NIDA Clinical Trials Network		
NIDA CIIIICAI TITAIS NELWOTK		
Adverse Events (AD1)		
Web Version: 1.0; 5.00; 07-26-		

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:(A 1SEVR2) □ No □ Yes 4. Is there a reasonable possibility that the intervention caused the event? (A1RELTIN) If "Unrelated" to study intervention, alternative etiology:(A 1ALTEB) If "Other," specify: (A1AEBSP) 5. Action taken with study intervention: (A1A CTBI) 6. Outcome of event: (A1 OUTCM) 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.

3. Was this event associated with: (A1ASSOC2)		
If "Death", date of death: (A1DTHDTE)	(mm/dd/yyyy)	
	7777	
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 r Preferred Term: (MEDRAPT)		
System Organ Class: (MEDRASOC)	Not Coded	
Cyston Organ Gass. (MEDIAGOO)		

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-Prolon gation 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)
Adverse Event Onset Date (AEDATE): Select Sequence Number (AESEQNUM):	
Initial narrative description of serious adverse	ent:
(A2 SUMM)	
2. Relevant Past Medical History: (A2SAEMHX	
Allergies, pregnancy, smoking and alcohol us	hypertension, diabetes, epilepsy, depression, etc.
(A2 MEDHX)	
3. Medications at the Time of the Event: (A2SA	ED) No Yes Unknown
Medication (Generic Name)	Indication
(A2_01DNM)	(A2_01DIN)
(A2_02DNM)	(A2_02DIN)
(A2_03DNM)	(A2_03DIN)
(A2 04DNM)	(A2 04DIN)

(A2_05DIN)

(A2_05DNM)

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(A2_06DNM)	(A2_06DIN)					
(A2_07DNM)	(A2_07DIN)					
(A2_08DNM)	(A2_08DIN)					
(A2_09DNM)	(A2_09DIN)					
(A2_10DNM)	(A2_10DIN)					
Treatments for the Event: (A2SAETRT) No	Unknown		•			
Treatment Torthe Event: (A2SAETRT) No 1 Yes	Indication	on	Date Treate	ed	7	
(A2_1TNME)	(A2_1 TIND)		(A2_1LTDT)	(mm/dd/yyyy	 ')	
(A2_2 TNME)	(A2_2 TIND)		(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	7)	
		-			_	
Labs/Tests Performed in Conjunction with this Event: (A2	S <i>AELAB</i>) No Yes	Unknown			D.J. (T.J.	
Lab/T est		Findings			Date of Test	_
(A2_1LBNM)	(A2_1LBNM) (A2_1LBDT) (mm/dd/yyyy)				(mm/dd/yyyy)	
(A2_2LBNM)	(A2_2LBIN)				(A2_2LBDT)	(mm/dd/yyyy)
(A2_3LBNM) (A2_3LBDT) (mm/dd/yy			(mm/dd/yyyy)			
(A2_4LBNN) (A2_4LBDT) (mm/dd/yyy			(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. (A2 FOLLUP)						
(A2 FOLLUP)						

(A2 ADDINF)		
Have all Medical Monitor requests been addressed?(A2RQADDR)	sed?(A2RQADDR)	es

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
Outland Advance From (Modical Deviations (ADO)	

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

Serious Advers	se Event Medical Reviewer (AD3)
Adverse Event Onset Date (AEDATE): Select Sequence Number (AESEQNUM):	
1. Was this determined to be a serious adverse event? (A3DETER) 2. Was this event considered associated with the study's behavioral intervention? (A3BHINT) 3. Was this event expected? (A3EXPECT) 4. Is this a standard expedited/reportable event? (i.e., is it serious, unexpected and related to therapy) (A3EXPFDA) 5. Is this an expedited/reportable event for other reasons? (A3EXPOTH) 6. Does the protocol need to be modified based on this event? (A3EXPDSM) 7. Does the consent form need to be modified based on this event? (A3CONSEN) 8. Is the review complete? (A3REVDNE) If "No", what additional information is required: (A3ADDINF)	No Yes No Yes
Assessed by:(A2 ASRID) Reviewed by:(A3REVID)	Ro bert Lindblad Radhika Kondapaka Ro bert 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

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Addition	al Demographics (ADE)
Segment (<i>PROTSEG</i>): Visit Number (<i>VISNO</i>):	
Date of assessment: (ADEASMDT)	(mm/dd/yyyy) Click here for cale ndar
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)	
a. What was the outcome of the last time you spoke to us about the study? (ADINTOUT)	
b. What happened the last time you spoke to us about the study?(ADINTCOM)	
2. What is your gender? (ADGENDER)	
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)	
4. What is your marital status?(ADMARRIE)	

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)	
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? (ADWA GEHR)	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)	
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) If income is greater than \$999,995 enter 999,995;	(xxxxxx) (ADTIDKRF) Don't know Refuse to answer
Which of the following is the category that your total family income from legal sources would be in?(ADINCFMW)	
Note that the participant's personal income should be included in total income.	
Are you covered by health insurance or some other kind of health care plan?(ADHLTINS)	
o. We you covered by frealth insurance of some other kind of fleatist care plant (ADF/E/Wey)	
me all plans that you have.	e). Exclude private plans that only provide extra cash while hospitalized. If you have more than one kind of health insurance, tell
a. Private health insurance(ADPRIHEA)	No Yes
b. Medicare(ADMEDCAR)	No Yes
c. Medi-gap (ADMEDIGA)	No Yes
d. Me dica id (ADMEDCAD)	No Yes State plan name:(ADMEDSTA)
e. SCHIP (CHIP/children's health insurance program)(ADSCHIP)	□ No □ Yes

f. Military health care (Tricare NA/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 <i>(ADADAP)</i>	□ No □ Yes
I. 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)	The state of the s
the number of days should be calculated with 1 month = 30 days(ADDAILD 1)	
10. Which of the following best describes your Hispanic ethnic background? (ADHISBGD)	
to. Without of the following best describes your maparite entitle background: (ADTITOBOD)	
If "Other", specify:(ADHISOTH)	
11. Which of the following best describes your Asian ethnic background? (ADASIBGD)	
If "Other", specify:(ADASIOTH)	
12. Which of the following best describes your Black ethnic background? (ADBKBGD)	
12. WITHOUT OF the following best describes your black ethilic background: (ADDADOD)	
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)	

Number of days in the previous 4 weeks with no food or money to buy food? (ADFDMON)	
14. In what country were you born?(ADCOUNTR)	
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 the 17. During the past six months, where did you live or sleep most of the time? (ADLIVSLP)	is hospital. How long have you lived in this area?"
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	(AD	LVJA	<i>IIL)</i> [
	I. Other, spe cify:(ADLIOTSP)	(AD	LIVE	от) 「							
	How long have you lived in this area (i.e., Zip Code)?(ADLIVLGT)										
20.	Who do you live with?	No		Yes	Refuse to						
	a. Alone	(ADAL ONE)			Allswei						
	b. Partner	(ADPARTNE)									
	c. Parents	(ADPARENT)									
	d. Children	(ADCHILDR)									
	e. Other Family	(ADFAMOTH)									
	f. Friends	(ADFRIEND)									
	g. Roommates/housemates	(ADRMMATE)									
	h. Other, specify:(ADL VWTSP)	(ADWHOOTH)									
22. 23.	Do you live with anyone who has a current alcohol problem?(ADLVALC) Do you live with anyone who uses illegal drugs or marijuana?(ADLVDR) Do you live with anyone who abuses prescription/OTC medications or of Do you have any children under the age of 18?(ADCHILD)	G)	(A DL \	VDRR	☐ No	☐ Yes ☐ Yes ☐ Yes	_				
	How many children under 18 do you have daily care and responsibility fo	or?(<i>ADRESPCA</i>)				(xx)					
26.	Which year did you get your first positive test for HIV?(ADPOSYR) Which month did you get your first positive test for HIV?(ADPOSMO)					(xxxx)	(ADYRDKR	F)-or- 🗆 [Oon't know	-or- Refu	se to answer

27. Have you ever had HIV primary care? By HIV primary care, we mean a clinician or team of clinicians who you regular basis and who works with you to manage your HIV/AIDS medicount and viral load. (ADHIVPRI)			
If "Yes", when was your last HIV primary care visit? (ADLASTVS)			
28. Have you taken medications specifically for your HIV? These would be antiretrovirals or a drug cocktail to reduce your viral I This means medications that attack HIV, not medications for other cor			
29. Are you currently taking medications specifically for HIV? (ADTKEMED))		
If "Yes," specify:(ADM EDSSP)			
30. How many times have you been hospitalized in the last 12 months?(AL	DLSTHSP)		(xxx)
The number of hospitalizations entered should include the current hos Of these, how many times have you been hospitalized in the last 6 m)	(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 treatm			□ No □ Yes
b. We re any of the se treatments in the past 6 months? (AD06ALDR)			□ No □ Yes
32. In the past 12 months, which of the following types of programs have ye	ou participated in?		
	No	Yes	
a. Drug free outpatient drug treatment	(AD12 OUTP)		
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, spe cify:(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 in carce rated

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-An gola

9- An guilla

10-Antarctica

11-Antiqua & Barbuda

12-Antilles, Netherlands

13-Argentina

14-Armenia

15-Aruba

16-Australia

17-Austria

18-Azerbai ian

19-Baha mas, 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-Brun ei Dar ussala m
- 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-Leb anon

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

144-Wall, 1516 UI

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-Pan ama
- 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-Sen egal
- 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-Zimba bwe
232-Ziiilba bwe
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

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/ersion: 1.0; 1.00; 07-10-12

Shortened HI	V Adherence Measures (ADH)	
Segment (PROTSEG): Visit Number (VISNO):		Web V
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 t last month.	he (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? "Yes" means you missed meds "No" means you did NOT miss meds(ADWKND)	□ No □ Yes	
The following questions ask about symptoms you might have had during the past month . Choose the RA Instruction: Provide participant with a reference card that lists all response options for his/here		
6. Fatigue or loss of energy?(ADENERGY)		
7. Fe vers, chills or sweats?(ADFEVER)		

8. Feeling dizzy or lightheaded?(ADDIZZY)	
9. Pain, numbness or tingling in the hands or feet? (ADNUMB)	
10. Trouble remembering?(ADRMBER)	
11. Nausea or vomiting?(ADVOMIT)	
12. Diarrhea or loose bowel movements?(ADBOWEL)	
13. Felt sad, down or depressed?(ADSADEN)	
14. Felt nervous or anxious? (ADNERVES)	
15. Difficulty falling or staying asleep?(ADSLEEP)	

16. Skin problems, such as rash, dryness or itching? <i>(ADSKNPRB)</i>	
17. Cough or trouble catching your breath?(ADCOUGH)	
18. He adache? (ADHEDACH)	
19. Loss of appetite or change in the taste of food?(ADAPETIT)	
20. Bloating, pain or gas in your stomach?(ADBLOAT)	
21. Muscle aches or joint pain? <i>(ADM SACHE)</i>	
22. Problems with having sex, such as loss of interest or lack of satisfaction? (ADSEX)	

23. Changes in the way your body looks, such as fat deposits or weight gain? (ADBDYCHG)	
24. Problems with weight loss or wasting?(ADWEIGHT)	
25. Hair loss or changes in the way your hair looks? (ADHAIRCG)	
Comments:(ADHCOMM)	

