

NIDA Clinical Trials Network

Adverse Event (AD1)

Web Version: 1.0; 4.00; 09-26-17

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

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

1. Adverse event name:(A1DESCPT)
2. Date site became aware of the event:(A1AWARDT)
3. Severity of event:(A1SEVRTY)
4. Is there a reasonable possibility that the intervention caused the event?(A1RINTVN)
If "Unrelated" to study intervention, alternative etiology:(A1AINTVN)

If "Other", specify:(A1AEBSP)

If "Related", action taken with study intervention:(A1ACTBI)

5. Outcome of event:(A1OUTCM)

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

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

7. Was this event associated with:(A1ASSOC)

- a. If "Death", date of death:(A1DTHDT)
- b. If "Inpatient admission to hospital or prolongation of hospitalization":
Date of hospital admission:(A1HOSPAD)
Date of hospital discharge:(A1HOSPCD)

Comments:(AD1COMM)

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

☐ No ☐ Yes

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

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

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

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

Additional Selection Options for AD1

Event number (AESEQNO) (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

If "Related", action taken with study intervention:
5-Participant terminated from study

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

Serious Adverse Event Summary (AD2)

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

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

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

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

2. Relevant past medical history:(A2SAEMHX)

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

☐ No ☐ Yes ☐ Unknown

3. Medications at the time of the event:(A2SAEMED)

☐ No ☐ Yes ☐ Unknown

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

4. Treatments for the event:(A2SAETRT)

☐ No ☐ Yes ☐ Unknown

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

5. Labs/tests performed in conjunction with this event:(A2SAELAB)

☐ No ☐ Yes ☐ Unknown

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

6. Follow-up:(A2FOLLUP)

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

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

Have all Medical Monitor requests been addressed?(A2RQADDR)

☐ Yes

Additional Selection Options for AD2

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

NIDA Clinical Trials Network

Serious Adverse Event Medical Reviewer (AD3)

Web Version: 1.0; 3.00; 03-09-18

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

- 1. Was this determined to be a serious adverse event?(A3SAE)
- 2. Was this event considered associated with the study's behavioral intervention?(A3RINTVN)
- 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)
If "No", is this an expedited/reportable event for other reasons?(A3EXPOTH)
- 5. Does the protocol need to be modified based on this event?(A3MPROT)
- 6. Does the consent form need to be modified based on this event?(A3MCNST)
- 7. Is the review complete?(A3REVDNE)
If "No", what additional information is required:(A3ADDINF)

- ☐ No ☐ Yes
- ☐ No ☐ Yes
- ☐ No ☐ Yes
- ☐ No ☐ Yes
- ☐ No ☐ Yes
- ☐ No ☐ Yes
- ☐ No ☐ Yes

Assessed by:(A3ASRID)
Reviewed by:(A3REVID)

Comments:(A3COMM)

(initials)

(initials)

Additional Selection Options for AD3

Event number (AESEQNO) (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

HIV Adherence Measures (ADH)

Web Version: 1.0; 1.00; 11-15-16

Segment (PROTSEG): A

Visit number (VISNO):

Date of assessment (ADHASMDT)

 (mm/dd/yyyy)

The next questions ask about your HIV medications. HIV medications are sometimes referred to as antiviral medications, antiretroviral medications, ART, or a "drug cocktail". These medications are taken to increase or maintain your T-cells and to reduce your viral load. HIV medications treat HIV specifically; they do not include other medications, even those for opportunistic infection (OI) prevention.

1. Have you taken prescribed medications specifically to treat HIV since your last CTN-0049 study visit? ☐ No ☐ Yes
(ADHIVRXH)

2. Do you have an active prescription for HIV medications? (ADHIVRXA) ☐ No ☐ Yes

By "active" prescription we mean any prescription you can currently fill or any medication you currently have in your possession.

If "Yes", have you taken HIV medications in the past 4 weeks? (ADHIVRXW) ☐ No ☐ Yes

If "Yes", are you currently taking HIV medications? (ADHIVRXC) ☐ No ☐ Yes

By "currently taking" we mean taking HIV medications on 2 or more days in the past 7 days.

The next questions ask about HIV medications you are currently taking. Many patients find it difficult to take all of their HIV medications exactly as prescribed.

3. How many doses of your HIV medications did you miss in the past 7 days? (ADDOSMS) (xx) doses

4. Provide your best guess about what percentage of your prescribed HIV medications you have taken in the past 4 weeks: %

It would be surprising if this was 100% for most people.

Examples: 0% means you have taken none of your medications in the past 4 weeks, 50% means you have taken half of your medications in the past 4 weeks, and 100% means you have taken every single dose of your medications in the past 4 weeks. (ADDOSTKP)

5. If you feel worse, do you sometimes stop taking your HIV medications? (ADWORSE) ☐ No ☐ Yes

6. Did you miss any of your HIV medications over the past weekend? (ADWKND) ☐ No ☐ Yes

"Yes" means you missed medications. "No" means you did NOT miss medications.

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

The following questions ask about symptoms you might have had during the past 4 weeks. Choose the response/answer that describes how much you have been bothered by each symptom.

In the past 4 weeks, have you been bothered by:	No	Yes	If "Yes", how much have you been bothered by the symptom?			
			Doesn't Bother Me	Bothers Me a Little	Bothers Me a Lot	Bothers Me Terribly

7. Fatigue or loss of energy?	(ADENERGY) <input type="checkbox"/>	<input type="checkbox"/>	(ADENBTHR) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Fevers, chills, or sweats?	(ADFEVER) <input type="checkbox"/>	<input type="checkbox"/>	(ADFBTHR) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Feeling dizzy or lightheaded?	(ADDIZZY) <input type="checkbox"/>	<input type="checkbox"/>	(ADDZBTHR) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Pain, numbness, or tingling in the hands or feet?	(ADNUMB) <input type="checkbox"/>	<input type="checkbox"/>	(ADNBTHR) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Trouble remembering?	(ADREMBER) <input type="checkbox"/>	<input type="checkbox"/>	(ADRBTHR) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Nausea or vomiting?	(ADVOMIT) <input type="checkbox"/>	<input type="checkbox"/>	(ADVBTHR) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Diarrhea or loose bowel movements?	(ADBOWEL) <input type="checkbox"/>	<input type="checkbox"/>	(ADWBTHR) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. Felt sad, down, or depressed?	(ADSAD) <input type="checkbox"/>	<input type="checkbox"/>	(ADSBTHR) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. Felt nervous or anxious?	(ADNERVES) <input type="checkbox"/>	<input type="checkbox"/>	(ADNVBTHR) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. Difficulty falling or staying asleep?	(ADSLEEP) <input type="checkbox"/>	<input type="checkbox"/>	(ADSPBTHR) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
In the past 4 weeks, have you been bothered by:	No	Yes	If "Yes", how much have you been bothered by the symptom?			
			Doesn't Bother Me	Bothers Me a Little	Bothers Me a Lot	Bothers Me Terribly
17. Skin problems, such as rash, dryness, or itching?	(ADSKNPRB) <input type="checkbox"/>	<input type="checkbox"/>	(ADSKBTHR) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. Cough or trouble catching your breath?	(ADCOUGH) <input type="checkbox"/>	<input type="checkbox"/>	(ADCHBTHR) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. Headache?	(ADHEDACH) <input type="checkbox"/>	<input type="checkbox"/>	(ADHDBTHR) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20. Loss of appetite or change in the taste of food?	(ADAPETIT) <input type="checkbox"/>	<input type="checkbox"/>	(ADAPBTHR) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21. Bloating, pain, or gas in your stomach?	(ADBLOAT) <input type="checkbox"/>	<input type="checkbox"/>	(ADBLBTHR) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22. Muscle aches or joint pain?	(ADM SACHE) <input type="checkbox"/>	<input type="checkbox"/>	(ADMSBTHR) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23. Problems with having sex, such as loss of interest or lack of satisfaction?	(ADSEXPRB) <input type="checkbox"/>	<input type="checkbox"/>	(ADSBTHR) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
24. Changes in the way your body looks, such as fat deposits or weight gain?	(ADBDYCHG) <input type="checkbox"/>	<input type="checkbox"/>	(ADBYBTHR) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	<input type="checkbox"/>		<input type="checkbox"/>			
25. Problems with weight loss or wasting?	(ADWTLOSS) <input type="checkbox"/>	<input type="checkbox"/>	(ADWTBTHR) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
26. Hair loss or changes in the way your hair looks?	(ADHAIRCG) <input type="checkbox"/>	<input type="checkbox"/>	(ADHRBTHR) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments: (ADHCOMM)

Additional Demographics (ADM)

Web Version: 1.0; 2.02; 10-14-16

Segment (PROTSEG): A

Visit number (VISNO):

Date of assessment: (ADMASMDT)

 (mm/dd/yyyy)

1. Some of our participants identify themselves as transgender. Do you identify yourself as transgender?
(ADTRANSG)

0-No
1-Yes - Transmale (female to male)
2-Yes - Transfemale (male to female)

If "Yes", have you had sex reassignment surgery? (ADSEXSUR)

☐ No ☐ Yes

2. Are you currently pregnant? (ADPREGNT)

☐ No ☐ Yes ☐ Don't know ☐ Refused to answer

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

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

If "Other", specify: (ADWORKOT)

1. Specify what kind of paid work 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 "hairstylist" or "manicurist". (ADKINDWK)

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

Hours: (xx)

3. What is your current wage for this job? (ADWAGEHR)

Hourly: (xxx.xx) -or- (ADWAGEYR) Annual: (xxxxxxx)

4. What was your total personal income in the last year from all sources? (ADINCPER)

(xxxxxx) (ADPIDKRF) ☐ Don't know ☐ Refused to answer

If "Don't know" or "Refused to answer", which of the following is the category that your total personal income from all sources would be in? (ADINCPRW)

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

5. What is your best estimate of the total income of all family members from all legal sources, before taxes, in the last calendar year? (ADINCFAM)

(xxxxxx) (ADTIDKRF) ☐ Don't know ☐ Refused to answer

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

If "Don't know" or "Refused to answer", which of the following is the category that your total family income from legal sources would be in? (ADINCFMW)

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

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

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

	No	Yes
a. Private health insurance:	(ADPRIHEA) <input type="checkbox"/>	<input type="checkbox"/>
b. Medicare:	(ADMEDCAR) <input type="checkbox"/>	<input type="checkbox"/>
c. Medi-gap:	(ADMEDIGA) <input type="checkbox"/>	<input type="checkbox"/>
d. Medicaid state plan name: (ADMDSTSP) <input type="text"/>	(ADMEDICD) <input type="checkbox"/>	<input type="checkbox"/>
e. SCHIP (CHIP/children's health insurance program):	(ADSCHIP) <input type="checkbox"/>	<input type="checkbox"/>
f. Military health care (Tricare/VA/champ-VA):	(ADMILTAR) <input type="checkbox"/>	<input type="checkbox"/>
g. Indian health service:	(ADINDIAN) <input type="checkbox"/>	<input type="checkbox"/>
h. State-sponsored health plan: (ADSTATES) <input type="text"/>	(ADSTATSP) <input type="checkbox"/>	<input type="checkbox"/>
i. Other government program:	(ADGOVOTH) <input type="checkbox"/>	<input type="checkbox"/>
j. Single service plan (e.g., dental, vision, prescriptions):	(ADSINGLE) <input type="checkbox"/>	<input type="checkbox"/>
k. ADAP:	(ADADAP) <input type="checkbox"/>	<input type="checkbox"/>
l. "Other insurance", specify: (ADINSOTH) <input type="text"/>	(ADINOTSP) <input type="checkbox"/>	<input type="checkbox"/>

7. 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 12 to 16 months from today?(ADLIVVIC)

☐ No ☐ Yes

8. During the past 6 months, where did you live or sleep most of the time?(ADLIVSLP)

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

9. In the past 6 months, indicate all the places you have lived.

	No	Yes	Refused to Answer	Number of Nights
a. Homeless (e.g., living on the street, in a park, in a bus station):	(ADHOMELE) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	(ADHMLSNT) <input type="text"/>
b. Emergency or homeless shelter:	(ADSHELTE) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	(ADSHLTNT) <input type="text"/>
c. Transitional (time-limited) single-room occupancy hotel:	(ADTRANSI) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	(ADTRNSNT) <input type="text"/>
d. Permanent single-room occupancy hotel:	(ADPERMAN) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	(ADPRMTNT) <input type="text"/>
e. HIV/AIDS housing/group home:	(ADGROUP) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	(ADGRPNT) <input type="text"/>
f. Drug treatment facility:	(ADDRUGTX) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	(ADDGFLNT) <input type="text"/>
g. Other residential facility or institution (e.g., health care facility, halfway house):	(ADRESOTH) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	(ADFLOTNT) <input type="text"/>
h. Staying with family/friends:	(ADFAMILY) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	(ADFMLYNT) <input type="text"/>
i. Rent an apartment/house (alone or with others):	(ADRENT) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	(ADRENTNT) <input type="text"/>
j. Own my home:	(ADOWNHOM) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	(ADOWNNT) <input type="text"/>
k. In jail:	(ADLVJAIL) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	(ADJAILNT) <input type="text"/>
l. "Other", specify: (ADLIOTSP) <input type="text"/>	(ADLIVEOT) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	(ADLVOTNT) <input type="text"/>

10. Indicate who you currently live with.

	No	Yes	Refused to Answer
a. Alone:	(ADALONE) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. Partner:	(ADPARTNE) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. Parents:	(ADPARENT) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. Children:	(ADCHILDR) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e. Other family:	(ADFAMOTH) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f. Friends:	(ADFRIEND) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g. Roommates/housemates:	(ADRMATE) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h. "Other", specify: (ADLVWTSP) <input type="text"/>	(ADWHOOOTH) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

11. Do you live with anyone who has a current alcohol problem?(ADL VALCH) ☐ No ☐ Yes
12. Do you live with anyone who uses illegal drugs or marijuana?(ADLVDRG) ☐ No ☐ Yes
13. Do you live with anyone who abuses prescription/OTC medications or other substances?(ADLVDRRX) ☐ No ☐ Yes

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

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

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

(xx)

15. How many times have you been hospitalized since your last CTN-0049 study visit? (ADHSP049)

(xxx)

Of these hospitalizations, how many times have you been hospitalized in the past 12 months? (AD12MHSP)

(xxx)

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

☐ No ☐ Yes

Have you participated in alcohol or drug treatment in the past 12 months? (AD12ALDR)

☐ No ☐ Yes

17. Indicate the types of programs you have participated in during the past 12 months and past 6 months.

	Past 12 Months		Past 6 Months	
	No	Yes	No	Yes
a. Drug free outpatient drug treatment:	(AD12OUTP) <input type="checkbox"/>	<input type="checkbox"/>	(AD06OUTP) <input type="checkbox"/>	<input type="checkbox"/>
b. Inpatient drug treatment:	(AD12IPTR) <input type="checkbox"/>	<input type="checkbox"/>	(AD06IPTR) <input type="checkbox"/>	<input type="checkbox"/>
c. Methadone maintenance:	(AD12METM) <input type="checkbox"/>	<input type="checkbox"/>	(AD06METM) <input type="checkbox"/>	<input type="checkbox"/>
d. Buprenorphine treatment:	(AD12BUPT) <input type="checkbox"/>	<input type="checkbox"/>	(AD06BUPT) <input type="checkbox"/>	<input type="checkbox"/>
e. Detoxification:	(AD12DTXT) <input type="checkbox"/>	<input type="checkbox"/>	(AD06DTXT) <input type="checkbox"/>	<input type="checkbox"/>
f. Residential treatment program:	(AD12RSDT) <input type="checkbox"/>	<input type="checkbox"/>	(AD06RSDT) <input type="checkbox"/>	<input type="checkbox"/>
g. Alcoholics Anonymous (AA):	(AD12AATR) <input type="checkbox"/>	<input type="checkbox"/>	(AD06AATR) <input type="checkbox"/>	<input type="checkbox"/>
h. Narcotics or Cocaine Anonymous (NA):	(AD12NRCT) <input type="checkbox"/>	<input type="checkbox"/>	(AD06NRCT) <input type="checkbox"/>	<input type="checkbox"/>
i. "Other", specify: (ADOTTRSP) <input type="text"/>	(AD12OTTR) <input type="checkbox"/>	<input type="checkbox"/>	(AD06OTTR) <input type="checkbox"/>	<input type="checkbox"/>

Comments: (ADMCOMM)

Additional Selection Options for ADM

We would like to know about what you do. Are you working now, looking for work, retired, keeping house, a student, or what?

6-Unemployed, not looking for work

7-Retired

8-Disabled, permanently or temporarily

9-Unpaid child care or housework

10-Student

11-Currently incarcerated

99-Other

If "Don't know" or "Refused to answer", 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

97-Don't know

98-Refused to answer

During the past 6 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, halfway house)

8-Staying with family/friends

9-Rent an apartment/house (alone or with others)

10-Own my home

11-In jail

99-Other

HIV Medical Care Part Two (Medical Record) (AM2)

Web Version: 1.0; 5.00; 12-14-17

Segment (PROTSEG): B
Visit number (VISNO):
Facility name (FACPRLC):
Sequence number (SEQNUM2):

This is a supplemental form to the Access to and Utilization of HIV Medical Care (Medical Record) (AUM) form.
This form is available to capture HIV Care visits and HIV CD4 and VL tests when all rows for these visits have been entered in the AUM form. If there is room in the AUM form, information should be entered in the AUM first.

HIV Care Visits and HIV Testing

RA Instruction: The following questions refer to medical records regarding HIV visits and HIV testing that occurred after the CTN-0064 baseline study visit. Tests collected as part of the CTN-0064 study visit should not be included in this abstraction.
RA Instruction: The following questions refer to medical records regarding HIV visits and HIV testing that occurred since the last abstraction and prior to the participant's final study visit. Tests collected as part of the CTN-0064 study visit should not be included in this abstraction. It is understood this abstraction may occur after the participant's final study visit.

1. Is there evidence the participant scheduled additional HIV care visit(s) since the last CTN-0064 study visit?(AMSHIVVS) ☐ No ☐ Yes

If "Yes", indicate the dates and outcomes for all HIV care visits scheduled since the participant's last CTN-0064 study visit.

Scheduled Visit Date	Visit Outcome
(AMVSDT19) <input type="text"/>	<div>0-Participant no show</div> <div>1-Participant attended appointment</div> <div>2-Appointment canceled by participant</div> <div>3-Appointment canceled by clinic</div> <div>4-Appointment canceled, other</div> <div>(AMVSOC19)</div>
(AMVSDT20) <input type="text"/>	<div>0-Participant no show</div> <div>1-Participant attended appointment</div> <div>2-Appointment canceled by participant</div> <div>3-Appointment canceled by clinic</div> <div>4-Appointment canceled, other</div> <div>(AMVSOC20)</div>
(AMVSDT21) <input type="text"/>	<div>0-Participant no show</div> <div>1-Participant attended appointment</div> <div>2-Appointment canceled by participant</div> <div>3-Appointment canceled by clinic</div> <div>4-Appointment canceled, other</div> <div>(AMVSOC21)</div>
(AMVSDT22) <input type="text"/>	<div>0-Participant no show</div> <div>1-Participant attended appointment</div> <div>2-Appointment canceled by participant</div> <div>3-Appointment canceled by clinic</div> <div>4-Appointment canceled, other</div> <div>(AMVSOC22)</div>
(AMVSDT23) <input type="text"/>	<div>0-Participant no show</div> <div>1-Participant attended appointment</div> <div>2-Appointment canceled by participant</div> <div>3-Appointment canceled by clinic</div> <div>4-Appointment canceled, other</div> <div>(AMVSOC23)</div>
(AMVSDT24) <input type="text"/>	<div>0-Participant no show</div> <div>1-Participant attended appointment</div> <div>2-Appointment canceled by participant</div> <div>3-Appointment canceled by clinic</div> <div>4-Appointment canceled, other</div> <div>(AMVSOC24)</div>
(AMVSDT25) <input type="text"/>	<div>0-Participant no show</div> <div>1-Participant attended appointment</div> <div>2-Appointment canceled by participant</div> <div>3-Appointment canceled by clinic</div> <div>4-Appointment canceled, other</div> <div>(AMVSOC25)</div>
(AMVSDT26) <input type="text"/>	

	(AMVSOC26)	0-Participant no show 1-Participant attended appointment 2-Appointment canceled by participant 3-Appointment canceled by clinic 4-Appointment canceled, other
(AMVSDT27)		0-Participant no show 1-Participant attended appointment 2-Appointment canceled by participant 3-Appointment canceled by clinic 4-Appointment canceled, other
(AMVSDT28)		0-Participant no show 1-Participant attended appointment 2-Appointment canceled by participant 3-Appointment canceled by clinic 4-Appointment canceled, other

2. Is there evidence the participant had additional CD4 count test(s) and/or HIV viral load test(s) since the last CTN-0064 study visit? (AMSHIVTS)

☐ No ☐ Yes

If "Yes", indicate the dates and results of all CD4 count tests and all HIV viral load tests performed since the participant's last CTN-0064 study visit.

@2Date Specimen Collected	@2Laboratory Name and Address (If Different from Facility Name)	@2HIV Test(s) Performed	@2CD4 Count (cells/ μ L)	@2CD4 Percent (%)	*2HIV Viral Load Undetectable?	@2If "Undetectable", Lab's Lower Limit (copies/mL)	@2If "Detectable", HIV Viral Load (copies/mL)	@2HIV Viral Load Assay Type
					No	Yes		
(AMTSDT13)	(AMPRLC13)	(AMTST13) 1-CD4 count 2-HIV viral load 3-Both	(AMCD4C13)	(AMCD4P13)	(AMVLUN13) <input type="checkbox"/>	(AMVLLW13) < 	(AMVL13)	(AMVLAS13)
(AMTSDT14)	(AMPRLC14)	(AMTST14) 1-CD4 count 2-HIV viral load 3-Both	(AMCD4C14)	(AMCD4P14)	(AMVLUN14) <input type="checkbox"/>	(AMVLLW14) < 	(AMVL14)	(AMVLAS14)
(AMTSDT15)	(AMPRLC15)	(AMTST15) 1-CD4 count 2-HIV viral load 3-Both	(AMCD4C15)	(AMCD4P15)	(AMVLUN15) <input type="checkbox"/>	(AMVLLW15) < 	(AMVL15)	(AMVLAS15)
(AMTSDT16)	(AMPRLC16)	(AMTST16) 1-CD4 count 2-HIV viral load 3-Both	(AMCD4C16)	(AMCD4P16)	(AMVLUN16) <input type="checkbox"/>	(AMVLLW16) < 	(AMVL16)	(AMVLAS16)
(AMTSDT17)	(AMPRLC17)	(AMTST17) 1-CD4 count 2-HIV viral load 3-Both	(AMCD4C17)	(AMCD4P17)	(AMVLUN17) <input type="checkbox"/>	(AMVLLW17) < 	(AMVL17)	(AMVLAS17)
(AMTSDT18)	(AMPRLC18)	(AMTST18) 1-CD4 count 2-HIV viral load 3-Both	(AMCD4C18)	(AMCD4P18)	(AMVLUN18) <input type="checkbox"/>	(AMVLLW18) < 	(AMVL18)	(AMVLAS18)
(AMTSDT19)	(AMPRLC19)	(AMTST19) 1-CD4 count 2-HIV viral load 3-Both	(AMCD4C19)	(AMCD4P19)	(AMVLUN19) <input type="checkbox"/>	(AMVLLW19) < 	(AMVL19)	(AMVLAS19)
(AMTSDT20)	(AMPRLC20)	(AMTST20) 1-CD4 count 2-HIV viral load 3-Both	(AMCD4C20)	(AMCD4P20)	(AMVLUN20) <input type="checkbox"/>	(AMVLLW20) < 	(AMVL20)	(AMVLAS20)
(AMTSDT21)	(AMPRLC21)	(AMTST21) 1-CD4 count 2-HIV viral load 3-Both	(AMCD4C21)	(AMCD4P21)	(AMVLUN21) <input type="checkbox"/>	(AMVLLW21) < 	(AMVL21)	(AMVLAS21)
(AMTSDT22)	(AMPRLC22)	(AMTST22)	(AMCD4C22)	(AMCD4P22)	(AMVLUN22) <input type="checkbox"/>	(AMVLLW22) < 	(AMVL22)	(AMVLAS22)

		1-CD4 count 2-HIV viral load 3-Both							
--	--	---	--	--	--	--	--	--	--

Comments:(AM2COMM)

Additional Selection Options for AM2

Sequence number (SEQNUM2) (key field):
01-1
02-2
03-3
04-4
05-5
06-6
07-7
08-8
09-9
10-10

Additional Psychiatric Diagnoses (Medical Record) (APD)

Web Version: 1.0; 1.00; 10-14-16

Segment (*PROTSEG*): A

Visit number (*VISNO*):

Date abstraction performed: (*APABSTDT*)

(mm/dd/yyyy)

1. Is there evidence the participant has ever received any of the following psychiatric diagnoses? (*APPSYCH*)

☐ No ☐ Yes

a. Drug use disorder: (*APDRUG*)

☐ No ☐ Yes

b. Alcohol use disorder: (*APALCOHO*)

☐ No ☐ Yes

c. Depression: (*APDEPRES*)

☐ No ☐ Yes

d. Bipolar: (*APBIPOLA*)

☐ No ☐ Yes

e. Schizophrenia: (*APSCHZPH*)

☐ No ☐ Yes

f. Schizoaffective disorder: (*APSCHZAF*)

☐ No ☐ Yes

g. Anxiety disorder: (*APANXIET*)

☐ No ☐ Yes

h. Post-traumatic stress disorder: (*APPTSD*)

☐ No ☐ Yes

i. Diagnosis unspecified but prescription for oral mood stabilizer(s): (*APRXMOOD*)

☐ No ☐ Yes

j. Diagnosis unspecified but prescription for antipsychotic medication(s): (*APRXANTI*)

☐ No ☐ Yes

Comments: (*APDCOMM*)

ARV Medication Log (Self Report) (ARS)

Web Version: 1.0; 3.00; 10-14-16

This is a participant self report form and should reflect only the information provided by the participant.

BA Instruction:

You may need to remind the participant s/he reported taking HIV medications since their last CTN-0049 study visit, currently taking HIV medications or having an "active" HIV medication prescription on the HIV Adherence Measures (AHM) form.

Prompt the participant as follows:

- "What are the names of your HIV medications?"
- "Do you have your medications or a list of medications with you?"
- "When did you start your current regimen?"

If the participant does not have the medication bottles or a list of medications, you may need to help him/her remember the HIV medications:

- Use the laminated card with pictures of the pills to help the participant identify his/her medication.
- Use the "Common Regimens" list to suggest names (use both generic and brand names to jog his/her memory).

If the participant is unable to recall an exact date, record an estimated date using the "Mid-month", "Mid-year", and "Mid-decade" convention:

- If the exact day is unknown, default to the middle of the month = 15 (e.g., mm/15/yyyy)
- If the month and day are unknown, default to the middle of year and month = 06/15 (e.g., 06/15/yyyy)
- If the year is unknown, default to the middle of the decade (e.g., '90's" = 1995 = 05/15/1995)

Enter all HIV medications taken since the participant's last CTN-0049 study visit and all active HIV medication prescriptions on the ARV Medication Log, even if the participant never started taking the medication or has poor adherence to the medication. Do NOT record other medications, even those for opportunistic infection (OI) prevention.

List all HIV medications that you have taken since your last CTN-0049 study visit, or for which you have received a prescription, or have an active prescription. An "active" prescription is a prescription you can currently fill or a medication you currently have in your possession.

HIV medications are sometimes referred to as antiretroviral medications, ART, or a "drug cocktail". These medications are taken to increase or maintain your T-cell count and to reduce your viral load. HIV medications treat HIV specifically; they do not include other medications, even those for opportunistic infection (OI) prevention.

@2Drug Name	@2Drug Not Started	@2Start Date	@2Stop Date	@2Ongoing at Termination	4Participant Brought "Active" Prescription Bottle			@2Facility Name and Address Where Medication Prescribed	@2Obtained MR Release	@2Pharmacy Name and Address		@2Obtained MR Release		
					No	Yes	Prescription Fill Date	Number of Pills		No	Yes	No	Yes	
1. (AR)DRUG(01) 01-Apivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below	(AR)NST01 <input type="checkbox"/>	(AR)SDT01 <input type="text"/>	(AR)SPDT01 <input type="text"/>	(AR)ONG01 <input type="checkbox"/>	(AR)ACTV01 <input type="checkbox"/>	<input type="checkbox"/>	(AR)RXDT01 <input type="text"/>	(AR)PILL01 <input type="text"/>	(AR)PRLC01 <input type="text"/>	(AR)RXMR01 <input type="checkbox"/>	<input type="checkbox"/>	(AR)PRLC10 <input type="text"/>	(AR)PHMR01 <input type="checkbox"/>	<input type="checkbox"/>
2. (AR)DRUG(02) 01-Apivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below	(AR)NST02 <input type="checkbox"/>	(AR)SDT02 <input type="text"/>	(AR)SPDT02 <input type="text"/>	(AR)ONG02 <input type="checkbox"/>	(AR)ACTV02 <input type="checkbox"/>	<input type="checkbox"/>	(AR)RXDT02 <input type="text"/>	(AR)PILL02 <input type="text"/>	(AR)PRLC02 <input type="text"/>	(AR)RXMR02 <input type="checkbox"/>	<input type="checkbox"/>	(AR)PRLC17 <input type="text"/>	(AR)PHMR02 <input type="checkbox"/>	<input type="checkbox"/>
3. (AR)DRUG(03) 01-Apivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below	(AR)NST03 <input type="checkbox"/>	(AR)SDT03 <input type="text"/>	(AR)SPDT03 <input type="text"/>	(AR)ONG03 <input type="checkbox"/>	(AR)ACTV03 <input type="checkbox"/>	<input type="checkbox"/>	(AR)RXDT03 <input type="text"/>	(AR)PILL03 <input type="text"/>	(AR)PRLC03 <input type="text"/>	(AR)RXMR03 <input type="checkbox"/>	<input type="checkbox"/>	(AR)PRLC18 <input type="text"/>	(AR)PHMR03 <input type="checkbox"/>	<input type="checkbox"/>
4. (AR)DRUG(04) 01-Apivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below	(AR)NST04 <input type="checkbox"/>	(AR)SDT04 <input type="text"/>	(AR)SPDT04 <input type="text"/>	(AR)ONG04 <input type="checkbox"/>	(AR)ACTV04 <input type="checkbox"/>	<input type="checkbox"/>	(AR)RXDT04 <input type="text"/>	(AR)PILL04 <input type="text"/>	(AR)PRLC04 <input type="text"/>	(AR)RXMR04 <input type="checkbox"/>	<input type="checkbox"/>	(AR)PRLC19 <input type="text"/>	(AR)PHMR04 <input type="checkbox"/>	<input type="checkbox"/>
5. (AR)DRUG(05) 01-Apivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below	(AR)NST05 <input type="checkbox"/>	(AR)SDT05 <input type="text"/>	(AR)SPDT05 <input type="text"/>	(AR)ONG05 <input type="checkbox"/>	(AR)ACTV05 <input type="checkbox"/>	<input type="checkbox"/>	(AR)RXDT05 <input type="text"/>	(AR)PILL05 <input type="text"/>	(AR)PRLC05 <input type="text"/>	(AR)RXMR05 <input type="checkbox"/>	<input type="checkbox"/>	(AR)PRLC20 <input type="text"/>	(AR)PHMR05 <input type="checkbox"/>	<input type="checkbox"/>
6. (AR)DRUG(06) 01-Apivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below	(AR)NST06 <input type="checkbox"/>	(AR)SDT06 <input type="text"/>	(AR)SPDT06 <input type="text"/>	(AR)ONG06 <input type="checkbox"/>	(AR)ACTV06 <input type="checkbox"/>	<input type="checkbox"/>	(AR)RXDT06 <input type="text"/>	(AR)PILL06 <input type="text"/>	(AR)PRLC06 <input type="text"/>	(AR)RXMR06 <input type="checkbox"/>	<input type="checkbox"/>	(AR)PRLC21 <input type="text"/>	(AR)PHMR06 <input type="checkbox"/>	<input type="checkbox"/>
7. (AR)DRUG(07) 01-Apivus - TPV 02-Atripla - EFV + TDF + FTC 03-Combivir - ZDV + 3TC or AZT + 3TC 04-Complera - RPV + TDF + FTV 05-Crixivan - IDV *Additional Options Listed Below	(AR)NST07 <input type="checkbox"/>	(AR)SDT07 <input type="text"/>	(AR)SPDT07 <input type="text"/>	(AR)ONG07 <input type="checkbox"/>	(AR)ACTV07 <input type="checkbox"/>	<input type="checkbox"/>	(AR)RXDT07 <input type="text"/>	(AR)PILL07 <input type="text"/>	(AR)PRLC07 <input type="text"/>	(AR)RXMR07 <input type="checkbox"/>	<input type="checkbox"/>	(AR)PRLC22 <input type="text"/>	(AR)PHMR07 <input type="checkbox"/>	<input type="checkbox"/>

