of getting help for a psychological or emotional issue?
These professionals could include psychologist, therapist, counselor, psychiatrist or other doctor. Include groups led by a professional counselor and visits to professionals to get medication for psychological and emotional issues.
Do not include unpaid professionals, such as clergy or other religious/spiritual advisors or healers. (SUPSYC)

0-No
1-Yes
97-Don't know
98-Refused to answer

Thinking about all the mental health care providers you visited in the past 6 months:

a. How many times did you visit any of these providers to talk about psychological or emotional issues?*(SUPSYEM)* _____ *(xxx)* times

b. In addition to these one-on-one counseling sessions, how many times did you visit any of these providers to discuss your use of prescribed medications for psychological and emotional issues? *(SUPSYMED)* _____ *(xxx)* times

8. During the past 6 months, did you see any professional for the primary purpose of getting alcohol or drug treatment, including methadone maintenance, or getting help for an alcohol or drug problem? ☐ No ☐ Yes
Include stays in detox hospitals and residential treatment programs as well as groups led by a professional counselor.
Do not include unpaid professionals, such as clergy or other religious/spiritual advisors or healers. (SUDRUG)

a. If "Yes," were you in a residential drug or alcohol treatment facility or detox hospital in which you stayed overnight during the past 6 months?*(SUDRUGOV)*

0-No
1-Yes (Follow-up with applicable module)
97-Don't know
98-Refused

1. How many separate stays did you have?*(SUDRUGVS)* _____ *(xxx)* stays

Answer the following questions for the past 6 months and for any outpatient substance abuse treatment that you have received.

b. How many different alcohol or drug treatment providers in an outpatient setting did you visit during the past 6 months?*(SUDRGOPT)* ☐ *(xx)* different providers

1. How many days did you attend intensive outpatient substance abuse treatment in the past 6 months?*(SUINTOPT)* ☐ *(xxx)* days
2. How many days did you attend regular outpatient substance abuse treatment in the past 6 months? *(SUREGOPT)* ☐ *(xxx)* days

Answer the following questions for the past 6 months for all outpatient substance abuse service providers that you met with.

c. How many times did you meet one-on-one with an outpatient substance abuse service provider to discuss substance use issues in the past 6 months?*(SUDGIND)* ☐ *(xxx)* times

d. How many times did you meet in group sessions with an outpatient substance abuse service provider to discuss substance use issues in the past 6 months?*(SUGRPSES)* ☐ *(xxx)* times

Answer the following questions for the past 6 months for all substance abuse providers or medical providers.

e. Are you taking any of the following medications for opioid treatments?

1. Methadone:*(SUOUTMET)* ☐ No ☐ Yes Methadone treatment center:*(SUMETHTX)* ☐
2. Buprenorphine (Suboxone):*(SUOUTSBX)* ☐ No ☐ Yes
3. Naltrexone oral:*(SUOUTONX)* ☐ No ☐ Yes
4. Naltrexone depot (intramuscular):*(SUOUTINJ)* ☐ No ☐ Yes

f. How many times did you pick up opioid replacement medications in the past 6 months?*(SUOUTOPI)* ☐ *(xxx)* times

9. During the past 6 months, did you participate in any other support group, group counseling or self-help group for emotional, substance abuse or health issues?
This would include groups led by an unpaid professional, for example clergy, or other providers.
(SUGR)

0-No
1-Yes
97-Don't know
98-Refused to answer

a. If "Yes," how many group sessions did you attend with one of these providers to discuss substance use issues?*(SUGRVS)* ☐ *(xxx)* group sessions

b. Which best describes the group you attend or attended?

1. Mental health self-help or support group:*(SUGRMN)* ☐ No ☐ Yes
   How many times did you attend?*(SUGRMNTM)* ☐ *(xxx)* times
2. Substance abuse self-help or support group:*(SUGRSB)* ☐ No ☐ Yes
   How many times did you attend?*(SUGRSBTM)* ☐ *(xxx)* times
3. HIV/AIDS self-help or support group:*(SUGRHI)* ☐ No ☐ Yes
   How many times did you attend?*(SUGRHITM)* ☐ *(xxx)* times
4. Other self-help or support group:*(SUGROT)* ☐ No ☐ Yes
   If "Other," specify*(SUGROTSP)* ☐
   How many times did you attend?*(SUGROTTM)* ☐ *(xxx)* times