NIDA Clinical Trials Network

Medication Adherence Self Efficacy (ADS)

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

Segr	ment (<i>PROTSEG)</i> :	
V is it	Number (VISNO):	

Date of assessment (ADSASMDT)		(mm/dd/yyyy) Click here for calend
-------------------------------	--	------------------------------------

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 $0 = \underline{you}$ cannot do at all, 5 = moderately (somewhat) certain \underline{you} can do and 10 = completely certain \underline{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)										
In tegrate 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)										
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 some thing 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)

If "No", specify reason: (ABREASON)

If "Other", specify (AB10THSP)

- 2. Date of assessment: (ABA SMTDT)
- 3. Alcohol Breathalyzer result: (ABRESULT)
- 4. Is a repeat test required? (ABREPTST)

If "Yes", complete the questions below.

a. Was the repeat Alcohol Breathalyzer performed? (ABREPPRF)

If "No", specify reason: (ABRREASN)

If "Other", specify (AB2OTHSP)

- b. Repeat test date:(ABREPDT)
- c. Repeat Alcohol Breathalyzer result: (ABREPRES)

Comments: (ALBCOMM)

□ No □	Yes		
Partici	pant refused to provide sample	Study staff error	Othe
	(mm/dd/yyyy)		
	(.xxx) mg/mL		
□ No	Yes		
_	Yes	_	_
L Partici	pant refused to provide sample	Study staff error	Othe
	(mm/dd/yyyy) (.xxx) mg/mL		

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)	(ARST01DT) Calendar	(ARSP01DT) Calendar	(ARSELFO1)	(ARMEDO1)
2.	(ARDRUG02)	(ARST02DT) Calendar	(ARSP02DT) Calendar	(ARSELFO2)	(ARMED02)
3.	(ARDRUG03)	(ARST03DT) Calendar	(ARSP03DT) Calendar	(ARSELF03)	(ARMEDO3)
4.	(ARDRUG04)	(ARST04DT) Calendar	(ARSP04DT) Calendar	(ARSELF04)	(ARMED04)

5.		(ARST05DT) Calenda	r (ARSP05DT) Calendar	(ARSELF05)	(ARMED05)
	(ARDRUG05)				
6.		(ARST06DT) Calenda	(ARS P06DT) Calendar	(ARSELF06)	(ARMED06)
	(ARDRUG06)				
7.		(ARST07DT) Calenda	(ARS P07DT) Calendar	(ARSELF07)	(ARMEDO7)
	(ARDRUG07)				
8.		(ARST08DT) Calenda	(ARSP08DT) Calendar	(ARSELF08)	(ARMEDO8)
	(ARDRUG08)				
9.		(ARST09DT) Calenda	(ARSP09DT) Calendar	(ARSELF09)	(ARMEDO9)
	(ARDRUG09)				
10.		(ARST10DT) Calenda	(ARSP10DT) Calendar	(ARSELF10)	(ARMED10)
	(ARDRUG10)				
11.		(ARST11DT) Calenda	(ARSP11DT) Calendar	(ARSELF1 1)	(ARMED11)
	(ARDRUG11)				

12.		(ARST12DT) Ca	alendar (ARS	SP12DT)	Calendar	(ARSELF12)	(ARMED12)
	(ARDRUG12)						
-	(ANDROGIZ)						_
13.		(ARST13DT) Ca	alendar (ARS	SP13DT)	<u>Calendar</u>	(ARSELF13)	(ARMED13)
	(ARDRUG13)						
14.		(ARST14DT) Ca	alendar (ARS	SP14DT)	<u>Calendar</u>	(ARSELF14)	(ARMED14)
	(ARDRUG14)						
15.	(ARDROG 14)						
15.		(ARST15DT) <u>Ca</u>	alendar (ARS	SP15DT)	Calendar	(ARSELF15)	(ARMED15)
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16.		(ARST16DT) Ca	alendar (ARS	SP16DT)	<u>Calendar</u>	(ARSELF16)	(ARMED16)
	(ARDRUG16)						
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\vdash	(ARDRUG17)				,		
18.		(ARST18DT) Ca	alendar (ARS	SP18DT)	<u>Calendar</u>	(ARSELF18)	(ARMED18)
	(ARDRUG18)						

19.		(ARST19DT) Calendar	(ARSP19DT) Calendar	(ARSELF19) (ARMED19)
	(ARDRUG19)			
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	(ARDRUG22)			
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27.		(ARST27DT) Cale	ndar (ARSP27DT) Calendar	(ARSELF27) (ARME	ED27) 🗆
	ARDRUG27)				
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29.		(ARST29DT) <u>Cale</u>	ndar (ARSP29DT) Calendar	(ARSELF29) (ARME	ED29) 🗆
_{(A}	ARDRUG29)				
30.					
30.		(ARST30DT) Cale	ndar (ARSP30DT) Calendar	(ARSELF30) (ARME	ED30)
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(A	RDRUG32)				
32.	ARDRUG31)	(ARST32DT) Cale	ndar (ARSP32DT) Calendar	(ARSELF32) (ARME	ED32) 🗆
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33.		(ARST33DT) Calendar	(ARSP33DT) Calendar	(ARSELF33) (ARMED33)
	(ARDRUG33)			
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34.		(ARST34DT) Calendar	(ARSP34DT) Calendar	(ARSELF34) \square (ARMED34) \square
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35.		(ARST35DT) Calendar	(ARSP35DT) Calendar	(ARSELF35) (ARMED35)
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	(ARDRUG35)			
36.		(ARST36DT) Calendar	(ARSP36DT) Calendar	(ARSELF36) (ARMED36)
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37.		(ARST37DT) Calendar	(ARSP37DT) Calendar	(ARSELF37) (ARMED37)
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38.		(ARST38DT) <u>Calendar</u>	(ARSP38DT) Calendar	(ARSELF38) (ARMED38)
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_	(ARDRUG38)			
39.		(ARST39DT) Calendar	(ARSP39DT) Calendar	(ARSELF39) \Box (ARMED39) \Box
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42.		(ARST42DT) Ca	alendar ((ARSP42DT)	Calondar	(ARSELF42)	(ARMED42)
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	(ARDRUG42)						
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	(ARDRUG43)						
4.					_	_	_
44.		(ARST44DT) <u>Cal</u>	alendar ((ARSP44DT)	Calendar	(ARSELF44)	(ARMED44)
	(ARDRUG44)						
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45.		(ARST45DT) Cal	alendar ((ARSP45DT)	Calendar	(ARSELF45)	(ARMED45)
	(4.55.54.0.45)						
	(ARDRUG45)						

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-Viramun e 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:	(ASA ASM DT)
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(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".

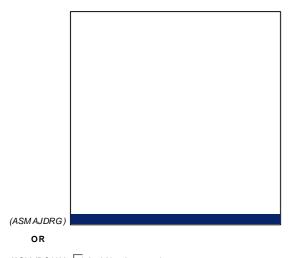
Substance		ast 30 ays)	D Route of Administration		Comments
D1 Alcohol (any use at all):	(ASALA30D)	(xx)		-	(ASALACOM)
D2 Alcohol (to intoxication):	(ASALI30D)	(xx)		-	(ASALICOM)
D3 Heroin	(ASHER30D)	(xx)			(ASHERCOM)
			(A SHERRTE)		
D4 Methadone/LAAM (prescribed):	(ASM DP 30D)	(xx)			(ASM DPCOM)
			(A SMDPRTE)		
D4a Methadone/LAAM (illicit):	(ASMLI30D)	(xx)			(ASMLICOM)
			(ASMLIRTE)		

D5 Other Opiates/Analgesics:	(ASO PI30D) (xx)		(ASOPICOM)
		(ASOPIRTE)	
D6 Barbiturates:	(ASBAR30D) (xx)		(ASBARCOM)
		(ASBARRTE)	
D7 Other Sedatives/ Hypnotics/Tranquilizers:	(ASSHT30D) (xx)		(ASSHTCOM)
		(ASSHTRTE)	
D8 Cocaine:		(ASSITIVE)	
Do Cocame:	(ASCOC30D) (xx)		(ASCOCCOM)
		(A SCOCRTE)	
D9 Amphetamines:	(ASAMP30D) (xx)		(ASAMPCOM)
	(7.6711/11 66.2)		
		(A SAM PRTE)	
D1 0 Cannabis:	(ASTHC30D) (xx)		(ASTHCCOM)
		(ASTHCRTE)	

D11 Hallucinogens:	(ASHAL 30D)	(x)		(ASHALCOM)
		(A SHALRTE,		
D1 2 Inhalants :	(ASINH30D) (ASINH30D)	x)		(ASINHCOM)
		(ASINHRTE)		
D13 More than 1 substance per day (including alcohol, excluding nicotine):	(ASG T1 30D)	(x)	-	(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.



(ASMJDGNA) (97) Not Answered

Comments:(ASMJDGCM)	
D17 How many times since your last ASI have you had Alcohol DTs?	
• <u>Delirium Tremens</u> (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 mo	пт репоа).
D19 Alcohol abuse:	
(ASALCTRT) (xx)	
OR	
(ASATRTNA) (97) Not Answered	
processing = (or) not his motor	

	Comments: (ASA TRTCM)	
D20	Drug abuse:	
	(ASDRGTRT) (xx)	
	OR	
	(ASDTRTNA) (97) Not Answered	
	Comments: (ASDTRTCM)	
How r	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: (ASA DTXCM)		
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 alcoh 	10/?	
(ASALCMNY) \$ (xxxxx)		
OR		
(ASAMNYNA) (97) Not Answered		

Comments: (ASAMNYCM)		
Drugs:		
Only count actual m	noney spent. What is the financial burden caused by drugs?	
(ASDRGMNY) \$	(xxxxx)	
OR		
(ASDMNYNA) [(97) No	t Answered	
Comments:(ASDMNYCM)		
025 How many days have you h	een treated in an outpatient setting for alcohol or drugs in the past 30 days:	2
many days nave you b	son as a second of the past of days	·

Include A A/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: (ASA P30CM)	
For questions D28-D31, please ask participant to use the Participant Rating Scale. The participant is rating th	e need for additional substance abuse treatment.
D28 How troubled or bothered have you been in the past 30 days by these alcohol problems?	

(ASAPB30D)

(ASAB30NA) [(97) Not Answered

Comments:(ASAB30CM)	
D30 How important to you now is treatment for these alcohol problems?	
(ASA PI30D)	
OR (ASA I30NA) □ (97) Not Answered	
(AGAISONA) — (87) NOTAISWEIGH	
Comments:(ASA/30CM)	
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)

OR

(ASDP30NA) [(97) Not Answered

(xx) days

Comme nts: (ASDP30CM)	
D29 How troubled or bothered have you been in the past 30 days by these drug problems?	
(ASDPB30D)	
OR	
(ASDB30NA) (97) Not Answered	
Comments: (ASDB30CM)	
D31 How important to you now is treatment for these drug problems?	