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

8. (ARDRUG08)	(ARNTST08)	(ARSTDT08)	(ARSPDT08)	(ARONG08)	(ARACTV08)	<input type="checkbox"/> (ARRXDT08)	(ARPILL08)	(ARPRLC08)		(ARRXMR08)	<input type="checkbox"/> (ARPRLC23)		(ARPHMR08)	<input type="checkbox"/>
9. (ARDRUG09)	(ARNTST09)	(ARSTDT09)	(ARSPDT09)	(ARONG09)	(ARACTV09)	<input type="checkbox"/> (ARRXDT09)	(ARPILL09)	(ARPRLC09)		(ARRXMR09)	<input type="checkbox"/> (ARPRLC24)		(ARPHMR09)	<input type="checkbox"/>
10. (ARDRUG10)	(ARNTST10)	(ARSTDT10)	(ARSPDT10)	(ARONG10)	(ARACTV10)	<input type="checkbox"/> (ARRXDT10)	(ARPILL10)	(ARPRLC10)		(ARRXMR10)	<input type="checkbox"/> (ARPRLC25)		(ARPHMR10)	<input type="checkbox"/>
11. (ARDRUG11)	(ARNTST11)	(ARSTDT11)	(ARSPDT11)	(ARONG11)	(ARACTV11)	<input type="checkbox"/> (ARRXDT11)	(ARPILL11)	(ARPRLC11)		(ARRXMR11)	<input type="checkbox"/> (ARPRLC26)		(ARPHMR11)	<input type="checkbox"/>
12. (ARDRUG12)	(ARNTST12)	(ARSTDT12)	(ARSPDT12)	(ARONG12)	(ARACTV12)	<input type="checkbox"/> (ARRXDT12)	(ARPILL12)	(ARPRLC12)		(ARRXMR12)	<input type="checkbox"/> (ARPRLC27)		(ARPHMR12)	<input type="checkbox"/>
13. (ARDRUG13)	(ARNTST13)	(ARSTDT13)	(ARSPDT13)	(ARONG13)	(ARACTV13)	<input type="checkbox"/> (ARRXDT13)	(ARPILL13)	(ARPRLC13)		(ARRXMR13)	<input type="checkbox"/> (ARPRLC28)		(ARPHMR13)	<input type="checkbox"/>
14. (ARDRUG14)	(ARNTST14)	(ARSTDT14)	(ARSPDT14)	(ARONG14)	(ARACTV14)	<input type="checkbox"/> (ARRXDT14)	(ARPILL14)	(ARPRLC14)		(ARRXMR14)	<input type="checkbox"/> (ARPRLC29)		(ARPHMR14)	<input type="checkbox"/>
15. (ARDRUG15)	(ARNTST15)	(ARSTDT15)	(ARSPDT15)	(ARONG15)	(ARACTV15)	<input type="checkbox"/> (ARRXDT15)	(ARPILL15)	(ARPRLC15)		(ARRXMR15)	<input type="checkbox"/> (ARPRLC30)		(ARPHMR15)	<input type="checkbox"/>

Comments:(ARSCOMM)

Additional Selection Options for ARS

- Drug name 01
06-Eduvant - RPV
07-Emtriva - FTC
08-Epivir - 3TC
09-Epizom - ABC + 3TC
10-Fuzon - T20
11-Intence - ETV
12-Inivase - SQV
13-Isentress - RAL
14-Isentress + Truvada - RAL + TDF + FTC
15-Kaletra - LPVr
16-Lesivir - FPV
17-Norvir - RTV
18-Pravista BD - DRV
19-Pravista OD - DRV
20-Pravista + Norvir + Truvada (DRVr twice daily) - DRVr + TDF + FTC
21-Pravista + Norvir + Truvada (once daily) - DRVr + TDF + FTC
22-Reyataz - ATV
23-Reyataz + Norvir + Truvada - ATVr + TDF + FTC
24-Rescriptor - DLV
25-Retrovir - AZT (or ZDV)
26-Selentry - MVC
27-Selentry+ Truvada - MVC + TDF + FTC
28-Stribild - EVG + COBI + TDF + FTC
29-Sustiva - EFV
30-Thecap(dolutegravir)
31-Trizivir - ABC + 3TC + ZDV (or AZT)
32-Truvada - TDF + FTC
33-Videx - dd
34-Viacapt - NFV
35-Viamune - NVP
36-Viamune XR (QD) - NVP
37-Viadv - TDF
38-Zerit - d4T
39-Zigen - ABC
40-Descovy (emtricitabine/TAF)
41-Evotaz
42-Genvoya
43-Qielsey (emtricitabine/ilpivirine/TAF)
44-Pravista
45-Trisuneq
46-Tybois
47-Viela
97-Don't know
99-Other Experimental/Blinded study

ARV Medications (Medical Record) (ARV)

Web Version: 1.0; 1.01; 10-14-16

ART medication name (ARTMED):

Sequence of medication (MEDSEQNO):

1. Is there evidence this ART medication was prescribed?

"Evidence this ART medication was prescribed" means documentation of a written prescription or documentation that the participant is currently taking this medication (e.g., clinician note, medication log, prescription log from clinic or pharmacy, pharmacy fill data). (AVPRSCRX)

☐ No ☐ Yes

- a. If "Yes", date of most recent evidence that medication was prescribed: (AVPRSCDT)

 (mm/dd/yyyy)

- b. If "Yes", facility name and address for evidence that medication was prescribed: (AVPRLC01)

2. Is there evidence this ART medication was stopped?

"Evidence this ART medication was stopped" means clinician documentation that the participant stopped taking this medication (e.g., clinician note, medication log). (AVSTOPRX)

☐ No ☐ Yes

- a. If "Yes", date of most recent evidence that medication was stopped: (AVSTOPDT)

 (mm/dd/yyyy)

- b. If "Yes", facility name and address for evidence that medication was stopped: (AVPRLC02)

Comments: (ARVCOMM)

Additional Selection Options for ARV

ART medication name (*ARTMED*) (key field):

01 -Aptivus - T PV
02 -Atripla - EFV + TDF + FTC
03 -Combivir - ZDV + 3TC or AZT + 3TC
04 -Complera - RPV + TDF + FT V
05 -Crixivan - IDV
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
14 -Isentress + Truvada - RAL + TDF + FTC
15 -Kaletra - LPV/r
16 -Lexiva - FPV
17 -Norvir - RTV
18 -Prezista BID - DRV
19 -Prezista QD - DRV
20 -Prezista + Norvir +Truvada (DRV/r twice daily) - DRV/r +TDF + FTC
21 -Prezista + Norvir + Truvada (once daily) - DRV/r + TDF + FTC
22 -Reyataz - ATV
23 -Reyataz + Norvir + Truvada
- ATV/r + TDF + FTC
24 -Rescriptor - DLV
25 -Retrovir - AZT (or ZDV)
26 -Selzentry - MVC
27 -Selzentry + Truvada - MVC + TDF + FTC
28 -Stribild - EVG + COBI + TDF + FTC
29 -Sustiva - EFV
30 -Tivacay (dolutegravir)
31 -Trizivir - ABC + 3TC + ZDV (or AZT)
32 -Truvada - TDF + FT C
33 -Videx - ddl
34 -Viracept - NFV
35 -Viramune - NVP
36 -Viramune XR (QD) - NVP
37 -Viread - TDF
38 -Zerit - d4T
39 -Ziagen - ABC
40 -Descovy (emtricitabine/TAF)
41 -Evotaz
42 -Genvoya
43 -Odefsey (emtricitabine/rilpivirine/TAF)
44 -Prezobix
45 -Triumeq
46 -Tybost
47 -Vitekta
99 -Other/Experimental/Blinded study

Sequence of medication (*MEDSEQNO*) (key field):

01 -1st medication use
02 -2nd medication use
03 -3rd medication use
04 -4th medication use
05 -5th medication use

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

Web Version: 1.0; 1.01; 10-14-16

Segment (PROTSEG): A

Visit number (VISNO):

Date of assessment (ASDASMDT)

 (mm/dd/yyyy)

CTN-ASI Lite v1.0: 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.

Substance	A. Past 30 Days (days)	B. Lifetime Use (years)	^2 C. Age of First Use (onset) (years)		D. Route of Administration	Comments
D1 Alcohol (any use at all):	(ADALA30D) <input type="text"/>	(ADALALFT) <input type="text"/>	(ADALAONS) <input type="text"/>	(ADALAONA) <input type="checkbox"/> N/A	-	(ADALACOM) <input type="text"/>
D2 Alcohol (to intoxication):	(ADALI30D) <input type="text"/>	(ADALILFT) <input type="text"/>	(ADALIONS) <input type="text"/>	(ADALIONA) <input type="checkbox"/> N/A	-	(ADALICOM) <input type="text"/>
D3 Heroin:	(ADHER30D) <input type="text"/>	(ADHERLFT) <input type="text"/>	(ADHERONS) <input type="text"/>	(ADHERONA) <input type="checkbox"/> N/A	(ADHERRTE) 1-(1) Oral 2-(2) Nasal 3-(3) Smoking 4-(4) Non IV injection 5-(5) IV injection 96-(96) Not applicable 97-(97) Not answered	(ADHERCOM) <input type="text"/>
D4 Methadone/LAAM (prescribed):	(ADM DP30D) <input type="text"/>	(ADM DP LFT) <input type="text"/>	(ADM DPONS) <input type="text"/>	(ADM DPONA) <input type="checkbox"/> N/A	(ADM DP RTE) 1-(1) Oral 2-(2) Nasal 3-(3) Smoking 4-(4) Non IV injection 5-(5) IV injection 96-(96) Not applicable 97-(97) Not answered	(ADM DP COM) <input type="text"/>

D4a Methadone/LAAM <i>(illicit):</i>	<i>(ADMDI30D)</i> <input type="text"/>	<i>(ADMDILFT)</i> <input type="text"/>	<i>(ADMDIONS)</i> <input type="text"/>	<i>(ADMDIONA)</i> <input type="checkbox"/> N/A	<i>(ADMDIRTE)</i> <input type="text"/> 1-(1) Oral 2-(2) Nasal 3-(3) Smoking 4-(4) Non IV injection 5-(5) IV injection 96-(96) Not applicable 97-(97) Not answered	<i>(ADMDICOM)</i> <input type="text"/>
D5 Other Opiates/Analgesics:	<i>(ADOPI30D)</i> <input type="text"/>	<i>(ADOPIFLT)</i> <input type="text"/>	<i>(ADOPIONS)</i> <input type="text"/>	<i>(ADOPIONA)</i> <input type="checkbox"/> N/A	<i>(ADOPIRTE)</i> <input type="text"/> 1-(1) Oral 2-(2) Nasal 3-(3) Smoking 4-(4) Non IV injection 5-(5) IV injection 96-(96) Not applicable 97-(97) Not answered	<i>(ADOPICOM)</i> <input type="text"/>
D6 Barbiturates:	<i>(ADBAR30D)</i> <input type="text"/>	<i>(ADBARLFT)</i> <input type="text"/>	<i>(ADBARONS)</i> <input type="text"/>	<i>(ADBARONA)</i> <input type="checkbox"/> N/A	<i>(ADBARTE)</i> <input type="text"/> 1-(1) Oral 2-(2) Nasal 3-(3) Smoking 4-(4) Non IV injection 5-(5) IV injection 96-(96) Not applicable 97-(97) Not answered	<i>(ADBARCOM)</i> <input type="text"/>
D7 Other Sedatives/Hypnotics /Tranquilizers:	<i>(ADSHT30D)</i> <input type="text"/>	<i>(ADSHTLFT)</i> <input type="text"/>	<i>(ADSHTONS)</i> <input type="text"/>	<i>(ADSHTONA)</i> <input type="checkbox"/> N/A	<i>(ADSHT RTE)</i> <input type="text"/> 1-(1) Oral 2-(2) Nasal 3-(3) Smoking 4-(4) Non IV injection 5-(5) IV injection 96-(96) Not applicable 97-(97) Not answered	<i>(ADSHTCOM)</i> <input type="text"/>
D8 Cocaine:	<i>(ADCOC30D)</i> <input type="text"/>	<i>(ADCOCFLT)</i> <input type="text"/>	<i>(ADCOCONS)</i> <input type="text"/>	<i>(ADCOCONA)</i> <input type="checkbox"/> N/A	<i>(ADCOC RTE)</i> <input type="text"/> 1-(1) Oral 2-(2) Nasal 3-(3) Smoking 4-(4) Non IV injection 5-(5) IV injection 96-(96) Not applicable 97-(97) Not answered	<i>(ADCOCOM)</i> <input type="text"/>
D9 Amphetamines:	<i>(ADAMP30D)</i> <input type="text"/>	<i>(ADAMPLFT)</i> <input type="text"/>	<i>(ADAMPONS)</i> <input type="text"/>	<i>(ADAMPONA)</i> <input type="checkbox"/> N/A	<i>(ADAMP RTE)</i> <input type="text"/>	<i>(ADAMPCOM)</i> <input type="text"/>

					1-(1) Oral 2-(2) Nasal 3-(3) Smoking 4-(4) Non IV injection 5-(5) IV injection 96-(96) Not applicable 97-(97) Not answered	
D9a Methamphetamine:	(ADMET30D) <input type="text"/>	(ADMETLFT) <input type="text"/>	(ADMETONS) <input type="text"/>	(ADMETONA) <input type="checkbox"/> N/A	(ADMETRTE) 1-(1) Oral 2-(2) Nasal 3-(3) Smoking 4-(4) Non IV injection 5-(5) IV injection 96-(96) Not applicable 97-(97) Not answered	(ADMETCOM) <input type="text"/>
D10 Cannabis:	(ADTHC30D) <input type="text"/>	(ADTHCLFT) <input type="text"/>	(ADTHCONS) <input type="text"/>	(ADTHCONA) <input type="checkbox"/> N/A	(ADTHCRTE) 1-(1) Oral 2-(2) Nasal 3-(3) Smoking 4-(4) Non IV injection 5-(5) IV injection 96-(96) Not applicable 97-(97) Not answered	(ADTHCCOM) <input type="text"/>
D11 Hallucinogens:	(ADHAL30D) <input type="text"/>	(ADHALLFT) <input type="text"/>	(ADHALONS) <input type="text"/>	(ADHALONA) <input type="checkbox"/> N/A	(ADHALRTE) 1-(1) Oral 2-(2) Nasal 3-(3) Smoking 4-(4) Non IV injection 5-(5) IV injection 96-(96) Not applicable 97-(97) Not answered	(ADHALCOM) <input type="text"/>
D12 Inhalants:	(ADINH30D) <input type="text"/>	(ADINHLFT) <input type="text"/>	(ADINHONS) <input type="text"/>	(ADINHONA) <input type="checkbox"/> N/A	(ADINHRTE) 1-(1) Oral 2-(2) Nasal 3-(3) Smoking 4-(4) Non IV injection 5-(5) IV injection 96-(96) Not applicable 97-(97) Not answered	(ADINHCOM) <input type="text"/>
D36 Nicotine:	(ADNIC30D) <input type="text"/>	(ADNICLFT) <input type="text"/>	(ADNICONS) <input type="text"/>	(ADNICONA) <input type="checkbox"/> N/A	-	(ADNICCOM) <input type="text"/>
D13 More than 1 substance per day	(ADGT130D) <input type="text"/>	(ADGT1LFT) <input type="text"/>	(ADGT1ONS) <input type="text"/>	(ADGT1ONA) <input type="checkbox"/> N/A	-	(ADGT1COM) <input type="text"/>

(including alcohol, excluding nicotine):

D14 Currently, which substance is the major problem?

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

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

(ADMAJDRG)

OR

(ADMJDGNA) ☐ (97) Not answered

Comments: (ADMJDGCM)

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

- Delirium Tremens (DT's): Occur 24-48 hours after last drink or after significant decrease in alcohol intake. Characterized by shaking, severe disorientation, fever, hallucinations; they usually require medical attention. DT's are not be confused with "the shakes" which occur about 6 hours after alcohol has been withdrawn and do not include delirium.

(ADALCDT) (xx)

OR

(ADALDTNA) ☐ (97) Not answered

Comments: (ADALDTCM)

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

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

Note: D19 and D20 ask about the number of different times the participant entered into a treatment program, **not** each session or meeting. For example, if the participant entered into a treatment program and attended multiple sessions or meetings within that period of treatment, only "1" treatment should be recorded. If the participant fell out of treatment and re-entered treatment later, then "2" treatments should be recorded.

D19 Alcohol abuse:

(ADALCTRT) (xx)

OR

(ADATRTNA) ☐ (97) Not answered

Comments: (ADATRTCM)

D20 Drug abuse:

(ADDRGTRT) (xx)

OR

(ADDTRTNA) ☐ (97) Not answered

Comments: (ADDTRTCM)

How many of these were detox only:

D21 Alcohol:

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

(ADALCDTX) (xx)

OR

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

Comments: (ADADTXCM)

D22 Drugs:

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

(ADDRGDTX) (xx)

OR

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

Comments: (ADDDTXCM)

How much money would you say you spent during the past 30 days on:

Max. = \$99999

D23 Alcohol:

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

(ADALCMNY) \$ (xxxxx)

OR

(ADAMNYNA) ☐ (97) Not answered

Comments: (ADAMNYCM)

D24 Drugs:

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

(ADDRGMNY) \$ (xxxxx)

OR

(ADDMNYNA) ☐ (97) Not answered

Comments: (ADDMNYCM)

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

- Include: AA/NA

(ADOUTTRT) days

OR

(ADOTRTNA) ☐ (97) Not answered

Comments: (ADOTRTCM)

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

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

(ADALCPRB) days

OR

(ADAPRBNA) ☐ (97) Not answered

Comments: (ADAPRBCM)

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

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

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

(ADALCBOT)

OR

(ADABOTNA) ☐ (97) Not answered

Comments: (ADABOTCM)

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

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

(ADALCIMP)

OR

(ADAIMPNA) ☐ (97) Not answered

Comments: (ADAIMPCM)

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

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

(ADDRGPRB) days

OR

(ADDPRBNA) ☐ (97) Not answered

Comments: (ADDPRBCM)

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

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

(ADDRGBOT)

OR

(ADDBOTNA) ☐ (97) Not answered

Comments: (ADDBOTCM)

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

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

(ADDRGIMP)

OR

(ADDIMPNA) ☐ (97) Not answered

Comments: (ADDIMPCM)

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

D34 Participant's misrepresentation?

(ADMISREP) ☐ (0) No ☐ (1) Yes

D35 Participant's inability to understand?

(ADUNDRST) ☐ (0) No ☐ (1) Yes

Comments: (ASDCOMM)

Access to Care (ATC)

Web Version: 1.0; 1.00; 11-15-16

Segment (PROTSEG): A

Visit number (VISNO):

Date of assessment:(ATCASMDT)

 (mm/dd/yyyy)

I am going to read you some statements that ask about your access to health care within the past 6 months. Tell me if you Strongly Agree, Somewhat Agree, feel Uncertain, Somewhat Disagree, or Strongly Disagree with each statement.

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

_____	Strongly Agree	Somewhat Agree	Uncertain	Somewhat Disagree	Strongly Disagree
1. If I need hospital care, I can get admitted without trouble.	(ATADMIT) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. It is hard for me to get medical care in an emergency.	(ATERCARE) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Sometimes I go without the medical care I need because it is too expensive.	(ATEXPNSV) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. I have easy access to the medical specialists that I need.	(ATACCESS) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Places where I can get medical care are very conveniently located.	(ATLOCATN) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. I am able to get medical care whenever I need it.	(ATMDCARE) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments:(ATCCOMM)

Modified Alcohol Use Disorders Identification Test - AUDIT (AUC)

Web Version: 1.0; 1.00; 10-14-16

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

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

Read questions as written. Record answers carefully. Begin the AUDIT by saying "Now I am going to ask you some questions about your use of alcoholic beverages since your last visit." Explain what is meant by "alcoholic beverages" by using local examples of beer, wine, vodka, etc. Code answers in terms of "standard drinks".

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

0-Never
1-Less than monthly
2-Monthly
3-Weekly
4-Daily or almost daily

2. How many drinks containing alcohol do you have on a typical day when drinking?(ACNUMBER)

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

	Never	Less Than Monthly	Monthly	Weekly	Daily or Almost Daily
3. How often do you have six or more drinks on one occasion? (AC6DRINK)					
4. How often since your last visit have you found that you were unable to stop drinking once you started? (ACNOSTP)					
5. How often since your last visit have you failed to do what was normally expected of you because of drinking? (ACEXPECT)					
6. How often since your last visit have you needed a first drink in the morning to get yourself going after a heavy drinking session? (ACAMDRNK)					
7. How often since your last visit have you felt guilt or remorse after drinking? (ACGUILTY)					
8. How often since your last visit have you been unable to remember what happened the night before because of drinking? (ACREMBR)					
9. Have you or someone else been injured as a result of your drinking?(ACINJURD)	No	Yes, but not since the last visit	Yes, since the last visit		
10. Has a relative, friend, doctor, or other health worker been concerned about your drinking or suggested you cut down?(ACDONCRN)	No	Yes, but not since the last visit	Yes, since the last visit		

Total score:(ACCSCORE) (xx)

Comments:(AUCCOMM)

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Access to and Utilization of HCV Medical Care (Medical Record) (AUH)

Web Version: 1.0; 4.00; 11-15-16

Segment (PROTSEG): A

Visit number (VISNO):

Facility name (FACPRLC):

Date abstraction performed:(AHABSTD T)

 (mm/dd/yyyy)

Earliest medical record date used to complete abstraction:(AHEARLDT)

 (mm/dd/yyyy)**HCV Care Visits and HCV Testing**

RA Instruction: The following questions refer to medical records regarding HCV visits and HCV testing that occurred prior to the CTN-0064 baseline study visit and do not include tests collected as part of the CTN-0064 baseline study visit. It is understood this "baseline" abstraction may occur after the CTN-0064 baseline study visit.

1. Is there evidence the participant scheduled a hepatitis C (HCV) care visit since the last CTN-0049 study visit? (AHCVVIS) ☐ No ☐ Yes

If "Yes", indicate the following for all HCV care visits scheduled since the participant's last CTN-0049 study visit.

@2 Scheduled Visit Date	^2 Same as HIV Provider?		@2 Visit Outcome
	No	Yes	
(AHVSDT01) <input type="text"/>	(AHVSPR01) <input type="checkbox"/>	<input type="checkbox"/>	0-Participant no show 1-Participant attended appointment 2-Appointment canceled by participant 3-Appointment canceled by clinic 4-Appointment canceled, other (AHVSOC01)
(AHVSDT02) <input type="text"/>	(AHVSPR02) <input type="checkbox"/>	<input type="checkbox"/>	0-Participant no show 1-Participant attended appointment 2-Appointment canceled by participant 3-Appointment canceled by clinic 4-Appointment canceled, other (AHVSOC02)
(AHVSDT03) <input type="text"/>	(AHVSPR03) <input type="checkbox"/>	<input type="checkbox"/>	0-Participant no show 1-Participant attended appointment 2-Appointment canceled by participant 3-Appointment canceled by clinic 4-Appointment canceled, other (AHVSOC03)

(AHVSDT04) <input type="text"/>	(AHVSPR04) <input type="checkbox"/>	<input type="checkbox"/>	0-Participant no show 1-Participant attended appointment 2-Appointment canceled by participant 3-Appointment canceled by clinic 4-Appointment canceled, other (AHVOC04)
(AHVSDT05) <input type="text"/>	(AHVSPR05) <input type="checkbox"/>	<input type="checkbox"/>	0-Participant no show 1-Participant attended appointment 2-Appointment canceled by participant 3-Appointment canceled by clinic 4-Appointment canceled, other (AHVOC05)
(AHVSDT06) <input type="text"/>	(AHVSPR06) <input type="checkbox"/>	<input type="checkbox"/>	0-Participant no show 1-Participant attended appointment 2-Appointment canceled by participant 3-Appointment canceled by clinic 4-Appointment canceled, other (AHVOC06)
(AHVSDT07) <input type="text"/>	(AHVSPR07) <input type="checkbox"/>	<input type="checkbox"/>	0-Participant no show 1-Participant attended appointment 2-Appointment canceled by participant 3-Appointment canceled by clinic 4-Appointment canceled, other (AHVOC07)
(AHVSDT08) <input type="text"/>	(AHVSPR08) <input type="checkbox"/>	<input type="checkbox"/>	0-Participant no show 1-Participant attended appointment 2-Appointment canceled by participant 3-Appointment canceled by clinic 4-Appointment canceled, other (AHVOC08)
(AHVSDT09) <input type="text"/> (mm/dd/yyyy)	(AHVSPR09) <input type="checkbox"/>	<input type="checkbox"/>	0-Participant no show 1-Participant attended appointment 2-Appointment canceled by participant 3-Appointment canceled by clinic 4-Appointment canceled, other (AHVOC09)
(AHVSDT10) <input type="text"/> (mm/dd/yyyy)	(AHVSPR10) <input type="checkbox"/>	<input type="checkbox"/>	0-Participant no show 1-Participant attended appointment 2-Appointment canceled by participant 3-Appointment canceled by clinic 4-Appointment canceled, other (AHVOC10)

(AHVSDT11) <input type="text"/> (mm/dd/yyyy)	(AHVSPR11) <input type="checkbox"/>	<input type="checkbox"/>	0-Participant no show 1-Participant attended appointment 2-Appointment canceled by participant 3-Appointment canceled by clinic 4-Appointment canceled, other (AHVSOC11)
(AHVSDT12) <input type="text"/> (mm/dd/yyyy)	(AHVSPR12) <input type="checkbox"/>	<input type="checkbox"/>	0-Participant no show 1-Participant attended appointment 2-Appointment canceled by participant 3-Appointment canceled by clinic 4-Appointment canceled, other (AHVSOC12)
(AHVSDT13) <input type="text"/> (mm/dd/yyyy)	(AHVSPR13) <input type="checkbox"/>	<input type="checkbox"/>	0-Participant no show 1-Participant attended appointment 2-Appointment canceled by participant 3-Appointment canceled by clinic 4-Appointment canceled, other (AHVSOC13)
(AHVSDT14) <input type="text"/> (mm/dd/yyyy)	(AHVSPR14) <input type="checkbox"/>	<input type="checkbox"/>	0-Participant no show 1-Participant attended appointment 2-Appointment canceled by participant 3-Appointment canceled by clinic 4-Appointment canceled, other (AHVSOC14)
(AHVSDT15) <input type="text"/> (mm/dd/yyyy)	(AHVSPR15) <input type="checkbox"/>	<input type="checkbox"/>	0-Participant no show 1-Participant attended appointment 2-Appointment canceled by participant 3-Appointment canceled by clinic 4-Appointment canceled, other (AHVSOC15)
(AHVSDT16) <input type="text"/> (mm/dd/yyyy)	(AHVSPR16) <input type="checkbox"/>	<input type="checkbox"/>	0-Participant no show 1-Participant attended appointment 2-Appointment canceled by participant 3-Appointment canceled by clinic 4-Appointment canceled, other (AHVSOC16)
(AHVSDT17) <input type="text"/> (mm/dd/yyyy)	(AHVSPR17) <input type="checkbox"/>	<input type="checkbox"/>	0-Participant no show 1-Participant attended appointment 2-Appointment canceled by participant 3-Appointment canceled by clinic 4-Appointment canceled, other (AHVSOC17)

(AHVSDT18) <input type="text"/> (mm/dd/yyyy)	(AHVSPR18) <input type="checkbox"/>	<input type="checkbox"/>	0-Participant no show 1-Participant attended appointment 2-Appointment canceled by participant 3-Appointment canceled by clinic 4-Appointment canceled, other (AHVSOC18)
(AHVSDT19) <input type="text"/> (mm/dd/yyyy)	(AHVSPR19) <input type="checkbox"/>	<input type="checkbox"/>	0-Participant no show 1-Participant attended appointment 2-Appointment canceled by participant 3-Appointment canceled by clinic 4-Appointment canceled, other (AHVSOC19)
(AHVSDT20) <input type="text"/> (mm/dd/yyyy)	(AHVSPR20) <input type="checkbox"/>	<input type="checkbox"/>	0-Participant no show 1-Participant attended appointment 2-Appointment canceled by participant 3-Appointment canceled by clinic 4-Appointment canceled, other (AHVSOC20)

2. Is there evidence the participant ever had a hepatitis C (HCV) antibody test?(AHANTTST)

☐ No ☐ Yes

If "Yes", indicate the following for the most recent HCV antibody test performed.

a. Date specimen collected:(AHANTDT)

(mm/dd/yyyy)

b. HCV antibody test result:(AHANTRSL)

☐ Nonreactive ☐ Reactive ☐ Indeterminate

c. HCV antibody assay type:(AHANTASY)

d. Laboratory name and address (if different from facility name):(AHPRLC01)

3. Is there evidence the participant ever had a hepatitis C (HCV) viral load (RNA) test?(AHRNATST)

☐ No ☐ Yes

If "Yes", indicate the following for the most recent HCV viral load test performed.

a. Date specimen collected:(AHRNADT)

(mm/dd/yyyy)

b. Was HCV viral load undetectable?(AHRNAUND)

☐ No ☐ Yes

1. If "Yes", lab's lower limit:(AHRNALLC)

(xxx.x) copies/mL - or - (AHRNALLI) (xxx) IU/mL

2. If "No", HCV viral load:(AHRNAC)

(xxxxxxxxx.x) copies/mL - or - (AHRNAI) (xxxxxxxxx) IU/mL

c. HCV viral load assay type:(AHRNAASY)

d. Laboratory name and address (if different from facility name):(AHPRLC02)

4. Is there evidence the participant's hepatitis C (HCV) status was discussed with the participant since the last CTN-0049 study visit? (AHSTATUS)

0-No evidence HCV status discussed
 1-Yes, active HCV infection discussed
 2-Yes, inactive HCV infection or 'cleared' virus discussed

If "Yes", date HCV status was discussed with the participant:(AHSTATDT)

(mm/dd/yyyy)

5. Is there evidence the participant ever had a hepatitis C (HCV) genotype/subtype test? (AHGENTST) ☐ No ☐ Yes

If "Yes", indicate the following for the most recent HCV genotype/subtype test performed.

a. Date specimen collected: (AHGENDT)

(mm/dd/yyyy)

b. HCV genotype/subtype: (AHGENTYP)

1-Genotype 1
2-Genotype 1a
3-Genotype 1b
4-Genotype 2
5-Genotype 3
*Additional Options Listed Below

If "Multiple genotypes" or "Other genotype", specify: (AHGENSP)

c. Laboratory name and address (if different from facility name): (AHPRLC03)

6. Is there evidence the participant achieved a sustained virologic response (SVR) since the last CTN-0049 study visit?

☐ No ☐ Yes

This would be a clinician note specifically stating "SVR" was achieved. (AHSVR)

If "Yes", date of most recent clinician note stating "SVR" was achieved: (AHSVRDT)

(mm/dd/yyyy)

7. Is there evidence the participant's liver status was evaluated since the last CTN-0049 study visit? (AHLVREVL)

☐ No ☐ Yes

If "Yes", date of most recent clinician note indicating the participant's liver status was evaluated: (AHLEVLDT)

(mm/dd/yyyy)

PI signs off there is evidence liver status was evaluated: (AHPILIV)

☐ Yes

8. Is there evidence liver diagnostic testing was ordered since the last CTN-0049 study visit? (AHLVRORD)

☐ No ☐ Yes

a. If "Yes", most recent HCV liver summary or diagnosis: (AHLVRDX)

0-No liver disease or normal liver
1-Mild liver disease
2-Moderate liver disease
3-Advanced fibrosis
4-Decompensated liver disease
*Additional Options Listed Below

b. If "No", is there evidence the clinician deferred the liver diagnostic testing? (AHLVRDFR)

☐ No ☐ Yes

If "Yes", indicate the reason liver diagnostic testing was deferred: (AHLVRRSN)

1-Participant non-adherent to appointments
2-Participant too sick
99-Other

If "Other", specify: (AHLVRSP)

9. Is there clinician documentation that the participant was offered hepatitis C (HCV) medication(s) since the last CTN-0049 study visit?

"Offering" HCV medication(s) includes a clinician note stating the participant should be on medication, paperwork initiating a prescription or a written prescription.(AHOFRRX)

a. If "Yes, medication offered but participant declined" or "Yes, paperwork initiated or prescription written", date HCV medication most recently offered:(AHOFRDT)

b. If "No", is there evidence HCV medication was deferred?(AHOFRDFR)

If "Yes", indicate the reason HCV medication was deferred:(AHOFRRSN)

If "Other", specify:(AHOFRSP)

0-No evidence medication offered
1-Yes, medication offered but participant declined
2-Yes, paperwork initiated or prescription written

(mm/dd/yyyy)

☐ No ☐ Yes

1-Provider felt HIV care should be addressed first
2-Provider felt substance use should be addressed first
3-Provider needed to adjust ART medication first, due to drug-drug interactions
4-Provider felt liver disease was too mild
5-Participant has life-threatening illness
*Additional Options Listed Below

10. Is there clinician documentation that the participant initiated hepatitis C (HCV) medication since the last CTN-0049 study visit?(AHINTRX)

a. If "Yes", date of most recent clinician documentation that HCV medication was initiated:
(AHINTNDT)

b. If "Yes", date HCV medication most recently initiated:(AHINTDT)

c. If "No", does the pharmacy record indicate HCV medication has been dispensed since the last CTN-0049 study visit?(AHINTPHM)

1. If "Yes", date of most recent HCV prescription:(AHIPRXDT)

2. If "Yes", date HCV prescription most recently filled:(AHIPFLDT)

☐ No ☐ Yes

(mm/dd/yyyy)

(mm/dd/yyyy)

☐ No ☐ Yes

(mm/dd/yyyy)

(mm/dd/yyyy)

11. Is there clinician documentation that the participant completed a course of hepatitis C (HCV) medication since the last CTN-0049 study visit?(AHCMPRX)

a. If "Yes", date of most recent clinician documentation that course of HCV medication was completed:(AHCMPNDT)

b. If "Yes", date course of HCV medication most recently completed:(AHCMPDT)

c. If "No", is there clinician documentation that the participant did not complete a course of HCV medication since the last CTN-0049 study visit?(AHSTPRX)

1. If "Yes", date of most recent clinician documentation that course of HCV medication was not completed:(AHSTPNDT)

2. If "Yes", date participant most recently stopped taking HCV medication:(AHSTPDT)

3. If "Yes", indicate the reason HCV medication was not completed:(AHSTPRSN)

☐ No ☐ Yes

(mm/dd/yyyy)

(mm/dd/yyyy)

☐ No ☐ Yes

(mm/dd/yyyy)

(mm/dd/yyyy)

1-Participant had adverse side effect or intolerance to medication(s)
2-Participant non-adherent to medication(s)
3-Participant non-adherent to appointments
4-Participant chose to stop medication(s)
99-Other

If "Other", specify:(AHSTPSP)

d. If no clinician documentation, does the pharmacy record indicate enough medication was dispensed to meet the prescribed duration of treatment?(AHCMPPHM)

1. If "Yes", date of most recent HCV prescription:(AHCPRXDT)

2. If "Yes", date HCV prescription most recently filled:(AHCPLDT)

☐ No ☐ Yes

(mm/dd/yyyy)

(mm/dd/yyyy)

PI signs off that enough medication was dispensed and enough time passed to complete the medication: (AHPIMED)

☐ Yes

Additional Diagnoses

Indicate whether there is evidence of any of the following diagnoses since the participant's last CTN-0049 study visit.