- OR -

Refused:*(SUGRRF)* ☐

Don't know:*(SUGRDK)* ☐

10. During the past 6 months, did you get any dental care?*(SUDENTAL)*

0-No
1-Yes
97-Don't know
98-Refused to answer

11. During the past 6 months, did you receive any help at home from professional health care providers, such as nurses, aides or therapists sent by a home health agency, or from other home-based services, such as Meals on Wheels? *(SUHOME)*

0-No
1-Yes
97-Don't know
98-Refused to answer

a. If "Yes," how many different professional home health care providers assisted you during the past 6 months? *(SUHOMEPV)* _____ *(xx)* providers

b. If "Yes," how many different home visits occurred during the past 6 months? *(SUHOMEVS)* _____ *(xxx)* home visits

c. What kind of home care professionals have visited you?
Let respondent give open-ended answer and mark appropriate response category. Read categories only if respondent cannot answer question.

1. Visiting nurse: *(SUNURSE)* ☐ No ☐ Yes
2. Home health aide: *(SUHMAID)* ☐ No ☐ Yes
3. Homemaker: *(SUHMMKR)* ☐ No ☐ Yes
4. Physical, occupational or respiratory therapist: *(SUTHRPST)* ☐ No ☐ Yes
5. Counselor or social worker: *(SUSOCIAL)* ☐ No ☐ Yes
6. Babysitter: *(SUBABYST)* ☐ No ☐ Yes
7. Meals on wheels worker: *(SUMEALS)* ☐ No ☐ Yes
8. Other: *(SUHOMEOT)* ☐ No ☐ Yes

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

12. During the past 6 months, did you receive any help because of a health problem or other disability from family members, friends, or neighbors?
This help could be for medical problems, taking care of yourself, housekeeping, shopping, or any other assistance you might need, including transportation.(SUFAMILY)

0-No
1-Yes
97-Don't know
98-Refused to answer

13. During the past 6 months, did you spend one or more nights in a homeless or emergency shelter? *(SUSHTR)*

0-No
1-Yes
97-Don't know
98-Refused to answer

a. If "Yes," how many nights did you spend in a homeless or emergency shelter during the past 6 months? *(SUSHTRVS)* _____ *(xxx)* nights

14. During the past 6 months, did you receive any help from case managers or social service workers with things like obtaining health care or legal services, housing, or easing money problems? *(SUCASE)*

0-No
1-Yes
97-Don't know
98-Refused to answer

a. How many different people have been your case manager, or caseworker in the last 6 months? *(SUCASENM)* _____ *(xx)* people

b. How many times did you have face-to-face meetings with one of your case managers over the past 6 months? *(SUCASEVS)* _____ *(xxx)* times

c. How often did you talk to one of your case managers on the telephone over the past 6 months? *(SUCASEPH)*

1-More than once a week
2-About once a week
3-Every other week
4-Once a month
5-No phone contact
*Additional Options Listed Below

15. During the past 6 months, did you receive any health care from providers or social service agencies we have not yet discussed?*(SUCAREOT)*

0-No
1-Yes
97-Don't know
98-Refused to answer

a. If "Yes," specify each additional provider and/or social service agencies from which you have received health care:

1. *(SUCAREO1)*
2. *(SUCAREO2)*
3. *(SUCAREO3)*
4. *(SUCAREO4)*
5. *(SUCAREO5)*

Save this form.
Perform assessments on all required modules before completing the remainder of this form.

Interview Confidence Rating

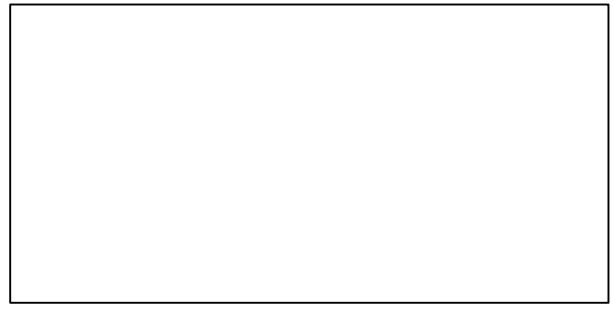
1. Confidence in assessment:*(SUCONFID)*