(ASDPI30D)

(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

Barbitur ates: Nembutal, Seconal, Tuinol, Amytal, Pentobarbital, Secobarbital, Phenobarbital, Fiorinol

Sed/Hyp/Tranq: Benzodia zepines = Valium, Librium, Ativan, Serax, Tranxene, Dalmane, Halcion, Xanax, Miltown, Other = Chloral Hydrate (Noctex), Qua aludes

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 (Phen cyclidine), 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					
	Acce	ss to Car	e Scale	(ATC)	
egment (<i>PROTSEG</i>): sit Number (<i>VISNO</i>):					
Now I'm going to read you some statements <u>about health care</u> that ask about the	past 6 months.				
RA Instruction: Provide participant with a reference card that lists all response of	otions for his/her eas	/ reference.			
Date of assessment: (ATCASMDT)			(mm/do	d/yyyy) Click I	here for cale
am going to read you some statements that ask about the <u>past 6 months</u> . Tell me if you strongly agree, somewhat agree, are uncertain, somewhat disagre	e, or strongly disagre	e with each st	tatement.		
In the past 6 months, would you say:	Strongly agree	Somewhat agree	Uncertain	Some what disagree	Strongly disagree
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)				
B. So metimes I go without the medical care I need because it is too expensive.	(ATEXPNSV)				
4. I have easy access to the medical special ists 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)					

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

	NIDA Clinical Trials Network	
Segment (PROTSEG):	AUDIT (AUC)	Web Version: 1.0; 4.01; 10-21-1
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. RA Instruction: Provide participant with a reference card that lists all response.		
Date of assessment: (AUCASMDT)	(mm/dd/yyyy) Click here for calendar	
How often do you have a drink containing alcohol? (AUALFREQ)		
How often do you have a drink containing alcohol? (AUALFREQ)		
(AUALFREQ) 2. How often do you have a drink containing alcohol?		

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

Se gr	nent	(PK	υı	SEG	<i>יו</i> :
V is it	Num	ber	(VI	SNC)):

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) \square 0 = Not at all \square 1 = A little bit \square 2 = Moderately \square 3 = Quite a bit \square 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	MODERATELY 2	QUITE A BIT	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)						
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Comments:(BS/COMM)							

NIDA Clinical Trials Network					
Computer Assisted Personal Interview (CAP)					
Segment (PROTSEG): Visit Number (VISNO):	Web Version: 1.0 ; 1.00; 03-15-1				
Where is this assessment being performed?(CAPLOCTN)					
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	Manageme	nt (CDP)	Web \	/ersion: 1.0; 1	.00; 07-19-12
Segment (PROTSEG): Session Date (PCSESDT):				ŕ	,
Date of assessment: (CDPASMDT) 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: Strate gize 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: (CDP CO MM)					

NIDA Clinical Trials Network

Debriefing Substance Abuse Treatment Visi	t - Patient Navigator and Contingenc	y Managem	ent (CDS	•	ersion: 1.0; 1	00: 07-25-41
Segment (PROTSEG): Session Date (PCSESDT):				webv	rersion: 1.0; 1	.00, 07-25-12
Date of assessment: (CDSASMDT) Patient navigator number: (CSPNNUM) Session length: (CSSESLEN)	(mm/dd/yyyy) Click here for calendar (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 demonstrated; verbally acknowledge participant strengths; if appropriate, explore with participation achieve a more positive outcome.	(CSSUPPOR)					
Discuss outstanding business: Ask participant to identify unanswered/unaddressed questions (see index card) and new questions/conce	(CSOUTSTN)					
Discuss and prepare for next steps in self-care: Strategize follow-up to substance abuse treatment plan, assist participant in setting specific substance abuse.	ouse treatment activities and rehearse preliminary steps.	(CSNEXTST)				
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 apother accomplishments (paperwork, labs, medication pick up, etc.); provide appropriate incentives; review participant of potential upcoming incentives participant can earn.		(CSCMSCH)				
Comme nts: (CDS COMM)						

NIDA Clinical Trials Network

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

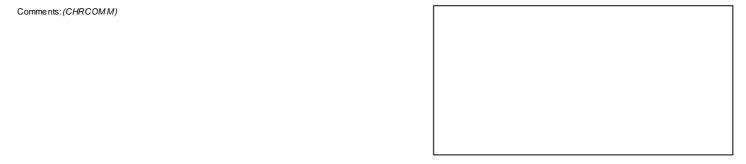
Web Version: 1.0; 3.00; 06-27-13

Segment (PROTSEG):	
Visit Number (VISNO):	
RA Instruction: Provide participant with a reference card that lists all response options for his/her easy r	eference.
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.	(CHO VRRCT)				
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)				



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NIDA Clinical Trials Network
Olivian II also Data (OLD)

Clinical Labs Data (CLD)

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

Segment (PROTSEG): Visit Number (VISNO):

isit Number (VISNO):	
Study Labs	
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)	(xxxxxxxxx) 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 Pl'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
1. Has the participant had an AIDS defining illness during the current hospital admission?(CDAIDS)	□ No □ Yes
If "Yes", specify:(CDAIDSSP)	
5. Was a sample collected?(CDCOLTD)	□ No □ Yes
If "Yes," date:(CDCOLTDT)	
6. CD4 collection method:(CDCD4CLT)	(mm/dd/yyyy) Click here for calendar
a. CD4 collection date:(CDCD4CDT)	(mm/dd/yyyy) Click here for calendar
b. CD4:(CDCD4C)	(xxxxx) (cells/µL)
c. CD4 %: (CDCD4P)	
7. Viral load collection method: (CDVLCLT)	(xxxx) %
a. Viral load collection date:(CDVLCDT)	(mm/dd/yyyy) Click here for calendar
b. Is HIV viral load undetectable?(CDHIVVLU)	□ No □ Yes
• • •	L 110 L 1 C3

c. If "Yes," what is your lab's lower limit? (CDL OWER) d. If "No," how many copies? (CDCOPIES)	<pre>(xxx) (copies/mL) (xxxxxxxx) (copies/mL)</pre>
e. VL Assay Type:(CDASSAY)	
8. CBC collection method: (CDCBCCLT)	
a. CBC collection date:(CDCBCCDT)	(mm/dd/yyyy) Click here for calendar
b. Hemoglob in: (CDHGB)	(xx.x) g/dL
c. Hematocrit (CDHCT)	(xx.x) %
d.WBC:(CDWBC)	(xxx.x) k/μL
e. Platelets: (CDPLAT)	(xxxx) k/µL
ВМІ	
9. Height:(CDHGHTIN)	(xx) in - OR - (CDHGHTCM) (xxx) cm
0. Weight:(CDWGHTLB)	(xxx.x) lbs - OR - (CDWGHTKG, (xxx.x) kg
Was weight measured or abstracted?(CDWGHTMA)	Measured Abstracted
1. BMI:(CDCALC)	
Abstracted Labs	
Lab values within the 6 months prior to Date of Randomization through 1 month a	after Date of Randomization

Lab Name	Date Collected		Date Collected		\	'alue	Alternate Value
12. Creatinine:	(CDCREDT)	Calendar	(CDCREDT)	Calendar	(CDCREAT)	(xx.xx) mg/dL	
13. eGFR calculated by lab:	(CDEGFRDT) Calendar		(CDEG FRDT) Calendar		(CDEGFR)	(xxx.x) mL/min/1.73	(CDEGFRNE) - OR - > (xxx) mL/min/1.73 m ²
14. Total bilirubin:	(CDTBILDT)	Calendar	(CDTBILDT)	Calendar	(CDTBILI)	(xx.xx) mg/dL	
15. Direct bi lirubin:	(CDDBILDT)	<u>Calendar</u>	(CDDBILDT)	Calendar	(CDDBILI)	(xx.xx) mg/dL	
16. Total protein:	(CDTPRODT) Calendar		(CDTPRODT) Calendar		(CDTPROT)	(xx.x) g/dL	
17. Albumin:	(CDALBDT)	Calendar	(CDALBDT)	<u>Calendar</u>	(CDALB)	(xx.x) g/dL	
18. AST:	(CDASTDT)	<u>Cale ndar</u>	(CDASTDT)	Calendar	(CDAST)	(xxxxx) U/L	
19. ALT:	(CDALTDT)	Calendar	(CDAL TDT)	<u>Calendar</u>	(CDALT)	(xxxxx) U/L	
20. ALK phos:	(CDALKDT)	Calendar	(CDALKDT)	<u>Calendar</u>	(CDALK)	(xxxxx) U/L	
-OR- no abstracted labs availal	ble:(CDNOABST)						

21. HCV antibody: (CDHCVAB)

HCV antibody collection date: (CDHCVDT)

Is the HCV viral load undetectable? (CDHCVVLU)

No Yes Unknown

HCV viral load collect	ion date:(CDHCVI	LDT)			(mm/dd/yyyy) Click here for calendar	
If "No", how many cop	pies?(CDHCVVL)				(xxxxxxxxx) (copies/mL)	
Лутрhnodes), HIV encepl lymphoma; Mycobacteriui	clude: candidiasis halopathy; Herpes m avium complex urrent salmonella	s (bronchi, trachea, lungs, s simplex (lung/esophageal or Mycobacterium kansasi septicemia; toxoplasmosis	esophageal); coccid or chronic ulcers>1 ii; Other mycobacteri	iomycosis (disseminate mo); histoplasmosis (dium (disseminated, extr	ed/extrapulmonary, cryptococcosis (extrapulmonary); c	cryptosporidiosis (>1 month), CMV (other than liver/spleen kitt's lymphoma; immu noblastic lymphoma; primary CNS vecii pneumonia; isosporiasis; progressive multifocal
Lab Name	Dat	te Collected	Va	alue		
23. PaO ₂ :	(CDPA O2DT)	Calendar	(CDPA O2)	(xxx) mmHg		
24. Sodium (Na):	(CDSO DIDT)	Calendar	(CDSODIUM)	(xxx) mEq/L		
25. Chloride (CI):	(CDCHLDT)	Calendar	(CDCHLOR)	(xxx) mmol/L		
26. Bicarbonate (CO ₂):	(CDBICADT)	Calendar	(CDBICARB)	(xx) mmol		
-OR- no ancillary labs ava	ilable:(CDNOANC	CL)				
27. Ab solute lymphocyte coun	t:(CDALYMPH)				(xx.xx) x 10 ⁹ /L Date collected:(CDALYMDT)	(mm/dd/yyyy) Calendar
- OR - 28. WBC: <i>(CDWBCAN)</i>					(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-Immun oblastic lymph oma
- 8-Primary CNS lymphoma
- 9-Mycobacterium avium complex or Mycobacterium kansasii 10-Other mycobacterium (disseminated, extrapulm)
- 11-M. Tube rculosis (any site)
- 12-Pneu mocystis jiro ve cii pne umon ia
- 13-Isosporiasis
- 14-Progressive multifocal leukoenceph alopathy
- 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 Conting	ency Mana	agement	•) /ersion: 1.0; 1	.00; 07-23-1
Segment (PROTSEG): Session Date (PCSESDT):					
Date of assessment: (CMAASMDT) 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
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 - Pa	tient Navigator and Contingency Mana	gem ent (Cl	MC)	Web V	ersion: 1.0; 1.	∩∩· ∩ 7-19-1
Segment (PROTSEG): Session Date (PCSESDT):						00, 07 10 1.
Date of assessment: (CMCASMDT) Patient navigator number: (CCPNNUM) Session length: (CCSESLEN)	(mm/dd/yyyy) Click here for calendar (xxx) minutes					
To what extent did the patient navigato	or:	Not at all	Somewhat	Mostly	Completely	Not rated
Familiarize the participant with the care agency: Review names and basic information about provider/agency staff; review pictures (if appropriate); revier requirements (ID, paperwork); discuss transportation to clinic.	w agency address; discuss typical visit flow; review visit	(CCFAMILR)				
Prepare the participant for meeting with care provider: Assist participant with questions to ask provider; write down questions/concerns/points on two index capotential barriers.	rds; rehearse provider interaction; discuss solutions to	(CCPRO VID)				
Prepare for navigator-participant meeting prior to care visit: Choose time and clear/specific place for patient navigator and participant to meet, discuss reminder photos.	one call/email; resolve transportation issues.	(CCNA VPPT)				
4. Discuss expectations of patient navigator/participant roles at care visit: Clarify clinic policy on patient navigator presence; discuss participant's expectation around patient navig by patient navigator. Note: If participant is ambivalent, roll with resistance (validate/discuss concerns of patient navigator/participant meeting, etc.).		(CCROLES)				
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 accomplishments (paperwork, labs, medication pick up, etc.); provide appropriate incentives and verbal 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 Manager	gement (Cl	MF)	Web V	ersion: 1.0; 1	.00; 07-19-1
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; a cknowledge/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
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.	(СІНІУНХ)				
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 i dentified 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 ar	nd Contingenc	y Managen	nent (CMI	•	ersion: 1.0; 1	00: 07 10 1
Segment (PROTSEG): Session Date (PCSESDT):				webv	ersion. 1.0, 1	.00, 07-19-1
Date of assessment: (CMUASMDT) Patient navigator number: (CUPNNUM) Session length: (CUSESLEN) (mm/dd/yyyy) Click! (xxx) minutes	here for calendar					
To what extent did the patient navigator:		Not at all	Somewhat	Mostly	Completely	Not rate d
1. Support participant's recent self-care efforts: Invite the participant to articulate <u>any</u> self-care efforts attempted and/or accomplished since last patient navigator meeting; elicit from participant learned and what strengths participant demonstrated; verbally acknowledge/affirm participant strengths; if appropriate, explore with participant 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 (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 impowhat 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 substance abuse treatment, dental, clothing, etc.); assist participant in setting specific steps and target dates for goal; discuss ways to overcore		(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 s other accomplishments (paper work, labs, medication pick up, etc.); provide appropriate incentives; review contingency management schedule participant of upcoming incentives that participant can earn.		(CUCMSCH)				
Comments: (CMUCOMM)						