	No	Yes
12. Acute hepatitis A:	(AHAVAACT) <input type="checkbox"/>	<input type="checkbox"/>
13. Acute hepatitis B:	(AHHBVACT) <input type="checkbox"/>	<input type="checkbox"/>
14. Acute hepatitis C:	(AHCVCVACT) <input type="checkbox"/>	<input type="checkbox"/>
15. Chronic HBV infection:	(AHHBVCHR) <input type="checkbox"/>	<input type="checkbox"/>
16. Chronic HCV infection:	(AHCVCVCHR) <input type="checkbox"/>	<input type="checkbox"/>
17. Resolved HCV infection:	(AHCVCVRSL) <input type="checkbox"/>	<input type="checkbox"/>
18. Hepatitis C related illness: <i>Hepatitis C related illnesses include Cryoglobulinemia, Non-Hodgkin's Lymphoma, Lichen planus, Leukocytoclastic vasculitis, Porphyria cutanea tarda, and glomerulonephritis.</i>	(AHCVCVILL) <input type="checkbox"/>	<input type="checkbox"/>
19. Cirrhosis:	(AHCIRRHS) <input type="checkbox"/>	<input type="checkbox"/>
20. Hepatocellular carcinoma:	(AHHEPCAR) <input type="checkbox"/>	<input type="checkbox"/>
21. Decompensated liver disease (e.g., ascites, encephalopathy):	(AHDECLVR) <input type="checkbox"/>	<input type="checkbox"/>

Comments: (AUHCOMM)

Additional Selection Options for AUH

HCV genotype/subtype:

- 6-Genotype 4
- 7-Genotype 5
- 8-Genotype 6
- 9-Multiple genotypes
- 99-Other genotype

If "Yes", most recent HCV liver summary or diagnosis:

- 99-Liver disease present, severity unspecified
- 95-Not documented

If "Yes", indicate the reason HCV medication was deferred:

- 6-Participant non-adherent to appointments
- 7-Insurance required substance use be addressed first
- 97-Reason for deferral not specified
- 99-Other

Access to and Utilization of HCV Liver Testing (Medical Record) (AUL)

Web Version: 1.0; 1.02; 10-14-16

Segment (PROTSEG): A

Visit number (VISNO):

Date abstraction performed: (ALABSTDT)

 (mm/dd/yyyy)

RA Instruction: The following questions refer to medical records regarding liver diagnostic testing that occurred prior to the CTN-0064 baseline study visit. It is understood this "baseline" abstraction may occur after the CTN-0064 baseline study visit.

If there is evidence in the medical record that liver diagnostic testing was ordered since the participant's last CTN-0049 study visit, indicate whether the liver diagnostic testing included the following tests or procedures. For each evaluation performed since the last CTN-0049 study visit, enter the date and facility information. If there is evidence a test or procedure was repeated, enter the date and facility information for the most recent evaluation.

@2Liver Evaluation	^2Evaluation Ordered		^2Evaluation Performed		@2Date of Most Recent Evaluation	@2Facility Name and Address
	No	Yes	No	Yes		
1. Liver fibroscan:	(ALFIBORD) <input type="checkbox"/>	<input type="checkbox"/>	(ALFIBPRF) <input type="checkbox"/>	<input type="checkbox"/>	(ALFIBDT) <input type="text"/>	(ALPRLC01) <input type="text"/>
2. Seromarker with score: (e.g., FibroSURE, APRI, Fib4, FIBROSpect II)	(ALSERORD) <input type="checkbox"/>	<input type="checkbox"/>	(ALSERPRF) <input type="checkbox"/>	<input type="checkbox"/>	(ALSERDT) <input type="text"/>	(ALPRLC02) <input type="text"/>
3. Liver sonogram:	(ALSONORD) <input type="checkbox"/>	<input type="checkbox"/>	(ALSONPRF) <input type="checkbox"/>	<input type="checkbox"/>	(ALSONDT) <input type="text"/>	(ALPRLC03) <input type="text"/>
4. Liver CT scan or MRI:	(ALSCNORD) <input type="checkbox"/>	<input type="checkbox"/>	(ALSCNPRF) <input type="checkbox"/>	<input type="checkbox"/>	(ALSCNDT) <input type="text"/>	(ALPRLC04) <input type="text"/>
5. Liver biopsy:	(ALBIOORD) <input type="checkbox"/>	<input type="checkbox"/>	(ALBIOPRF) <input type="checkbox"/>	<input type="checkbox"/>	(ALBIODT) <input type="text"/>	(ALPRLC05) <input type="text"/>

6. If "Liver fibroscan" was performed, indicate the result: (ALFIBSC)

 (xx.x) kPa

7. If "Seromarker with score" was performed, indicate the seromarker test(s) performed and the associated score(s).

If FibroSURE test was performed, indicate both the fibrosis and necroinflammatory activity scores.

	No	Yes	Score	Fibrosis Score	Necroinflammatory Activity Score
a. FibroSURE:	(ALFSURE)	<input type="checkbox"/>	N/A	(ALSURFSC)	(ALSURNSC)
	<input type="checkbox"/>				

0-F0: No fibrosis
 1-F0-F1
 2-F1: Portal fibrosis
 3-F1-F2
 4-F2: Bridging fibrosis, few septa
 *Additional Options Listed Below

0-A0: No activity
 1-A0-A1
 2-A1: Minimal activity
 3-A1-A2
 4-A2: Moderate activity
 *Additional Options Listed Below

b. APRI:	(ALAPRI) <input type="checkbox"/> <input type="checkbox"/>	(ALAPRISC) <input type="text"/>
		(xxx.xx)
c. Fib4:	(ALFIB4) <input type="checkbox"/> <input type="checkbox"/>	(ALFIB4SC) <input type="text"/>
		(xxx.xx)
d. FIBROSpect II:	(ALFSPCT) <input type="checkbox"/> <input type="checkbox"/>	(ALSPCTSC) <input type="text"/>
		(xxx)
e. Other seromarker test, specify:(ALSEROSP)	(ALSEROT) <input type="checkbox"/> <input type="checkbox"/>	(ALSEROSC) <input type="text"/>
<input type="text"/>		(xxx.xx)

8. If "Liver sonogram" was performed, indicate the results below.

	No	Yes
a. Normal liver:	(ALSONNRM) <input type="checkbox"/>	<input type="checkbox"/>
b. Hepatomegaly:	(ALSONHPM) <input type="checkbox"/>	<input type="checkbox"/>
c. Fatty liver:	(ALSONFAT) <input type="checkbox"/>	<input type="checkbox"/>
d. Nodular contour:	(ALSONCON) <input type="checkbox"/>	<input type="checkbox"/>
e. Cirrhosis:	(ALSONCIR) <input type="checkbox"/>	<input type="checkbox"/>
f. Splenomegaly:	(ALSONSPL) <input type="checkbox"/>	<input type="checkbox"/>
g. Hepatic cyst:	(ALSONCYS) <input type="checkbox"/>	<input type="checkbox"/>
h. Hepatic nodule or lesion needing further evaluation:	(ALSONNOD) <input type="checkbox"/>	<input type="checkbox"/>
i. Ascites:	(ALSONASC) <input type="checkbox"/>	<input type="checkbox"/>
j. Other, specify:(ALSONOSP) <input type="text"/>	(ALSONOTH) <input type="checkbox"/>	<input type="checkbox"/>

9. If "Liver CT scan or MRI" was performed, indicate the results below.

	No	Yes
a. Normal liver:	(ALSCNNRM) <input type="checkbox"/>	<input type="checkbox"/>
b. Evidence of hepatocellular cancer:	(ALSCNCNC) <input type="checkbox"/>	<input type="checkbox"/>
c. Hepatomegaly:	(ALSCNHPM) <input type="checkbox"/>	<input type="checkbox"/>
d. Hepatic cyst:	(ALSCNCYS) <input type="checkbox"/>	<input type="checkbox"/>
e. Cirrhosis:	(ALSCNCIR) <input type="checkbox"/>	<input type="checkbox"/>

- f. Ascites: (ALSCNASC) ☐ ☐
- g. Splenomegaly: (ALSCNSPL) ☐ ☐
- h. Other, specify: (ALSCNOSP) (ALSCNOTH) ☐ ☐

10. If "Liver biopsy" was performed, indicate the results below.

a. Type of grade (activity) score:

(ALBIOGRD)

1-METAVIR grade score
2-Batts-Ludwig grade score

METAVIR grade score:

(ALBIOMTG)

0-A0 (None)
1-A1 (Mild)
2-A2 (Moderate)
3-A3 (Severe)
94-Uninterpretable
*Additional Options Listed Below

Batts-Ludwig grade score:

(ALBIOBLG)

0-(0) None
1-(1) Minimal
2-(2) Mild
3-(3) Moderate
4-(4) Severe
*Additional Options Listed Below

b. Steatosis (fat):

(ALBIOSTF)

0-<5% of hepatocytes affected
1-5-33% of hepatocytes affected
2-34-66% of hepatocytes affected
3-67-100% of hepatocytes affected
94-Uninterpretable
*Additional Options Listed Below

c. Steatohepatitis:

(ALBIOSTH)

0-Absent
1-Present
94-Uninterpretable
95-Not documented

d. Pericentral fibrosis:

(ALBIOPER)

0-Absent
1-Present, delicate perisinusoidal fibrosis
2-Present, dense perisinusoidal fibrosis
94-Uninterpretable
95-Not documented

e. Type of fibrosis score:

(ALBIOFIB)

1-METAVIR fibrosis score
2-Ishak fibrosis score
3-Batts-Ludwig fibrosis score
99-Other fibrosis scoring system

METAVIR fibrosis score:

- 0-(0) No fibrosis
- 1-(1) Portal fibrosis without septa
- 2-(2) Portal fibrosis with rare speta
- 3-(3) Numerous septa without cirrhosis
- 4-(4) Cirrhosis
- *Additional Options Listed Below

(ALBIOMTF)

Ishak fibrosis score:

- 0-(0) No fibrosis
- 1-(1) Fibrous expansion of some portal areas, with or without short fibrous septa
- 2-(2) Fibrous expansion of most portal areas, with or without short fibrous septa
- 3-(3) Fibrous expansion of most portal areas, with occasional portal-to-portal bridging
- 4-(4) Fibrous expansion of portal areas with marked bridging as well as portal-central
- *Additional Options Listed Below

(ALBIOISF)

Batts-Ludwig fibrosis score:

- 0-(0) No fibrosis
- 1-(1) Portal fibrosis
- 2-(2) Periportal fibrosis (periportal or rare P-P septa)
- 3-(3) Septal fibrosis (fibrous septa with architectural distortion but no obvious cirrhosis)
- 4-(4) Cirrhosis
- *Additional Options Listed Below

(ALBIOBLF)

Other fibrosis score, specify: (ALBIOOSP)

(ALBIOOSC)

f. Additional liver biopsy comments:

(ALBIOCOM)

Comments: (AULCOMM)

Additional Selection Options for AUL

- FibroSURE fibrosis score
 - 5-F2-F3
 - 6-F3: Bridging fibrosis, many septa
 - 7-F3-F4
 - 8-F4: Cirrhosis
- FibroSURE necroinflm scro
 - 5-A2-A3
 - 6-A3: Severe activity
- Biopsy METAVIR grade
 - 95-Not documented
- Biopsy Batts-Lud grade
 - 94-Uninterpretable
 - 95-Not documented
- Biopsy steatosis (fat)
 - 95-Not documented
- Biopsy METAVIR fibrosis
 - 94-Uninterpretable
 - 95-Not documented
- Biopsy Ishak fibrosis
 - 5-(5) Marked bridging with occasional nodules (incomplete cirrhosis)
 - 6-(6) Cirrhosis, probable or definite
 - 94-Uninterpretable
 - 95-Not documented
- Biopsy Batts-Lud fibrosis
 - 94-Uninterpretable
 - 95-Not documented

Access to and Utilization of HIV Medical Care (Medical Record) (AUM)

Web Version: 1.0; 5.00; 02-28-17

Segment (PROTSEG): A
Visit number (VISNO):
Facility name (FACPLC):

Date abstraction performed: (AMABSTDY) (mm/dd/yyyy)
Earliest medical record date used to complete abstraction: (AMEARLDY) (mm/dd/yyyy)

HIV Care Visits and HIV Testing
RA Instruction: The following questions refer to medical records regarding HIV visits and HIV testing that occurred prior to the CTN-0064 baseline study visit and do not include tests collected as part of the CTN-0064 baseline study visit. It is understood this "baseline" abstraction may occur after the CTN-0064 baseline study visit.

1. Is there evidence the participant's scheduled an HIV care visit since the last CTN-0049 study visit? (AMHVVVS) ☐ No ☐ Yes

If "Yes", indicate the dates and outcomes for all HIV care visits scheduled since the participant's last CTN-0049 study visit.

Scheduled Visit Date	Visit Outcome
(AMVSDT01) <input type="text"/>	<div>0-Participant no show 1-Participant attended appointment 2-Appointment canceled by participant 3-Appointment canceled by clinic 4-Appointment canceled, other</div> <div>(AMVSOC01)</div>
(AMVSDT02) <input type="text"/>	<div>0-Participant no show 1-Participant attended appointment 2-Appointment canceled by participant 3-Appointment canceled by clinic 4-Appointment canceled, other</div> <div>(AMVSOC02)</div>
(AMVSDT03) <input type="text"/>	<div>0-Participant no show 1-Participant attended appointment 2-Appointment canceled by participant 3-Appointment canceled by clinic 4-Appointment canceled, other</div> <div>(AMVSOC03)</div>
(AMVSDT04) <input type="text"/>	<div>0-Participant no show 1-Participant attended appointment 2-Appointment canceled by participant 3-Appointment canceled by clinic 4-Appointment canceled, other</div> <div>(AMVSOC04)</div>
(AMVSDT05) <input type="text"/>	<div>0-Participant no show 1-Participant attended appointment 2-Appointment canceled by participant 3-Appointment canceled by clinic 4-Appointment canceled, other</div> <div>(AMVSOC05)</div>
(AMVSDT06) <input type="text"/>	<div>0-Participant no show 1-Participant attended appointment 2-Appointment canceled by participant 3-Appointment canceled by clinic 4-Appointment canceled, other</div> <div>(AMVSOC06)</div>
(AMVSDT07) <input type="text"/>	<div>0-Participant no show 1-Participant attended appointment 2-Appointment canceled by participant 3-Appointment canceled by clinic 4-Appointment canceled, other</div> <div>(AMVSOC07)</div>

(AMVSDT08) <input type="text"/>	(AMVSOC08)	0-Participant no show 1-Participant attended appointment 2-Appointment canceled by participant 3-Appointment canceled by clinic 4-Appointment canceled, other
(AMVSDT09) <input type="text"/>	(AMVSOC09)	0-Participant no show 1-Participant attended appointment 2-Appointment canceled by participant 3-Appointment canceled by clinic 4-Appointment canceled, other
(AMVSDT10) <input type="text"/>	(AMVSOC10)	0-Participant no show 1-Participant attended appointment 2-Appointment canceled by participant 3-Appointment canceled by clinic 4-Appointment canceled, other
(AMVSDT11) <input type="text"/>	(AMVSOC11)	0-Participant no show 1-Participant attended appointment 2-Appointment canceled by participant 3-Appointment canceled by clinic 4-Appointment canceled, other
(AMVSDT12) <input type="text"/>	(AMVSOC12)	0-Participant no show 1-Participant attended appointment 2-Appointment canceled by participant 3-Appointment canceled by clinic 4-Appointment canceled, other
(AMVSDT13) <input type="text"/> (m m d d/yyyy)	(AMVSOC13)	0-Participant no show 1-Participant attended appointment 2-Appointment canceled by participant 3-Appointment canceled by clinic 4-Appointment canceled, other
(AMVSDT14) <input type="text"/> (m m d d/yyyy)	(AMVSOC14)	0-Participant no show 1-Participant attended appointment 2-Appointment canceled by participant 3-Appointment canceled by clinic 4-Appointment canceled, other
(AMVSDT15) <input type="text"/> (m m d d/yyyy)	(AMVSOC15)	0-Participant no show 1-Participant attended appointment 2-Appointment canceled by participant 3-Appointment canceled by clinic 4-Appointment canceled, other
(AMVSDT16) <input type="text"/> (m m d d/yyyy)	(AMVSOC16)	0-Participant no show 1-Participant attended appointment 2-Appointment canceled by participant 3-Appointment canceled by clinic 4-Appointment canceled, other
(AMVSDT17) <input type="text"/> (m m d d/yyyy)	(AMVSOC17)	0-Participant no show 1-Participant attended appointment 2-Appointment canceled by participant 3-Appointment canceled by clinic 4-Appointment canceled, other
(AMVSDT18) <input type="text"/> (m m d d/yyyy)	(AMVSOC18)	0-Participant no show 1-Participant attended appointment 2-Appointment canceled by participant 3-Appointment canceled by clinic 4-Appointment canceled, other

2. Is there evidence the participant had a CD4 count test and/or HIV viral load test since the last CTN-0049 study visit? (AMHVTST)

☐ No ☐ Yes

If "Yes", indicate the dates and results of all CD4 count tests and all HIV viral load tests performed since the participants last CTN-0049 study visit.

@2Date Specimen Collected	@2Laboratory Name and Address (If Different from Facility Name)	@2HIV Test(s) Performed	@2CD4 Count (cells/μL)	@2CD4 Percent (%)	@2HIV Viral Load Undetectable?	@2# "Undetectable", Lab's Lower Limit (copies/mL)	@2# "Detectable", HIV Viral Load (copies/mL)	@2HIV Viral Load Assay Type
					No	Yes		
(AMTSDT01)	(AMPRLC01)	(AMTST01) 1-CD4 count 2-HIV viral load 3-Both	(AMCD4C01)	(AMCD4P01)	(AMVLUN01)	<input type="checkbox"/>	(AMVLLW01) <	(AMVL01)
(AMTSDT02)	(AMPRLC02)	(AMTST02) 1-CD4 count 2-HIV viral load 3-Both	(AMCD4C02)	(AMCD4P02)	(AMVLUN02)	<input type="checkbox"/>	(AMVLLW02) <	(AMVL02)
(AMTSDT03)	(AMPRLC03)	(AMTST03) 1-CD4 count 2-HIV viral load 3-Both	(AMCD4C03)	(AMCD4P03)	(AMVLUN03)	<input type="checkbox"/>	(AMVLLW03) <	(AMVL03)
(AMTSDT04)	(AMPRLC04)	(AMTST04) 1-CD4 count 2-HIV viral load 3-Both	(AMCD4C04)	(AMCD4P04)	(AMVLUN04)	<input type="checkbox"/>	(AMVLLW04) <	(AMVL04)
(AMTSDT05)	(AMPRLC05)	(AMTST05) 1-CD4 count 2-HIV viral load 3-Both	(AMCD4C05)	(AMCD4P05)	(AMVLUN05)	<input type="checkbox"/>	(AMVLLW05) <	(AMVL05)
(AMTSDT06)	(AMPRLC06)	(AMTST06) 1-CD4 count 2-HIV viral load 3-Both	(AMCD4C06)	(AMCD4P06)	(AMVLUN06)	<input type="checkbox"/>	(AMVLLW06) <	(AMVL06)
(AMTSDT07)	(AMPRLC07)	(AMTST07) 1-CD4 count 2-HIV viral load 3-Both	(AMCD4C07)	(AMCD4P07)	(AMVLUN07)	<input type="checkbox"/>	(AMVLLW07) <	(AMVL07)
(AMTSDT08)	(AMPRLC08)	(AMTST08) 1-CD4 count 2-HIV viral load 3-Both	(AMCD4C08)	(AMCD4P08)	(AMVLUN08)	<input type="checkbox"/>	(AMVLLW08) <	(AMVL08)
(AMTSDT09)	(AMPRLC09)	(AMTST09) 1-CD4 count 2-HIV viral load 3-Both	(AMCD4C09)	(AMCD4P09)	(AMVLUN09)	<input type="checkbox"/>	(AMVLLW09) <	(AMVL09)
(AMTSDT10)	(AMPRLC10)	(AMTST10) 1-CD4 count 2-HIV viral load 3-Both	(AMCD4C10)	(AMCD4P10)	(AMVLUN10)	<input type="checkbox"/>	(AMVLLW10) <	(AMVL10)
(AMTSDT11)	(AMPRLC11)	(AMTST11) 1-CD4 count 2-HIV viral load 3-Both	(AMCD4C11)	(AMCD4P11)	(AMVLUN11)	<input type="checkbox"/>	(AMVLLW11) <	(AMVL11)
(AMTSDT12)	(AMPRLC12)	(AMTST12) 1-CD4 count 2-HIV viral load 3-Both	(AMCD4C12)	(AMCD4P12)	(AMVLUN12)	<input type="checkbox"/>	(AMVLLW12) <	(AMVL12)

3. Is there evidence the HIV provider referred the participant for hepatitis C (HCV) care since the last CTN-0049 study visit? (AMHCVRR)

If "No", is there evidence the HCV referral was deferred? (AMHCVDFR)

☐ No ☐ Yes

☐ No ☐ Yes

If "Yes", indicate the reason the HCV referral was deferred:

No Yes

Provider felt HIV care should be addressed first:

(AMDFRHV) ☐ ☐

Provider felt substance use should be addressed first:

(AMDFRSUB) ☐ ☐

Participant was non-adherent to appointments:

(AMDFRAPT) ☐ ☐

Participant did not have sufficient insurance and/or funding:

(AMDFRINS) ☐ ☐

Other, specify (AMDFROSP)

(AMDFROTH) ☐ ☐

Additional Diagnoses

Indicate whether there is evidence of any of the following diagnoses since the participant's last CTN-0049 study visit.

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

☐ No ☐ Yes

5. Diabetes: (AMDIABET)

☐ No ☐ Yes

6. Reduced kidney function, as evidenced by dialysis: (AMKIDNEY)

☐ No ☐ Yes

Number of times/week participant receives dialysis: (AMDIALYS)

(x) times/week

Individual Serum Tests

Indicate whether any of the following serum tests were performed since the participant's last CTN-0049 study visit. For each serum test that was performed, record the most recent date and result.

	No	Yes	Result	Date Specimen Collected
7. Hemoglobin:	(AMHGB) <input type="checkbox"/>	<input type="checkbox"/>	(AMHGBRS) <input type="text"/> (xx.x) g/dL	(AMHGBDT) <input type="text"/>
8. Hematocrit:	(AMHCT) <input type="checkbox"/>	<input type="checkbox"/>	(AMHCTRS) <input type="text"/> (xx.x) %	(AMHCTDT) <input type="text"/>
9. WBC:	(AMWBC) <input type="checkbox"/>	<input type="checkbox"/>	(AMWBCRS) <input type="text"/> (xx.x) k/ μ L	(AMWBCDT) <input type="text"/>
10. Platelets:	(AMPLT) <input type="checkbox"/>	<input type="checkbox"/>	(AMPLTRS) <input type="text"/> (xxxx) k/ μ L	(AMPLTDT) <input type="text"/>
11. SGOT (AST):	(AMAST) <input type="checkbox"/>	<input type="checkbox"/>	(AMASTRS) <input type="text"/> (xxxx.x) IU/L	(AMASTDT) <input type="text"/>
12. SGPT (ALT):	(AMALT) <input type="checkbox"/>	<input type="checkbox"/>	(AMALTRS) <input type="text"/> (xxxx.x) IU/L	(AMALDT) <input type="text"/>
13. Alkaline phosphatase:	(AMALP) <input type="checkbox"/>	<input type="checkbox"/>	(AMALPRS) <input type="text"/> (xxxx.x) IU/L	(AMALPDT) <input type="text"/>
14. Albumin:	(AMALB) <input type="checkbox"/>	<input type="checkbox"/>	(AMALBRS) <input type="text"/> (x.x) g/dL	(AMALBDT) <input type="text"/>
15. BUN:	(AMBUN) <input type="checkbox"/>	<input type="checkbox"/>	(AMBUNRS) <input type="text"/> (xxx.x) mg/dL	(AMBUNDT) <input type="text"/>
16. Creatinine:	(AMCRTN) <input type="checkbox"/>	<input type="checkbox"/>	(AMCRTNRS) <input type="text"/> (xx.xx) mg/dL	(AMCRTNDT) <input type="text"/>
17. eGFR:	(AMEGFR) <input type="checkbox"/>	<input type="checkbox"/>	(AMEGFRRS) <input type="text"/> (xxx.x) mL/min	(AMEGFRDT) <input type="text"/>
18. Total bilirubin:	(AMTBIL) <input type="checkbox"/>	<input type="checkbox"/>	(AMTBILRS) <input type="text"/> (xx.x) mg/dL	(AMTBILDT) <input type="text"/>
19. Direct bilirubin:	(AMDBIL) <input type="checkbox"/>	<input type="checkbox"/>	(AMDBILRS) <input type="text"/> (xx.x) mg/dL	(AMDBILDT) <input type="text"/>
20. INR for prothrombin time (PT):	(AMINR) <input type="checkbox"/>	<input type="checkbox"/>	(AMINRRS) <input type="text"/> (xx.xx)	(AMINRDT) <input type="text"/>
21. Total protein:	(AMTPRO) <input type="checkbox"/>	<input type="checkbox"/>	(AMTPRORS) <input type="text"/> (xx.x) g/dL	(AMTPRODT) <input type="text"/>

Viral Hepatitis Tests and Vaccinations

Indicate whether there is evidence of any of the following viral hepatitis tests. For each test that was performed, record the most recent date and result.

@2	@2No	@2Yes	@2Result		@2Date Specimen Collected
			No re active	Re active	
22. Total antibody to hepatitis A virus (total anti-HAV):	(AMAHAV) <input type="checkbox"/>	<input type="checkbox"/>	(AMAHAVRS) <input type="checkbox"/>	<input type="checkbox"/>	(AMAHAVDT) <input type="text"/>
23. Hepatitis B surface antigen (HBsAg):	(AMHBSAG) <input type="checkbox"/>	<input type="checkbox"/>	(AMHBSARS) <input type="checkbox"/>	<input type="checkbox"/>	(AMHBSADT) <input type="text"/>
24. Hepatitis B surface antibody (anti-HBs):	(AMAHBS) <input type="checkbox"/>	<input type="checkbox"/>	(AMAHBSRS) <input type="checkbox"/>	<input type="checkbox"/>	(AMAHBSDT) <input type="text"/>
25. Total antibody to hepatitis B core antigen (total anti-HBc):	(AMAHBC) <input type="checkbox"/>	<input type="checkbox"/>	(AMAHBCRS) <input type="checkbox"/>	<input type="checkbox"/>	(AMAHBCDT) <input type="text"/>
26. Total antibody to hepatitis D virus (total anti-HDV):	(AMAHDV) <input type="checkbox"/>	<input type="checkbox"/>	(AMAHDVRS) <input type="checkbox"/>	<input type="checkbox"/>	(AMAHDVDT) <input type="text"/>

Indicate whether there is evidence of any of the following hepatitis vaccinations.

	No	Yes	Vaccination Date 1	Vaccination Date 2	Vaccination Date 3
27. Hepatitis A vaccination series:	(AMHAVVAC) <input type="checkbox"/>	<input type="checkbox"/>	(AMHAVDT1) <input type="text"/>	(AMHAVDT2) <input type="text"/>	N/A
28. Hepatitis B vaccination series:	(AMHBVVAC) <input type="checkbox"/>	<input type="checkbox"/>	(AMHBVDT1) <input type="text"/>	(AMHBVDT2) <input type="text"/>	(AMHBVDT3) <input type="text"/>

Comments:(AUMCOMM)

NIDA Clinical Trials Network

Access to and Utilization of Medical Care (Self Report) (AUS)

Web Version: 1.0; 3.01; 02-28-17

Segment (PROTSEG): A

Visit number (VISNO):

RA Instruction: This is a participant self report form and should reflect only the information provided by the participant.

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

The following questions ask for dates of medical care visits, tests, and diagnoses. If the participant is unable to recall the exact date, an estimated date should be recorded using the "Mid-month", "Mid-year", and "Mid-decade" convention.

- If the exact day is unknown, default to the middle of the month = 15 (e.g., mm/15/yyyy)
- If the month and day are unknown, default to the middle of year and month = 06/15 (e.g., 06/15/yyyy)
- If the year is unknown, default to the middle of the decade (e.g., "90s" = 1995 = 06/15/1995)

1. Indicate all the facilities in which you have received health care since your last CTN-0049 study visit.

Facility Name and Address	Obtained MR Release	
	No	Yes
a. (ASPRLC01) <input type="text"/>	(ASFCMR01) <input type="checkbox"/>	<input type="checkbox"/>
b. (ASPRLC02) <input type="text"/>	(ASFCMR02) <input type="checkbox"/>	<input type="checkbox"/>
c. (ASPRLC03) <input type="text"/>	(ASFCMR03) <input type="checkbox"/>	<input type="checkbox"/>
d. (ASPRLC04) <input type="text"/>	(ASFCMR04) <input type="checkbox"/>	<input type="checkbox"/>
e. (ASPRLC05) <input type="text"/>	(ASFCMR05) <input type="checkbox"/>	<input type="checkbox"/>
f. (ASPRLC06) <input type="text"/>	(ASFCMR06) <input type="checkbox"/>	<input type="checkbox"/>

HIV Care

2. Since your last CTN-0049 study visit, have you attended an HIV care visit?

By "HIV care visit", we mean a visit to a clinic/office or a doctor or other provider who works with you to manage your HIV/AIDS medications, blood test results, T-cell count, and/or HIV viral load. (ASHIVVIS)

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

a. If "Yes", when was your most recent HIV care visit? (ASHVLST)

1-Less than 6 months ago
2-More than 6 months but less than 12 months ago
3-More than 12 months ago
97-Don't know
98-Refused to answer

If you reported attending HIV care visits since your last CTN-0049 study visit or if you answered "Don't know" or "Refused to answer", answer the following item.

b. Indicate the locations of all HIV care visits attended since your last CTN-0049 study visit.

Facility Name and Address	Obtained MR Release	
	No	Yes
1.(ASPRLC07) <input type="text"/>	(ASHIVMR1) <input type="checkbox"/>	<input type="checkbox"/>
2.(ASPRLC08) <input type="text"/>	(ASHIVMR2) <input type="checkbox"/>	<input type="checkbox"/>
3.(ASPRLC09) <input type="text"/>	(ASHIVMR3) <input type="checkbox"/>	<input type="checkbox"/>
4.(ASPRLC10) <input type="text"/>	(ASHIVMR4) <input type="checkbox"/>	<input type="checkbox"/>
5.(ASPRLC11) <input type="text"/>	(ASHIVMR5) <input type="checkbox"/>	<input type="checkbox"/>
6.(ASPRLC12) <input type="text"/>	(ASHIVMR6) <input type="checkbox"/>	<input type="checkbox"/>

3. Since your last CTN-0049 study visit, have you had an HIV viral load test and/or CD4 count test? (ASHIVTST)

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

a. If "Yes", when was your most recent HIV viral load and/or CD4 count test performed? (ASHITLST)

1-Less than 6 months ago
2-More than 6 months but less than 12 months ago
3-More than 12 months ago
97-Don't know
98-Refused to answer

If you reported having HIV viral load tests and/or CD4 count tests since your last CTN-0049 study visit or if you answered "Don't know" or "Refused to answer", answer the following item.

b. Indicate the locations of all HIV viral load tests and/or CD4 count tests performed since your last CTN-0049 study visit.

Facility Name and Address	HIV Tests Performed	Obtained MR Release	
		No	Yes
1.(ASPRLC13) <input type="text"/>	(ASHITST1) 1-CD4 count 2-HIV viral load 3-Both 97-Don't know 98-Refused to answer	(ASHITMR1) <input type="checkbox"/>	<input type="checkbox"/>
2.(ASPRLC14) <input type="text"/>	(ASHITST2) 1-CD4 count 2-HIV viral load 3-Both 97-Don't know 98-Refused to answer	(ASHITMR2) <input type="checkbox"/>	<input type="checkbox"/>
3.(ASPRLC15) <input type="text"/>	(ASHITST3) 1-CD4 count 2-HIV viral load 3-Both 97-Don't know 98-Refused to answer	(ASHITMR3) <input type="checkbox"/>	<input type="checkbox"/>
4.(ASPRLC16) <input type="text"/>	(ASHITST4) 1-CD4 count 2-HIV viral load 3-Both 97-Don't know 98-Refused to answer	(ASHITMR4) <input type="checkbox"/>	<input type="checkbox"/>
5.(ASPRLC17) <input type="text"/>	(ASHITST5) 1-CD4 count 2-HIV viral load 3-Both 97-Don't know 98-Refused to answer	(ASHITMR5) <input type="checkbox"/>	<input type="checkbox"/>
6.(ASPRLC18) <input type="text"/>	(ASHITST6) 1-CD4 count 2-HIV viral load 3-Both 97-Don't know 98-Refused to answer	(ASHITMR6) <input type="checkbox"/>	<input type="checkbox"/>

HCV Care

4. Are you currently enrolled in a hepatitis C (HCV) related study?(ASSTUDY)

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

a. If "Yes", in what type of HCV study are you enrolled?(ASSTYTP)

1-HCV medication study or trial
2-Behavioral study (e.g., case management, patient navigation, support group)
97-Don't know
98-Refused to answer
99-Other

If "Other", specify:(ASSTYSP)

b. If "Yes", name of HCV study:(ASSTYNAM)

- or - (ASSTYNDK) ☐ Don't know

5. Have you ever been tested for hepatitis C (HCV)?

This could have been done via a finger stick, a blood test or a liver test. Do not include testing performed as part of the CTN-0064 baseline study visit.(ASHCVTST)

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

If "Yes", you have been tested for HCV, answer sub-questions "a" and "b".

a. Did you ever receive the results? (ASHCTRCV)

0-No, I did not receive the results
1-Yes, the results were negative
2-Yes, the results were positive
3-Yes, but I did not understand the results
4-Yes, but I do not know the results

b. Where were you most recently tested?(ASHCTLOC)

1-Needle exchange program
2-HIV/AIDS street outreach program or mobile unit
3-Adult HIV/AIDS specialty clinic
4-Sexually transmitted disease (STD) clinic
5-Community health center/public health clinic
*Additional Options Listed Below

If "Other", specify:(ASHCTLSP)

If "No", you have not been tested for HCV, if you "Don't know" if you have been tested for HCV, or if you "Refused to answer", answer sub-question "c".

c. Have you ever been told you were positive for HCV?(ASHCVTLD)

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

If "Yes", you have been tested for HCV, or "Yes", you have been told you were positive for HCV, answer sub-questions "d" and "e".

d. Have you ever been told you had "active" HCV or an active infection?(ASHCVACT)

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

e. Indicate the dates and locations of your two most recent HCV tests.