1-Not at all
2-Slightly confident
3-Somewhat confident
4-Mostly confident
5-Very confident

2. Explain here if validity of assessment is questionable.
   a. Participant appeared under the influence:*(SUINFLUN)* ☐ No ☐ Yes
   b. Participant was uncooperative:*(SUCOOPER)* ☐ No ☐ Yes
   c. Participant appeared to be lying:*(SULYING)* ☐ No ☐ Yes
   d. Participant had poor mental recall:*(SUMENTAL)* ☐ No ☐ Yes
   e. Participant had difficulty understanding questions (other than language barriers):*(SUUNDER)* ☐ No ☐ Yes
   f. Participant had difficulty understanding questions (due to language barriers):*(SULANGAG)* ☐ No ☐ Yes

---

Comments:*(SUDCOMM)*



Additional Selection Options for SUD

How often did you talk to one of your case managers on the telephone over the past 6 months?
97-Don't know
98-Refused

NIDA Clinical Trials Network

Urine Drug Screen (UDS)

Web Version: 1.0; 5.00; 05-10-12

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

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

   a. If "No", provide reason:*(UD1NCLRS)*

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

   b. If "Other", specify:*(UD1NOCSP)*

1st Urine Drug Screen

2. Date 1st urine specimen collected:*(UDCOLDT)* *(mm/dd/yyyy)* Click here for calendar

3. Time 1st urine specimen collected (24 hour format):*(UD1COLTM)* *(hh:mm)*

4. Was the 1st urine temperature within range? (90 - 100 °F)*(UD1TMP)* ☐ No ☐ Yes

5. Was the 1st urine specimen determined to be adulterated?*(UD1ADULT)* ☐ No ☐ Yes

1st Urine Drug Screen Results

6.

Drug Name (Abbreviation)	Negative	Positive	Invalid
Benzodiazepines (BZO):	*(UD1BZO)* ☐	☐	☐
Amphetamine (AMP):	*(UD1AMP)* ☐	☐	☐
Marijuana (THC):	*(UD1THC)* ☐	☐	☐
Methamphetamine (MET):	*(UD1MET)* ☐	☐	☐
Opiates (2000 ng) (OPI):	*(UD1OPI)* ☐	☐	☐
Cocaine (COC):	*(UD1COC)* ☐	☐	☐
Ecstasy (MDMA):	*(UD1MDMA)* ☐	☐	☐
Oxycodone (OXY):	*(UD1OXY)* ☐	☐	☐
Methadone (MTD):	*(UD1MTD)* ☐	☐	☐
Barbiturate (BAR):	*(UD1BAR)* ☐	☐	☐

2nd Urine Drug Screen

7. If the 1st urine specimen was determined to be adulterated, was a second specimen collected? *(UD2COLNY)*

☐ No ☐ Yes

a. If "No", provide reason:*(UD2NCLRS)*

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

b. If "Other", specify:*(UD2NOCSP)*

8. Time 2nd urine specimen collected (24 hour format):*(UD2COLTM)*

(hh:mm)

9. Was the 2nd urine temperature within range? (90 - 100 °F)*(UD2TMP)*

☐ No ☐ Yes

10. Was the 2nd urine specimen determined to be adulterated?*(UD2ADULT)*

☐ No ☐ Yes

2nd Urine Drug Screen Results

11.

Drug Name (Abbreviation)	Negative	Positive	Invalid
Benzodiazepines (BZO):	*(UD2BZO)* ☐	☐	☐
Amphetamine (AMP):	*(UD2AMP)* ☐	☐	☐
Marijuana (THC):	*(UD2THC)* ☐	☐	☐
Methamphetamine (MET):	*(UD2MET)* ☐	☐	☐
Opiates (2000 ng) (OPI):	*(UD2OPI)* ☐	☐	☐
Cocaine (COC):	*(UD2COC)* ☐	☐	☐
Ecstasy (MDMA):	*(UD2MDMA)* ☐	☐	☐
Oxycodone (OXY):	*(UD2OXY)* ☐	☐	☐
Methadone (MTD):	*(UD2MTD)* ☐	☐	☐
Barbiturate (BAR):	*(UD2BAR)* ☐	☐	☐

Comments:*(UDSCOMM)*