	NIDA Clinical Trials Network
	Cognitive Screening (COG)
Segment (<i>PROTSEG</i>): Visit Number (<i>VISNO</i>):	Web Version: 1.0; 1.00; 03-09-12
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 patient you will ask for recall of the words again a bit later.	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
Motor Speed: Have the patient tap the thumb and forefinger of the non-dominant hand as quickly as possible. (COMOTSPD)	s widely and as
 2. Psychomotor Speed: Have the patient perform the following movements with the non-dom 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. 	nin ant hand as
Demonstrate and have patient perform twice for practice.(COPSYSPD)	
Memory-Recall - Ask the patient to recall the four words. For words not recalled, prompt	t with a semantic clue as follows: animal (dog); piece of clothing (hat); vegetable (bean); color (red).
1. Recall: dog(COMEDOG)	
2. Recall: hat(COMEHAT)	
3. Recall: bean <i>(COMEBEAN)</i>	
4. Recall: red (COMERED)	

Comments: (COGCOMM)	

NIDA Clinical Trials Network

Demographics (DEM)

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

. Date of birth: (DEBRTHDT)	(mm/dd/yyyy)
. Sex:(DEGENDER)	☐ Male ☐ Female ☐ Participant chooses not to answer
. Ethnicity: (DEETHNIC)	☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Participant chooses not to answer
Race: American Indian or Alaska Native(DEAMEIND) Asian(DEASIAN) Black or African American(DEBLACK) Native Hawaiian or Pacific Islander(DEHAWAII) White(DEWHITE) Other(DEOTHER) If "Yes", specify:(DEOTHRSP)	No Yes No Yes No Yes No Yes No Yes No Yes
OR	
Unknown(DEUNKNOW) Participant chooses not to provide their race(DENORACE)	☐ Yes ☐ Yes
Comments: (DEMCOMM)	

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

DAST-10 (DST)			
Segment (PROTSEG): Visit Number (VISNO):			
The next several questions are about drug use. Please answer No or Yes.			
Date of assessment: (DSTA SMDT)	(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) Bate of death (DTDTHDT): 1. Time of death (24-hour format):(DTDTHTM) 2. Date staff notified of death:(DTNCFVDT) (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

If "Other", specify:(DTOTHER)

6. Secondary cause of death: (DT2COD)

If "Other", specify:(DT2CODSP)

7. Source: (DTSOURCE) 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) If "No", where did the death occur? (DTPLACE)	□ No □ Yes □ Unknown
10. Was participant seen in the emergency department within one week prior to death?(DTEDVIST) If "Yes", date of ED visit.(DTEDDT)	□ No □ Yes □ Unknown (mm/dd/yyyy) Click here for calendar
11. Was participant hospitalized within one week prior to death?(DTHSVIST) If "Yes", admit date:(DTHSDT)	□ No □ Yes □ Unknown (mm/dd/yyyy) Click here for calendar
12. Was the participant discharged prior to death?(DTDISCHG) If "Yes", discharge date:(DTDSCHDT)	□ No □ Yes □ Unknown (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)	

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		
OD/OR (END)		

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

	0049B (ENR)
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
 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: (R6L/VRET)	□ 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
 Participant reports any opioid and/or stimulant and/or heavy alcohol use within the past year:(R6DRGUSE) 	□ No □ Yes □ Un known
 Participant has an indication of any opioid and/or stimulant and/or heavy alcohol use within the past 12 months:(R6DRGUSE) 	□ No □ Yes □ Un known
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 □ Un known
 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 □ Un kno wn
c. The hospital system medical record for this participant has evidence of opioid or stimulant use in the p ast 12 months: (R6SUBHR)	□ No □ Yes □ Un known
d. The hospital system medical record for this participant has evidence of heavy alcohol use in the past 12 months:(R6AUCHR)	□ No □ Yes □ Un known
 Participant has a detectable (>200 copies/mL) viral load or unknown level in the past 6 months: (R6VRLOAD) 	□ No □ Yes □ Un known
a. If "Yes" or "No", specify viral load: (R6LOADVL)	(xxxxxxxxx) 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 □ Un known
a. If "Yes" or "No", specify CD4 count (R6CD4 VAL)	(xxxxx) cells/uL
b. Date CD4 count obtained:(R6CD4DT)	(mm/dd/yyyy)
11. Participant meets on e or more of the following: (R6VLCD4)	□ No □ Yes
a. Participant has an AIDS-defining illness during the current hospital admission:(R6AIDS)	□ No □ Yes □ Un known
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:(R6VL CD6)	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 Pl'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 □ Un kno wn

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)	
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:(R6L CATOR)	□ No □ Yes □ Unknown
14. A baseline blood draw has been completed for this participant: (R6BLO OD)	□ 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	□ No □ Yes □ Un known
provide informed consent: (R6S/GCOG)	
2. Participant is terminated via site PI decision with agreement from study LI: (R6TERM)	□ No □ Yes □ Unknown
If "Yes", specify:(R6TERMSP)	
Eligibility for Randomization	
A letter out the state of the fourth and 1 0/DODTE (O)	
I. Is the participant eligible for the study?(R6PTELIG) Is the participant eligible for randomization?(R6PTRAND)	□ No □ Yes
a. If "No", specify: (R6NORASP)	∐ No
a.ii No , specily.(kolvokase)	
b. If "Judgment of CTP/research staff", specify:(R6JUDGSP)	
c. If "Other", specify:(R6OTHRSP)	
with Other , specify. [NOOT FINSE]	

Comments:(R6COMM)	

N	IIDA Clinical Trials Network

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

Fagerstrom T	est for Nicotine Dependence (FTA)
egment (PROTSEG): sit Number (VISNO):	
The next few questions are about smoking habits.	
Date of assessment: (FAASMTDT)	(mm/dd/yyyy) Click here for calend
Do you currently smoke cigarettes?(FASMOKE)	□ No □ Yes
Please read each question below. For each question enter the answer choice which best describes	s your responses.
1. How soon after you wake up do you smoke your first cigarette? (FAFSTCIG)	
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)	
3. Which cigarette would you hate most to give up?(FAGIVEUP)	
4. How many cigarettes/day do you smoke?(FAPERDAY)	
5. Do you smoke more frequently during the first hours after waking than during the rest of the day?(FAFREQ)	
6. Do you smoke if you are so ill that you are in bed most of the day?(FAILL)	

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.
В.	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 E	3ehavic	ors - Modified (GRB)		
Segment (<i>PROTSEG</i>): Visit Number (<i>VISNO</i>):		Web Version: 1.0 ; 1.00; 10-25-1		
Date of assessment (GRBASMDT)		(mm/dd/yyyy) Click here for calendar		
·		eading infectious diseases. Remember that all of your answers are strictly confidential. The first questions are about the clude 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)				
During the past 12 months, did you a. Use a needle to shoot up drugs?(GRNDSTUP)	Π			
b. Reuse a needle that you had used before? (GRNDREUS)	_	☐ Yes ☐ Yes		
c. Reuse a needle without cleaning it with bleach or boiling water first?(GRNDNOCL)	_	☐ Yes		
d. Use a needle that you knew or suspected someone else had used before?(GRNDELSE)	_	☐ Yes		
e. Use someone else's rinse water, cooker, or cotton after they did? (GRNDH20)	_	☐ Yes		
f. Ever skip cleaning your needle with bleach or boiling water after you were done?(GRNDSKIP)	_	□ Yes		
g. Let someone else use a needle after you used it? (GRNDAFTR)		□ Yes		
h. Let someone else use the rinse water, cooker, or cotton after you did?(GRNDH20A)		☐ 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) 		(χ People)		
1. How many of these people were HIV negative or you did not know their HIV status?(GR90DPGH)		(xx People)		
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 <u>taken</u> 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)		

(xx Days)