Date of Test	Facility Name and Address	Obtained MR Release	
		No	Yes
1.(ASHCTDT1) <input type="text"/>	(ASPRLC19) <input type="text"/>	(ASHCTMR1) <input type="checkbox"/>	<input type="checkbox"/>
2.(ASHCTDT2) <input type="text"/>	(ASPRLC20) <input type="text"/>	(ASHCTMR2) <input type="checkbox"/>	<input type="checkbox"/>

6. Have you ever been told you cleared the hepatitis C (HCV) virus from your blood?(ASHCVCLR)

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

a. If "Yes", have you been told you ever cleared the HCV virus since your last CTN-0049 study visit?
(ASCLRLST)

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

If you were told you ever cleared the HCV virus since your last CTN-0049 study visit, indicate the following for the most recent time you were told.

b. Facility name and address:(ASPRLC21)

c. RA obtained medical record release:(ASCLRMR)

- ☐ No ☐ Yes

7. Have you ever seen a specialist or other provider for hepatitis C (HCV) care?

By "specialist or other provider for hepatitis C (HCV) care", we mean a visit to a clinic/office or a doctor or other provider who works with you to take care of your HCV by managing your HCV medications and blood tests and/or by recommending you get further evaluation (e.g., liver biopsy, seromarkers, fibroscan).(ASHCVVIS)

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

If "Yes", answer the following questions regarding your HCV care visits.

a. Is your HCV provider the same provider who takes care of your HIV?(ASHCVPRO)

- ☐ No ☐ Yes

b. When was your most recent HCV care visit?(ASHCVLST)

- 1-Less than 6 months ago
2-More than 6 months but less than 12 months ago
3-More than 12 months ago
97-Don't know
98-Refused to answer

If you have seen a specialist or other provider for HCV care since your last CTN-0049 visit, answer the following.

c. Indicate the locations of all HCV care visits attended since your last CTN-0049 study visit.

Facility Name and Address	Obtained MR Release
<input type="text"/>	<input type="checkbox"/>

	No	Yes
1. (ASPRLC23) <input type="text"/>	(ASHCVMR1) <input type="checkbox"/>	<input type="checkbox"/>
2. (ASPRLC24) <input type="text"/>	(ASHCVMR2) <input type="checkbox"/>	<input type="checkbox"/>
3. (ASPRLC25) <input type="text"/>	(ASHCVMR3) <input type="checkbox"/>	<input type="checkbox"/>
4. (ASPRLC26) <input type="text"/>	(ASHCVMR4) <input type="checkbox"/>	<input type="checkbox"/>

8. Have you ever had a hepatitis C (HCV) medical or liver evaluation?

"HCV medical or liver evaluation" means you were seen by a liver specialist or another clinician to see how HCV might have affected your liver and to see if you should receive treatment for HCV.(ASHCVLVR)

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

If "Yes", indicate whether you had any of the following HCV liver consultation visits, tests or procedures. If any of the visits, tests or procedures were repeated, provide information for the most recent visit, test or procedure.

Liver Evaluation	Evaluation Performed		Since Last CTN-0049 Study Visit?		Facility Name and Address	Obtained MR Release	
	No	Yes	No	Yes		No	Yes
a. Initial consultation visit:	(ASLVRCNS) <input type="checkbox"/>	<input type="checkbox"/>	(ASCNSLST) <input type="checkbox"/>	<input type="checkbox"/>	(ASPRLC27) <input type="text"/>	(ASCNSMR) <input type="checkbox"/>	<input type="checkbox"/>
b. Liver fibroscan:	(ASLVRFIB) <input type="checkbox"/>	<input type="checkbox"/>	(ASFIBLST) <input type="checkbox"/>	<input type="checkbox"/>	(ASPRLC28) <input type="text"/>	(ASFIBMR) <input type="checkbox"/>	<input type="checkbox"/>
c. Liver blood test:	(ASLVRLD) <input type="checkbox"/>	<input type="checkbox"/>	(ASBLDLST) <input type="checkbox"/>	<input type="checkbox"/>	(ASPRLC29) <input type="text"/>	(ASBLDMR) <input type="checkbox"/>	<input type="checkbox"/>
d. Liver sonogram:	(ASLVRSO) <input type="checkbox"/>	<input type="checkbox"/>	(ASSONLST) <input type="checkbox"/>	<input type="checkbox"/>	(ASPRLC30) <input type="text"/>	(ASSONMR) <input type="checkbox"/>	<input type="checkbox"/>
e. Liver CT scan or MRI:	(ASLVRSO) <input type="checkbox"/>	<input type="checkbox"/>	(ASSONLST) <input type="checkbox"/>	<input type="checkbox"/>	(ASPRLC31) <input type="text"/>	(ASSONMR) <input type="checkbox"/>	<input type="checkbox"/>
f. Liver biopsy:	(ASLVRLD) <input type="checkbox"/>	<input type="checkbox"/>	(ASBLDLST) <input type="checkbox"/>	<input type="checkbox"/>	(ASPRLC32) <input type="text"/>	(ASBLDMR) <input type="checkbox"/>	<input type="checkbox"/>

9. Have you ever been told your hepatitis C (HCV) was of a particular strain, type, genotype and/or subtype?(ASHCVGEN)

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

If "Yes", indicate the following for your most recent HCV genotype and/or subtype test.

a. Date HCV genotyping performed: (ASGENDT)

(mm/dd/yyyy)

b. HCV genotype and/or subtype: (ASGENTYP)

1-Genotype 1
2-Genotype 1a
3-Genotype 1b
4-Genotype 2
5-Genotype 3
*Additional Options Listed Below

If "Multiple genotypes" or "Other genotype", specify: (ASGENTSP)

c. Facility name and address: (ASPRLC33)

d. RA obtained medical record release: (ASGENMR)

☐ No ☐ Yes

If you have seen a specialist or other provider for HCV care, the following question must not be answered "N/A".

10. Has your doctor ever recommended you take medication(s) for treatment of hepatitis C (HCV)?
(ASHCVRX)

0-No
1-Yes, prescription written
2-Yes, paperwork initiated
3-Yes, but I did not wish to take the medication
96-N/A
*Additional Options Listed Below

If "Yes, prescription written", "Yes, paperwork initiated", or "Yes, but I did not wish to take the medication", indicate the following for the most recent time your doctor recommended you take HCV medication(s).

a. Has your doctor recommended HCV medication(s) since your last CTN-0049 study visit?
(ASRXLST)

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

b. Were the recommended prescription(s) for injections, pills, or both? (ASRXTYPE)

1-Injections
2-Pills
3-Both
97-Don't know

c. Did you have health insurance that covered the HCV medication(s) you were recommended?
By "health insurance" we mean private health insurance or public health insurance or coverage such as Medicaid, Medicare, Medi-gap, Affordable Care Act coverage, or other government insurance. (ASRXINS)

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

If your doctor recommended HCV medication(s) since your last CTN-0049 study visit, indicate the following for the most recent time medication(s) were recommended.

d. Facility name and address: (ASPRLC34)

e. RA obtained medical record release: (ASRXMR)

☐ No ☐ Yes

If your doctor has recommended you take medication(s) for treatment of HCV, the following question must not be answered "N/A".

If your doctor has not recommended you take medication(s) for treatment of HCV, the following question must be answered "N/A".

11. Have you ever received any hepatitis C (HCV) medication(s)? (ASRXRCV)

0-No

1-Yes

96-N/A

98-Refused to answer

If you have received any HCV medication(s), the following question must not be answered "N/A".
If you have not received any HCV medication(s), the following question must be answered "N/A".

12. Have you ever taken any hepatitis C (HCV) medication(s)? (ASRXTAKE)

0-No

1-Yes

96-N/A

98-Refused to answer

a. If "Yes", are you currently taking HCV medication(s)? (ASRXTAKC)

0-No

1-Yes

98-Refused to answer

b. If "Yes", have you ever completed a course of HCV medication (taken the pills and/or injections for the length of time they were prescribed)? (ASRXCML)

0-No

1-Yes

98-Refused to answer

If "Yes", have you completed a course of HCV medication within the past 12 weeks?
(ASRXCM12)

0-No

1-Yes

98-Refused to answer

Comments: (AUSCOMM)

Additional Selection Options for AUS

HCV genotype and/or subtype:
6-Genotype 4
7-Genotype 5
8-Genotype 6
9-Multiple genotypes
97-Don't know
99-Other genotype

NIDA Clinical Trials Network

Barriers to Medical Care (BMC)

Web Version: 1.0; 1.00; 10-14-16

Segment (PROTSEG): A

Visit number (VISNO):

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

People can have many different types of problems getting their medical care. Think of the reasons why you **may not have gotten** the medical care you needed or that was recommended for you. Please indicate "No" or "Yes" for all of the following reasons for why you **may not have gotten needed medical care in the past month**.

In the past month:	No	Yes
1. I was unable to pay for medical care.	(BMNOPAY) <input type="checkbox"/>	<input type="checkbox"/>
2. I was not sure where to go to get medical care.	(BMWHERE) <input type="checkbox"/>	<input type="checkbox"/>
3. I did not have transportation to medical care.	(BM TRANSP) <input type="checkbox"/>	<input type="checkbox"/>
4. The clinic's hours of operation were inconvenient for me.	(BM HOURS) <input type="checkbox"/>	<input type="checkbox"/>
5. I was treated poorly at a clinic in the past.	(BM TXPOOR) <input type="checkbox"/>	<input type="checkbox"/>
6. I did not want to be seen at a clinic.	(BM NOCLNC) <input type="checkbox"/>	<input type="checkbox"/>
7. I do not trust doctors.	(BMTRUST) <input type="checkbox"/>	<input type="checkbox"/>
8. I don't really care about taking care of myself at this time.	(BM TKCARE) <input type="checkbox"/>	<input type="checkbox"/>
9. I did not have child care.	(BM CHILD) <input type="checkbox"/>	<input type="checkbox"/>
10. I was too drunk or high.	(BMALCDRG) <input type="checkbox"/>	<input type="checkbox"/>

Comments:(BMCCOMM)

Reference: Kalichman, S.C., Catz, S., and Ramachandran, B. (1999). Barriers to HIV/AIDS treatment and adherence among African-American adults with disadvantaged education. *Journal of the National Medical Association*, 91, 439-446.

Brief Symptom Inventory (BSI)

Web Version: 1.0; 1.01; 11-15-16

Segment (PROTSEG): A

Visit number (VISNO):

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

The next set of questions consists 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) ☐ Not at All ☐ A Little Bit ☐ Moderately ☐ Quite a Bit ☐ Extremely

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

	Not at All	A Little Bit	Moderately	Quite a Bit	Extremely
How much were you distressed by:	0	1	2	3	4
1. Faintness or dizziness:	(BSFNTDIZ) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Feeling no interest in things:	(BSNOINT) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Nervousness or shakiness inside:	(BSNERVOS) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Pains in heart or chest:	(BSPAINHR) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Feeling lonely:	(BSLONELY) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Feeling tense or keyed up:	(BSTENSE) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Nausea or upset stomach:	(BSNAUSE) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Feeling blue:	(BSBLUE) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Suddenly scared for no reason:	(BSSCARED) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Trouble getting your breath:	(BSBREATH) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Feelings of worthlessness:	(BSWORTH) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Spells of terror or panic:	(BSTERRO) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

13. Numbness or tingling in parts of body:	(BSNUMB) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. Feeling hopeless about the future:	(BSHOPELS) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. Feeling so restless you couldn't sit still:	(BSRESTLS) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. Feeling weak in parts of your body:	(BSWEAK) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. Thoughts of ending your life:	(BSENDLIF) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. Feeling fearful:	(BSFEARFL) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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Comments:(BSICOMM)

Care Facilitator Intervention Visit (CAI)

Web Version: 1.0; 6.00; 02-23-18

Segment (PROTSEG): B
Contact date (CONTCTDT):
Contact type (CNTCTTYP):
Start time (24-hour time) (STRTTIME):

Face-to-Face Care Facilitator/Participant Visit
Non Face-To-Face Care Facilitator/Participant Contact:

1. Location of contact:(CIVISLOC)

If "Provider clinic", specify clinic type:(CICLINTP)

If "Other", specify:(CICLTPSP)

2. Location where Care Facilitator was before visit:(CICFSLOC)

3. Care Facilitator travel time from prior location to meeting location:(CICSTSTM)

Calculate the distance traveled by the Care Facilitator to the meeting location from the location where the Care Facilitator was prior to the meeting location by entering the prior location address and the meeting location address into Google Maps. Choose the shortest route provided by Google Maps. If the address of a location is unknown, enter in the address of the nearest landmark, or enter in the intersection nearest to the location. Click on the below link to open Google Maps.

[Google Maps](#)

4. Distance traveled by the Care Facilitator from prior location to the meeting:(CICFSTDS)

5. Duration of call (use 24-hour time):(CICNTSTM)

6. Purpose of Care Facilitator/Participant Visit (check all that apply):

7. Purpose of call (check all that apply):

a. Confirm an upcoming appointment (check all that apply):(CICNFAPP)

	No	Yes
Care Facilitator meeting:	(CICNFCF)	
HIV care:	(CICNFHIV)	
HCV care:	(CICNFHCV)	
Substance use treatment:	(CICNFSTX)	
Mental health:	(CICNFMHL)	
Housing:	(CICNFHS)	
Other:	(CICNFOTH)	
If "Other", specify: (CICNFOSP)		

b. Type of Care Facilitator/Participant Visit (check all that apply):

c. Conduct Care Facilitator/Participant session over telephone (check all that apply):(CITELVIS)

	No	Yes
Discuss next steps in care:	(CINXTSTP)	
Troubleshoot care issue:	(CITRBLSH)	
Provide support:	(CIPRSUPP)	
HCV RNA results/education visit:	(CIHCVRSL)	

1-Care Facilitator office
2-Field
3-Provider clinic
4-Care Facilitator traveled to participant's location

1-HIV care
2-HCV care
3-Substance use treatment
4-Housing
5-Mental health
*Additional Options Listed Below

1-Office
2-Care Facilitator home
3-Field

From: (hh:mm) (CICSTETM)To: (hh:mm)

(xxx.x) miles

From: (hh:mm) (CICNTETM)To: (hh:mm)

No Yes

No Yes

Needs assessment visit:	(CINEDSAS)
Strengths assessment visit:	(CISTRNTH)
Substance use assessment visit:	(CISUBSAS)
Mental health referral visit:	(CIMHREF)
Crisis management visit:	(CICRISIS)
Housing provider visit:	(CIHOUSNG)
Motivational enhancement visit:	(CIMTVENH)
Additional motivation (outside of scripted visits outlined in the Care Facilitator Intervention Manual, MOP 05):	(CIADDMTV)
Additional education (outside of scripted visits outlined in the Care Facilitator Intervention Manual, MOP 05):	(CIEDUCAT)
Final Care Facilitator/participant visit:	(CIFNLVIS)

	No	Yes
Prepare to meet provider visit (check all that apply):	(CIPRMPRV)	
HIV care:	(CIPMPHIV)	
HCV care:	(CIPMPHCV)	
Substance use treatment:	(CIPMPSTX)	
Mental health:	(CIPMPMHL)	
Housing:	(CIPMPHS)	
Other:	(CIPMPOTH)	
If "Other", specify: (CIPMPOSP)		

	No	Yes
Accompanied provider visit (check all that apply):	(CIACPRVD)	
HIV care:	(CIAPHIV)	
HCV care:	(CIAPHCV)	
Substance use treatment:	(CIAPSTX)	
Mental health:	(CIAPMHL)	
Housing:	(CIAPHHS)	
Other:	(CIAPOTH)	
If "Other", specify: (CIAPOSP)		

	No	Yes
Debrief provider visit (check all that apply):	(CIDBRPRV)	
HIV care:	(CIDPHIV)	
HCV care:	(CIDPHCV)	
Substance use treatment:	(CIDPSTX)	
Mental health:	(CIDPMHL)	
Housing:	(CIDPHHS)	
Other:	(CIDPOTH)	
If "Other", specify: (CIDPOSP)		

	No	Yes
Complete paperwork for care (check all that apply):	(CIPPWCR)	
HIV care:	(CIPPWIV)	
HCV care:	(CIPPWCV)	
Substance use treatment:	(CIPPWSTX)	
Mental health:	(CIPPWMHL)	
Housing:	(CIPPWHS)	
Other:	(CIPPWOTH)	

If "Other", specify: (CIPPWOSP)

	No	Yes
Schedule an appointment (check all that apply):	(CISCHEDL)	
Care Facilitator meeting:	(CISCHCF)	
HIV care:	(CISCHHIV)	
HCV care:	(CISCHHCV)	
HCV evaluation (e.g., liver biopsy, Fibroscan):	(CISCHEVL)	
Substance use treatment:	(CISCHSTX)	
Mental health:	(CISCHMHL)	
Housing:	(CISCHHS)	
Other:	(CISCHOTH)	
If "Other", specify: (CISCHOSP)		

	No	Yes
Reschedule an appointment (check all that apply):	(CIRESCHD)	
Care Facilitator meeting:	(CIRESCF)	
Reason for reschedule:		1-Care Facilitator canceled original appointment 2-Clinic canceled original appointment 3-Participant canceled original appointment (notified clinic/Care Facilitator of cancellation) 4-Participant missed or was a no-show to original appointment 99-Other
If "Other", specify:		(CIRSRCF) (CIRRCFSP)

	No	Yes
HIV care:	(CIRESHIV)	
Reason for reschedule:		1-Care Facilitator canceled original appointment 2-Clinic canceled original appointment 3-Participant canceled original appointment (notified clinic/Care Facilitator of cancellation) 4-Participant missed or was a no-show to original appointment 99-Other
If "Other", specify:		(CIRSRHIV) (CIRRHISP)

	No	Yes
HCV care:	(CIRESHCV)	
Reason for reschedule:		1-Care Facilitator canceled original appointment 2-Clinic canceled original appointment 3-Participant canceled original appointment (notified clinic/Care Facilitator of cancellation) 4-Participant missed or was a no-show to original appointment 99-Other
If "Other", specify:		(CIRSRHCV) (CIRRH CSP)

	No	Yes
HCV evaluation (e.g., liver biopsy, Fibroscan):	(CIRESEVL)	
Reason for reschedule:		1-Care Facilitator canceled original appointment 2-Clinic canceled original appointment 3-Participant canceled original appointment (notified clinic/Care Facilitator of cancellation) 4-Participant missed or was a no-show to original appointment 99-Other
If "Other", specify:		(CIRSREVL) (CIRREVSP)

	No	Yes
Substance use treatment:	(CIRESSTX)	
Reason for reschedule:		1-Care Facilitator canceled original appointment 2-Clinic canceled original appointment 3-Participant canceled original appointment (notified clinic/Care Facilitator of cancellation) 4-Participant missed or was a no-show to original appointment 99-Other
If "Other", specify:		(CIRSSTX) (CIRRSTSP)

	No	Yes	
Mental health:	(CIRESMHL)		
Reason for reschedule:			1-Care Facilitator canceled original appointment 2-Clinic canceled original appointment 3-Participant canceled original appointment (notified clinic/Care Facilitator of cancellation) 4-Participant missed or was a no-show to original appointment 99-Other
	(CIRSRMHL)		
If "Other", specify:	(CIRRMHSP)		
Housing:	No	Yes	
	(CIRESHS)		
Reason for reschedule:			1-Care Facilitator canceled original appointment 2-Clinic canceled original appointment 3-Participant canceled original appointment (notified clinic/Care Facilitator of cancellation) 4-Participant missed or was a no-show to original appointment 99-Other
	(CIRSRHS)		
If "Other", specify:	(CIRRHSSP)		
Other:	No	Yes	
	(CIRESOTH)		
Specify other reason: (CIRESOSP)			
Reason for reschedule:			1-Care Facilitator canceled original appointment 2-Clinic canceled original appointment 3-Participant canceled original appointment (notified clinic/Care Facilitator of cancellation) 4-Participant missed or was a no-show to original appointment 99-Other
	(CIRSROTH)		
If "Other", specify:	(CIRROTSP)		
Other visit type:	No	Yes	
	(CIOTHVIS)		
If "Other", specify: (CIOVISSP)			
8. What was the main type, focus, or purpose of this visit?(CIFOOCUS)			01-Rapid HCV Antibody Reactive 02-Rapid Reactive/RNA Undetected (Neg) 03-Rapid HCV Reactive/RNA Positive 04-Needs and Strengths Assessment 05-Substance Use Discussion Meeting *Additional Options Listed Below
9. Time participant spent meeting with Care Facilitator, Medical Care or other provider (use 24-hour time):(CICNTSTM)	From:	(hh:mm) (CICNTETM)	To: (hh:mm)
10. Categorize how participant spent time during meeting (check all that apply):			
a. Participant intervention time (time spent having intervention related conversation with Care Facilitator regardless of where the conversation occurs, e.g., phone, in clinic, etc.):	No	Yes	
			(CIPTINTM)
b. Participant transportation time during meeting with Care Facilitator, but without intervention related conversation:			(CIPTTRTM)
c. Participant waiting time without intervention related conversation (e.g., participant waiting to meet with medical care provider or other provider):			(CIPTWTM)
d. Participant time with non-Care Facilitator provider (time spent meeting with medical care or other provider):			(CIPTPRTM)
e. Other:			(CIPTOTTM)
If "Other", specify: (CIPTOTSP)			
11. Time Care Facilitator spent meeting with the participant (exclude time spent on other work-related activities unrelated to this participant):(CICFPTTM)	(xxx) minutes		
12. Categorize time Care Facilitator spent meeting with the participant (exclude time spent on other work-related activities unrelated to this participant) (check all that apply):			
a. Care Facilitator intervention time (time spent having intervention related conversation with participant regardless of where the conversation occurs, e.g., phone, in clinic):	No	Yes	
			(CICFINTM)
b. Care Facilitator transportation time during meeting with participant, but without intervention related conversation:			(CICFTRTM)
c. Care Facilitator waiting time without intervention related conversation (e.g., Care Facilitator waiting while participant is engaged in other activities):			(CICFWTM)
d. Other:			(CICFOTTM)

If "Other", specify: (CICFOTSP)

13. Location where Care Facilitator goes after visit:(CICFELOC)

1-Office
2-Care Facilitator home
3-Field

14. Care Facilitator's travel time from meeting location to post visit location (use 24-hour time):(CICETSTM)

From: (hh:mm) (CICETETM)To: (hh:mm)

Calculate the distance traveled by the Care Facilitator from the meeting location to the post visit location by entering the meeting location address and post meeting address into Google Maps. Choose the shortest route provided by Google Maps. If the address of a location is unknown, enter in the address of the nearest landmark, or enter in the intersection nearest to the location. Click on the below link to open Google Maps.
[Google Maps](#)

15. Distance traveled by the Care Facilitator from the meeting location to post visit location:(CICFETDS)(xxx.x) miles

16. Participant form of travel from participant home (or other participant start point) to meeting location:(CIPSTRTP)

1-Care Facilitator provided
2-Public transportation
3-Taxi
4-Drove
5-Friend/family member/other drove
*Additional Options Listed Below

If "Other", specify:(CIPSTTSP)

17. Participant travel time from participant home (or other participant start point) to meeting location (use 24-hour time):(CIPSTSTM)

From: (hh:mm) (CIPSETETM)To: (hh:mm)

Calculate the distance traveled by the participant from the participant's home (or other participant start point) to the meeting by entering the prior location address and the meeting location address into Google Maps. Choose the shortest route provided by Google Maps. If the address of a location is unknown, enter in the address of the nearest landmark, or enter in the intersection nearest to the location. Click on the below link to open Google Maps.
[Google Maps](#)

18. Distance traveled by the participant from home (or other start point) to meeting location:(CIPSTRDS)(xx.x) miles

19. Participant form of travel from meeting location to home (or end point) after meeting:(CIPETRTP)

1-Care Facilitator provided
2-Public transportation
3-Taxi
4-Drove
5-Friend/family member/other drove
*Additional Options Listed Below

If "Other", specify:(CIPETTSP)

20. Participant travel time from meeting location to home (or end point) (use 24-hour time):(CIPETSTM)

From: (hh:mm) (CIPETETM)To: (hh:mm)

Calculate the distance traveled by the participant from the meeting location to home (or end point) by entering the meeting location address and participant's home address (or end point) into Google Maps. Choose the shortest route provided by Google Maps. If the address of a location is unknown, enter in the address of the nearest landmark, or enter in the intersection nearest to the location. Click on the below link to open Google Maps.
[Google Maps](#)

21. Distance traveled by the participant from meeting location to home (or end point):(CIPETRDS)(xx.x) miles

Contact with Others (Care Facilitator with Person Other than Participant)

22. Contact type:(CIOTCNTP)

1-In-person
2-Telephone
3-Email
4-Text

23. Did this contact take place in a location other than the Care Facilitator office?(CIOToloc)

NoYes

24. Care Facilitator travel time from prior location to provider location:(CICSTSTM)

From: (hh:mm) (CICSETETM)To: (hh:mm)

Calculate the distance traveled by the Care Facilitator to the provider's location from the location where the Care Facilitator was prior to the provider's location by entering the prior location address and the provider location address into Google Maps. Choose the shortest route provided by Google Maps. If the address of a location is unknown, enter in the address of the nearest landmark, or enter in the intersection nearest to the location. Click on the below link to open Google Maps.
[Google Maps](#)

25. Distance traveled by the Care Facilitator from prior location to the provider's location:(CICFSTDS)(xxx.x) miles

26. Duration of contact (use 24-hour time):(CICNTSTM)

From: (hh:mm) (CICNTETM)To: (hh:mm)

27. Conversation was with:(CIOTCNID)

1-Provider
2-Case Manager/Social Worker
3-Family member/friend

If "Provider", select provider type (check all that apply):

	No	Yes
HIV provider:	(CIOTPHIV)	
HCV provider:	(CIOTPHCV)	
Substance use treatment provider:	(CIOTPSTX)	
Mental health:	(CIOTPMHL)	

http://wfbui:9220/WFB/navigateReportList.action

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Housing provider: (CIOTPHS)
Clinical laboratory: (CIOTPLAB)
Ultrasound/Fibroscan/Radiology: (CIOTPUFR)
Other: (CIOTPOTH)
If "Other", specify: (CIOTPOSP)

28. Purpose of contact (check all that apply):

	No	Yes
Confirm upcoming visit:	(CIOTCONF)	
Schedule upcoming appointment:	(CIOTSCHD)	
Reschedule upcoming appointment:	(CIOTRESC)	
Advocacy:	(CIOTADVC)	
Monitoring (participant treatment progress):	(CIOTMONT)	
Coordinating care:	(CIOTCOOR)	
Insurance and other paperwork:	(CIOTINSR)	
Other:	(CIOTPRPS)	
If "Other", specify: (CIOTPPSP)		

29. Location where Care Facilitator goes after the provider's location:(CICFELOC)

1-Office
2-Care Facilitator home
3-Field

30. Care Facilitator's travel time from provider's location to post contact location (use 24-hour time):(CICETSTM)

From: (hh:mm) (CICETETM)To: (hh:mm)

Calculate the distance traveled by the Care Facilitator from the provider's location to the post contact location by entering the provider's location address and post contact address into Google Maps. Choose the shortest route provided by Google Maps. If the address of a location is unknown, enter in the address of the nearest landmark, or enter in the intersection nearest to the location. Click on the below link to open Google Maps.

[Google Maps](#)

31. Distance traveled by the Care Facilitator from the provider's location to post contact location:(CICFETDS)

(xxx.x) miles

Comments:(CAICOMM)

Additional Selection Options for CAI

Contact type (CNTCTTYP) (key field):
1-Face-to-Face Care Facilitator/Participant Visit
2-Non Face-to-Face Facilitator/Participant Contact
3-Contact with Others (Care Facilitator with Person Other Than Participant)

If "Provider clinic", specify clinic type:
99-Other

What was the main type, focus, or purpose of this visit?
06-Prepare to Meet HCV/HIV/Substance Abuse Treatment Provider
07-Debrief HCV/HIV/Substance Abuse Treatment Provider Visit
08-Enhancing Motivation for Care
09-Final Participant Meeting
10-Unscripted
11-Accompany to Provider, No Intervention Delivered

Participant form of travel from participant home (or other participant start point) to meeting location:
6-Walked
99-Other

NIDA Clinical Trials Network

Computer Assisted Personal Interview (CAP)

Web Version: 1.0; 1.00; 10-14-16

Segment (PROTSEG): A

Visit number (VISNO):

Where is this assessment being performed? (CAPLOCTN)

1-On site
2-Off site
3-Telephone

Do not read these lines of text to the participant

Welcome!

You will be administering some questions using this computer. To navigate to the first assessment, click on the "Save" button at the top or bottom of the screen, then click the link containing the assessment's name in the box above.

NIDA Clinical Trials Network

Community Cohesion Scale (CCS)

Web Version: 1.0; 1.00; 10-14-16

Segment (PROTSEG): A

Visit number (VISNO):

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

Now I'm going to read some statements about things that people in your neighborhood may or may not do.
For each of these statements, tell me whether you Strongly Agree, Agree, Disagree, or Strongly Disagree.

	Strongly Agree	Agree	Disagree	Strongly Disagree
1. My neighborhood is a close-knit neighborhood.	(CCCLSKNT) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. People in my neighborhood are willing to help their neighbors.	(CCHelp) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. People in my neighborhood generally don't get along with each other.	(CCALONG) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. People in my neighborhood do not share the same values.	(CCVALUES) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. People in my neighborhood can be trusted.	(CCTRUST) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments:(CCSCOMM)

Needs and Strengths Assessment (CFA)

Web Version: 1.0; 1.00; 10-14-16

Segment (PROTSEG): B
Session date (CFSESNDT):

Reviewer:(CAREVWID)

9-Dummy Reviewer

Date of review:(CAREVWDT)

(mm/dd/yyyy)

Care facilitator:(CACFID)

9999999-Dummy Care Facilitator ID

Session length:(CASESLEN)

(xxx) minutes

Review type:(CARVTYPE)

CertificationFidelity

Adherence Ratings: 0 = Material **not at all** covered; 1 = Material **somewhat** covered; 2 = Material **mostly** covered; 3 = Material **completely** covered; 96 = Material **not delivered for legitimate reason**; 97 = **Could not be rated** (poor quality, too much noise, etc.)

To what extent did the Care Facilitator:

Not at All

Somewhat

Mostly

Completely

Not Delivered for Legitimate Reason

Could Not Be Rated

1. Assess participant's overall needs:

Invite the participant to list the various needs participant has related to health, housing, food, substance use, HIV, HCV, etc; if HCV (liver health)/HIV/substance use treatment is not on list, inquire about putting these items on the list; Ask participant to put needs in order of importance; inquire about importance of untreated HIV and HEP C/Liver health on needs.

(CAASSESS)

2. Create a treatment plan:

Help participant create steps for accomplishing some of the most important needs; assess about readiness to access HCV care provider to find out about health of liver and/or HIV care and/or substance use treatment.

(CATXPLAN)

3. Assess participant's overall strengths:

Offer to use strengths guide to discuss participant's strengths in various aspects of participant's life; discuss how participant's personal strengths can be used to accomplish steps in meeting treatment goals.

(CASTRENG)

4. Agree to continue strengths conversation:

Care Facilitator and participant to discuss idea of discussing participant's strengths throughout the time participant and Care Facilitator are working together.

(CAAGREE)

Comments:(CAMCOMM)

NIDA Clinical Trials Network

Control Arm: Rapid HCV Reactive/RNA Positive (CFC)

Web Version: 1.0; 1.00; 10-14-16

Segment (PROTSEG): B
Session date (CFSESNDT):

Reviewer:(CCREVWID)

9-Dummy Reviewer

Date of review:(CCREVWDT)

(mm/dd/yyyy)

Care facilitator:(CCCFID)

9999999-Dummy Care Facilitator ID

Session length:(CCSELEN)

(xxx) minutes

Review type:(CCRVTYPE)

Certification

Fidelity

Adherence Ratings: 0 = Material **not at all** covered; 1 = Material **somewhat** covered; 2 = Material **mostly** covered; 3 = Material **completely** covered; 96 = Material **not delivered for legitimate reason**; 97 = **Could not be rated** (poor quality, too much noise, etc.)

	Not at All	Somewhat	Mostly	Completely	Not Delivered for Legitimate Reason	Could Not Be Rated
To what extent did the Care Facilitator:						
1. Provide HCV RNA positive result and let participant respond: Share RNA positive test result; reiterate meaning of test result (infected with Hep C virus); provide time for participant to respond, answer any participant questions.						(CCHCVPOS)
2. Reiterate Hep C infection and convey positive message: HCV will stay in body unless take HCV treatment to get rid of HCV; new treatment works well, and can get rid of virus; treatment usually just pills, well tolerated and completed in few months.						(CCREITER)
3. Provide positive reinforcement: Many things you can do to stay healthier: get liver assessment, do things to take care of liver, can discuss new HCV treatment with care provider (that can cure HCV); can prevent HCV transmission.						(CCPOS)
4. Provide HCV pamphlet and review helping liver: Avoid or cut down on alcohol; get on HIV treatment; see provider for liver tests and discuss newer medications.						(CCPAMPH)
5. Discuss Hep A and Hep B Vaccinations: Explain how Hep A and B are spread; discuss need for tests to see if immune and importance of getting vaccinated if not immune.						(CCVACCIN)
6. Discuss HCV transmission reduction: Avoid others coming in contact with your blood: not sharing needles or works; not sharing snorting equipment [straws]; not sharing personal items: razors, nail clippers, toothbrushes; tattoos/piercings only from licensed settings; avoid or reduce multiple partners, avoid rough vaginal/anal sex; condoms to reduce HIV and other STDs; How HCV is NOT spread: kissing, hugging, sharing food, coughing, sneezing.						(CCTRANS)
7. Discuss next step offer/attempt to make HCV care appointment: We can try to set up appointment for HCV provider for you, if wanted provide reminder card; or provide referral if appointment could not be made.						(CCSTEP)
8. Remind participant of study visit schedule and procedures: Will ask for you to come back in 6 and 12 months from today, if contact us between ___ and ___ will be compensated _ at your 6 month visit; will provide reminder of upcoming visits; review/update contact information.						(CCREMIND)

Comments:(CCHCOMM)

Debrief HCV/HIV/Substance Abuse Treatment Provider Visit (CFD)

Web Version: 1.0; 1.00; 10-14-16

Segment (PROTSEG): B
Session date (CFSESNDT):

Reviewer:(CDREVWID)9-Dummy Reviewer

Date of review:(CDREVWDT)(mm/dd/yyyy)

Care facilitator:(CDCFID)9999999-Dummy Care Facilitator ID

Session length:(CDSESLN)(xxx) minutes

Review type:(CDRVTYPE)CertificationFidelity

Adherence Ratings: 0 = Material **not at all** covered; 1 = Material **somewhat** covered; 2 = Material **mostly** covered; 3 = Material **completely** covered; 96 = Material **not delivered for legitimate reason**; 97 = **Could not be rated** (poor quality, too much noise, etc.)

To what extent did the Care Facilitator:

Not at AllSomewhatMostlyCompletelyNot Delivered for Legitimate ReasonCould Not Be Rated

1. **Support participant efforts:**
Invite participant to articulate positive outcomes from HCV/HIV/substance abuse treatment provider care visit and participant's efforts. Elicit from participant what participant learned and the 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.

(CDSUPPOR)
2. **Discuss outstanding business:**
Ask participant to identify unanswered/unaddressed questions (see index card); clarify any new questions/concerns that may have come up during or after the HCV/HIV/substance abuse treatment provider visit.

(CDOUSTN)
3. **Discuss and prepare for next steps in self-care:**
Discuss and strategize the next steps in care e.g., additional lab or medical testing; medication pick-up and medication start date, attending or entering substance abuse treatment; assist with setting dates, rehearse preliminary steps; if appropriate, encourage participant to discuss taking medications with pharmacy staff.

(CDNEXTST)
4. **Plan next Care Facilitator/participant meeting:**
Schedule appointment; review locator information; reinforce participant interest/effort in self-care; discuss reminder phone call/email; resolve any transportation issues.

(CDPLAN)

Comments:(CFDCOMM)

Final Participant Meeting (CFF)

Web Version: 1.0; 1.00; 11-15-16

Segment (PROTSEG): B
Session date (CFSESNDT):

Reviewer:(CFREVWID)

9-Dummy Reviewer

Date of review:(CFREVWDT)

(mm/dd/yyyy)

Care facilitator:(CFCFID)

99999999-Dummy Care Facilitator ID

Session length:(CFSESLEN)

(xxx) minutes

Review type:(CFRVTYPE)

Certification Fidelity

Adherence Ratings: 0 = Material **not at all** covered; 1 = Material **somewhat** covered; 2 = Material **mostly** covered; 3 = Material **completely** covered; 96 = Material **not delivered for legitimate reason**; 97 = **Could not be rated** (poor quality, too much noise, etc.)

To what extent did the Care Facilitator:	Not at All	Somewhat	Mostly	Completely	Not Delivered for Legitimate Reason	Could Not Be Rated
1. Review self-care progress since initial Care Facilitator/participant meeting: Invite/help participant to acknowledge ways that participant demonstrated self-care in last 6 months (related to HCV, HIV, substance abuse, housing, etc.); acknowledge and support attempts at self-care and any and all successes (securing ID, meeting with providers, learning more about HCV, HIV health, receiving treatment, etc.).					(CFPROGRS)	
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's past; reinforce strengths participant demonstrated.					(CFCHLLNG)	
3. Discuss and prepare for any next steps in any self-care: Strategize what participant may want to accomplish between now and next Care Facilitator/participant visit related to self-care (HCV and/or HIV care, substance abuse treatment, etc.); assist participant in setting specific steps and target dates for goal; discuss ways to overcome potential barriers.					(CFNXTSTP)	
4. Explore the experience of working together: Encourage participant to share participant's benefits and challenges of working together. Care Facilitator to share care facilitator's experience, focusing on positive and successful resolutions of challenges.					(CFEXPRNC)	
5. Discuss upcoming HOPE HCV study (non-care facilitator) follow up visit: Review date/activities for 6 month follow-up visit (including blood and toxicology screening; provide appointment card, remind participant of 6 month reimbursement and express appreciation for the participant's study involvement; review locator information; reinforce participant interest/effort in continued HCV/HIV/substance abuse self-care; provide appropriate verbal encouragement on participant's ability to make progress in self-care.					(CFFUVIST)	

Comments:(CFFCOMM)

Rapid Reactive/RNA Undetected (Neg) (CFG)

Web Version: 1.0; 1.01; 10-14-16

Segment (PROTSEG): B
Session date (CFSESNDT):

Reviewer:(CGREVWID)9-Dummy Reviewer

Date of review:(CGREVWDT)(mm/dd/yyyy)

Care facilitator:(CGCFID)99999999-Dummy Care Facilitator ID

Session length:(CGSELEN)(xxx) minutes

Review type:(CGRVTYPE)CertificationFidelity

Adherence Ratings: 0 = Material **not at all** covered; 1 = Material **somewhat** covered; 2 = Material **mostly** covered; 3 = Material **completely** covered; 96 = Material **not delivered for legitimate reason**; 97 = **Could not be rated** (poor quality, too much noise, etc.)

To what extent did the Care Facilitator:	Not at All	Somewhat	Mostly	Completely	Not Delivered for Legitimate Reason	Could Not Be Rated
1. Provide HCV RNA negative test result: Share that confirmatory test result was negative and that participant does not have HCV but that because participant has antibodies (from rapid screening test) participant was infected with HCV at some previous time; reiterate meaning of test result, and answer any participant questions.						(CGHCVNEG)
2. Explain about clearing the virus: Share that while most people develop chronic infection, some infected are able to clear hepatitis C virus. Having cleared HCV infection does NOT protect participant from getting HCV infected again.						(CGCLEAR)
3. Remind participant about need to test again: If participant injects drugs, shares works, exposed to someone's blood, if participant is MSM, or if multiple partners suggest HCV testing at least annually.						(CGREMIND)
4. Review ways to reduce risk for HCV: Explain that participant can get re-infected with virus. Remind participant of ways to reduce HCV exposure: avoid sharing needles or works, avoid sharing snorting equipment [straws]; avoid sharing razors, nail clippers, toothbrushes; using condoms; tattoos/piercings only from licensed settings.						(CGREDUCE)
5. Discuss Hep A and Hep B vaccinations: Explain how Hep A and B are spread; explain that CDC recommends everyone get vaccinated for A and B.						(CGVACCIN)
6. Assess last HIV care appointment and attempt to schedule: Inquire about (or check record) about last HIV care appointment. Provide offer to make HIV care appointment; inquire best days/times for participant; attempt to make appointment.						(CGLAST)
7. Inform participant about continued study participation: Set out testing materials, put on gloves, collect sample; process sample; log test and record time; have participant wait for results either in office or lobby.						(CGSTUDY)

Comments:(CFGCOMM)

Pre-HCV Rapid Results (CFH)

Web Version: 1.0; 1.00; 11-15-16

Segment (PROTSEG): B
Session date (CFSESNDT):

Reviewer:(CHREVWID)

Date of review:(CHREVWDT)
Care facilitator:(CHCFID)

Session length:(CHSELEN)
Review type:(CHRVTYPE)

9-Dummy Reviewer

(mm/dd/yyyy)

99999999-Dummy Care Facilitator ID

(xxx) minutes

Certification

Fidelity

Adherence Ratings: 0 = Material **not at all** covered; 1 = Material **somewhat** covered; 2 = Material **mostly** covered; 3 = Material **completely** covered; 96 = Material **not delivered for legitimate reason**; 97 = **Could not be rated** (poor quality, too much noise, etc.)

To what extent did the Care Facilitator:	Not at All	Somewhat	Mostly	Completely	Not Delivered for Legitimate Reason	Could Not Be Rated
1. Introduce self and provide overview of today's visit: Greet participant; introduce each to the other, describe activities for this visit.	(CHINTROD)					
2. Provide brief overview of rapid HCV testing procedures: Preparing collection site, collecting sample, processing sample; results available in 20 minutes.	(CHOVRVIW)					
3. Explain briefly what rapid HCV test is looking for: Detection of HCV antibodies.	(CHLKSFOR)					
4. Explain possible test results and any appropriate next steps: If negative - no further testing; if antibody positive - additional testing (RNA) to determine if cleared virus or not; if invalid - no valid test result, need to test again.	(CHPOSSBL)					
5. Obtain participant written consent (if not already received): Inquire if participant has any further questions; have participant print and sign name and write correct date; staff member to follow suit.	(CHCNSENT)					
6. Conduct HCV rapid test according to protocol: Set out testing materials, put on gloves, collect sample; process sample; log test and record time; have participant wait for results either in office or lobby.	(CHCNDUCT)					

Comments:(CFHCOMM)

NIDA Clinical Trials Network

Intervention Arm: Rapid HCV Reactive/RNA Positive (CFI)

Web Version: 1.0; 1.00; 10-14-16

Segment (PROTSEG): B
Session date (CFSESNDT):

Reviewer:(CIREVWID)9-Dummy Reviewer

Date of review:(CIREVWDT)(mm/dd/yyyy)

Care facilitator:(CICFID)99999999-Dummy Care Facilitator ID

Session length:(CISESLEN)(xxx) minutes

Review type:(CIRVTYPE)CertificationFidelity

Adherence Ratings: 0 = Material not at all covered; 1 = Material somewhat covered; 2 = Material mostly covered; 3 = Material completely covered; 96 = Material not delivered for legitimate reason; 97 = Could not be rated (poor quality, too much noise, etc.)

	To what extent did the Care Facilitator:	Not at All	Somewhat	Mostly	Completely	Not Delivered for Legitimate Reason	Could Not Be Rated
1. Provide HCV RNA positive result and allow participant to respond: Share RNA positive test result; reiterate meaning of test result (infected with Hep C virus); provide time for participant to respond, provide support, and answer any participant questions.							
2. Reiterate Hep C infection and convey positive message: HCV will stay in body unless take HCV treatment to get rid of HCV; new treatment works well, and can get rid of virus; treatment usually just pills, well tolerated and completed in few months; as your Care Facilitator, can assist in getting more information on liver and other ways to take care of self.							
3. Provide positive reinforcement: Many things you can do to stay healthier: get liver assessment, do things to take care of liver, can discuss new HCV treatment with care provider (that can cure HCV); can prevent HCV transmission; remind participant that Care Facilitator is here to help out.							
4. Provide information of care facilitation services: Can meet up to 12 times in next 6 months; can also have telephone, email, etc. contact; can assist with care appointments, paperwork; assist with community resources; part of your team (with others).							
5. Provide HCV pamphlet and review ways to help liver: Avoid or cut down on alcohol; get on HIV treatment; see provider for liver tests and discuss newer medications; untreated HIV can contribute to cirrhosis; important to treat both HIV and Hep C.							
6. Discuss Hep A and Hep B vaccinations: Explain how Hep A and B are spread; discuss need for tests to see if immune and importance of getting vaccinated if not immune.							
7. Discuss HCV transmission reduction: Avoid others coming in contact with your blood: not sharing needles or works; not sharing snorting equipment [straws]; not sharing personal items: razors, nail clippers, toothbrushes; tattoos/piercings only from licensed settings; avoid or reduce multiple partners, avoid rough vaginal/anal sex; condoms to reduce HIV and other STDs; How HCV is NOT spread: kissing, hugging, sharing food, coughing, sneezing.							
8. Discuss/provide motivation for seeking information on liver health: Ask 0-10 scale question about concern for liver health, or importance of getting more info on liver health; what are some reasons for wanting to live longer, healthier? Concerns for seeing provider? How ready to make an appointment?							
9. Discuss next step HCV care appointment: By meeting with provider you can get some questions answered and get more information; Care Facilitator typically can help set up a participant; if participant refuses, inquire reasons why; ask if can talk again about HCV provider visit.							
10. Reinforce working together and schedule next Care Facilitator/participant meeting: Support participant's effort in coming to get RNA results; look forward to working with participant (being on participant's team); can accomplish a lot in next 6 months; inquire of questions.							
Comments:(CFICOMM)							

Enhancing Motivation for Care (CFM)

Web Version: 1.0; 1.00; 11-15-16

Segment (PROTSEG): B
Session date (CFSESNDT):

Reviewer:(CMREVWID)
Date of review:(CMREVWDT)
Care facilitator:(CMCFID)
Session length:(CMSELEN)
Review type:(CMRVTYPE)

9-Dummy Reviewer

(mm/dd/yyyy)

99999999-Dummy Care Facilitator ID

(xxx) minutes

Certification

Fidelity

Adherence Ratings: 0 = Material **not at all** covered; 1 = Material **somewhat** covered; 2 = Material **mostly** covered; 3 = Material **completely** covered; 96 = Material **not delivered for legitimate reason**; 97 = **Could not be rated** (poor quality, too much noise, etc.)

To what extent did the Care Facilitator:		Not at All	Somewhat	Mostly	Completely	Not Delivered for Legitimate Reason	Could Not Be Rated
1. Support participant's recent self-care efforts: Invite the participant to articulate any self-care efforts attempted and/or accomplished since last care facilitator/participant 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 future to achieve more positive outcomes; continue to build/maintain rapport.	(CMEFFRTS)						
2. Assist participant in addressing ambivalence re: self care: Using MI techniques (OARS) and manual tools, address ambivalence: ask participant to identify pros/cons of status quo; pros/cons of change (self-care behaviors); ask what participant sees for self in 3 or 5 years if no change occurs; what hopes participant has for future; what is important for participant; what needs to happen for participant to be more ready to make change.	(CMAMBVLC)						
3. Discuss and prepare for any next steps in any self-care: Strategize what participant may want to accomplish between now and next Care Facilitator/participant visit related to self-care (HCV and/or HIV care, substance abuse treatment, etc.); assist participant in setting specific steps and target dates for goal; discuss ways to overcome potential barriers.	(CMNXTSTP)						
4. Plan next Care Facilitator/participant meeting: Schedule appointment; review locator information; reinforce participant interest/effort in self-care; discuss reminder phone call/email; resolve any transportation issues.	(CMNXTMTG)						
Comments:(CFMCOMM)							

Rapid HCV Antibody Negative (CFN)

Web Version: 1.0; 1.00; 11-15-16

Segment (PROTSEG): B
Session date (CFSESNDT):

Reviewer:(CNREVWID)

9-Dummy Reviewer

(mm/dd/yyyy)

Care facilitator:(CNCFID)

99999999-Dummy Care Facilitator ID

(xxx) minutes

Review type:(CNRVTYPE)

Certification

Fidelity

Adherence Ratings: 0 = Material **not at all** covered; 1 = Material **somewhat** covered; 2 = Material **mostly** covered; 3 = Material **completely** covered; 96 = Material **not delivered for legitimate reason**; 97 = **Could not be rated** (poor quality, too much noise, etc.)

	To what extent did the Care Facilitator:	Not at All	Somewhat	Mostly	Completely	Not Delivered for Legitimate Reason	Could Not Be Rated
1. Provide rapid HCV antibody non-reactive screening result: Share non-reactive screening result; reiterate meaning of test result (i.e., no antibodies detected) and answer participant questions about HCV or HCV screening results.							
2. Explain about retesting if exposure within window: If participant has had recent (i.e., within past 6 months) HCV exposure (e.g., injected drugs, shared works, been exposed to someone's blood), suggest retesting in the community about 6 months from most recent exposure; provide list of testing agencies.							
3. Briefly share information on ways to stay HCV negative: Remind participant of ways to reduce HCV exposure (e.g., not sharing needles or works, not sharing snorting equipment [straws]; not sharing razors, nail clippers, toothbrushes; using condoms; getting tattoos only from licensed settings); mention testing and vaccine for HAV/HBV and provide testing referrals.							
4. Inform participant how HCV is NOT transmitted: Explain that HCV is NOT spread by kissing, hugging, shaking hands, sharing food or utensils, coughing, sneezing, mosquitos, or animals.							
5. Inform participant that study participation is completed: Express appreciation for participant's study involvement; remind participant of study reimbursement.							

Comments:(CFNCOMM)

Prepare to Meet HCV/HIV/Substance Abuse Treatment Provider (CFP)

Web Version: 1.0; 1.00; 11-15-16

Segment (PROTSEG): B
Session date (CFSESNDT):

Reviewer:(CPREVWID)9-Dummy Reviewer

Date of review:(CPREVWDT)(mm/dd/yyyy)

Care facilitator:(CPCFID)99999999-Dummy Care Facilitator ID

Session length:(CPSELEN)(xxx) minutes

Review type:(CPRVTYPE)CertificationFidelity

Adherence Ratings: 0 = Material **not at all** covered; 1 = Material **somewhat** covered; 2 = Material **mostly** covered; 3 = Material **completely** covered; 96 = Material **not delivered for legitimate reason**; 97 = **Could not be rated** (poor quality, too much noise, etc.)

To what extent did the Care Facilitator:	Not at All	Somewhat	Mostly	Completely	Not Delivered for Legitimate Reason	Could Not Be Rated
1. Familiarize the participant with the HCV/HIV/substance abuse treatment 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.						(CPFAMLRZ)
2. Prepare the participant for meeting with care provider: Discuss any concerns participant may have; assist participant with questions to ask provider; write questions/concerns on 2 index cards; rehearse provider interaction if appropriate; discuss solutions to potential barriers.						(CPPREPCP)
3. Discuss expectations of Care Facilitator/participant roles at care visit: Clarify clinic policy on Care Facilitator presence; discuss participant's expectation around Care Facilitator presence; clarify Care Facilitator's role during care visit and discuss nature of support provided by Care Facilitator. <i>Note: If participant ambivalent, roll with resistance (validate/discuss concerns of treatment/care).</i>						(CPROLES)
4. Prepare for Care Facilitator/participant meeting prior to care visit: Choose time and clear/specific place for Care Facilitator and participant to meet prior to HCV/HIV/substance abuse treatment care visit; discuss reminder phone call/email; resolve any transportation issues.						(CPPREPCF)
5. Prepare for next Care Facilitator/participant meeting: Schedule appointment; review locator information; reinforce participant interest in self-care; provide appropriate verbal support on any and all self-care efforts; mention that Care Facilitator/staff will make reminder call/email regarding upcoming care and Care Facilitator/participant meetings.						(CPPLANCF)

Comments:(CFPCOMM)

Rapid HCV Antibody Reactive (CFR)

Web Version: 1.0; 1.00; 11-15-16

Segment (PROTSEG): B
Session date (CFSESNDT):

Reviewer:(CRREVWID)

9-Dummy Reviewer

(mm/dd/yyyy)

Care facilitator:(CRCFID)

99999999-Dummy Care Facilitator ID

(xxx) minutes

Review type:(CRRVTYPE)

Certification

Fidelity

Adherence Ratings: 0 = Material **not at all** covered; 1 = Material **somewhat** covered; 2 = Material **mostly** covered; 3 = Material **completely** covered; 96 = Material **not delivered for legitimate reason**; 97 = **Could not be rated** (poor quality, too much noise, etc.)

To what extent did the Care Facilitator:	Not at All	Somewhat	Mostly	Completely	Not Delivered for Legitimate Reason	Could Not Be Rated
1. Provide rapid HCV antibody reactive screening result: Share reactive screening result, reiterate meaning of test result (i.e., exposed to HCV at some point and antibodies to HCV were found in blood); answer any participant questions.						(CRRESULT)
2. Explain importance of additional testing: Additional testing needed to determine if currently infected with HCV; some people clear the infection (i.e., without medications) but most people do not, next test will determine if infected with HCV or if cleared HCV. Second test, called an RNA test, looks for presence of virus not antibodies to virus.						(CRADTEST)
3. Provide information on ways to reduce HCV transmission: Not sharing needles or works; not sharing snorting equipment [straws]; not sharing razors, nail clippers, toothbrushes; using condoms; tattoos only from licensed settings); mention testing and vaccine for HAV/HBV and provide HAV/HBV testing referrals.						(CRREDUCE)
4. Explain how HCV is not spread: HCV is NOT spread by kissing, hugging, shaking hands, sharing food, utensils, coughing, sneezing, mosquitoes, or animals.						(CRNOTRAN)
5. Inform participant of next steps in today's study participation: Blood draw; randomization to intervention or control arm; conversation with staff person about HCV and the liver; a reminder card to return for RNA results; participant reimbursement for today's visit.						(CRNXTSTP)
Comments:(CFRCOMM)						

Substance Use Discussion Meeting (CFU)

Web Version: 1.0; 1.00; 10-14-16

Segment (PROTSEG): B
Session date (CFSESNDT):

Reviewer:(CUREVWID)

9-Dummy Reviewer

Date of review:(CUREVWDT)

(mm/dd/yyyy)

Care facilitator:(CUCFID)

99999999-Dummy Care Facilitator ID

Session length:(CUSESLEN)

(xxx) minutes

Review type:(CURVTYPE)

CertificationFidelity

Adherence Ratings: 0 = Material **not at all** covered; 1 = Material **somewhat** covered; 2 = Material **mostly** covered; 3 = Material **completely** covered; 96 = Material **not delivered for legitimate reason**; 97 = **Could not be rated** (poor quality, too much noise, etc.)

To what extent did the Care Facilitator:	Not at All	Somewhat	Mostly	Completely	Not Delivered for Legitimate Reason	Could Not Be Rated
1. Assess overall substance use: Invite participant to share current substance use (including alcohol), amount, quantity, frequency, and method of use. Explore if participant uses mainly with others or on own.	(CUASSESS)					
2. Assess advantages/disadvantages of substance use: Ask participant to share all the benefits participant experiences from using (i.e. the rush, to forget, reduce pain, fun, etc.) Ask participant to share about all the disadvantages to using: missing appointments, not taking medications, not taking care of HIV/HCV health, losing things, stealing, arguments, family and other relationship issues, employment issues, jail or prison time, etc.	(CUADVDIS)					
3. Discuss participant's view of self in future (with and without substances): Assuming participant is still using, have participant predict what the future may bring around housing, family and social relationships, employment, participant's overall health, participant's HIV health, and HCV health. Assuming that participant is NOT using in the future, have participant predict what the future may bring around housing, family and social relationships, employment, participant's overall health, participant's HIV health, and HCV health.	(CUSELF)					
4. Discuss participant's history of substance use treatment: Explore durations of treatment including longest period of treatment/abstinence, what lead up to treatment, and what contributed to success of treatment. Explore the barriers to continued treatment/abstinence, and what participant learned about self for future success in treatment/abstinence.	(CUHISTORY)					
5. Assess participant's readiness to change substance use: Discuss participant's interest and motivation level for substance abuse treatment or harm reduction by using the readiness ruler or the 0-10 scale. Discuss what, if anything, the participant is ready to change now and/or discuss what would need to happen for participant to be ready to change.	(CUCCHANGE)					
6. Discuss next steps, if any, about substance abuse treatment or reduction: If the participant is interested and ready for treatment, then discuss possible treatment options for the participant. If the participant is NOT ready, interested in treatment or harm reduction, secure participant buy-in that substance use can and will be an ongoing discussion.	(CUSTEPS)					

Comments:(CFUCOMM)

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

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

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

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

Please rate the extent to which each of the following statements describes how you have been feeling or acting in the past week.
For example, if you feel the statement very accurately describes how you have been feeling in the past week, you would give a rating of "Strongly Agree." If you feel the statement is not at all how you have been feeling in the past week, you would give a rating of "Strongly Disagree."

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

Comments:(CHPCOMM)

Clinical Labs Data (CLD)

Web Version: 1.0; 3.03; 11-15-16

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

All laboratory tests below refer to clinical labs obtained as part of the CTN-0064 study visit. Non-study lab results abstracted from the participant's medical record must be recorded on the Access to and Utilization of Medical Care (Medical Record Abstraction) forms (i.e., AUM for HIV labs, AUH for HCV labs).

1. Was a blood sample collected for this visit?(CLBLDCLT)
a. If "No", specify:(CLBLDNSP)

NoYes

1-Participant refused to provide sample
2-Difficulty with blood draw
3-Study staff error
99-Other

If "Yes", a blood sample was collected, indicate the following.
b. Date of collection:(CLBLDDT)
c. Location of collection:(CLBLDLOC)

(mm/dd/yyyy)

1-Blood draw at research site
2-Blood collection offsite

2. Were CD4 results obtained via blood draw?(CLCD4BLD)
a. If "No", specify:(CLCD4NSP)

NoYes

1-Not enough specimen
2-Problem with shipment
3-Lab unable to test sample
4-Lab processing error
99-Other

b. If "Yes", CD4 count:(CLCD4CNT) (xxxxx) cells/ μ L - and - (CLCD4PCT)CD4 %: (xxx.xx) %

3. Were HIV viral load results obtained via blood draw?(CLHIVBLD)
a. If "No", specify:(CLHIVNSP)

NoYes

1-Not enough specimen
2-Problem with shipment
3-Lab unable to test sample
4-Lab processing error
99-Other

If "Yes", HIV viral load results were obtained, indicate the following.
b. HIV viral load assay type:(CLHIVASY)
c. Was HIV viral load undetectable?(CLHIVUND)
If "Yes", lab's lower limit:(CLHIVLWC)

NoYes

020-20
040-40
050-50
075-75
400-400
*Additional Options Listed Below

< (xxxxxxxx) copies/mL

If "No", HIV viral load:(CLHIVVLC)

4. Were HCV viral load results obtained via blood draw?(CLHCVBLD)
a. If "No", specify:(CLHCVNSP)

NoYes

1-Not enough specimen
2-Problem with shipment
3-Lab unable to test sample
4-Lab processing error
99-Other

If "Yes", HCV viral load results were obtained, indicate the following.
b. HCV viral load assay type:(CLHCVASY)
c. Was HCV viral load undetectable?(CLHCVUND)
If "Yes", lab's lower limit:(CLHCVLWC)

NoYes

005-5
010-10
015-15
025-25
050-50
*Additional Options Listed Below

< (xxxxxxxxx) copies/mL

- or - (CLHCVLW)<

005-5
010-10
015-15
025-25
050-50
*Additional Options Listed Below

< (xxxxxxxx) IU/mL

- or - (CLHCVVL)

< (xxxxxxxx) IU/mL

If "No", HCV viral load:(CLHCVVLC)

Additional Selection Options for CLD

If "Yes", lab's lower limit:
99-Other

If "Yes", lab's lower limit:
100-100
615-615
99-Other

NIDA Clinical Trials Network

Conflictual Social Interaction Scale (CSI)

Web Version: 1.0; 1.01; 10-14-16

Segment (*PROTSEG*): AVisit number (*VISNO*):Date of assessment:(*STSASMDT*) (mm/dd/yyyy)*RA Instruction: Provide participant with a reference card that lists all response options for his/her easy reference.**The next questions are about your interactions with others.**Phrase questions 1-3: "During the past 4 weeks, how much of the time have you (insert question)? Would you say, "None of the Time", "A Little of the Time", "Some of the Time", "Most of the Time", or "All of the Time"?"*

During the <u>past 4 weeks</u> , how much of the time have you:	None of the Time	A Little of the Time	Some of the Time	Most of the Time	All of the Time
1. Had serious disagreements with your <u>family</u> about things that were important to you?	(<i>STDISFAM</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Had serious disagreements with your <u>friends</u> about things that were important to you?	(<i>STDISFR</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Felt that others were trying to make changes in you that you did not want to make?	(<i>STCHANGE</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

*People sometimes look to others for companionship, assistance, or other types of support.**Phrase questions 4-8: "During the past 4 weeks, how often did you have (insert question)? Would you say, "None of the Time", "A Little of the Time", "Some of the Time", "Most of the Time", or "All of the Time"?"*

During the <u>past 4 weeks</u> , how often did you have:	None of the Time	A Little of the Time	Some of the Time	Most of the Time	All of the Time
4. Someone to love and make you feel wanted?	(<i>STWANTED</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Someone to help with daily chores (e.g., child care, buying food, preparing meals) if you were sick?	(<i>STCHORES</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Someone to help you buy medicines?	(<i>STMED</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Someone to help with transportation?	(<i>STTRAN</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Someone to give you money if you need it?	(<i>STMONEY</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments:(*STSCOMM*)

NIDA Clinical Trials Network

1. Date of birth:(DEBRTHDT)

(mm/dd/yyyy)

2. Sex:(DESEX)

☐ Male

☐ Female

☐ Don't know

☐ Refused to answer

☐ No

☐ Yes

☐ Don't know

☐ Refused to answer

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

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

1-Puerto Rican

2-Dominican (Republic)

3-Mexican/Mexican American

5-Chicano

6-Cuban/Cuban American

*Additional Options Listed Below

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

American Indian or Alaska Native:(DEAMEIND)

Asian:(DEASIAN)

Asian Indian:(DEASAIIND)

Chinese:(DECHINA)

Filipino:(DERLIPIN)

Japanese:(DEJAPAN)

Korean:(DEKOREA)

Vietnamese:(DEVIENTNM)

Specify other Asian:(DEASIAOT)

Black or African American:(DEBLACK)

Native Hawaiian or Pacific Islander:(DEHAWAII)

Native Hawaiian:(DENATHAW)

Guamanian or Chamorro:(DEGUAM)

Samoa:(DESAMOAN)

Specify other Pacific Islander:(DEPACISO)

White:(DEWHITE)

Some other race:(DERACEOT)

- or -

Don't know:(DERACEDK)

Refused:(DERACERF)

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

00-Never attended / kindergarten only

01-1st grade

02-2nd grade

03-3rd grade

04-4th grade

*Additional Options Listed Below

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

01-Married

02-Widowed

03-Divorced

04-Separated

05-Never married

*Additional Options Listed Below

Comments:(DEMCOMM)

Web Version: 1.0; 4.01; 05-15-17

92/176

Additional Selection Options for DEM

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

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

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

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

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

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

NIDA Clinical Trials Network

DAST-10 (DST)

Web Version: 1.0; 2.00; 11-15-16

Segment (PROTSEG): A

Visit number (VISNO):

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

The next several questions are about drug use. Answer "No" or "Yes".

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

Total score:(DSTSCORE) (xx)

Comments:(DSTCOMM)

Death Form (DTH)

Web Version: 1.0; 4.00; 02-21-18

1. Date of Death;(DTHDT)

(mm/dd/yyyy)

2. Month and year of death per NDI (if applicable);(DTNDIM)

01-January
02-February
03-March
04-April
05-May
*Additional Options Listed Below

month (DTNDIY)

(xxxx) year

3. Time of death (24-hour format);(DTHDTM)

(hh:mm)

4. Date staff notified of death;(DTNTFYDT)

(mm/dd/yyyy)

5. Date of last contact with participant;(DTNCTCDT)

(mm/dd/yyyy)

6. Date of participant's last primary care visit;(DTPRIMDT)

(mm/dd/yyyy)

7. Primary and secondary causes of death:
Primary cause of death: Enter underlying disease, injury, or complications that initiated the events resulting in death. Do not enter terminal events like cardiac arrest, respiratory arrest, or cardiopulmonary arrest as primary cause of death.
Secondary cause of death: Enter other significant conditions contributing to death, but not resulting in the underlying cause of death given in the primary cause of death.

Cause of Death

If "Other", Specify

Primary Cause of Death:

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

(DTPCODSP)

Secondary Cause of Death:

1-Tuberculosis
2-Serious liver disease (cirrhosis, varices, hepatic failure, encephalopathy)
3-Cardiovascular disease (MI, CAD, CHF)
4-End stage renal disease
5-Cerebrovascular disease
*Additional Options Listed Below

(DT2CODSP)

Secondary Cause of Death:

1-Tuberculosis
2-Serious liver disease (cirrhosis, varices, hepatic failure, encephalopathy)
3-Cardiovascular disease (MI, CAD, CHF)
4-End stage renal disease
5-Cerebrovascular disease
*Additional Options Listed Below

(DT2CD2SP)

Secondary Cause of Death:

1-Tuberculosis
2-Serious liver disease (cirrhosis, varices, hepatic failure, encephalopathy)
3-Cardiovascular disease (MI, CAD, CHF)
4-End stage renal disease
5-Cerebrovascular disease
*Additional Options Listed Below

(DT2CD3SP)

Secondary Cause of Death:

1-Tuberculosis
2-Serious liver disease (cirrhosis, varices, hepatic failure, encephalopathy)
3-Cardiovascular disease (MI, CAD, CHF)
4-End stage renal disease
5-Cerebrovascular disease
*Additional Options Listed Below

(DT2CD4SP)

Secondary Cause of Death:

1-Tuberculosis
2-Serious liver disease (cirrhosis, varices, hepatic failure, encephalopathy)
3-Cardiovascular disease (MI, CAD, CHF)
4-End stage renal disease
5-Cerebrovascular disease
*Additional Options Listed Below

(DT2CD5SP)

8. Source for cause of death;(DTSOURCE)

http://wfbui:9220/WFB/navigateReportList.action

95/149

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

No	Yes	Unknown
No	Yes	Unknown

No	Yes	Unknown
----	-----	---------

No Yes Unknown

No Yes Unknown
(mm/dd/yyyy)

No Yes Unknown
(mm/dd/yyyy)

No	Yes	Unknown
No	Yes	Unknown

No Yes Unknown

No Yes Unknown

No Yes Unknown

No Yes Unknown

No Yes Unknown

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

Additional Selection Options for DTH

Month and year of death per NDI (if applicable):
06-June
07-July
08-August
09-September
10-October
11-November
12-December

Primary cause of death
7-Acute renal failure
95-Not obtainable
97-Unknown
99-Other

Secondary cause of death
6-Malignancy (excluding skin cancer)
7-Diabetes
95-Not obtainable
97-Unknown
99-Other

Fife's Experience of Illness Scale (EIS)

Web Version: 1.0; 2.00; 10-14-16

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

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

The following questions are for persons who are hepatitis C (HCV) positive. If you are HCV negative or you do not know your HCV status, answer these questions thinking about how you (and others around you) might feel or behave if you were HCV positive.