2. On how many **days** did you take needles/works/rinse water or cotton from someone to use after them?(GR90DDTK)

The next questions are about having sex. When we refer to sex it includes vaginal, oral and anal sex we onto the other person's penis or vagina. Anal sex is when a man puts his penis into another person's an		one. (Vaginal sex is when a man puts his penis into a woman's vagina. Oral sex is when one person puts his or her mout utt.)
4. When was the last time, if ever, that you had any kind of vaginal, oral, or anal sex with another person? (GRLASTSX)		
5. During the past 12 months, did you	_	
a. Have sex while you were high on alcohol or on other drugs?(GRSEXHGH)	No	
b. Have sex with someone who was an injection drug user?(GRSEXINJ)	No	
c. Have sex involving anal intercourse (penis to butt)?(GRSEXANL)	☐ No	O Yes
d. Have sex against your will (you were forced or coerced)?(GRSEXAGS)	☐ No	o Yes
e. Trade sex to get drugs, gifts or money?(GRSEXTRD)	☐ No	o
f. Use drugs, gifts, or money to purchase or get sex?(GRSEXDRG)	☐ No	o
g. Have sex with someone who you thought was HIV negative or you did not know their HIV status? (GRSEXNEG)	□ No	yes Yes
h. Have two or more different sex partners (not necessarily at the same time)? (GRSEX2PP)	☐ No	o 🗆 Yes
i. Have sex with a male partner? (GRSEXMAL)	☐ No	yes Yes
j. Have sex with a female partner ?(GRSEXFEM)	☐ No	o 🗌 Yes
k. Have sex without using any any kind of condom to protect you and your partner from diseases or pregnancy?(GRSEXCND)	□ No	o Yes
I. Have a lot of pain during sex or after having had sex?(GRSEXPAN)	☐ No	o 🗆 Yes
m. Use alcohol or other drugs to make sex last longer or hurt less? (GRSEXLST)	☐ No	yes Yes
We want to ask you some questions about your sexual partners.		
6. During the past 90 days		
a. How many sexpartners 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? (GR9SX HG H)		(xxx Partners)
d. Have you had a partner that you consider a primary partner? (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)	□ No	o
1. Your primary partner's gender is: (GRPRIMGN)	☐ Male	ale Female

2. How long have the two of you been seeing each other?(GRRELTLT)	
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
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 an al sex with your primary partner, did you use a condom from start to finish? (GRPRIMCN)	(xxx)
7. How many times when you had an alor 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 prima. Did you have vaginal or anal sex with HIV positive partners?(<i>GRSEXHVP</i>)	
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)
	(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

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

House	nold Food Survey (HFS)
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
I. In the past four weeks, did you worry that you would not have enough food?(HFNFOOD) How often did this happen?(HFHOFTEN)	□ No □ Yes
2. In the past four weeks, were you not able to eat the kinds of foods you preferred because of a lack of resources? "Yes" means you were NOT able to eat. "No" means you were able to eat (HSPREFER) How often did this happen? (HSPRE OFT)	□ No □ Yes
In the past four weeks, did you have to eat a limited variety of foods due to a lack of resources? (HSVARIET) How often did this happen?(HSVAROFT)	□ No □ Yes
I. 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) How often did this happen? (HSNOTOFT)	□ No □ Yes
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) How often did this happen?(HSSMAOFT)	□ No □ Yes
6. In the past four weeks, did you have to eat fewer meals in a day because there was not enough	□ No □ Yes

food?(HSFFEWER)

How often did this happen?(HSFEWOFT)	
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) How often did this happen?(HSLACKOF)	□ No □ Yes
8. In the past four weeks, did you go to sleep at night hungry because there was not enough food?(HSNOTFOO) How often did this happen?(HSNIGOFT)	□ No □ Yes
9. In the past four weeks, did you go a whole day and night without eating anything because there was not enough food?(HFWHOLED) How often did this happen?(HFWHOOFT)	□ No □ Yes
Comments: (HFS COMM)	

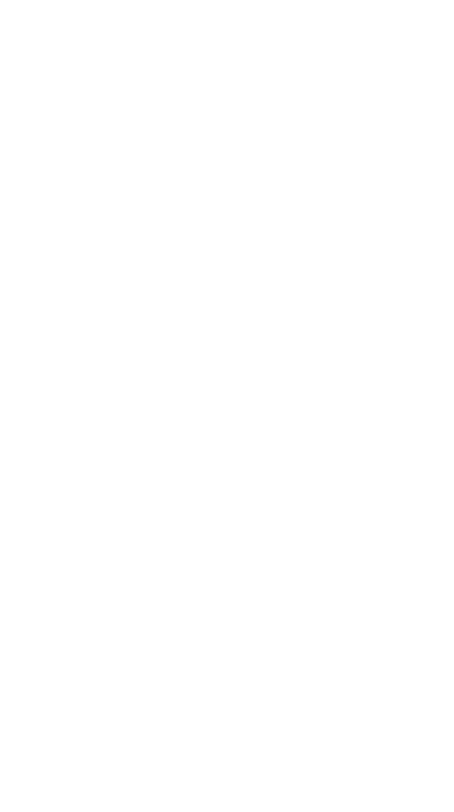
NIDA Clinical Trials Network

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

Modified	I Illegal Activities (MIA)
Segment (<i>PROTSEG</i>):	3 ,
/isit 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 in carcerated in the past 6 months? (MIIN6M DY)	(xxx)
The next several questions are about illegal activities.	
Illegal Activities	
1. Have you been intoxicated (high or drunk) from a loohol 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?(MIIA PAR)	□ 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?(MIIA FEN)	□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)? (MIGAMA 6M)		(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)? (MIBAE16M)		(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)?(MIBA EA6M)		(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 shop lifting/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? $(MIROBl6M)$		(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? (MIAAAB)	□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)
l	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)
l	b. How many times in the past 6 months have you been arrested for kidn apping /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)
ļ	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)
ļ	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)
ı	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)
ı	b. How many times in the past 6 months have you been arrested for vandalism/property damage/tagging?(MIVANA6M)	(xxx)
	Have you been involved in sex offenses (rape/aggravated assault/sex with a minor) since the last visit? (MIIA SEX)	□ No □ Yes
;	a. How many times in the past 6 months have you been involved in a sex offense (rape/aggravated assault/sexwith 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)
ı	b. How many times in the past 6 months have you been arrested for probation/parole violations? (MIPRBA6M)	(xxx)
	Have you been involved in other crimes not listed above since the last visit? If "Yes", specify in comments(MIIAOTH)	□ No □ Yes
;	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)		(m	nm/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 relation ship 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 relation ship 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? (MICONTRI)	□ No	Yes	Refuse to answer

Comments:(M IV CO MM)	

			Medica	l Mistr	ust (N	ИМТ)	
Medical Mistrust (MMT) Segment (PROTSEG): (isit Number (VISNO):							
Please tell me how much you agree	tements to you about health care and or <u>dis</u> agree with each statement on a rith a reference card that lists all 5 res	scale of 1 to 5 where	1 = strongly	disagree			care system.
Date of assessment: (MMTASMDT)					(mm/c	ld/yyyy) Click ho	ere for calenda
		Strongly Disagree	Disagree	Neither	Agree	Strongly Agree	
Doctors and health care workers hide information from patients who be		(MMHIDE)					
2. Doctors have the best interests o	f people of my ethnic group in mind.	(MMBEST)					
3. People of my ethnic group should and health care workers because it	(MMCONFI)						
4. People of my ethnic group should information from doctors and health	(MMSUSPI)						
5. People of my ethnic group cannot	. (MMTRUST)						
6. People of my ethnic group should	be suspicious of modern medicine.	(MMMEDIC)					
7. Doctors and health care workers ethnic group like "guinea pigs".	treat people of my	(MMGUINE)					
8. People of my ethnic group receive doctors and health care workers as		(MMSAME)					
9. Doctors and health care workers complaints of people of my ethnic gr		(MMCOMPL)					
10. People of my ethnic group are tr of other groups by doctors and heal		(MMTREAT)					
11. In most hospitals, people of differeceive the same kind of care.	(MMHOSP)						
	corty or unfairly by	(MMPERSO)					
12. I have personally been treated p doctors or health care workers beca		(2.130)					

HIV status?
 Gender?

(MMGENDE)

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

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

Comments: (MMTCOMM)

NIDA Clinical Trials Network

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

Readiness	for Substance Use Treatment (MTT)
Segment (PROTSEG): lisit Number (VISNO):	
Date of assessment (MTTASMDT)	(mm/dd/yyyy) Click here for calenda
The following questions ask about "substances". By "substance" we mean drugs or alcohol.	
Treatment could be your last chance to solve your substance use problems.(MTLASTC)	
f you enter treatment, you will stay for a while.(MTSTAY)	
Treatment could really help you.(MTCOULDH)	
You want to be in a treatment program.(MTWANTIN)	
Most counselors in substance use treatment programs are "squares" who don't understand substusers.(MTCOUNS)	tance
Substance use treatment programs have too many rules and regulations for me.(MTTOORUL)	

7. I don't think I could trust many of the people who work in the substance use treatment programs. (MTTRUST)	
8. It takes too much time and effort to get into a substance use treatment program. (MTTOOTIM)	
Comments: (MTTCOMM)	

	NIDA Clinical Trials Network	
	Missed Visit Form (MVF)	
Segment (PROTSEG): Visit Number (VISNO):		Web Version: 1.0; 3.01; 05-31-13
Reason for missed visit: (MVREASON)		
If "Other", specify: (MVOTHRSP)		

Additional Selection Options for MVF

Reason for missed visit:

14-Participant incarcerated

15-CTP dosed

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 participant initiated.

Date (mm/dd/yyyy)	Day (of Week)	Start Time (hh:mm)	End Time (hh:mm)	Length of Time (Minutes) (xxx)	Activity
(NIA CO 1DT)	(NIDAY01)	(NISTM01)	(NIETM 01)	(NILENG01)	(NIDES CO 1)
<u>Calendar</u>					
(NIA CO2DT)	(NIDAY02)	(NISTM02)	(NIETM 02)	(NILENG02)	(NIDES CO2)
<u>Calendar</u>					
(NIA CO3DT)	(NIDAY03)	(NISTM03)	(NIETM 03)	(NILENG03)	(NIDES CO3)
<u>Calendar</u>					
(NIA CO4DT)	(NIDAY04)	(NISTM04)	(NIETM 04)	(NILENG04)	(NIDESCO4)
Calendar					
(NIA C05DT)	(NIDAY05)	(NISTM05)	(NIETM 05)	(NILENG05)	(NIDES CO 5)
<u>Calendar</u>					
(NIA CO6DT)	(NIDAY06)	(NISTM06)	(NIETM 06)	(NILENG06)	(NIDESC06)
<u>Calendar</u>					
(NIA CO7DT)	(NIDAY07)	(NISTM07)	(NIETM 07)	(NILENG07)	(NIDES CO7)
<u>Calendar</u>					
(NIA CO8DT)	(NIDAY08)	(NISTM08)	(NIETM 08)	(NILENG08)	(NIDES CO8)
<u>Calendar</u>					
(NIA CO9DT)	(NIDAY09)	(NISTM09)	(NIETM 09)	(NILENG09)	(NIDESCO9)
<u>Calendar</u>					
(NIA C1 0DT)	(NIDAY10)	(NISTM10)	(NIETM 10)	(NILENG10)	(NIDESC10)

Calendar	 i .	
<u>Odioridai</u>		

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 (I	PDP)		Web	Version: 1.0; 1	1.00; 07-19-1
Segment (PROTSEG): Session Date (PCSESDT):					
Date of assessment (PDPASMDT) Patient navigator number: (PPPNNUM) Session length: (PPSESLEN) (mm/dd/ywy) Click here for calendar (xxx) minutes					
To what extent did the patient navigator:	Not at all	Som e w hat	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.	(РРМЕЕТ)				
Comments: (PDPCOMM)					

	NIDA Clinical Trials Network	
Debriefing	Substance Abuse Treatment Visit - Patient Navigator (PDS)	
Segment (PROTSEG): Session Date (PCSESDT):		Web Version: 1.0; 1.00; 07-19-12