	Strongly Agree	Agree	Disagree	Strongly Disagree
1. My employer/co-workers have discriminated against me.	(EIEMPLOY)			
2. Some people act as though I am less competent than usual.	(EITRTCMP)			
3. I feel I have been treated with less respect than usual by others.	(EIRESPECT)			
4. I feel others are concerned they could "catch" my Hepatitis C (HCV) through contact like a handshake or eating food I prepare.	(EICONTRACT)			
5. I feel others avoid me because of my HCV.	(EIAVOID)			
6. Some family members have rejected me because of my HCV.	(EIFAMILY)			
7. I feel some friends have rejected me because of my HCV.	(EIFRIEND)			
8. I encounter embarrassing situations as a result of my HCV.	(EIEMBRSS)			
9. Due to my HCV others seem to feel awkward and tense when they are around me.	(EIAWKWRD)			
10. I have experienced financial hardship that has affected how I feel about myself.	(EIFNCMYS)			
11. My job security has been affected by my HCV.	(EIJOBSEC)			
12. I have experienced financial hardship that has affected my relationship with others.	(EIFNCREL)			
	Strongly Agree	Agree	Disagree	Strongly Disagree
13. I feel others think I am to blame for my HCV.	(EIBLMME)			
14. I do not feel I can be open with others about my HCV.	(EIOPEN)			
15. I fear someone telling others about my HCV without my permission.	(EIFEAR)			
16. I feel I need to keep my HCV a secret.	(EISECRET)			
17. I feel I am at least partially to blame for my HCV.	(EIBLMMYS)			
18. I feel set apart from others who are well.	(EIAPART)			
19. I have a greater need than usual for reassurance that others care about me.	(EIREASSR)			
20. I feel lonely more often than usual.	(EILONLY)			
21. Due to my HCV, I have a sense of being unequal in my relationships with others.	(EIUNEQUAL)			
22. I feel less competent than I did before HCV.	(EIFELCMP)			
23. Due to my HCV, I sometimes feel useless.	(EIUSELESS)			
24. Changes in my appearance have affected my social relationships.	(EIAPPEAR)			

Comments:(EISCOMM)

NIDA Clinical Trials Network

Urine Ethyl Glucuronide (ETG)

Web Version: 1.0; 1.03; 10-14-16

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

Date of assessment:(ETGASMDT)

(mm/dd/yyyy)

1. Was the urine ethyl glucuronide (EtG) sample collected?(ETCOLLCT)

☐ No ☐ Yes

a. If "Yes", date of collection:(ETCOLLDT)

(mm/dd/yyyy)

b. If "Yes", accession number:(ETACCNUM)

(xxxxxxxxxx)

c. If "No", reason not collected:(ETCLRSN)

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

If "Other", specify:(ETCLRNSP)

2. Was the urine ethyl glucuronide (EtG) sample shipped?(ETSHIP)

☐ No ☐ Yes

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

(mm/dd/yyyy)

b. If "No", reason not shipped:(ETSHRSN)

1-Sample lost
2-Sample processing or storage error
3-Sample not picked up for shipment
99-Other

If "Other", specify:(ETSHRNSP)

Comments:(ETGCOMM)

0064B (ENR)

Web Version: 1.0; 1.02; 12-08-17

Your site is unable to randomize participants due to insufficient enrollment into 0049.

Date of assessment:(R2ASMDT) (mm/dd/yyyy)

Inclusion Criteria

In order to meet eligibility for Component 2 ALL Inclusion answers must be "Yes".

1. Participant provided informed consent, which includes being willing to provide sufficient locator information and to be tested for anti-HCV antibodies and, if antibody positive, tested for active HCV infection:(R2INFORM)	No	Yes	
2. Participant reports living in the vicinity and is able to return for follow-up visits:(R2LIVRET)	No	Yes	Unknown
3. Participant signed HIPAA form/medical record release form to facilitate medical record abstraction:(R2HIPAA)	No	Yes	
4. Participant provided sufficient locator information:(R2LCATOR)	No	Yes	Unknown
5. A baseline assessment has been completed for this participant:(R2BASELN)	No	Yes	
6. A baseline blood draw has been completed for this participant:(R2BLOOD)	No	Yes	
7. Participant tested positive for HCV antibody via Component 1:(R2HCVPOS)	No	Yes	Unknown
8. Participant agreed to be randomized in Component 2:(R2RAND2)	No	Yes	Unknown

Exclusion Criteria

In order to meet eligibility for Component 2 ALL Exclusion answers must be "No".

1. Participant has a significant cognitive or developmental impairment:(R2SIGCOG)	No	Yes	Unknown
2. Participant is terminated via site PI decision/discretion with agreement from study LI:(R2TERM) If "Yes", specify:(R2TERMSP)	No	Yes	Unknown
3. Participant is currently in jail, prison or any inpatient overnight facility as required by court of law or has a pending legal action which may prevent the individual from completing the study:(R2PRISON)	No	Yes	Unknown
4. Participant is on HCV therapy/medications at baseline, based on self report:(R2HCVMED)	No	Yes	Unknown
5. Participant completed a course of HCV medications in the 12 weeks prior to baseline, based on self report:(R2COMPLT)	No	Yes	Unknown

Stratification

Participant self-reported currently receiving HIV care and taking HIV ART drugs:(R2HIVART)	No	Yes
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Eligibility for Randomization

1. Is the participant eligible for the study?(R2ELGSTY)	No	Yes
2. Will the participant be randomized?(R2ELGRND) If "No", specify:(R2NORASP)	No	Yes

- 1-Failed to return to clinic
2-Declined study participation
3-Death
99-Other

If "Judgment of site research staff" or "Other", specify:(R2OTHRSP)

Comments:(R2COMM)

Facilitators and Barriers to Care (FBC)

Web Version: 1.0; 1.02; 10-14-16

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

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

Facilitators to Care

1. Sometimes there are things that make it easier for people to get HIV and HCV care. I am going to read a list of things that some people might find helpful. Please identify all of these that helped you to get HIV and or HCV care or made getting HIV/HCV care easier and check all that apply.

	No	Yes	N/A
a. My doctor (nurse, staff) seemed to care about me.	(FBHHHCARE)		
b. My doctor (nurse, staff) seemed warm and non-judgmental.	(FBHHHWARM)		
c. My doctor (nurse, staff) explained things clearly to me.	(FBHHHCCLER)		
d. When I called my doctor (nurse, staff) with a question, I got a timely return call.	(FBHHHCALL)		
e. The staff at the clinic/doctor's office were helpful.	(FBHHHHELP)		
f. Someone at the clinic/doctor's office helped me with the paperwork.	(FBHHHPRWK)		
g. Someone reminded me of my doctor's appointments.	(FBHHHRMND)		
h. The clinic/doctor's office or pharmacy made it easy for me to refill my medication.	(FBHHHRFLL)		
i. I could get all my medical care in one place.	(FBHHHONE)		
j. Child care was provided for me by the clinic/doctor's office.	(FBHHHCHLD)		
k. I didn't have to wait a long time at the clinic/doctor's office.	(FBHHHWAIT)		
l. The clinic/doctor's office was located near where I lived or worked.	(FBHHHNEAR)		
m. Transportation was provided for me to the clinic/doctor's office.	(FBHHHTRNS)		
n. The clinic/doctor's office offered convenient appointment times.	(FBHHHCNVT)		
o. Everything at the clinic/doctor's office was private and confidential.	(FBHHHCNFD)		
p. It was easy for me to talk with people at the clinic/doctor's office.	(FBHHHEASY)		
q. I had insurance for this care and treatment.	(FBHHHINSR)		
r. Other people I knew had this kind of care and treatment.	(FBHHHPEOP)		
s. People I was close to were supportive of my having this care and treatment.	(FBHHHSUPP)		
t. People I was close to helped me with child care or other responsibilities when I had to go to the clinic/doctor's office.	(FBHHHRESP)		
u. I believed that treating my HIV/HCV would make my life better.	(FBHHHBTTR)		
v. Solving my other problems first (e.g., housing instability, drug and/or alcohol dependence) made it easier for me to focus on my HIV/HCV care.	(FBHHHSOLV)		
w. I felt sick.	(FBHHHSICK)		
x. "Other", specify:(FBHHHOTSP)	(FBHHHOTHR)		

Barriers to Care

2. Indicate all the reasons you have not had an HIV care visit since your last CTN-0064 study visit.

	No	Yes	N/A
a. I did not know I needed to have an HIV care visit.	(FBHVKNOW)		
b. I did not know where to go for an HIV care visit.	(FBHVWHRE)		
c. I forgot to schedule an HIV care visit.	(FBHVFRGT)		
d. I felt too sick to go to an HIV care visit.			

	(FBHVSICK)
e. I felt healthy and did not see a need to go to the doctor.	(FBHVHTHY)
f. I was up to date on my medications and did not see a need to go to the doctor.	(FBHVNEED)
g. Even though I had insurance, I was unable to pay co-pays for my HIV care visits.	(FBHVCPAY)
h. I didn't have health insurance and I was unable to pay for my HIV care visits.	(FBHVINSR)
i. I didn't have transportation to the clinic/doctor's office.	(FBHVTRNS)
j. The clinic/doctor's office hours were inconvenient.	(FBHVHOUR)
k. In the past, I have had difficulty communicating with my doctor or other health care staff.	(FBHVCOMM)
l. In the past, I was treated poorly by clinic/doctor's office staff (e.g., doctors, nurses, front desk staff).	(FBHVPOOR)
m. Other things were more important to me.	(FBHVOTHR)
n. I felt depressed.	(FBHVDEPR)
o. I was overwhelmed.	(FBHVOVER)
p. I got high or relapsed on drugs or I was drinking or relapsed on alcohol.	(FBHVHIGH)

3. Indicate all the reasons you are not taking HIV medications.

	No	Yes	N/A
a. I did not know I needed to continue taking HIV medications when I ran out of pills.	(FBHRKNOW)		
b. I forgot to refill my HIV medications.	(FBHRFRGT)		
c. I felt too sick to keep up with my HIV medications.	(FBHRSICK)		
d. I felt healthy and did not know I needed to continue taking HIV medications.	(FBHRHTHY)		
e. Even though I had insurance, I was unable to pay co-pays for my HIV medications.	(FBHRCPAY)		
f. I didn't have health insurance and I was unable to pay for my medications.	(FBHRINSR)		
g. My insurance did not pay for my HIV medications.	(FBHRNOPY)		
h. My prescription ran out and I did not know how to get it refilled.	(FBHRPRAN)		
i. I had side effects from the HIV medications.	(FBHRSIDE)		
j. My HIV medication regimen was too complicated.	(FBHRCMPL)		
k. I had too many other medications to take.	(FBHRMEDS)		
l. I didn't have transportation to pick up my HIV medications.	(FBHRTRNS)		
m. The pharmacy hours were inconvenient.	(FBHRHOUR)		
n. In the past, I have had difficulty communicating with my doctor or other health care staff.	(FBHRCOMM)		
o. In the past, the pharmacy staff treated me poorly.	(FBHRPOOR)		
p. Other things were more important to me.	(FBHROTHR)		
q. I felt depressed.	(FBHRDEPR)		
r. I felt overwhelmed.	(FBHROVER)		
s. I got high or relapsed on drugs or I was drinking or relapsed on alcohol.	(FBHRHIGH)		

4. Indicate all the reasons you did not return for your CTN-0064 HCV viral load results.

	No	Yes	N/A
a. I did not know I needed to receive the results.	(FBRSKNOW)		
b. I did not know where to go to receive the results.	(FBRSWHER)		
c. I forgot to go back to receive the results.	(FBRSFRTGT)		
d. Even though I had health insurance, I was unable to pay a co-pay for another visit.	(FBRSCPAY)		
e. I didn't have health insurance and I was unable to pay for another visit.	(FBRSSINSR)		
f. I feared knowing the results of such a test.	(FBRSFEAR)		
g. I was not interested in knowing if I had HCV.	(FBRSSINTR)		

- h. I was embarrassed/ashamed to receive my results.

(FBRSEMBR)
- i. I didn't have transportation to a clinic/doctor's office to obtain the results.

(FBRSTRNS)
- j. The clinic/doctor's office hours were inconvenient.

(FBRSHOUR)
- k. In the past, I have had difficulty communicating with my doctor or other health care staff.

(FBRSCOMM)
- l. In the past, I was treated poorly by clinic/doctor's office staff (doctors, nurses, front desk staff).

(FBRSPOOR)
- m. I believed test results were often wrong.

(FBRSWRNG)
- n. Other things were more important to me.

(FBRSOTHR)
- o. I felt depressed.

(FBRSDDEPR)
- p. I felt overwhelmed.

(FBRSOEVER)

5. Indicate all the reasons you have not had a hepatitis C (HCV) medical or liver evaluation since your last CTN-0064 study visit.

- | | No | Yes | N/A |
|---|------------|-----|-----|
| a. I did not know I needed to have a liver evaluation. | (FBLVKNOW) | | |
| b. I was not given a referral to see a specialist for a liver evaluation. | (FBLVRFRL) | | |
| c. I did not know where to get a liver evaluation. | (FBLVWHER) | | |
| d. Even though I had health insurance, I was unable to pay a co-pay for such a test. | (FBLVCPAY) | | |
| e. I did not think my insurance would pay for such a test. | (FBLVNOPY) | | |
| f. I did not have health insurance and I was unable to pay for such an evaluation. | (FBLVINSR) | | |
| g. I feared knowing the results of such an evaluation. | (FBLVFEAR) | | |
| h. I was not interested in knowing whether I have liver problems. | (FBLVINTR) | | |
| i. I was embarrassed/ashamed to get a liver evaluation. | (FBLVEMBR) | | |
| j. I didn't have transportation to a clinic/doctor's office to undergo such an evaluation. | (FBLVTRNS) | | |
| k. The clinic/doctor's office hours were inconvenient. | (FBLVHOUR) | | |
| l. In the past, I was treated poorly by clinic/doctor's office staff (doctors, nurses, front desk staff). | (FBLVPOOR) | | |
| m. I believed that medical test results were often wrong. | (FBLVWRNG) | | |
| n. I feared that my personal information would not be confidential. | (FBLVCNFD) | | |
| o. I feared that the evaluation and tests would be painful. | (FBLVPAIN) | | |
| p. Other things were more important to me. | (FBLVOTHR) | | |
| q. I felt depressed. | (FBLVDEPR) | | |
| r. I felt overwhelmed. | (FBLVOVER) | | |

6. Indicate all the reasons you think your doctor has not recommended you take medication(s) for treatment of hepatitis C (HCV) since your last CTN-0064 study visit.

- | | No | Yes | N/A |
|---|-------------|-----|-----|
| a. I do not know. | (FBDRKNOW) | | |
| b. I thought it was because I did not have health insurance. | (FBDRNOHI) | | |
| c. I was told my insurance would not cover it because my liver disease was too mild. | (FBDRMILD) | | |
| d. I was told my insurance would not cover it because of my drug or alcohol use. | (FBDRUSE) | | |
| e. I was told that my insurance would not cover it, but the reason was not specified. | (FBDRUNSP) | | |
| f. My doctor told me I needed to control my HIV. | (FBDRHIV) | | |
| g. My doctor told me I needed to stop using drugs. | (FBDRDRUG) | | |
| h. My doctor told me I needed to stop using alcohol. | (FBDRALCO) | | |
| i. My doctor told me I was not serious enough about getting HCV treatment. | (FBDRSERI) | | |
| j. My doctor told me I miss too many appointments. | (FBDRMISS) | | |
| k. I thought I was too sick to take HCV medication. | (FBDRSICK) | | |
| l. I thought it was because I was too healthy to need HCV medication. | (FBDRHETHY) | | |

- m. I was not given a prescription because my liver disease is mild.

(FBDRMLD)
- n. I was not offered medications because I did not get the extra tests that were needed.

(FBDREXTR)
- o. I could not get the medications because I did not have an address they could deliver the medications to.

(FBDRADDR)
- p. I thought it was because doctors don't like people like me.

(FBDRLIKE)
- q. I thought it was because I was homeless.

(FBDRHOME)

7. Indicate all the reasons you have not received any hepatitis C (HCV) medication(s) since your last CTN-0064 study visit.

- | | No | Yes | N/A |
|---|-------------|-----|-----|
| a. I did not know I was eligible for HCV medications. | (FBRKNOW) | | |
| b. I forgot to fill the prescription for the HCV medications. | (FBRFRGRT) | | |
| c. It was difficult for me to complete the paperwork because I did not understand it. | (FBRFUNDNR) | | |
| d. I could not complete the paperwork because it asked for things I do not have such as home address or income stubs. | (FBRFRSTUB) | | |
| e. My insurance did not cover the prescribed medication. | (FBRFCOVR) | | |
| f. My health insurance would not cover it because of my alcohol or drug use. | (FBRFRUSE) | | |
| g. My health insurance would not cover it because I was not sick enough (my liver disease was too mild). | (FBRFRMILD) | | |
| h. I thought I needed health insurance to get it. | (FBRFRNEED) | | |
| i. Even though I had health insurance, I was unable to pay the co-pay for the medication. | (FBRFRCPAY) | | |
| j. I did not have health insurance and I was unable to pay for the HCV medication. | (FBRFRINSR) | | |
| k. In the past, the pharmacy staff treated me poorly. | (FBRFRPOOR) | | |
| l. I did not want to take the HCV medications because I heard they were toxic. | (FBRFRTXIC) | | |
| m. I did not want to take the HCV medications because I took HCV medications in the past and they made me sick. | (FBRFRWANT) | | |
| n. I did not think my HCV was a serious risk to my health. | (FBRFRRISK) | | |
| o. I was afraid to take the HCV medication. | (FBRFRFEAR) | | |
| p. I felt depressed. | (FBRFRDEPR) | | |
| q. I felt overwhelmed. | (FBRFROVER) | | |

8. Indicate all the reasons you have not taken any hepatitis C (HCV) medication(s) since your last CTN-0064 study visit.

- | | No | Yes | N/A |
|---|-------------|-----|-----|
| a. I lost the HCV medication. | (FBTRLOST) | | |
| b. I forgot to take the HCV medication. | (FBTRFRGRT) | | |
| c. I felt too sick to take the HCV medication. | (FBTRSICK) | | |
| d. I sold the HCV medication. | (FBTRSOLD) | | |
| e. I did not think that my HCV was a serious risk to my health. | (FBTRRRISK) | | |
| f. I did not want to take the HCV medications because I heard they were toxic. | (FBTRTXIC) | | |
| g. I did not want to take the HCV medications because I took HCV medications in the past and they made me sick. | (FBTRPAST) | | |
| h. I was afraid to take the HCV medication. | (FBTRFEAR) | | |
| i. I felt depressed. | (FBTRDEPR) | | |
| j. I felt overwhelmed. | (FBTROVER) | | |

9. Indicate all the reasons you have not completed any course of hepatitis C (HCV) medication(s) since your last CTN-0064 study visit.

- | | No | Yes | N/A |
|---|-------------|-----|-----|
| a. I felt better so I stopped taking the HCV medication. | (FBCPBTTR) | | |
| b. The HCV medication gave me side effects that I could not tolerate. | (FBCPSSIDE) | | |
| c. I did not get the needed refills for the HCV medication. | (FBCPRFLL) | | |
| d. My doctor never refilled the HCV medication. | (FBCPDRRF) | | |
| e. My doctor told me to stop taking the HCV medication. | (FBCPTOLD) | | |

f. Even though I had health insurance, I could no longer pay my co-pays for HCV medication.

(FBCPCPAY)

g. I did not have health insurance and I was unable to pay for the HCV medication.

(FBCPNOHI)

h. My health insurance stopped paying for my HCV medication.

(FBCPINSR)

i. I did not think that my HCV was a serious risk to my health.

(FBCPRIISK)

j. Other things were more important to me.

(FBCPOTHr)

k. I felt depressed.

(FBCPDEPR)

l. I felt overwhelmed.

(FBCPOVER)

10. Do you know whether or not you have cleared the hepatitis C (HCV) virus from your blood since your last CTN-0064 study visit?(FBCURED)

NoYes

Indicate all the reasons you do not know whether or not you have cleared the HCV virus from your blood since your last CTN-0064 study visit.

NoYesN/A

a. I never went back to be checked.

(FBCRWENT)

b. Nobody told me if I was cured.

(FBCRNBDY)

c. I did not know I had to go back and be checked to see if the medications worked.

(FBCRKNOw)

d. In the past, I have had difficulty communicating with my doctor or other health care staff.

(FBCRSTAF)

Comments:(FBCCOMM)

NIDA Clinical Trials Network

Fagerstrom Test for Nicotine Dependence (FND)

Web Version: 1.0; 1.00; 10-14-16

Segment (*PROTSEG*): AVisit number (*VISNO*):Date of assessment: (*FNDASMDT*) (mm/dd/yyyy)Do you currently smoke cigarettes? (*FNSMOKE*)☐ No ☐ Yes*If "Yes", read each question below. For each question enter the answer choice which best describes your responses.*1. How soon after you wake up do you smoke your first cigarette? (*FNFIRST*)
3-Within 5 minutes
2-6 - 30 minutes
1-31 - 60 minutes
0-After 60 minutes2. Do you find it difficult to refrain from smoking in places where it is forbidden (e.g., in church, at the library, in cinema)? (*FNFORBDN*)☐ No ☐ Yes3. Which cigarette would you hate most to give up? (*FNGIVEUP*)☐ The first one in the morning ☐ All others4. How many cigarettes a day do you smoke? (*FNNODAY*)
0-10 or less
1-11-20
2-21-30
3-31 or more5. Do you smoke more frequently during the first hours after waking than during the rest of the day? (*FNREQ*)☐ No ☐ Yes6. Do you smoke if you are so ill that you are in bed most of the day? (*FNSICK*)☐ No ☐ YesComments: (*FNDCOMM*)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

Gain Risk Behaviors (GRB)

Web Version: 1.0; 4.00; 01-19-17

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

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

We would like to ask a few personal questions about behaviors that may have affected your risk of getting or spreading infectious diseases. Remember that all of your answers are strictly confidential.

The first questions are about the use of a needle to inject you with drugs or medication. Do **not** include shots given by a doctor or nurse, but **do** include if you were injected by someone besides a doctor or nurse **or** if you injected prescribed medication.

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

6-Within the past 2 days
5-3 to 7 days ago
4-1 to 4 weeks ago
3-1 to 3 months ago
2-4 to 12 months ago
*Additional Options Listed Below

During the past 12 months, did you:

2. Use a needle to shoot up drugs?(GRNDSTUP)

☐ No ☐ Yes
3. Reuse a needle that **you** had used before?(GRNDREUS)

☐ No ☐ Yes
4. Reuse a needle **without** cleaning it with bleach or boiling water first?(GRNDNOCL)

☐ No ☐ Yes
5. Use a needle that you knew or suspected **someone else** had used before?(GRNDELSE)

☐ No ☐ Yes
6. Use someone else's **rinse water, cooker, or cotton** after they did?(GRNDH2O)

☐ No ☐ Yes
7. Ever **skip** cleaning your needle with bleach or boiling water **after** you were done?(GRNDSKIP)

☐ No ☐ Yes
8. Let someone else use a needle **after** you used it?(GRNDAFTR)

☐ No ☐ Yes
9. Let someone else use the **rinse water, cooker, or cotton** after you did?(GRNDH2OA)

☐ No ☐ Yes
10. Allow someone else to inject you with drugs?(GRNDINJT)

☐ No ☐ Yes

During the past 90 days:

11. On how many **days** did you use a needle to inject any kind of drug or medication?(GR90DUN)

(xx) days

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

(xx) days

b. On how many **days** did you give needles/works/rinse water or cotton to be used after you?(GR90DDG)

(xx) days
12. With how many **people** have you given needles/works/rinse water or cotton to use after you?(GR90DPG)

(xx) people

How many of these people were HIV negative or you did not know their HIV status?(GR90DPGH)

(xx) people
13. From how many **people** have you taken needles/works/rinse water or cotton to use after them?(GR90DPT)

(xx) people

How many of these people were HIV negative or you did not know their HIV status?(GR90DPTH)

(xx) people

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

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

6-Within the past 2 days
5-3 to 7 days ago
4-1 to 4 weeks ago
3-1 to 3 months ago
2-4 to 12 months ago
*Additional Options Listed Below

If ever, have you had sex with (choose all that apply):

a. Males:(GRESXM)

☐ No ☐ Yes

b. Females:(GRESXF)

☐ No ☐ Yes

c. Transmales:(GRESXTRM)

☐ No ☐ Yes

d. Transfemales:(GRESXTRF)

☐ No ☐ Yes

-OR-

e. Don't know:(GRESXDK)

☐ Yes

f. Refused to answer:(GRESXRF)

☐ Yes

During the past 12 months, did you:

15. Have sex while you **were high on alcohol or on other drugs**?(GRSEXHGH)

☐ No ☐ Yes

16. Have sex with someone who was an **injection drug user**?(GRSEXINJ)

☐ No ☐ Yes

17. Have sex involving **anal intercourse** (penis to butt)?(GRSEXANL)

☐ No ☐ Yes

18. Have sex against your will (you were forced or coerced)?(GRSEXAGS)

☐ No ☐ Yes

19. **Trade** sex to get drugs, gifts or money?(GRSEXTRD)

☐ No ☐ Yes

20. Use drugs, gifts, or money to **purchase** or get sex?(GRSEXDRG)

☐ No ☐ Yes

21. Have sex with someone who you thought was **HIV negative** or you did not know their HIV status?
(GRSEXNEG)

☐ No ☐ Yes

22. Have **two or more** different sex partners (not necessarily at the same time)?(GRSEX2PP)

☐ No ☐ Yes

23. Have sex with a **male partner**?(GRSEXMAL)

☐ No ☐ Yes

24. Have sex with a **female partner**?(GRSEXFEM)

☐ No ☐ Yes

25. Have sex **without** using any any kind of condom to protect you and your partner from diseases or pregnancy?(GRSEXCOND)

☐ No ☐ Yes

26. Have a lot of **pain** during sex or after having had sex?(GRSEXPAN)

☐ No ☐ Yes

27. Use alcohol or other drugs to make sex **last longer or hurt less**?(GRSEXLST)

☐ No ☐ Yes

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

During the past 90 days:

28. How many sex partners did you have who were male?(GR9SXMAL)

(xxx) partners

How many of your male sex partners were HIV negative or you did not know their HIV status?
(GR9SXMHV)

(xxx) partners

29. 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

30. With how many of your male or female partners have you been high on alcohol or drugs when having sex at least once in the **past 90 days**? (GR9SXHGH)

(xxx) partners

31. Have you had a partner that you consider a primary partner?

☐ No ☐ Yes

(By primary we mean someone with whom you felt a special emotional commitment, someone you have dated or would call your boyfriend, girlfriend, spouse, significant other, or life time partner.) (GRPRIMPT)

a. Your primary partner's gender is: (GRPRIMGN)

☐ Male ☐ Female

b. How long have the two of you been seeing each other? (GRELTLT)

1-Less than 2 months
2-2 - 4 months
3-4 - 6 months
4-6 - 12 months
5-1 - 2 years
*Additional Options Listed Below

c. What is your primary partner's HIV status? (GRPRIMHS)

☐ Positive ☐ Negative ☐ Unknown

d. Do you believe this relationship to be exclusive or monogamous (i.e., that neither of you have sex with other partners)? (GRPRIMEX)

☐ No ☐ Yes

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

(xxx) times

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

(xxx) times

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

(xxx) times

During the past 90 days, when you had sex with your male and/or female partner(s) (excluding your primary partner, if you had one), how many times:

32. Did you have vaginal or anal sex with HIV positive partners? (GRSEXHVP)

(xxx) times

33. 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

34. Did you have sex while you were **high on alcohol or other drugs**? (GRNPMHGH)

(xxx) times

35. Did you **trade sex** for drugs, gifts, or money? (GRNPMTRD)

(xxx) times

36. Use drugs, gifts, or money to purchase or get sex? (GRNPMDRG)

(xxx) times

Comments: (GRBCOMM)

Additional Selection Options for GRB

When was the last time, if ever, that you used a needle to inject drugs or medication?

Include medication prescribed by a doctor.

1-More than 12 months ago

0-Never

How long have the two of you been seeing each other?

6-Over 2 years

When was the last time, if ever, that you had any kind of vaginal, oral, or anal sex with another person?

1-More than 12 months ago

0-Never

HCV Medications (Medical Record) (HCM)

Web Version: 1.0; 1.02; 10-14-16

HCV medication name (HCVMED):
Sequence of medication (MEDSEQNO):

1. Facility name and address for evidence that this HCV medication was offered:
"Evidence that this HCV medication was offered" means documentation of a written prescription or initiated paperwork. (HMPRLC01)

2. Duration of medication regimen:(HMDURATN)

(xx) weeks

3. Is there evidence this HCV medication was filled or received?
"Evidence this HCV medication was filled or received" means documentation that the participant filled, received and/or is currently taking this medication (e.g., clinician note, medication log, prescription log from clinic or pharmacy, pharmacy fill data). (HMFILLRX)
a. If "Yes", date medication was filled or received:(HMFILLDT)
b. If "Yes", facility name and address for evidence that medication was filled or received:(HMPRLC02)
c. If "No", specify reason medication was not filled or received:(HMNOFILL)

☐ No ☐ Yes

(mm/dd/yyyy)

- 1-Participant still trying to obtain the medication
2-Participant never picked up the medication
3-Insurance denied the medication
4-Alternative medication regimen filled
97-Reason unspecified

- 1-Requires negative toxicity screen or substance abuse treatment
2-Mild disease present
99-Other

1. If "Insurance denied the medication", specify reason:(HMDENY)

If "Other", specify:(HMDENYSP)

2. If "Alternative medication regimen filled", specify medication:(HMAITMED)

- 1-PEGASYS (pegylated interferon (peginterferon alfa-2a)) or PEG-Intron (peginterferon alfa-2b)
2-Virazole, Rebetol, or Copegus (ribavirin)
3-Rebetron (ribavirin + interferon alfa-2b)
4-Victrelis (boceprevir)
5-Incivek (telaprevir)
*Additional Options Listed Below

If "Other HCV medication", specify:(HMAITSP)

4. Is there evidence this HCV medication was stopped?(HMSTOPRX)
a. If "Yes", date of most recent evidence that medication was stopped:(HMSTOPDT)
b. If "Yes", facility name and address for evidence that medication was stopped:(HMPRLC03)

☐ No ☐ Yes

(mm/dd/yyyy)

Comments:(HCMCOMM)

Additional Selection Options for HCM

HCV medication name (HCVMED) (key field):
1-PEGASYS (pegylated interferon (peginterferon alfa-2a)) or PEG-Intron (peginterferon alfa-2b)
2-Virazole, Rebetol, or Copegus (ribavirin)
3-Rebetron (ribavirin + interferon alfa-2b)
4-Victrelis (boceprevir)
5-Incivek (telaprevir)
6-Olysio (simeprevir)
7-Sovaldi (sofosbuvir)
8-Harvoni (ledipasvir + sofosbuvir)
9-Viekira Pak (ombitasvir/paritaprevir/ritonavir + dasabuvir)
10-Daclatasvir
99-Other HCV medication

Sequence of medication (MEDSEQNO) (key field):
01-1st medication use
02-2nd medication use
03-3rd medication use
04-4th medication use
05-5th medication use

HCV Medication Log (Self Report) (HCS)

Web Version: 1.0; 2.00; 10-14-16

RA Instruction:

This is a participant self report form and should reflect only the information provided by the participant.

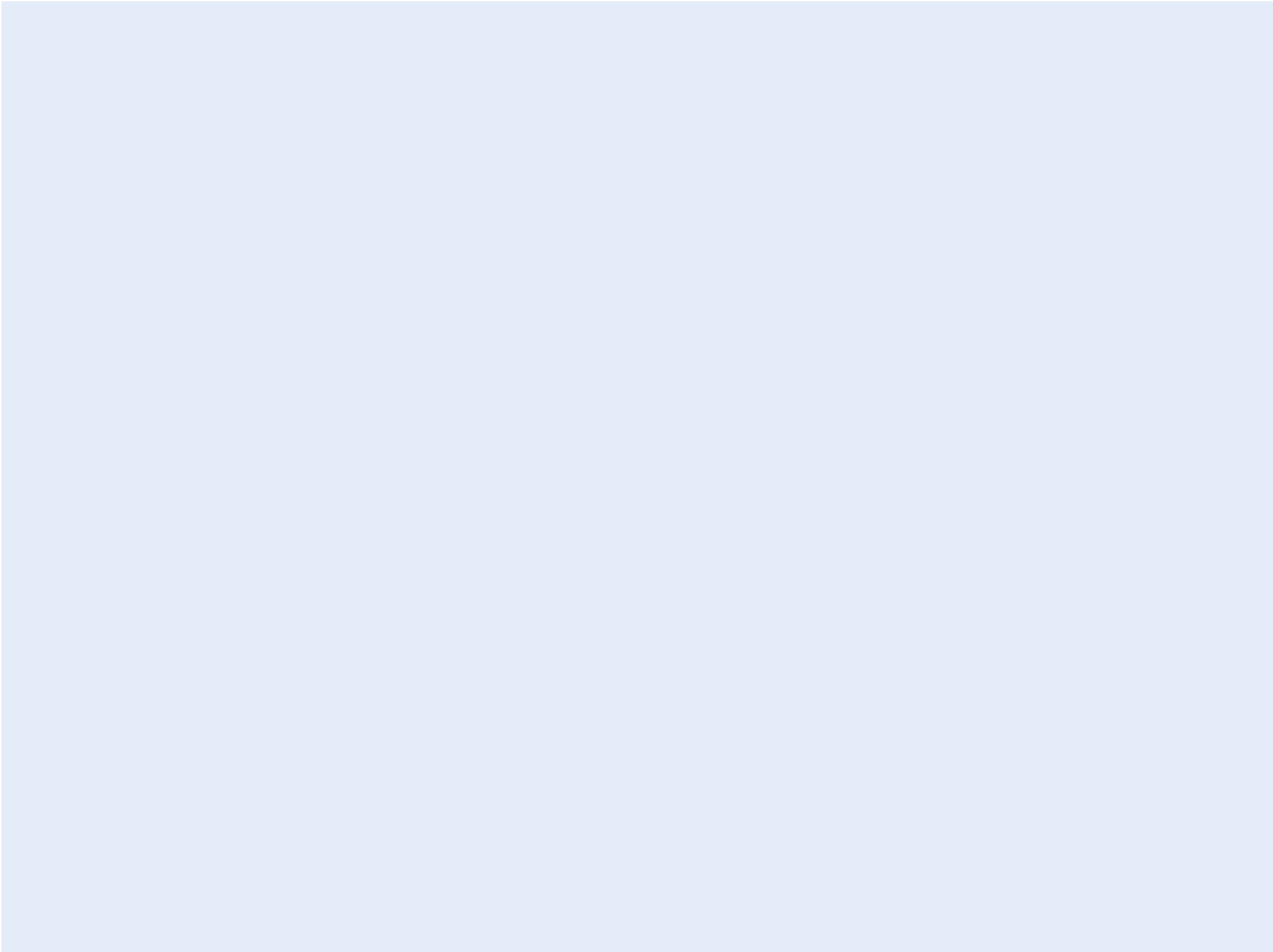
You may need to remind the participant s/he reported taking HCV medications on the Access to and Utilization of Medical Care Self Report (AUS) form.
If the participant is unable to recall an exact date, record an estimated date using the "Mid-month", "Mid-year", and "Mid-decade" convention:

- If the exact day is unknown, default to the middle of the month = 15 (e.g., mm/15/yyyy)
- If the month and day are unknown, default to the middle of year and month = 06/15 (e.g., 06/15/yyyy)
- If the year is unknown, default to the middle of the decade (e.g., 90's = 1995 = 06/15/1995)

If the participant reports "Other HCV medication", the name of the medication must be recorded in the "Comments" field.

List all HCV medications you have ever been prescribed, even if you never stated taking the medication or had poor adherence to the medication.

@2Drug Name	@2Drug Not Stated	@2Start Date	@2Stop Date	@2Ongoing at Termination	^2Did You Complete the Course of Medication?	@2Facility Name and Address Where Medication Prescribed	^2Obtained MR Release	@2Pharmacy Name and Address	^2Obtained MR Release
					No Yes		No Yes		No Yes
1. (HCDRUG01) 1-PEGASYS (pegylated interferon (peginterferon alfa-2a)) or PEG-Intron (peginterferon alfa-2b) 2-Virazole, Rebetol, or Copegus (ribavirin) 3-Pariteton (pariteton + interferon alfa 2b) 4-Victrelis (boceprevir) 5-Incyvek (telaprevir) *Additional Options Listed Below	(HONTST01) <input type="checkbox"/>	(HCSTD01) <input type="text"/>	(HCSPT01) <input type="text"/>	(HCONG01) <input type="checkbox"/>	(HCCMPL01) <input type="checkbox"/>	(HOPRLC01) <input type="text"/>	(HCRXMR01) <input type="checkbox"/>	(HOPRLC01) <input type="text"/>	(HCPHMR01) <input type="checkbox"/>
2. (HCDRUG02) 1-PEGASYS (pegylated interferon (peginterferon alfa-2a)) or PEG-Intron (peginterferon alfa-2b) 2-Virazole, Rebetol, or Copegus (ribavirin) 3-Pariteton (pariteton + interferon alfa 2b) 4-Victrelis (boceprevir) 5-Incyvek (telaprevir) *Additional Options Listed Below	(HONTST02) <input type="checkbox"/>	(HCSTD02) <input type="text"/>	(HCSPT02) <input type="text"/>	(HCONG02) <input type="checkbox"/>	(HCCMPL02) <input type="checkbox"/>	(HOPRLC02) <input type="text"/>	(HCRXMR02) <input type="checkbox"/>	(HOPRLC02) <input type="text"/>	(HCPHMR02) <input type="checkbox"/>
3. (HCDRUG03) 1-PEGASYS (pegylated interferon (peginterferon alfa-2a)) or PEG-Intron (peginterferon alfa-2b) 2-Virazole, Rebetol, or Copegus (ribavirin) 3-Pariteton (pariteton + interferon alfa 2b) 4-Victrelis (boceprevir) 5-Incyvek (telaprevir) *Additional Options Listed Below	(HONTST03) <input type="checkbox"/>	(HCSTD03) <input type="text"/>	(HCSPT03) <input type="text"/>	(HCONG03) <input type="checkbox"/>	(HCCMPL03) <input type="checkbox"/>	(HOPRLC03) <input type="text"/>	(HCRXMR03) <input type="checkbox"/>	(HOPRLC03) <input type="text"/>	(HCPHMR03) <input type="checkbox"/>
4. (HCDRUG04) 1-PEGASYS (pegylated interferon (peginterferon alfa-2a)) or PEG-Intron (peginterferon alfa-2b) 2-Virazole, Rebetol, or Copegus (ribavirin) 3-Pariteton (pariteton + interferon alfa 2b) 4-Victrelis (boceprevir) 5-Incyvek (telaprevir) *Additional Options Listed Below	(HONTST04) <input type="checkbox"/>	(HCSTD04) <input type="text"/>	(HCSPT04) <input type="text"/>	(HCONG04) <input type="checkbox"/>	(HCCMPL04) <input type="checkbox"/>	(HOPRLC04) <input type="text"/>	(HCRXMR04) <input type="checkbox"/>	(HOPRLC04) <input type="text"/>	(HCPHMR04) <input type="checkbox"/>
5. (HCDRUG05) 1-PEGASYS (pegylated interferon (peginterferon alfa-2a)) or PEG-Intron (peginterferon alfa-2b) 2-Virazole, Rebetol, or Copegus (ribavirin) 3-Pariteton (pariteton + interferon alfa 2b) 4-Victrelis (boceprevir) 5-Incyvek (telaprevir) *Additional Options Listed Below	(HONTST05) <input type="checkbox"/>	(HCSTD05) <input type="text"/>	(HCSPT05) <input type="text"/>	(HCONG05) <input type="checkbox"/>	(HCCMPL05) <input type="checkbox"/>	(HOPRLC05) <input type="text"/>	(HCRXMR05) <input type="checkbox"/>	(HOPRLC05) <input type="text"/>	(HCPHMR05) <input type="checkbox"/>
6. (HCDRUG06) 1-PEGASYS (pegylated interferon (peginterferon alfa-2a)) or PEG-Intron (peginterferon alfa-2b) 2-Virazole, Rebetol, or Copegus (ribavirin) 3-Pariteton (pariteton + interferon alfa 2b) 4-Victrelis (boceprevir) 5-Incyvek (telaprevir) *Additional Options Listed Below	(HONTST06) <input type="checkbox"/>	(HCSTD06) <input type="text"/>	(HCSPT06) <input type="text"/>	(HCONG06) <input type="checkbox"/>	(HCCMPL06) <input type="checkbox"/>	(HOPRLC06) <input type="text"/>	(HCRXMR06) <input type="checkbox"/>	(HOPRLC06) <input type="text"/>	(HCPHMR06) <input type="checkbox"/>
7. (HCDRUG07) 1-PEGASYS (pegylated interferon (peginterferon alfa-2a)) or PEG-Intron (peginterferon alfa-2b) 2-Virazole, Rebetol, or Copegus (ribavirin) 3-Pariteton (pariteton + interferon alfa 2b) 4-Victrelis (boceprevir) 5-Incyvek (telaprevir) *Additional Options Listed Below	(HONTST07) <input type="checkbox"/>	(HCSTD07) <input type="text"/>	(HCSPT07) <input type="text"/>	(HCONG07) <input type="checkbox"/>	(HCCMPL07) <input type="checkbox"/>	(HOPRLC07) <input type="text"/>	(HCRXMR07) <input type="checkbox"/>	(HOPRLC07) <input type="text"/>	(HCPHMR07) <input type="checkbox"/>
8. (HCDRUG08) 1-PEGASYS (pegylated interferon (peginterferon alfa-2a)) or PEG-Intron (peginterferon alfa-2b) 2-Virazole, Rebetol, or Copegus (ribavirin) 3-Pariteton (pariteton + interferon alfa 2b) 4-Victrelis (boceprevir) 5-Incyvek (telaprevir) *Additional Options Listed Below	(HONTST08) <input type="checkbox"/>	(HCSTD08) <input type="text"/>	(HCSPT08) <input type="text"/>	(HCONG08) <input type="checkbox"/>	(HCCMPL08) <input type="checkbox"/>	(HOPRLC08) <input type="text"/>	(HCRXMR08) <input type="checkbox"/>	(HOPRLC08) <input type="text"/>	(HCPHMR08) <input type="checkbox"/>



Additional Selection Options for HCS

- Drug name 01
- 6-Clysis (amopavir)
- 7-Soveldi (sidosbuir)
- 8-Harvoni (ledipasvir + sofosbuvir)
- 9-Velera Pak (ombitasvir/paritaprevir/ritonavir + dasabuvir)
- 10-Dasabuvir
- 97-Don't know
- 99-Other HCV medication

HCV Knowledge Questionnaire (HKQ)

Web Version: 1.0; 1.00; 10-14-16

Segment (PROTSEG): A

Visit number (VISNO):

Date of assessment: (HKQASMDT)

(mm/dd/yyyy)

	True	False	Don't Know
1. People with hepatitis C can safely share their toothbrushes and razors with other people.	(HKSHRAZ) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Nowadays, hepatitis C can be treated in 6 months or less with oral medications.	(HKTRTORL) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. People with hepatitis C can safely take any herbal medicine.	(HKHRBMD) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. People who are HIV+ can also receive hepatitis C treatment.	(HKHPCTRT) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. People living with hepatitis C can damage their liver when they drink alcohol.	(HKALCHLV) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. People who received a blood transfusion in the United States before 1992 may have been infected with hepatitis C.	(HKBLDTRN) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. To help stop the spread of hepatitis C, a person with hepatitis C should not share any injection drug equipment.	(HKSHEQUP) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. There is a hepatitis C vaccine that can be used to prevent people from getting infected with the hepatitis C virus.	(HKPREVNT) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. It is a good idea for people living with hepatitis C to be vaccinated against hepatitis A and B.	(HKVACINE) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Studies show that more than 60% of people who inject street drugs with 'used needles' are infected with hepatitis C.	(HKSTRDRG) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. People can live with hepatitis C for many years without knowing that they have been infected with the virus.	(HKINFUNK) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. There is some risk that hepatitis C can be given to someone by snorting cocaine with shared straws, rolled money, etc.	(HKCOCSNR) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	True	False	Don't Know
13. Some treatments for hepatitis C, such as interferon, can cause depression as a side effect in some patients.	(HKINTDEP) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. Using 'new' (i.e., never used before) needles, syringes, and equipment reduces the risk of being infected with hepatitis C.	(HKNEWEQP) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. Babies born to hepatitis C pregnant women can be infected with hepatitis C at birth.	(HKBRTHIN) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. Hepatitis C can be given to someone during sexual intercourse.	(HKSEXINF) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. Coughing and sneezing can spread hepatitis C.	(HKCOUGH) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. Current treatments for hepatitis C don't work for African Americans.	(HKAATRT) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. Successful hepatitis C treatments can result in the hepatitis C virus being completely removed (or cleared) from one's blood.	(HKVIRRMV) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

20. All treatments for hepatitis C can cause depression and flu-like symptoms.	(HKFLUDEP) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21. The hepatitis C virus can be spread from shared kitchen cups, plates or utensils.	(HKSHRUTN) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22. Once someone's hepatitis C virus has been completely treated and cleared, one cannot get re-infected with hepatitis C.	(HKREINF) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23. People can get infected with hepatitis C from tattoos and body piercing.	(HKTATOO) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
24. Hepatitis C can be given by hugs or handshakes.	(HKHNDSHK) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
25. Hepatitis C can lead to liver cancer.	(HKLVCNCR) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments: (HKQCOMM)

NIDA Clinical Trials Network

HCV Self-Efficacy Questionnaire (HSE)

Web Version: 1.0; 1.01; 10-14-16

Segment (PROTSEG): A

Visit number (VISNO):

Date of assessment: (HSEASMDT)

 (mm/dd/yyyy)

The following questions are for persons who are hepatitis C (HCV) positive. If you are HCV negative or if you do not know your HCV status, please answer these questions thinking about how you might feel or behave if you were HCV positive.

Communication Self-Efficacy	Cannot Do at All	^3Cannot Do at All			^3Moderately Certain Can Do			^3Probably Can Do			Certain Can Do
How confident are you that you can...	0	1	2	3	4	5	6	7	8	9	10
1. Ask your doctor things about Hepatitis C (HCV) that concern you?	(HSASKDR) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Discuss openly with your doctor any personal problems that may be related to your HCV?	(HSDISCDR) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Work out difficulties with your HCV provider/doctor if they arise?	(HSDIFFDR) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Physical Coping Self-Efficacy	Cannot Do at All	^3Cannot Do at All			^3Moderately Certain Can Do			^3Probably Can Do			Certain Can Do
How confident are you that you can...	0	1	2	3	4	5	6	7	8	9	10
4. Keep any fatigue you might have, that may be caused by your HCV, from interfering with the things you want to do?	(HSFATIG) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Keep any physical discomfort or pain you might have, that may be caused by your HCV, from interfering with the things you want to do?	(HSDSCMFT) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Keep any symptoms or health problems you might have, that may be caused by your HCV, from interfering with the things you want to do?	(HSSYMP TM) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Control any symptoms or health problems you might have, related to your HCV, so they don't interfere with the things you want to do?	(HSCNTS YM) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Psychological Coping Self-Efficacy	Cannot Do at All	^3Cannot Do at All			^3Moderately Certain Can Do			^3Probably Can Do			Certain Can Do
How confident are you that you can...	0	1	2	3	4	5	6	7	8	9	10
8. Keep from feeling sad or down in the dumps?	(HSSAD) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Keep yourself from feeling lonely?	(HSLONELY) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

10. Do something to make yourself feel better when you are feeling lonely?	(HSFBLNLY) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Do something to make yourself feel better when you are feeling discouraged?	(HSFBDSCG) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Do something to make yourself feel better when you feel sad or down in the dumps?	(HSFBSAD) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Treatment Adherence Self-Efficacy How confident are you that you can...	Cannot Do at All	^3Cannot Do at All			^3Moderately Certain Can Do			^3Probably Can Do			Certain Can Do
	0	1	2	3	4	5	6	7	8	9	10
13. Inject interferon every week, if prescribed and if you needed to, exactly as directed, without ever missing a dose?	(HSINJECT) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. Take your HCV pills twice a day, exactly as directed, if prescribed, without ever missing a dose?	(HSRXBID) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. Take your HCV medicines, every day, even when feeling very tired or depressed?	(HSRXTRDP) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. Remember to take your HCV medications, every day, for the next 30 days?	(HSRX30D) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. Keep all your HCV doctor visits without ever missing an appointment?	(HSDRAPPT) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments: (HSECOMM)

NIDA Clinical Trials Network

HIV Treatment Adherence Self-Efficacy Scale (HIV-ASES) (HTA)

Web Version: 1.0; 2.01; 10-14-16

Segment (PROTSEG): A

Visit number (VISNO):

Date of assessment (HTAASMDT)

 (mm/dd/yyyy)

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

The next several questions ask about your confidence with taking HIV medications. HIV medications are sometimes referred to as antiviral medications, antiretroviral medications, ART, or a "drug cocktail". These medications are taken to increase or maintain your T-cells and to reduce your viral load. HIV medications treat HIV specifically; they do not include other medications, even those for opportunistic infection (OI) prevention.

Respond on a scale of 0 to 10 where 0 = you Cannot Do at All, 5 = Moderately (Somewhat) Certain you Can Do, and 10 = Completely Certain you Can Do.

	Cannot Do at All					Moderately Certain Can Do					Completely Certain Can Do
	0	1	2	3	4	5	6	7	8	9	10
In the <u>past month, including today</u> , how confident have you been that you can:	0	1	2	3	4	5	6	7	8	9	10
If you were to take HIV medication in the <u>next month</u> , how confident are you that you can:	0	1	2	3	4	5	6	7	8	9	10
1. Stick to your treatment plan even when side effects begin to interfere with daily activities?	(HTSIDEEF) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Integrate your treatment into your daily routine?	(HTROUTN) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Integrate your treatment into your daily routine even if it means taking medication or doing other things in front of people who don't know you are HIV-infected?	(HTPPLSEE) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Stick to your treatment schedule even when your daily routine is disrupted?	(HTDYDSRP) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Stick to your treatment schedule when you aren't feeling well?	(HTNOTWEL) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Stick to your treatment schedule when it means changing your eating habits?	(HTCHGEAT) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Continue with your treatment even if doing so interferes with your daily activities?	(HTACTVTY) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Continue with the treatment plan your physician prescribed even if your T-cells/CD4 cells drop significantly in the next three months?	(HTTCELLS) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Continue with your treatment even when you are feeling discouraged about your health?	(HTDISCRG) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Continue with your treatment even when getting to your clinic appointments is a major hassle?	(HTCLINIC) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

11. Continue with your treatment even when people close to you tell you that they don't think that it is doing any good?

12. Get something positive out of your participation in treatment, even if the medication you are taking does not improve your health?

NIDA Clinical Trials Network

Participant Satisfaction (INS)

Web Version: 1.0; 1.00; 10-14-16

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

RA instruction: Please hand the laminated response card to the participant.

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

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

					Agree	Strongly Agree
1. I feel my patient navigator understood me.	(INUNDERS) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. I believe my patient navigator cared about me.	(INCARED) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. I think I had a good relationship with my patient navigator.	(INRELATI) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. I liked my patient navigator as a person.	(INLIKED) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. When I wanted or needed to talk with my patient navigator he or she made time to talk with me.	(INTALKTI) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. My patient navigator repeatedly offered me help with my health care needs.	(INHECANE) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. My patient navigator really knows how to work with the HIV health care system.	(INHIVSYS) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. My patient navigator repeatedly offered me help with my substance use treatment needs.	(INSUBTXN) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. My patient navigator really knows how to work with the substance use treatment system.	(INSUTXSY) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. My patient navigator clearly explained the money I could earn by completing certain tasks.	(INMONEYE) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. After I completed certain tasks, my patient navigator paid me my incentive promptly (after verifying the completion of the task).	(ININCENT) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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

Comments:(INSCOMM)

NIDA Clinical Trials Network

Interpersonal Violence Scale (IVS)

Web Version: 1.0; 1.00; 10-14-16

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

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

The next questions are about abuse and interpersonal violence. 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 would like to do so.

1. Have you been beaten, physically attacked, or physically abused <u>since your last CTN-0049 study visit?</u>	(IVATTACK) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Were you in a relationship where a sexual partner did this to you?	(IVPRATAK) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Have you been sexually attacked, raped, or sexually abused <u>since your last CTN-0049 study visit?</u>	(IVSEXABU) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Were you in a relationship where a sexual partner did this to you?	(IVPRTABU) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Have you been in a relationship where a sexual partner threatened you with violence <u>since your last CTN-0049 study visit?</u>	(IVTHREAT) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Have you been in a relationship where a sexual partner threw, broke, or punched things <u>since your last CTN-0049 study visit?</u>	(IVPUNCHD) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Have you been in a relationship where you felt controlled by a sexual partner <u>since your last CTN-0049 study visit?</u>	(IVCONTRL) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments:(IVSCOMM)

NIDA Clinical Trials Network

Modified Illegal Activities (MIA)

Web Version: 1.0; 2.00; 11-15-16

Segment (*PROTSEG*): AVisit number (*VISNO*):Date of assessment: (*MIAASMDT*) (mm/dd/yyyy)Have you been arrested since your last CTN-0049 study visit? (*MIARREST*)☐ No ☐ YesHave you been arrested in the past 6 months? (*MIARST6M*)☐ No ☐ YesHave you been incarcerated since your last CTN-0049 study visit? (*MIINCARC*)☐ No ☐ YesHave you been incarcerated in the past 6 months? (*MIINCA6M*)☐ No ☐ YesHow many days have you been incarcerated since your last CTN-0049 study visit? (*MIINLFDY*) (xxxx) daysHow many days have you been incarcerated in the past 6 months? (*MIIN6MDY*) (xxx) days**The next several questions are about illegal activities.****Illegal Activities**1. Have you been intoxicated (high or drunk) from alcohol or drugs in public since your last CTN-0049 study visit? (*MIAPUB*)☐ No ☐ Yesa. How many times in the past 6 months have you been intoxicated (high or drunk) from alcohol or drugs in public? (*MIITX16M*) (xxx)b. Have you been arrested for public intoxication since your last CTN-0049 study visit? (*MIARSTTO*)☐ No ☐ Yesc. 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 your last CTN-0049 study visit? (*MIADUI*)☐ No ☐ Yesa. How many times in the past 6 months have you driven under the influence of alcohol or drugs? (*MIDUI16M*) (xxx)b. Have you been arrested for driving under the influence of alcohol since your last CTN-0049 study visit? (*MIARDUI*)☐ No ☐ Yesc. 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 your last CTN-0049 study visit? (*MIIAPOS*)☐ No ☐ Yesa. How many times in the past 6 months have you used or possessed illegal drugs? (*MIPOSI6M*) (xxx)b. Have you been arrested for using or possessing illegal drugs since your last CTN-0049 study visit? (*MIARPOSS*)☐ No ☐ Yesc. 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 your last CTN-0049 study visit? (*MIADST*)☐ No ☐ Yes

a. How many times in the past 6 months have you possessed illegal drugs with the intent to distribute? (MIDSTI6M)	<input type="text"/> (xxx)
b. Have you been arrested for possession of drugs with the intent to distribute since your last CTN-0049 study visit?(MIARDIST)	<input type="checkbox"/> No <input type="checkbox"/> Yes
c. How many times in the past 6 months have you been arrested for possession of illegal drugs with the intent to distribute?(MIDSTA6M)	<input type="text"/> (xxx)
5. Have you had possession of drug paraphernalia since your last CTN-0049 study visit?(MIIAPAR)	<input type="checkbox"/> No <input type="checkbox"/> Yes
a. How many times in the past 6 months have you possessed drug paraphernalia?(MIPARI6M)	<input type="text"/> (xxx)
b. Have you been arrested for possession of drug paraphernalia since your last CTN-0049 study visit?(MIARPARA)	<input type="checkbox"/> No <input type="checkbox"/> Yes
c. How many times in the past 6 months have you been arrested for possession of drug paraphernalia?(MIPARA6M)	<input type="text"/> (xxx)
6. Have you manufactured or grown drugs since your last CTN-0049 study visit?(MIIAGR W)	<input type="checkbox"/> No <input type="checkbox"/> Yes
a. How many times in the past 6 months have you manufactured or grown drugs?(MIGRWI6M)	<input type="text"/> (xxx)
b. Have you been arrested for manufacturing or growing drugs since your last CTN-0049 study visit?(MIARGROW)	<input type="checkbox"/> No <input type="checkbox"/> Yes
c. How many times in the past 6 months have you been arrested for manufacturing or growing drugs?(MIGRWA6M)	<input type="text"/> (xxx)
7. Have you sold or distributed drugs since your last CTN-0049 study visit?(MIIASAL)	<input type="checkbox"/> No <input type="checkbox"/> Yes
a. How many times in the past 6 months have you been involved in the sale or distribution of drugs?(MISALI6M)	<input type="text"/> (xxx)
b. Have you been arrested for the sale or distribution of drugs since your last CTN-0049 study visit?(MIARSALE)	<input type="checkbox"/> No <input type="checkbox"/> Yes
c. How many times in the past 6 months have you been arrested for selling or distributing drugs?(MISALA6M)	<input type="text"/> (xxx)
8. Have you been involved in forgery or fraud (bad checks, credit card fraud, etc.) since your last CTN-0049 study visit?(MIIAFRD)	<input type="checkbox"/> No <input type="checkbox"/> Yes
a. How many times in the past 6 months have you been involved in forgery/fraud (bad checks, credit card fraud, etc.)?(MIFRDI6M)	<input type="text"/> (xxx)
b. Have you been arrested for forgery or fraud (bad checks, credit card fraud, etc.) since your last CTN-0049 study visit?(MIARFRD)	<input type="checkbox"/> No <input type="checkbox"/> Yes
c. How many times in the past 6 months have you been arrested for forgery/fraud (bad checks, credit card fraud, etc.)?(MIFRDA6M)	<input type="text"/> (xxx)
9. Have you been involved in fencing (buying or selling stolen property) since your last CTN-0049 study visit?(MIIAFEN)	<input type="checkbox"/> No <input type="checkbox"/> Yes
a. How many times in the past 6 months have you been involved in fencing (buying or selling stolen property)?(MIFENI6M)	<input type="text"/> (xxx)
b. Have you been arrested for fencing (buying or selling stolen property) since your last CTN-0049 study visit?(MIARFENC)	<input type="checkbox"/> No <input type="checkbox"/> Yes
c. How many times in the past 6 months have you been arrested for fencing (buying or selling stolen property)?(MIFENA6M)	<input type="text"/> (xxx)
10. Have you been involved in illegal gambling (running numbers) since your last CTN-0049 study visit?(MIIAGAM)	<input type="checkbox"/> No <input type="checkbox"/> Yes
a. How many times in the past 6 months have you been involved in illegal gambling (running numbers)?(MIGAMI6M)	<input type="text"/> (xxx)
b. Have you been arrested for illegal gambling (running numbers) since your last CTN-0049 study visit?(MIARGAMB)	<input type="checkbox"/> No <input type="checkbox"/> Yes

c. How many times in the past 6 months have you been arrested for illegal gambling (running numbers)? (xxx)
(MIGAMA6M)

11. Have you been involved in prostitution or pimping since your last CTN-0049 study visit? (MIIAPRS) ☐ No ☐ Yes

a. How many times in the past 6 months have you been involved in prostitution or pimping? (MIPRSI6M) (xxx)

b. Have you been arrested for prostitution or pimping since your last CTN-0049 study visit? (MIARPRST) ☐ No ☐ Yes

c. How many times in the past 6 months have you been arrested for prostitution or pimping? (xxx)
(MIPRSA6M)

12. Have you been involved in burglary/attempted burglary/breaking and entering (home, auto, business) since your last CTN-0049 study visit? (MIIABAE) ☐ No ☐ Yes

a. How many times in the past 6 months have you been involved in burglary/attempted burglary/breaking and entering (home, auto, business)? (MIBAEI6M) (xxx)

b. Have you been arrested for burglary/attempted burglary/breaking and entering (home, auto, business) since your last CTN-0049 study visit? (MIARBURG) ☐ No ☐ Yes

c. How many times in the past 6 months have you been arrested for being involved in burglary/attempted burglary/breaking and entering (home, auto, business)? (MIBAEA6M) (xxx)

13. Have you been involved in shoplifting/larceny/embezzlement since your last CTN-0049 study visit? (MIIALAR) ☐ No ☐ Yes

a. How many times in the past 6 months have you been involved in shoplifting/larceny/embezzlement? (MILARI6M) (xxx)

b. Have you been arrested for shoplifting/larceny/embezzlement since your last CTN-0049 study visit? (MIARLARC) ☐ No ☐ Yes

c. How many times in the past 6 months have you been arrested for shoplifting/larceny/embezzlement? (xxx)
(MILARA6M)

14. Have you been involved in auto theft/carjacking since your last CTN-0049 study visit? (MIIACAR) ☐ No ☐ Yes

a. How many times in the past 6 months have you been involved in auto theft/carjacking? (MICARI6M) (xxx)

b. Have you been arrested for auto theft/carjacking since your last CTN-0049 study visit? (MIARCAR) ☐ No ☐ Yes

c. 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 your last CTN-0049 study visit? (MIIAROB) ☐ No ☐ Yes

a. How many times in the past 6 months have you been involved in robbery/attempted robbery/mugging? (MIROBI6M) (xxx)

b. Have you been arrested for robbery/attempted robbery/mugging since your last CTN-0049 study visit? (MIARROB) ☐ No ☐ Yes

c. 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 your last CTN-0049 study visit? (MIIAAAB) ☐ No ☐ Yes

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

b. Have you been arrested for assault/aggravated assault/battery (does not include rape or sexual assault) since your last CTN-0049 study visit? (MIARAAB) ☐ No ☐ Yes

c. 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 your last CTN-0049 study visit? (MIIAKID) ☐ No ☐ Yes

a. How many times in the past 6 months have you been involved in kidnapping/hostage taking? (MIKID/6M)	<input type="text"/> (xxx)
b. Have you been arrested for kidnapping/hostage taking since your last CTN-0049 study visit? (MARKID)	<input type="checkbox"/> No <input type="checkbox"/> Yes
c. How many times in the past 6 months have you been arrested for kidnapping/hostage taking? (MIKIDA6M)	<input type="text"/> (xxx)
18. Have you been involved in terrorist threats/acts since your last CTN-0049 study visit?(MIATER)	
a. How many times in the past 6 months have you been involved in terrorist threats/acts?(MITER/6M)	<input type="text"/> (xxx)
b. Have you been arrested for terrorist threats/acts since your last CTN-0049 study visit?(MIARTER)	<input type="checkbox"/> No <input type="checkbox"/> Yes
c. How many times in the past 6 months have you been arrested for terrorist threats/acts?(MITERA6M)	<input type="text"/> (xxx)
19. Have you been involved in homicide/manslaughter/attempted homicide since your last CTN-0049 study visit?(MIAHOM)	
a. How many times in the past 6 months have you been involved in homicide/manslaughter/attempted homicide?(MIHOM/6M)	<input type="text"/> (xxx)
b. Have you been arrested for homicide/manslaughter/attempted homicide since your last CTN-0049 study visit?(MIARHOM)	<input type="checkbox"/> No <input type="checkbox"/> Yes
c. How many times in the past 6 months have you been arrested for homicide/manslaughter/attempted homicide?(MIHOMA6M)	<input type="text"/> (xxx)
20. Have you been involved in arson offenses since your last CTN-0049 study visit?(MIAARS)	
a. How many times in the past 6 months have you been involved in arson offenses?(MIARSI/6M)	<input type="text"/> (xxx)
b. Have you been arrested for an arson offense since your last CTN-0049 study visit?(MIARARS)	<input type="checkbox"/> No <input type="checkbox"/> Yes
c. How many times in the past 6 months have you been arrested for arson offenses?(MIARSA6M)	<input type="text"/> (xxx)
21. Have you been involved in weapons offenses since your last CTN-0049 study visit?(MIAWEP)	
a. How many times in the past 6 months have you been involved in weapons offenses?(MIWEPI/6M)	<input type="text"/> (xxx)
b. Have you been arrested for a weapons offense since your last CTN-0049 study visit?(MIARWEP)	<input type="checkbox"/> No <input type="checkbox"/> Yes
c. How many times in the past 6 months have you been arrested for weapons offenses?(MIWEPA6M)	<input type="text"/> (xxx)
22. Have you been involved in vandalism/property damage/tagging since your last CTN-0049 study visit? (MIAVAN)	
a. How many times in the past 6 months have you been involved with vandalism/property damage/tagging?(MIVANI/6M)	<input type="text"/> (xxx)
b. Have you been arrested for vandalism/property damage/tagging since your last CTN-0049 study visit? (MIARVAN)	<input type="checkbox"/> No <input type="checkbox"/> Yes
c. How many times in the past 6 months have you been arrested for vandalism/property damage/tagging?(MIVANA6M)	<input type="text"/> (xxx)
23. Have you been involved in sex offenses (rape/aggravated assault/sex with a minor) since your last CTN-0049 study visit?(MIASEX)	
a. How many times in the past 6 months have you been involved in a sex offense (rape/aggravated assault/sex with a minor)?(MSEX/6M)	<input type="text"/> (xxx)
b. Have you been arrested for a sex offense (rape/aggravated assault/sex with a minor) since your last CTN-0049 study visit?(MIARSEX)	<input type="checkbox"/> No <input type="checkbox"/> Yes
c. How many times in the past 6 months have you been arrested for a sex offense (rape/aggravated assault/sex with a minor)?(MSEXA6M)	<input type="text"/> (xxx)
24. Have you been involved in probation/parole violations since your last CTN-0049 study visit?(MIIAPRB)	
	<input type="checkbox"/> No <input type="checkbox"/> Yes

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

(xxx)
- b. Have you been arrested for probation/parole violation since your last CTN-0049 study visit?
(MIARPRB)

☐ No ☐ Yes
- c. How many times in the past 6 months have you been arrested for probation/parole violations?
(MIPRBA6M)

(xxx)

25. Have you been involved in other crimes not listed above since your last CTN-0049 study visit?
(MIIAOTH)

If "Yes", specify in comments.

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

(xxx)
- b. Have you been arrested for other crimes not listed above since your last CTN-0049 study visit?
(MIAROTH)

☐ No ☐ Yes
- c. How many times in the past 6 months have you been arrested for this crime? (MIOTHA6M)

(xxx)

Comments:(MIACOMM)

NIDA Clinical Trials Network

Group Based Medical Mistrust Scale (MMT)

Web Version: 1.0; 2.00; 11-15-16

Segment (PROTSEG): A

Visit number (VISNO):

Date of assessment:(MM TASMDT) (mm/dd/yyyy)

RA Instruction: Provide participant with a reference card that lists all 5 response options for his/her easy reference.

Now I'm going to read a series of statements to you about health care and the experiences of people like you or of your group with the health care system.
Tell me how much you Agree or Disagree with each statement on a scale of 1 to 5, where 1 = Strongly Disagree and 5 = Strongly Agree.

	Strongly Disagree	Disagree	Neither Agree Nor Disagree	Agree	Strongly Agree
	1	2	3	4	5
1. Doctors and health care workers sometimes hide information from people like me.	(MMHIDE) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Doctors have the best interests of people like me in mind.	(MMBEST) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. People like me should not confide in doctors and health care workers because it will be used against us.	(MMCONF) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. People like me should be suspicious of information from doctors and health care workers.	(MMSUSPI) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. People like me cannot trust doctors and health care workers.	(MMTRUST) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. People like me should be suspicious of modern medicine.	(MMMEDIC) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Doctors and health care workers treat people like me like "guinea pigs".	(MMGUINE) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. People like me receive the same medical care from doctors and health care workers as people from other groups.	(MMSAME) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Doctors and health care workers do not take the medical complaints of people like me seriously.	(MMCOMPL) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. People like me are treated the same as people of other groups by doctors and health care workers.	(MMTREAT) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. In most hospitals, people like me receive the same kind of care as anyone else.	(MMHOSP) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. I personally have been treated poorly or unfairly by doctors or health care workers because of the group(s) to which I belong.	(MMPERSO) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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

	No	Yes	Don't Know	Refused to Answer
1. HIV status?	(MMHIV) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Missed Visit (MVF)

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

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

Reason for missed visit:(MVREASON)

If "Other", specify:(MVOTHRSP)

Comments:(MVFCOMM)

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

Additional Selection Options for MVF

Reason for missed visit:
6-Participant moved from area
7-Participant incarcerated
8-Site closed
9-Participant withdrew consent
10-Participant deceased
99-Other

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Non-Participant Contact Log (NPC)

Web Version: 1.0; 1.00; 10-14-16

Segment (PROTSEG): B
 Contact log number (NPCLOGNO):

This log will only be used to record contacts with individuals other than the participant. Only contacts involving scheduling, rescheduling, and confirming appointments will be logged. No contact that constitutes an intervention session will be tracked in this log.