Debriefing Substance Abuse Treatment Visit - Patient Navigator	(PDS)				
Segment (PROTSEG): Session Date (PCSESDT):			Web	Version: 1.0; 1	00; 07-19-
Date of assessment (PDSASMDT) Patient navigator number: (PSPNNUM) Session length: (PSSESLEN) (mm/dd/yyyy) Click here for calendar (xxx) minutes					
To what extent did the patient navigator:	Notatall	Somewhat	Mostly	Completely	Not rate of
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 C	linical Trial	s Network			
		Perceived H	ealth Stat	us SF-12 (PH	S)		W-1. V
egment <i>(PROTSEG):</i> isit Number <i>(VISNO)</i> :							Web Ve
Sk Humber (FISHO).							
Date of assessment: (PHSASMDT)				(mm/dd/yyyy) Click t	ne re for calendar		
RA Instruction: Provide participant with referen	ce cards for each questio	n that list all resp	oonse options	for his/her easy	reference.		
This survey asks for your views about your hea		oonse that best o	describes you	ır answer. This in	formation will he	lp keep track of how y	you feel and how
your usual activities. Thank you for completing	•	.,					
For each of the following questions, please ch	eck the box that best desc	ribes your answe	er.				
In general, would you say your health is: Excellent	Very good	Good		Fair		Poor	
EXCENEIII	very good	Good		raii		FOOI	
	_						
(PHHEALTH)							
	I		health now lin		ctivities? If so h		
	I		health now lin	nit you in these a	Yes,	ow much?	
	I		health now lin	nit you in these a		ow much?	
(PHHEALTH) The following questions are about activities yo	I		health now lin	nit you in these ac Yes, Iimited	Yes, limited	ow much? No, not limited	
The following questions are about activities yo a. Moderate activities, such as moving a table	ı might do during a typical	day. Does <u>your</u>		nit you in these ac Yes, Iimited	Yes, limited a little	ow much? No, not limited at all	
The following questions are about activities yo	ı might do during a typical	day. Does <u>your</u>		nit you in these ac Yes, Iimited a lot	Yes, limited a little	ow much? No, not limited at all	
The following questions are about activities you a. Moderate activities, such as moving a table b. Climbing several flights of stairs:	n might do during a typical	day. Does <u>your</u>	laying golf:	Yes, limited a lot (PHM ODACT)	Yes, limited a little	No, not limited at all	hysical health?
The following questions are about activities yo a. Moderate activities, such as moving a table	n might do during a typical	day. Does <u>your</u>	laying golf:	Yes, limited a lot (PHM ODACT)	Yes, limited a little	No, not limited at all	hysical health?
The following questions are about activities you a. Moderate activities, such as moving a table b. Climbing several flights of stairs:	e, pushing a vacuum clear	day. Does <u>your</u> er, bowling, or pl ollowing problem Most of	laying golf:	Yes, Ilimited a lot (PHMODACT) (PHSTAIRS) Tork or other regulation of the	Yes, limited a little	No, not limited at all	hysical health?
The following questions are about activities you a. Moderate activities, such as moving a table b. Climbing several flights of stairs:	e, pushing a vacuum clear	day. Does <u>your</u> er, bowling, or pl ollowing problem Most of	laying golf:	Yes, Ilimited a lot (PHMODACT) (PHSTAIRS) Tork or other regulation of the	Yes, limited a little	No, not limited at all	hysical health?
The following questions are about activities you a. Moderate activities, such as moving a table b. Climbing several flights of stairs: During the past 4 weeks, how much of the time	e, pushing a vacuum clear have you had any of the f All of the time	er, bowling, or pl ollowing problem Most of the time	aying golf:	Yes, limited a lot (PHM ODACT) (PHSTAIRS) OORK OF OTHER regulations of the time	Yes, limited a little	No, not limited at all	hysical health?
The following questions are about activities you a. Moderate activities, such as moving a table b. Climbing several flights of stairs: During the past 4 weeks, how much of the time a. Accomplished less than you would like:	n might do during a typical part of the time (PHPACCMP) tivities: (PHPKDWRK)	day. Does <u>your</u> er, bowling, or pl following problem Most of the time	aying golf:	Yes, limited a lot (PHM ODACT) (PHSTAIRS) TORK OF OTHER regul	Yes, limited a little	No, not limited at all	

				the	e time	the time	the time	of the	the tir
a. Accomplished	<u>less</u> than you w	ould like:	((PHEA CC	:MP) 🗆				
b. Did work or oth	neractivities <u>les</u>	s carefully than	usual:	(PHEWO	RK)				
During the past 4 w	eeks how murl	h did nain inter	fere with v	our nor	mal work (ii	ocludina both	work outside t	ne home an	d housework)?
Not at all	A little bit	Moderately	Quite		Extremely		Work outside t	ic nome an	a nousewonk).
(PHNRMWRK)									
				All of e time	Most	.	ne of A	ittle	None of
				- uiiie	the tin	ne the		the me	the time
a. Have you felt c	alm and peacef	ul?	(PHCALI		the tin		ti		the time
a. Have you felt c	•	ul?	(PHCALI	м) 🗆		Γ	ti	me	
	lot of energy?		•	м)			t	me	
b. Did you have a	lot of energy?	d depressed?	(PHENER	м)			t	me	

THANK YOU FOR COMPLETING THESE QUESTIONS!

(PHSOCIAL)

NIDA Clinical Trials Network	

Preparing for Initial Substance Abuse Treatment Visit - Patient Navigat	Web Version: 1.0; 1.00; 07-19-1				
Segment (PROTSEG): Session Date (PCSESDT):			web	reision. 1.0, 1	.00, 07-19-12
Date of assessment: (PNAASMDT) Patient navigator number: (PAPNNUM) Session length: (PASESLEN) (mm/dd/yyyy) Click here for calendar (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								
NIDA CIIIICAI IIIAIS NELWOIK								
Preparing to Meet Care Provider - Patient Navigator (PN	C)							
	-,		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 rate d			
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.).								
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 instruction and conduct screens; provide appropriate verbal support on screen results and any other accomplishments (paperwork, labs, medication pick up, etc.).	ons (PCMEET)							
Comments: (PNCCOMM)								

NIDA Clinical Trials Network					
Final Patient Navigator Meeting - Patient Navigator (PNF) Segment (PROTSEG): Session Date (PCSESDT):			Web \	/ersion: 1.0; 1.	.00; 07-19-12
Date of assessment: (PNFASMDT) 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.	(PFEXPL OR)				
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) Patient navigator number: (PIPNNUM)	(mm/dd/yyyy) Click here for calendar
Session length: (PISESLEN)	(xxx) minutes

To what extent did the patient navigator:	Not at all	Somewhat	Mostly	Completely	Not rated
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.	(РІМОТІV)				
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.	(РІОРТІМ) 🗆				
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/add ress 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;	(PIMEET)				

Comme nts: (PNICO MM)	

	(5)10)					
Patient Navigator Satisfaction	on (PNS)			Web	Versio	n: 1.0 ; 1.00; 02-15-
ment (PROTSEG): Number (VISNO):						
Please answer the following questions about your time working with your patient navigator.						
Pate of assessment: (PNSASMDT) (mm/dd/y	yyy) Click here for ca	<u>endar</u>				
	Strongly Disagree	Disagree	Slightly Disagree	Slightly Agree	Agree	Strongly Agree
I feel my patient navigator understood me.	(PNUNDERS)					
2. I believe my patient na vigator cared about me.	(PNCARED)					
3. I think I had a good relationship with my patient na vigator.	(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)					
s there anything else you would like to say about your patient navigator?(PNANYTHI)		1				

Comments:(PNSCOMM)	

NIDA Clinical Trials Network					
Unscripted Patient Navigator/Participant Visit - Patient Navigator	(PNU)				
Segment (PROTSEG): Session Date (PCSESDT):			Web V	ersion: 1.0; 1	.00; 07-19-1
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 rate d
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.					
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:	(PUMEET)				

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.).

Comments: (PNUCOMM)

			NID	A Clin	ical	rials Network	
	F	Physi	cian	Patie	ent	elationship (PPR)	
egment (<i>PROTSEG</i>): sit Number (<i>VISNO</i>):							Web Version: 1.0; 2.01; 10-
Date of assessment:(PPRASMDT)						(mm/dd/yyyy) Click here for calendar	
The following questions ask about the healthcare provider (doctor/r RA Instruction: Provide participant with a reference card that lists a		-				care of your HIV.	
Does the participant have a healthcare provider (doctor/nurse practiakes care of their HIV?(PPHIVDR)	itioner/physician's as	sistant)	who		No	Yes	
Overall communication Please rate the health care provider who takes care of your HI How is the health care provider who takes care of your HIV at:		llowing	things	5.			
	Excellent	Very	Good	l 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)						
	(PPFACTS) (PPTELL)						
4. Telling you what to do if certain problems or symptoms occur?	, ,			+			
 3. Giving you facts about the benefits and risks of treatment? 4. Telling you what to do if certain problems or symptoms occur? 5. Demonstrating caring, compassion, and understanding? 6. Understanding your health worries and concerns? 	(PPTELL)						
 4. Telling you what to do if certain problems or symptoms occur? 5. Demonstrating caring, compassion, and understanding? 6. Understanding your health worries and concerns? 	(PPTELL) [
4. Telling you what to do if certain problems or symptoms occur? 5. Demonstrating caring, compassion, and understanding? 6. Understanding your health worries and concerns? HIV - specific information	(PPTELL) (PPDEM ON) (PPUNDER) (PPUNDER)						
4. Telling you what to do if certain problems or symptoms occur? 5. Demonstrating caring, compassion, and understanding? 6. Understanding your health worries and concerns? HIV - specific information	(PPTELL) (PPDEMON) (PPUNDER)	v				юг	
4. Telling you what to do if certain problems or symptoms occur? 5. Demonstrating caring, compassion, and understanding? 6. Understanding your health worries and concerns? HIV - specific information low is the health care provider who takes care of your HIV at:	(PPTELL) (PPDEM ON) (PPUNDER) (PPUNDER)	V	ery G			oor	
4. Telling you what to do if certain problems or symptoms occur? 5. Demonstrating caring, compassion, and understanding? 6. Understanding your health worries and concerns? HIV - specific information low is the health care provider who takes care of your HIV at: 7. Talking with you about your sex life?	(PPTELL) (PPDEM ON) (PPUNDER) Excellent (PPSEX)	V	ery Good	Good			
4. Telling you what to do if certain problems or symptoms occur?5. Demonstrating caring, compassion, and understanding?	(PPTELL) (PPDEM ON) (PPUNDER) Excellent (PPSEX)	V	ery cood	Good I			

	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 medicine	es?	(PPARI	PRBM) [
13. Helping you solve problems you have taking your antiretroviral medicine	solv) [
Participatory decision-making RA Instruction: Provide participant with reference cards for subsequent items	c (as those item	s are re	ed to the p	articin	ant) tha	t list a	ll rosr	onse or	otions fo	or his/har ag	vy reference
AA IISTIUCIOII. FTOVIDE PAITICIPAIT WITH TELETETICE CAIDS TOT SUBSEQUENT TEHTS		ery		T	netime	1	Ť	Never]	ıı IIIS/IIEI Eds	sy rererence.
		ften					,				
14. How often does the health care provider who takes care of your HIV infeask you to take some of the responsibility for your treatment?	ection (PPRSF	PTRT)									
	Definite yes	ely	Probably yes	Unc	ertain	Proba	•	Definit not	- 1		
15. If there was a choice between treatments, would the health care provide who takes care of your HIV infection ask you to help make the decision?	er (PPHELPDI	E) 🗆									
		ery fte n	Often	Some	etimes	Rare	ely N	Never			
16. How often does the health care provider who takes care of your HIV infemake an effort to give you some control over treatment decisions?	ection (PPTRE	EAT)		[
How often does the health care provider who takes care of your HIV inf	fection do the	followin	a thinas:								
ton energe date the median edge provides who takes date of your first inte	All of the time		Most of	Some		A little		None of			
17. Offer choices in your medical care?	(PPOFFER)										
18. Discuss the pros and cons of each choice with you?	(PPPROCON	ı) 🗆									
19. Get you to state which choice or option you would prefer?	(PPSTATE)										
$20. \ \ {\rm Take\ your\ preferences\ in\ to\ account\ when\ making\ treatment\ decisions?}$	(PPPREFER,) 🗆									
Overall satisfaction with health care provider How would you rate the health care provider who takes care of your HI	V infection in	each of	the follow	ving:							
			Excellent	t	Very g	joo d	Good	d Fair	Poor		
21. Personal manner - courtesy, respect, sensitivity, friendliness:		(PP	PERSON)								
22. Communication skills - listening carefully, answering questions, giving d	le ar e xplan atio r	ns: (PF	СОММИ)								
23. Technical skills - thoroughness, carefulness, competence:		(PI	PTECHN)								
24. Your health care provider's overall care:		(PF	OVERAL)								
Willingness to recommend											
					Definit will n		- 1	robably will not	1	1	Definitely will
25. Do you plan to continue to see the health care provider who takes care $\frac{1}{2}$	of your HIV infe	ection in	the future?	(PF	PCTNSE	EE) [
26. Do you plan to recommend the health care provider who takes care of y	our HIV infectio	n to oth	ers?	(PP	RECOM	им) [

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 L	₋og (PVL)	Web Version: 1.0; 3.04; 10-04-1
Date of Violation (PVDATE): Protocol Violation Number (PVSEQNUM):			web version: 1.0; 3.04; 10-04-1
To be filled in by person(s) reporting this protocol violation:			
1. Violation type:(PVTYPE49)			
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)	
Comments: (PVL COMM)	

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:

01 Z-Other (specify)

02-INCLUSION / EXCLUSION CRITERIA

03-CONCOMITANT MEDICATION/ THERAPY

Z04-LABORATORY ASSESSMENT/PROCEDURES

04 A-Required testing not obtained

04B-Testing completed outside window

04 C-Testing not completed as per protocol

04 D-Un authorized test/procedure obtained

04Z-Other (specify)

Z05-OTHER PROCEDURES / ASSESSMENTS

05 A-Protocol required procedures not obtained

05 B-Procedures / assessments not completed as per protocol

05 C-Procedures / assessmentsobtained outside the visit timeframe

05 Z-Other (specify)

Z07-RANDOMIZATION PROCEDURES

07 A-Randomization procedures not followed (e.g. outside window, out of sequence, etc.)

07 B-Ineligible participatn randomized

07 E-Incorrect treatment assignment

07 Z-Other (specify)

Z09-BEHAVIORAL INTERVENTION

09 A-Intervention not provided per protocol schedule or visit window timeframe

09B-Incorrect intervention assignment

09 Z-Other (specify)

Z10-VISIT SCHEDULE / INTERVAL

10 A-Visit conducted outside of window

10 Z-Other (specify)

Z99-OTHER SIGNIFICANT VIOLATIONS

99 A-Destroying study materials proior to authorization from Lead Node and other appropriate parties

99 B-Participating site starting the study prior to obtaining appropriate IRB(s) and/or CTM approvals

99 C-Using advertising materials or brochures without prior IRB approval

99 Z-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)
- 2. What section of the protocol does this event refer to?(PVSECTN)
- 3. Does this event require retraining? (PVTRAIN)
- 4. Does the protocol need to be modified based on this event? (PVPRTMOD)
- 5. Does the consent need to be modified based on this event? (PVCNTMOD)
- 6. Is the review of this event complete?(PVREVCMP)

If "No", what additional information is requested? (P VADTINF)

Assessed by:(PVREVBY)

Comments: (PVCOMM)

☐ Major ☐ Minor	
□ No □ Yes	

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

N	IDA Clinical Trials Network	
SUI	O - Cost Information (SCI)	
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 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 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 v Cost Information for Residential Substance Use Treatment Visit #1 Fill Out only for Most Recent Residential Substance Use Treatment Visit #1 Fill Out only for Most Recent Outpatient Substance Use Treatment Visit #1 Fill Out only for Most Recent Outpatient Substance Use Treatment Visit #1	e HIV related fill out for most recent visit.	sit (for whatever reason).
1. How long did this session (visit to facility) take? Be sure to include any time you were waiting to be a. Waiting time:(SCWAITHR)	seen, the time it took to get to and from the session and (xx) Hour(s) (SCWAITMN)	the time for the session itself? (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)		
If "Other", specify: (SCTRNTSP)		
3. Did you get home the same way?(SCTRNSSM) If "No", how did you get back home?(SCTRNSHM)	□ No □ Yes	
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 ways)? (SCMILE) 5. If you "Drove yourself" or were "driven by a friend", did you have to pay for parking? (SCPARK) If "Yes", what was the amount? (SCPARKCS)	e both (xxx) No Yes (xxx.xx)	
6. Did you have to arrange child care to go to this session (visit to facility)?(SCCHILD)	□ No □ Yes	

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

If "Yes", what child care arrangements did you make?(SCCHLDTP)	
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) If "Yes", what was the total value of your vouchers/reimbursements? (SCVCHRVL)	No Yes (xxx.xx)
B. Did you take time off from work to attend this session (visit to facility)?(SCWORK) a. If "Yes", how much time did you take off from paid work to attend this session (visit to facility)? (SCWRKHR) b. If "Yes", will you lose pay because of this?(SCWRKPAY) 9. Did you take time off from unpaid child care or other household duties to attend this session (visit to facility)?(SEUNPD) How much time did you take off from unpaid child care or other household duities to attend this session (visit to facility)?(SCUNPDHR)	No Yes (xx) Hour(s) (SCWRKMN) (xx) Minute(s) No Yes (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

-08-14

Si	JD - Module B. Inpatient Hospital (SDB)
Segment (PROTSEG): Report Type (REPORT): Hospital Visit Date (SDBIH):	Web Version: 1.0; 3.03; 09-
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 mention Secure an appropriate medical release to facilitate medical record abstraction.	ned having over the past 6 months.
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 a .Intensive care unit (ICU/Coronary care unit (CCU): (SBSPCICU) b. Psychiatric unit:(SBSPCPSY)	Nights: (SBNGTICU, (xxx)
c. Drug/alcohol unit:(SBSPCDRG)	Nights: (SBNG TPSY) (xxx)
	Nights: (SBNG TDRG) (xxx)
5. What were the first three discharge diagnoses for this hospitalization?	
a. (SBDISDX)	
b. (SBDISDX2)	

Comme nts: (SDBCOMM)	

Additional Selection Options for SDB

- 2-Ab stracted medical record only
 3-Combined self-report/ab stracted medical record

NIDA Clinical Trials Network
CUD. Madula D. Davilla anital/Davial Hagnitalization December (CDD)

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

	. Бау позрітант	artiai	Hospitaliz	ation Program (SDD)
Segment (PROTSEG): Visit Number (VISNO): cility Name (PROGRMNM): Report Type (REPORT):				
Now I'm going to ask you to tell me about each of the Day Hospital/Partial Hospitalizat Secure an appropriate medical record release to facilitate medical record abstraction.	tion Programs that you m	entioned v	isiting in each h	ospital/program over the past 6 mont
How many days did you attend this program during the past 6 months?(SDDAYS)		(xxx)		
How many days did the participant attend this program during the past 6 months?(SDD)	AYS)	(xxx)		
What type of services did you get in this program? 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)			
Did the the participant sign an appropriate release form to collect medical records?(SDF	PTSIGN)	☐ Yes	S	
Comments:(SDDCOMM)				

Additional Selection Options for SDD

- 2-Ab stracted medical record only
 3-Combined self-report/ab stracted medical record

	NIDA Clinical Trials Network					
	S	SUD - Module E.	Hospital Clinic	:/Outpatier	nt Department & Doctor's Office (SDI	Web Version: 1.0; 5.01; 06-24-
Segment (PROTSEG Visit Number (VISNO Facility Name (PROGRMNM Report Type (REPORT)): (1):					
Now I'm going to ask you to Secure an appropriate med			t Departments that you	mentioned visitii	ing over the past 6 months.	
Date of assessment: (SDEA	ASMDT)				(mm/dd/yyyy) Click here for calendar	
1. Was the visit to a "clinic/out	•	,		Clinical/ou	utpatient department Doctor's office	
How many times did you vis (SEVISIT)	sit this hospital clinic or out	tpatient department during	the past 6 months?	(xx)	x)	
3. How many times did you vis						
Month (mmm)	Year (yyyy)	Number of Visits (xx)				
(SEM OV1)	(SEYRV1)	(SENUMV1)				
(SEM OV2)	(SEYRV2)	(SENUMV2)				
(SEM OV3)	(SEYRV3)	(SENUMV3)				
(SEM OV4)	(SEYRV4)	(SENUMV4)				
(SEM OV5)	(SEYRV5)	(SENUMV5)				
(SEM OV6)	(SEYRV6)	(SENUMV6)				
(SEM OV7)	(SEYRV7)	(SENUMV7)				
4. Date of first visit:(SEPRGD	T)				(mm/dd/yyyy) Click here for calendar	
5. Date of last (most recent) vi	isit:(SELASTDT)				(mm/dd/yyyy) Click here for calendar	
6. If the facility is a hospital, who (SEDEPT)	hat is the name of the clini	ic or outpatient departmen t	within the hospital?	(SEDEPUNK)	g) □ Unknown	- OR
7. If the facility is a "Doctor's of	office", what is the name of	your doctor?(SEDRNAME	. (, , , , , , ,	,	- OR - (SEDRUNK) Unknown

□ No □ Yes

8. Did the participant sign an appropriate release form to collect medical records?(SEPTSIGN)

Comments:(SDECOMM)	

Additional Selection Options for SDE

- 2-Ab stracted medical record only
 3-Combined self-report/ab stracted medical record

NIDA Clinical Trials Network		
SUD Medule I Pecidential Treatment for Substance Abuse (SDI)		

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/detoxhospital for this stay?(SINIGHTS) (xxx) 3. During this stay, what did you receive treatment for? (SIRCVTRT) If treated for "Drug abuse", did you receive methadone or Buprenorphine maintenance? (SIMTHBUP) Comments:(SDICOMM)

Additional Selection Options for SDI

- 2-Ab stracted medical record only
 3-Combined self-report/ab stracted medical record

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1			SUD - Module	e A. Emer	gency Room (SMA)	Web Verries 4 0 0 04 00 40 40
Segment (PROTSEG Visit Number (VISNO Hospital Name (SDHSPNM Report Type (REPORT):):):					Web Version: 1.0; 2.01; 06-10-13
Now I'm going to ask you t Secure an appropriate me		its that you mentioned havir nedical record abstraction.	ng in each hospital ove	rthe past 6 mor	nths.	
Date of assessment: (SMA 1. How many ER visits did yo		ne past 6 months?			(mm/dd/yyyy) Click here for calendar	
Month (mmm)	Year (yyyy)	Number of Visits (xx)				
(SAMO V1)	(SAYRV1)	(SANUMV1)				
(SAMO V2)	(SAYRV2)	(SANUMV2)				
(SAMO V3)	(SAYRV3)	(SANUMV3)				
(SAMO V4)	(SAYRV4)	(SANUMV4)				
(SAMO V5)	(SAYRV5)	(SANUMV5)				
(SAMO V6)	(SAYRV6)	(SANUMV6)				
(SAMO V7)	(SAYRV7)	(SANUMV7)				
2. Did the participant sign an	appropriate release form to	o collect medical records?(S	SAPTSIGN)	□ No □	Yes	
Comments: (SMA COMM)						

Additional Selection Options for SMA

- 2-Ab stracted medical record only
 3-Combined self-report/ab stracted medical record

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Segment (PROTSEG Visit Number (VISNO Facility name (SDCNAME):):	. Nursing Home, F	espite Card	e, Personal	Care Hom	ne rehabilita	ition And Ho	spice Facili	ty (SMC) Web Version: 1.0; 1.02; 07-01-1
Report Type (REPORT)):								
Now I'm going to ask you	to tell me about the nursing	g home, respite care, persona	care home rehab	ilitation and hospi	ice visits that yo	u mentioned havin	g in each facility ove	r the past 6 months	3.
Date of assessment: (SM)	CASMDT)				(mm/dd/yyyy	y) Click here for cal	<u>endar</u>		
1. What type of facility was t	his:(SCFACTYP)								
2. How many nights were yo	ou in the facility for each mo	nth in the past 6 months?							
Month (mmm):	Year <i>(уууу)</i> :	Number of Nights (xx):							
(SCMOV1)	(SCYRV1)	(SCNUM V1)							
(SCMOV2)	(SCYRV2)	(SCNUM V2)							
(SCMOV3)	(SCYRV3)	(SCNUM V3)							
(SCMOV4)	(SCYRV4)	(SCNUM V4)							
(SCMOV5)	(SCYRV5)	(SCNUM V5)							
(SCMOV6)	(SCYRV6)	(SCNUM V6)							
(SCMOV7)	(SCYRV7)	(SCNUM V7)							
2 Did the nerticipant sign of	annonriata ralagga form to a	alle at modical records 2/9007	IC A II						
3. Did the participant sign ap	opropriate release form to co	ollect medical records?(SCP7	GN)	No 🗆	Yes				
Comments: (SMCCOMM)									

Additional Selection Options for SMC

- 2-Ab stracted medical record only
 3-Combined self-report/ab stracted medical record

	NIDA Clinic	al Trials	Network	(
Confli	ctual Social	Interac	tion Sca	ale (ST	S)	
egment (<i>PROTSEG</i>): sit Number (<i>VISNO</i>):						Web Version: 1.0; 1.00; 07
Date of assessment (STSASMDT)		(n	nm/dd/yyyy)	Click here	for calenda	
RA Instruction: Provide participant with a reference card that lists all response options for h. The next questions are about your interactions with others. During the past four weeks, how the time?			ert question,). Would yo	u say none	of the time, a little of the time, some of the time, most of the time, or a
	None of the time	A little of the time	Some of the time	Most of the time	All of the time	
Had serious disagreements with your <u>family</u> about things that were important to you?	(STDISFAM)					
2. Had serious disagreements with your <u>friends</u> 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 do you have:	How often was <u>each</u>	of the follow		1	1	ou (during the past 4 weeks) if you needed it?
*	the time	the tim				_
Someone to love and make you feel wanted?	(STWANTED)					_
2. So meone to help with daily chores (child care, buying food, preparing meals) if you were sick?	(STCHORES)					
3. So meone 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)						

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	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)				
If "Participant terminated for other reason", provide other reason:(TRTRM OSP)				
Comments:(STTCOMM)				
Investigator's Signature				
I have reviewed all the data recorded on all CRF pages and certify that they are accurate and c	omplete 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

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

Service U	tilization Detail (SUD)
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 re Date of assessment:(SUDASMDT)	eference. (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)	
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
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.(SUO VHS)	
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)	
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. (SUDA YH)	
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)	
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) b. If "Yes," were any of these HIV primary care visits?(SUPRMCRE)	(xx) clinics, departments, and/or centers
1. What was the date of the <u>first</u> HIV primary care visit to one of these clinics in the last 6 months? (SUOUT1DT) 2. What was the date of the <u>last</u> HIV primary care visit to one of these clinics in the last 6 months? (SUOUT2DT)	(mm/dd/yyyy) Click here for calendar (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)	
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
What was the date of the <u>first</u> 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 <u>last HIV-related visit to one of these doctor's offices in the last 6 months?</u> (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) 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) 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 (xxx) times
8. During the past 6 months, did you see any professional for the primary purpose of getting a loohol or drug treatment, including methadone maintenance, or getting help for an alcohol or drug problem? 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)	No Yes
a. If "Yes," were you in a residential drug or a loohol treatment facility or detox hospital in which you stayed overnight during the past 6 months? (SUDRUGOV)	
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
 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 provide	ers that you met with.
c. How many times did you meet <u>one-on-one</u> 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 <u>group sessions</u> 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 <u>past 6 months</u> for <u>all substance abuse providers</u> or medical prov	iders.
e. Are you taking any of the following medications for opioid treatments?	
1. Methadone: (SUOUTMET)	□ No □ Yes Methadone treatment center:(SUMETHTX)
2. B upren orphin e (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)	
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 be st 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," spe cify (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)	

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)	
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 of 1. Visiting nurse: (SUNURSE)	nly if respondent cannot answer question. 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: (SUSO CIAL)	□ No □ Yes
6. Babysitter: (SUBABYST)	□ No □ Yes
7. Meals on wheels worker:(SUMEALS)	□ No □ Yes
8. Other:(SUHOMEOT)	□ No □ Yes
If "Other," spe cify:(SUHOMESP)	103
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)	
13. During the past 6 months, did you spend one or more nights in a homeless or emergency shelter? (SUSHTR)	
 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)	
a. How many different people have been your case manager, or caseworker in the last 6 months? (SUCA SENM)	(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

(SUCASEPH)		
15. During the past 6 months, did you receive any health care from providers or social service agencies whave not yet discussed? (SUCAREOT)		
a. If "Yes," specify each additional provider and/or social service agencies from which you have rec	eived health care:	
1. (SUCAREO1)		
2. (SUCAREO2)		
3. (SUCAREO3)		
4. (SUCAREO4)		
5. (SUCAREO5)		
Save this form. Perform assessments on all required modules before complete.	eting the remainder of this form.	
Interview Confidence Rating		
Interview Confidence Rating 1. Confidence in assessment: (SUCONFID)		
Confidence in assessment: (SUCONFID) 2. Explain here if validity of assessment is questionable.		
1. Confidence in assessment: (SUCONFID)	No Yes No Yes	
Confidence in assessment: (SUCONFID) 2. Explain here if validity of assessment is questionable. a. Participant appeared under the influence: (SUINFLUN)	No Yes No Yes No Yes No Yes	
1. Confidence in assessment: (SUCONFID) 2. Explain here if validity of assessment is questionable. a. Participant appeared under the influence: (SUINFLUN) b. Participant was uncooperative: (SUCOOPER)	□ No □ Yes	
1. Confidence in assessment: (SUCONFID) 2. Explain here if validity of assessment is questionable. a. Participant appeared under the influence: (SUINFLUN) b. Participant was uncooperative: (SUCOOPER) c. Participant appeared to be lying: (SULYING)	□ No □ Yes □ Yes	
1. Confidence in assessment: (SUCONFID) 2. Explain here if validity of assessment is questionable. a. Participant appeared under the influence: (SUINFLUN) b. Participant was uncooperative: (SUCOOPER) c. Participant appeared to be lying: (SULYING) d. Participant had poor mental recall: (SUMENTAL)	□ No □ Yes □ No □ Yes □ No □ Yes	
1. Confidence in assessment: (SUCONFID) 2. Explain here if validity of assessment is questionable. a. Participant appeared under the influence: (SUINFLUN) b. Participant was uncooperative: (SUCOOPER) c. Participant appeared to be lying: (SULYING) d. Participant had poor mental recall: (SUMENTAL) e. Participant had difficulty understanding questions (other than language barriers): (SUUNDER)	□ No □ Yes □ No □ Yes □ No □ Yes □ 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) Segment (PROTSEG): Visit Number (VISNO): 1. Was a urine drug screen performed? (UDTSTPRF) a. If "No", provide reason: (UD1 NCLRS) b. If "Other", specify: (UD1NOCSP)

□ No □ Yes

1st Urine Drug Screen

- 2. Date 1st urine specimen collected:(UDCOLDT)
- 3. Time 1st urine specimen collected (24 hour format): (UD1 COLTM)
- 4. Was the 1st urine temperature within range? (90 100 °F)(UD1TMP)
- 5. Was the 1st urine specimen determined to be adulterated? (UD1ADULT)

1st Urine Drug Screen Results

6.	Drug Name (Abbreviation)	Ne gative	Positive	Invalid
	Benzodiazepines (BZO):	(UD1BZO)		
	Amphetamine (AMP):	(UD1AMP)		
	Marijuana (THC):	(UD1THC)		
	Methamphetamine (MET):	(UD1MET)		
	Opiates (2000 ng) (OPI):	(UD10PI)		
	Cocaine (COC):	(UD1COC)		
	Ecstasy (MDMA):	(UD1MDMA)		
	Oxycodone (OXY):	(UD10XY)		
	Methadone (MTD):	(UD1MTD)		
	Barbiturate (BAR):	(UD1BAR)		

(mm/dd/yyyy) Click here for calendar

2nd Urine Drug Screen

. If the 1st urine specimen was d (UD2COLNY)	letermined to be adu	Iterated, wa	as a seco
a. If "No", provide reason: (UD2	NCLRS)		
b. If "Other", specify:(UD2NC	OCSP)		
Time and uring an asimon calle	ata d / 24 haur farmat)./UD2.CO.I	TAA)
. Time 2nd urine specimen collec	cted (24 nour format).(UD2 CUL	_
. Was the 2nd urine temperature	within range? (90 -	100 °F) <i>(UL</i>	02 TM P)
. Was the 2nd urine specimen do	etermined to be adul	tera te d?(U	D2ADUL:
On Ittida - Barra O Branch	.lu -		
2nd Urine Drug Screen Resu	IITS		
Drug Name (Abbreviation)	Ne gative	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)		
Oversedens (OVV):	(UD2OXY)		
Oxycodone (OXY):	(OBEOXI)		
Methadone (MTD):	(UD2MTD)		