Date	Day of Week	Start Time (24-hour format)	End Time (24-hour format)	Length of Time (minutes)	Contact Type	Individual Contacted	Other Individual Contacted	Purpose of Contact	Other Purpose of Contact	Result	Other Result
(NPCNDT01)	(NPDAY01)	(NPSTM01)	(NPETM01)	(NPLENG01)	(NPCNTP01)	(NPCNID01)	(NPCIO1SP)	(NPCNPR01)	(NPCP01SP)	(NPRSLT01)	(NPCR01SP)
					1-In-person 2-Telephone 3-Email 4-Text	01-Family member/Friend 02-Case manager/Social worker 03-HIV provider 04-HCV provider 05-HIV/HCV provider *Additional Options Listed Below		010-SCHEDULE APPOINTMENT 01A--HIV care 01B--HCV care 01C--HIV/HCV care 01D--Substance use treatment *Additional Options Listed Below		01-Connected - in progress 02-Left message 03-No answer 04-Completed task 99-Other	
(NPCNDT02)	(NPDAY02)	(NPSTM02)	(NPETM02)	(NPLENG02)	(NPCNTP02)	(NPCNID02)	(NPCIO2SP)	(NPCNPR02)	(NPCP02SP)	(NPRSLT02)	(NPCR02SP)
					1-In-person 2-Telephone 3-Email 4-Text	01-Family member/Friend 02-Case manager/Social worker 03-HIV provider 04-HCV provider 05-HIV/HCV provider *Additional Options Listed Below		010-SCHEDULE APPOINTMENT 01A--HIV care 01B--HCV care 01C--HIV/HCV care 01D--Substance use treatment *Additional Options Listed Below		01-Connected - in progress 02-Left message 03-No answer 04-Completed task 99-Other	
(NPCNDT03)	(NPDAY03)	(NPSTM03)	(NPETM03)	(NPLENG03)	(NPCNTP03)	(NPCNID03)	(NPCIO3SP)	(NPCNPR03)	(NPCP03SP)	(NPRSLT03)	(NPCR03SP)
					1-In-person 2-Telephone 3-Email 4-Text	01-Family member/Friend 02-Case manager/Social worker 03-HIV provider 04-HCV provider 05-HIV/HCV provider *Additional Options Listed Below		010-SCHEDULE APPOINTMENT 01A--HIV care 01B--HCV care 01C--HIV/HCV care 01D--Substance use treatment *Additional Options Listed Below		01-Connected - in progress 02-Left message 03-No answer 04-Completed task 99-Other	
(NPCNDT04)	(NPDAY04)	(NPSTM04)	(NPETM04)	(NPLENG04)	(NPCNTP04)	(NPCNID04)	(NPCIO4SP)	(NPCNPR04)	(NPCP04SP)	(NPRSLT04)	(NPCR04SP)
					1-In-person 2-Telephone 3-Email 4-Text	01-Family member/Friend 02-Case manager/Social worker 03-HIV provider 04-HCV provider 05-HIV/HCV provider *Additional Options Listed Below		010-SCHEDULE APPOINTMENT 01A--HIV care 01B--HCV care 01C--HIV/HCV care 01D--Substance use treatment *Additional Options Listed Below		01-Connected - in progress 02-Left message 03-No answer 04-Completed task 99-Other	
(NPCNDT05)	(NPDAY05)	(NPSTM05)	(NPETM05)	(NPLENG05)	(NPCNTP05)	(NPCNID05)	(NPCIO5SP)	(NPCNPR05)	(NPCP05SP)	(NPRSLT05)	(NPCR05SP)
					1-In-person 2-Telephone 3-Email 4-Text	01-Family member/Friend 02-Case manager/Social worker 03-HIV provider 04-HCV provider 05-HIV/HCV provider *Additional Options Listed Below		010-SCHEDULE APPOINTMENT 01A--HIV care 01B--HCV care 01C--HIV/HCV care 01D--Substance use treatment *Additional Options Listed Below		01-Connected - in progress 02-Left message 03-No answer 04-Completed task 99-Other	
(NPCNDT06)	(NPDAY06)	(NPSTM06)	(NPETM06)	(NPLENG06)	(NPCNTP06)	(NPCNID06)	(NPCIO6SP)	(NPCNPR06)	(NPCP06SP)	(NPRSLT06)	(NPCR06SP)
					1-In-person 2-Telephone 3-Email 4-Text	01-Family member/Friend 02-Case manager/Social worker 03-HIV provider 04-HCV provider 05-HIV/HCV provider *Additional Options Listed Below		010-SCHEDULE APPOINTMENT 01A--HIV care 01B--HCV care 01C--HIV/HCV care 01D--Substance use treatment *Additional Options Listed Below		01-Connected - in progress 02-Left message 03-No answer 04-Completed task 99-Other	
(NPCNDT07)	(NPDAY07)	(NPSTM07)	(NPETM07)	(NPLENG07)	(NPCNTP07)	(NPCNID07)	(NPCIO7SP)	(NPCNPR07)	(NPCP07SP)	(NPRSLT07)	(NPCR07SP)
					1-In-person 2-Telephone 3-Email 4-Text	01-Family member/Friend 02-Case manager/Social worker 03-HIV provider 04-HCV provider 05-HIV/HCV provider *Additional Options Listed Below		010-SCHEDULE APPOINTMENT 01A--HIV care 01B--HCV care 01C--HIV/HCV care 01D--Substance use treatment *Additional Options Listed Below		01-Connected - in progress 02-Left message 03-No answer 04-Completed task 99-Other	
(NPCNDT08)	(NPDAY08)	(NPSTM08)	(NPETM08)	(NPLENG08)	(NPCNTP08)	(NPCNID08)	(NPCIO8SP)	(NPCNPR08)	(NPCP08SP)	(NPRSLT08)	(NPCR08SP)
					1-In-person 2-Telephone 3-Email 4-Text	01-Family member/Friend 02-Case manager/Social worker 03-HIV provider 04-HCV provider 05-HIV/HCV provider *Additional Options Listed Below		010-SCHEDULE APPOINTMENT 01A--HIV care 01B--HCV care 01C--HIV/HCV care 01D--Substance use treatment *Additional Options Listed Below		01-Connected - in progress 02-Left message 03-No answer 04-Completed task 99-Other	

<div>(NPCNDT09)</div>	<div>(NPDAY09)</div>	<div>(NPSTM09)</div>	<div>(NPETM09)</div>	<div>(NPLENG09)</div>	<div>(NPCNTP09)</div> <div>1-In-person 2-Telephone 3-Email 4-Text</div>	<div>(NPCNID09)</div> <div>01-Family member/Friend 02-Case manager/Social worker 03-HIV provider 04-HCV provider 05-HIV/HCV provider *Additional Options Listed Below</div>	<div>(NPC109SP)</div>	<div>(NPCNPR09)</div> <div>010-SCHEDULE APPOINTMENT 01A---HIV care 01B---HCV care 01C---HIV/HCV care 01D---Substance use treatment *Additional Options Listed Below</div>	<div>(NPCP09SP)</div>	<div>(NPRSLT09)</div> <div>01-Connected - in progress 02-Left message 03-No answer 04-Completed task 99-Other</div>	<div>(NPCR09SP)</div>
<div>(NPCNDT10)</div>	<div>(NPDAY10)</div>	<div>(NPSTM10)</div>	<div>(NPETM10)</div>	<div>(NPLENG10)</div>	<div>(NPCNTP10)</div> <div>1-In-person 2-Telephone 3-Email 4-Text</div>	<div>(NPCNID10)</div> <div>01-Family member/Friend 02-Case manager/Social worker 03-HIV provider 04-HCV provider 05-HIV/HCV provider *Additional Options Listed Below</div>	<div>(NPC110SP)</div>	<div>(NPCNPR10)</div> <div>010-SCHEDULE APPOINTMENT 01A---HIV care 01B---HCV care 01C---HIV/HCV care 01D---Substance use treatment *Additional Options Listed Below</div>	<div>(NPCP10SP)</div>	<div>(NPRSLT10)</div> <div>01-Connected - in progress 02-Left message 03-No answer 04-Completed task 99-Other</div>	<div>(NPCR10SP)</div>

Comments:(NPCCOMM)

Additional Selection Options for NPC

- Contact log number (NPCLOGNO) (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
- Contact individual 01
- 06-Substance use treatment provider
 - 07-Mental health provider
 - 08-Housing provider
 - 93-Other provider
 - 99-Other
- Contact purpose 01
- 01E---Mental health
 - 01F---Clinical laboratory
 - 01G---Ultrasound/Fibrosan/Radiology
 - 01H---Housing
 - 020-RESCHEDULE APPOINTMENT
 - 02A---HIV care
 - 02B---HCV care
 - 02C---HIV/HCV care
 - 02D---Substance use treatment
 - 02E---Mental health
 - 02F---Clinical laboratory
 - 02G---Ultrasound/Fibrosan/Radiology
 - 02H---Housing
 - 030-CONFIRM UPCOMING APPOINTMENT
 - 03A---HIV care
 - 03B---HCV care
 - 03C---HIV/HCV care
 - 03D---Substance use treatment
 - 03E---Mental health
 - 03F---Clinical laboratory
 - 03G---Ultrasound/Fibrosan/Radiology
 - 03H---Housing
 - 990-OTHER
 - 99Z---Other (specify)

Protocol Deviation (PDV)

Web Version: 1.0; 2.03; 05-10-18

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

1. Is this deviation related to one or more participants?(PDPTREL)
If "Yes", how many participants?(PDPRELNO)

No	Yes
01-1	
02-2	
03-3	
04-4	
05-5	
*Additional Options Listed Below	

Select related participants:
Participant ID 1:(PDPT01)

99999999999999999999-DUMMYPARTICIPANTID

Participant ID 2:(PDPT02)

99999999999999999999-DUMMYPARTICIPANTID

Participant ID 3:(PDPT03)

99999999999999999999-DUMMYPARTICIPANTID

Participant ID 4:(PDPT04)

99999999999999999999-DUMMYPARTICIPANTID

Participant ID 5:(PDPT05)

99999999999999999999-DUMMYPARTICIPANTID

Participant ID 6:(PDPT06)

99999999999999999999-DUMMYPARTICIPANTID

Participant ID 7:(PDPT07)

99999999999999999999-DUMMYPARTICIPANTID

Participant ID 8:(PDPT08)

99999999999999999999-DUMMYPARTICIPANTID

Participant ID 9:(PDPT09)

99999999999999999999-DUMMYPARTICIPANTID

Participant ID 10:(PDPT10)

99999999999999999999-DUMMYPARTICIPANTID

Participant ID 11:(PDPT11)

99999999999999999999-DUMMYPARTICIPANTID

Participant ID 12:(PDPT12)

99999999999999999999-DUMMYPARTICIPANTID

Participant ID 13:(PDPT13)

99999999999999999999-DUMMYPARTICIPANTID

Participant ID 14:(PDPT14)

99999999999999999999-DUMMYPARTICIPANTID

Participant ID 15:(PDPT15)

99999999999999999999-DUMMYPARTICIPANTID

Participant ID 16:(PDPT16)

99999999999999999999-DUMMYPARTICIPANTID

Participant ID 17:(PDPT17)

99999999999999999999-DUMMYPARTICIPANTID

Participant ID 18:(PDPT18)

99999999999999999999-DUMMYPARTICIPANTID

Participant ID 19:(PDPT19)

99999999999999999999-DUMMYPARTICIPANTID

Participant ID 20:(PDPT20)

99999999999999999999-DUMMYPARTICIPANTID

2. Date deviation identified:(PDVDATE)

(mm/dd/yyyy)

3. Deviation type:(PDTYPE)

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

If "Other", specify:(PDTYPEPSP)

4. Brief description of what occurred:(PDDESCPT)

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

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

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

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

If "Yes", date of planned submission:(PDIRBPDY)

If "No", date of actual submission:(PDIRBADY)

No	Yes
No	Yes
	(mm/dd/yyyy)
	(mm/dd/yyyy)

Comments:(PDVCOMM)

Additional Selection Options for PDV

- Protocol deviation number (PDSEQNO) (key field):
- 01-1st Protocol Deviation of the day
 - 02-2nd Protocol Deviation of the day
 - 03-3rd Protocol Deviation of the day
 - 04-4th Protocol Deviation of the day
 - 05-5th Protocol Deviation of the day
 - 06-6th Protocol Deviation of the day
 - 07-7th Protocol Deviation of the day
 - 08-8th Protocol Deviation of the day
 - 09-9th Protocol Deviation of the day
 - 10-10th Protocol Deviation of the day
- If "Yes", how many participants?
- 06-6
 - 07-7
 - 08-8
 - 09-9
 - 10-10
 - 11-11
 - 12-12
 - 13-13
 - 14-14
 - 15-15
 - 16-16
 - 17-17
 - 18-18
 - 19-19
 - 20-20
- Deviation type:
- 01E--- Informed consent/assent process not properly conducted and/or documented
 - 01Z--- Other informed consent/assent procedures issues (specify)
 - 020-INCLUSION/EXCLUSION CRITERIA
 - 02A--- Ineligible participant randomized/inclusion/exclusion criteria not met
 - 02B--- Ineligible participant enrolled/inclusion/exclusion criteria not met
 - 02Z--- Other inclusion/exclusion criteria issues (specify)
 - 040-LABORATORY ASSESSMENTS
 - 04A--- Biologic specimen not collected/processed as per protocol
 - 04Z--- Other laboratory assessments issues (specify)
 - 050-STUDY PROCEDURES/ASSESSMENTS
 - 05A--- Protocol required visit/assessment not scheduled or conducted
 - 05B--- Study assessments not completed/followed as per protocol
 - 05C--- Inappropriate unblinding
 - 05Z--- Other study procedures/assessments issues (specify)
 - 060-ADVERSE EVENT
 - 06A--- AE not reported
 - 06B--- SAE not reported
 - 06C--- AE/SAE reported out of protocol specified reporting timeframe
 - 06D--- AE/SAE not elicited, observed and/or documented as per protocol
 - 06E--- Safety assessment (e.g. labs, ECG, clinical referral to care) not conducted per protocol
 - 06Z--- Other adverse events issues (specify)
 - 070-RANDOMIZATION PROCEDURES
 - 07A--- Stratification error
 - 07Z--- Other randomization procedures issues (specify)
 - 080-STUDY MEDICATION MANAGEMENT
 - 08A--- Medication dispensed to ineligible participant
 - 08B--- Medication dispensed to incorrect participant
 - 08C--- Medication dosing errors (protocol specified dose not dispensed)
 - 08D--- Participant use of protocol prohibited medication
 - 08Z--- Other study medication management issues (specify)
 - 090-STUDY BEHAVIORAL INTERVENTION
 - 09A--- Study behavioral intervention was not provided/performed as per protocol
 - 09Z--- Other study behavioral intervention issues (specify)
 - 100-STUDY DEVICES
 - 10A--- Study devices dispensed to ineligible participant
 - 10Z--- Other study devices issues (specify)
 - 110-SAFETY EVENT
 - 11A--- Safety event not reported
 - 11B--- Safety event reported out of protocol specified reporting timeframe
 - 11C--- Safety event not elicited, observed and/or documented as per protocol
 - 11D--- Safety event assessment not conducted per protocol
 - 11Z--- Other safety event issues (specify)
 - 990-OTHER SIGNIFICANT DEVIATIONS
 - 99A--- Destruction of study materials without prior authorization from sponsor
 - 99B--- Breach of Confidentiality
 - 99Z--- Other significant deviations issues (specify)

NIDA Clinical Trials Network

Physician Patient Relationship with HCV Doctor and Health Care System (PPH)

Web Version: 1.0; 1.01; 10-14-16

Segment (PROTSEG): A

Visit number (VISNO):

Date of assessment (PPHASMDT)

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

1. Do you have a healthcare provider (doctor/nurse practitioner/physician's assistant) who takes care of your HCV? (PHHCVPR) ☐ No ☐ Yes
2. Is the provider that takes care of your HCV the same as the provider that takes care of your HIV? (PHPROVDR) ☐ No ☐ Yes

*Rate the health care provider who takes care of your HCV in each of the following things.***Overall Communication**

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

	Excellent	Very Good	Good	Fair	Poor
3. Explaining the results of tests in a way that you understand? (PHRESULT) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Giving you facts about the benefits and risks of treatment? (PHFACTS) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Telling you what to do if certain problems or symptoms occur? (PHTELL) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Demonstrating caring, compassion, and understanding? (PHDEMON) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. Understanding your health worries and concerns? (PHUNDER) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

HCV - Specific Information

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

	Excellent	Very Good	Good	Fair	Poor
8. Asking about problems with alcohol? (PHALCOH) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Asking about problems with street drugs like heroin and cocaine? (PHSTREET) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Adherence Dialogue

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

	Excellent	Very Good	Good	Fair	Poor
--	-----------	-----------	------	------	------

10. Giving you information about the right way to take your HCV medicines?	(PHINFMED) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Understanding the problems you have taking your HCV medicines?	(PHPRBMED) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Helping you solve problems you have taking your HCV medicines right away?	(PHSLVPRB) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Understanding problems you have getting your HCV medications?	(PHMEDPRB) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. Making sure your treatment options are linked to your health insurance options?	(PHTRTINS) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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

Participatory Decision-Making

How often does the health care provider who takes care of your HCV do the following:

	All of the Time	Most of the Time	Some of the Time	A Little of the Time	None of the Time
15. Offer choices in your medical care?	(PHOFFER) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. Discuss the pros and cons of each choice with you?	(PHPROCON) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. Get you to state which choice or option you would prefer?	(PHSTATE) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. Take your preferences into account when making treatment decisions?	(PHPREFER) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Overall Satisfaction with Health Care Provider

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

	Excellent	Very Good	Good	Fair	Poor
19. Personal manner - courtesy, respect, sensitivity, friendliness?	(PHPRMANR) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20. Communication skills - listening carefully, answering questions, giving clear explanations?	(PHCOMMN) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21. Technical skills - thoroughness, carefulness, competence?	(PHTECHNL) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22. Your health care provider's care?	(PHOVRCRE) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Willingness to Recommend

23. Do you plan to continue to see the health care provider who takes care of your HCV in the future?

(PHCTNSEE)

1-Definitely will not
2-Probably will not
3-Not sure
4-Probably will
5-Definitely will

24. Do you plan to recommend the health care provider who takes care of your HCV to others?

(PHRECMND)

1-Definitely will not
2-Probably will not
3-Not sure
4-Probably will
5-Definitely will

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
25. I can tell my health care provider anything, even things that I might not tell anyone else.	(PHTELLPR) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
26. My health care provider cares more about holding down costs than about doing what is needed for my health.	(PHPRCOST) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
27. My health care provider cares as much as I do about my health.	(PHPRHLTH) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
28. If a mistake was made in my treatment, my health care provider would try to hide it from me.	(PHTXMIS) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Least Trust Possible									Most Trust Possible
	1	2	3	4	5	6	7	8	9	10
29. All things considered, how much do you trust your health care provider?	(PHTRUST) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Navigating Health Insurance

	All of the Time	Most of the Time	Some of the Time	A Little of the Time	None of the Time
30. How often does your provider, or someone who works as part of your HCV care team or in your HCV clinic/setting, help you navigate your insurance to get HCV medications?	(PHNAVIGT) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
31. Is the information that your insurance provides to you clear and helpful?	(PHINSRIF) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
32. How often do you trust that your insurance will cover the care and tests your provider feels you need for your HCV?	(PHINSCST) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Least Trust Possible									Most Trust Possible
	1	2	3	4	5	6	7	8	9	10
33. All things considered, how much do you trust your health insurance?	(PHTRSTIN) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments: (PPHCOMM)

NIDA Clinical Trials Network

Physician Patient Relationship with HIV Doctor and Health Care System (PPR)

Web Version: 1.0; 1.01; 11-15-16

Segment (PROTSEG): A

Visit number (VISNO):

Date of assessment:(PPRASMDT)

 (mm/dd/yyyy)

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

The following questions ask about the healthcare provider (doctor/nurse practitioner/physician's assistant) who takes care of your HIV.

1. Do you have a healthcare provider (doctor/nurse practitioner/physician's assistant) who takes care of your HIV?(PPHIVPR) ☐ No ☐ Yes

Rate the health care provider who takes care of your HIV in each of the following categories.

Overall Communication

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

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

HIV - Specific Information

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

	Excellent	Very Good	Good	Fair	Poor
7. Talking with you about your sex life? (PPSEX) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Asking about stresses in your life that may affect your health? (PPSTRESS) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Asking about problems with alcohol? (PPALCOH) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Asking about problems with street drugs like heroin and cocaine? (PPSTREET) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Adherence Dialogue

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

	Excellent	Very Good	Good	Fair	Poor
11. Giving you information about the right way to take your HIV medications?	(PPINFMED) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Understanding the problems you have taking your HIV medications?	(PPPRBMED) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Helping you solve problems you have taking your HIV medications right away?	(PPSLVPRB) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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

Participatory Decision-Making

14. How often does the health care provider who takes care of your HIV ask you to take some of the responsibility for your treatment?

1-Very often
2-Often
3-Sometimes
4-Rarely
5-Never

(PPRSPTRT)

15. If there was a choice between treatments, would the health care provider who takes care of your HIV ask you to help make the decision?

1-Definitely yes
2-Probably yes
3-Uncertain
4-Probably not
5-Definitely not

(PPHELPDE)

16. How often does the health care provider who takes care of your HIV make an effort to give you some control over treatment decisions?

1-Very often
2-Often
3-Sometimes
4-Rarely
5-Never

(PPTREAT)

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

	All of the Time	Most of the Time	Some of the Time	A Little of the Time	None of the Time
17. Offer choices in your medical care?	(PPOFFER) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. Discuss the pros and cons of each choice with you?	(PPPROCON) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. Get you to state which choice or option you would prefer?	(PPSTATE) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20. Take your preferences into account when making treatment decisions?	(PPPREFER) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Overall Satisfaction with Health Care Provider

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

	Excellent	Very Good	Good	Fair	Poor
21. Personal manner - courtesy, respect, sensitivity, friendliness?	(PPPRMANR) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22. Communication skills - listening carefully, answering questions, giving clear explanations?	(PPCOMMN) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

23. Technical skills - thoroughness, carefulness, competence?
24. Your health care provider's care?
25. Do you plan to continue to see the health care provider who takes care of your HIV in the future?

26.

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:

27. I can tell my health care provider anything, even things that I might not tell anyone else.
28. My health care provider cares more about holding down costs than about doing what is needed for my health.
29. My health care provider cares as much as I do about my health.
30. If a mistake was made in my treatment, my health care provider would try to hide it from me.

	Least Trust Possible									Most Trust Possible
	1	2	3	4	5	6	7	8	9	10
31. All things considered, how much do you trust your health care provider?	(PPTRUST)									<input type="text"/>
<div></div>										

NIDA Clinical Trials Network

Readiness for Substance Use Treatment (RST)

Web Version: 1.0; 1.00; 10-14-16

Segment (*PROTSEG*): AVisit number (*VISNO*):Date of assessment: (*RSTASMDT*) (mm/dd/yyyy)

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

	Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree
1. Treatment could be your last chance to solve your substance use problems.	(<i>RSSLVPRB</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. If you enter treatment, you will stay for a while.	(<i>RSSTAY</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Treatment could really help you.	(<i>RSHELP</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. You want to be in a treatment program.	(<i>RSPROGRM</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree
5. Most counselors in substance use treatment programs are "squares" who don't understand substance users.	(<i>RSCOUNSL</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. Substance use treatment programs have too many rules and regulations for me.	(<i>RSRULES</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. I don't think I could trust many of the people who work in the substance use treatment programs.	(<i>RSTRUST</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. It takes too much time and effort to get into a substance use treatment program.	(<i>RSEFFORT</i>) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments: (*RSTCOMM*)

NIDA Clinical Trials Network

SUD - Cost Information (SCI)

Web Version: 1.0; 1.01; 10-14-16

Segment (PROTSEG): A

Visit number (VISNO):

SUD module (SUD_MOD):

The next questions ask about costs/expenses associated with only the **most recent** hospital clinic, hospital outpatient department, community clinic, or neighborhood health center visit that was HIV-related. If no hospital clinic, hospital outpatient department, community clinic, or neighborhood health center visit was HIV-related, fill out for most recent hospital clinic, hospital outpatient department, community clinic, or neighborhood health center visit (for whatever reason).

The next questions ask about costs/expenses associated with only the **most recent** doctor's office appointment that was HIV-related. If no doctor's office visit was HIV-related, fill out for most recent doctor's office visit (for whatever reason).

The next questions ask about costs/expenses associated with only the **most recent** residential drug or alcohol treatment facility or detox hospital visit.

The next questions ask about costs/expenses associated with only the **most recent** outpatient substance abuse treatment.

1. Indicate the amount of time spent on the following:

a. Waiting time: (SCWAITHR)

 (xx) hour(s) (SCWAITMN) (xx) minute(s)

b. Session time: (SCSESNHR)

 (xxx) hour(s) (SCSESNMN) (xx) minute(s)

c. Round-trip travel time: (SCTRVLHR)

 (xx) hour(s) (SCTRVLMN) (xx) minute(s)

Round-trip travel time: (SCTRVLHR)

 (xx) hour(s) (SCTRVLMN) (xx) minute(s)

2. How did you get to this facility? (SCTRNSTO)

1-Drove myself
 2-Driven by a friend
 3-Took train or bus
 4-Took cab or shuttle
 5-Walked
 *Additional Options Listed Below

If "Other", specify: (SCTRNSSP)

3. Did you get home the same way? (SCTRNSSM)

☐ No ☐ Yes

If "No", how did you get back home? (SCTRNSHM)

1-Drove myself
 2-Driven by a friend
 3-Took train or bus
 4-Took cab or shuttle
 5-Walked
 *Additional Options Listed Below

If "Other", specify: (SCTRNHSP)

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

 (xxx)

5. If you "drove yourself" or were "driven by a friend", did you have to pay for parking? (SCPARK)

☐ No ☐ Yes

6. Did you have to arrange child care to go to this session (visit to facility)?(SCCHILD)

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

)

8. 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)?(SCUNPD)

Additional Selection Options for SCI

SUD module (*SUD_MOD*) (key field):

- 1-Module E. Hospital clinic/outpatient department
- 2-Module E. Doctor's office
- 3-Module I. Residential drug or alcohol treatment facility or detox hospital
- 4-Question 8b: Outpatient substance abuse treatment

How did you get to this facility?

- 6-Taken by ambulance
- 99-Other

NIDA Clinical Trials Network

SUD - Module A. Emergency Room (SDA)

Web Version: 1.0; 2.00; 10-14-16

Segment (PROTSEG): A
Visit number (VISNO):
Report type (REPORT):
Facility name (FACPRLC):

RA Instruction: Secure an appropriate medical release to facilitate medical record abstraction. This is a participant self report form and should reflect only the information provided by the participant.

Now I'm going to ask you to tell me about the ER visits that you mentioned having in each hospital since your last CTN-0049 study visit.

Date of assessment (SDAASMDT) (mm/dd/yyyy)

1. How many ER visits did you have in this hospital since your last CTN-0049 study visit?
2. How many ER visits did the participant have in this hospital since their last CTN-0049 study visit?

Month	Year	Number of Visits
(SAM OV1) <input type="text"/>	(SAYRV1) <input type="text"/>	(SANUMV1) <input type="text"/>
(SAM OV2) <input type="text"/>	(SAYRV2) <input type="text"/>	(SANUMV2) <input type="text"/>
(SAM OV3) <input type="text"/>	(SAYRV3) <input type="text"/>	(SANUMV3) <input type="text"/>
(SAM OV4) <input type="text"/>	(SAYRV4) <input type="text"/>	(SANUMV4) <input type="text"/>
(SAM OV5) <input type="text"/>	(SAYRV5) <input type="text"/>	(SANUMV5) <input type="text"/>
(SAM OV6) <input type="text"/>	(SAYRV6) <input type="text"/>	(SANUMV6) <input type="text"/>
(SAM OV7) <input type="text"/>	(SAYRV7) <input type="text"/>	(SANUMV7) <input type="text"/>
(SAM OV8) <input type="text"/>	(SAYRV8) <input type="text"/>	(SANUMV8) <input type="text"/>
(SAM OV9) <input type="text"/>	(SAYRV9) <input type="text"/>	(SANUMV9) <input type="text"/>
(SAM OV10) <input type="text"/>	(SAYRV10) <input type="text"/>	(SANUMV10) <input type="text"/>
(SAM OV11) <input type="text"/>	(SAYRV11) <input type="text"/>	(SANUMV11) <input type="text"/>
(SAM OV12) <input type="text"/>	(SAYRV12) <input type="text"/>	(SANUMV12) <input type="text"/>
(SAM OV13) <input type="text"/>	(SAYRV13) <input type="text"/>	(SANUMV13) <input type="text"/>
(SAM OV14) <input type="text"/>	(SAYRV14) <input type="text"/>	(SANUMV14) <input type="text"/>

(SAM OV15) <input type="text"/>	(SAYRV15) <input type="text"/>	(SANUMV15) <input type="text"/>
(SAM OV16) <input type="text"/>	(SAYRV16) <input type="text"/>	(SANUMV16) <input type="text"/>
(SAM OV17) <input type="text"/>	(SAYRV17) <input type="text"/>	(SANUMV17) <input type="text"/>
(SAM OV18) <input type="text"/>	(SAYRV18) <input type="text"/>	(SANUMV18) <input type="text"/>
(SAM OV19) <input type="text"/>	(SAYRV19) <input type="text"/>	(SANUMV19) <input type="text"/>
(SAM OV20) <input type="text"/>	(SAYRV20) <input type="text"/>	(SANUMV20) <input type="text"/>
(SAM OV21) <input type="text"/>	(SAYRV21) <input type="text"/>	(SANUMV21) <input type="text"/>
(SAM OV22) <input type="text"/>	(SAYRV22) <input type="text"/>	(SANUMV22) <input type="text"/>
(SAM OV23) <input type="text"/>	(SAYRV23) <input type="text"/>	(SANUMV23) <input type="text"/>
(SAM OV24) <input type="text"/>	(SAYRV24) <input type="text"/>	(SANUMV24) <input type="text"/>
(SAM OV25) <input type="text"/>	(SAYRV25) <input type="text"/>	(SANUMV25) <input type="text"/>
(SAM OV26) <input type="text"/>	(SAYRV26) <input type="text"/>	(SANUMV26) <input type="text"/>
(SAM OV27) <input type="text"/>	(SAYRV27) <input type="text"/>	(SANUMV27) <input type="text"/>
(SAM OV28) <input type="text"/>	(SAYRV28) <input type="text"/>	(SANUMV28) <input type="text"/>
(SAM OV29) <input type="text"/>	(SAYRV29) <input type="text"/>	(SANUMV29) <input type="text"/>
(SAM OV30) <input type="text"/>	(SAYRV30) <input type="text"/>	(SANUMV30) <input type="text"/>
(SAM OV31) <input type="text"/>	(SAYRV31) <input type="text"/>	(SANUMV31) <input type="text"/>
(SAM OV32) <input type="text"/>	(SAYRV32) <input type="text"/>	(SANUMV32) <input type="text"/>
(SAM OV33) <input type="text"/>	(SAYRV33) <input type="text"/>	(SANUMV33) <input type="text"/>
(SAM OV34) <input type="text"/>	(SAYRV34) <input type="text"/>	(SANUMV34) <input type="text"/>
(SAM OV35) <input type="text"/>	(SAYRV35) <input type="text"/>	(SANUMV35) <input type="text"/>
(SAM OV36) <input type="text"/>	(SAYRV36) <input type="text"/>	(SANUMV36) <input type="text"/>
(SAM OV37) <input type="text"/>	(SAYRV37) <input type="text"/>	(SANUMV37) <input type="text"/>
(SAM OV38) <input type="text"/>	(SAYRV38) <input type="text"/>	(SANUMV38) <input type="text"/>
(SAM OV39) <input type="text"/>	(SAYRV39) <input type="text"/>	(SANUMV39) <input type="text"/>
(SAM OV40) <input type="text"/>	(SAYRV40) <input type="text"/>	(SANUMV40) <input type="text"/>
(SAM OV41) <input type="text"/>	(SAYRV41) <input type="text"/>	(SANUMV41) <input type="text"/>

(SAM OV42) <input type="text"/>	(SAYRV42) <input type="text"/>	(SANUMV42) <input type="text"/>
(SAM OV43) <input type="text"/>	(SAYRV43) <input type="text"/>	(SANUMV43) <input type="text"/>
(SAM OV44) <input type="text"/>	(SAYRV44) <input type="text"/>	(SANUMV44) <input type="text"/>
(SAM OV45) <input type="text"/>	(SAYRV45) <input type="text"/>	(SANUMV45) <input type="text"/>
(SAM OV46) <input type="text"/>	(SAYRV46) <input type="text"/>	(SANUMV46) <input type="text"/>
(SAM OV47) <input type="text"/>	(SAYRV47) <input type="text"/>	(SANUMV47) <input type="text"/>
(SAM OV48) <input type="text"/>	(SAYRV48) <input type="text"/>	(SANUMV48) <input type="text"/>
(SAM OV49) <input type="text"/>	(SAYRV49) <input type="text"/>	(SANUMV49) <input type="text"/>

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

☐ No ☐ Yes

Comments:(SDACOMM)

Additional Selection Options for SDA

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

- 1-Self-report only
- 2-Abstracted medical record only

NIDA Clinical Trials Network

SUD - Module B. Inpatient Hospital (SDB)

Web Version: 1.0; 2.01; 11-15-16

Segment (PROTSEG): A
Report type (REPORT):
Date of admission (ADMITDT):

Was the date of admission exact or an approximation:(SBDTEXAP) ☐ Exact ☐ Approximation

RA Instruction: Secure an appropriate medical release to facilitate medical record abstraction. This is a participant self report form and should reflect only the information provided by the participant.

Now I'm going to ask you to tell me about each of the hospitalizations that you mentioned having since your last CTN-0049 study visit.

1. Hospital name:(SBPRLC01)

2. How many nights were you in the hospital for this stay?(SBNIGHT)

(xxx)

3. How many nights was the participant in the hospital for this stay?(SBNIGHT)

(xxx)

4. During this hospitalization, did the participant spend any nights in the following types of special units?

a. Intensive care unit (ICU/Coronary care unit (CCU):(SBSPCICU)

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

Nights:(SBNGTICU)

(xxx)

b. Psychiatric unit:(SBSPCPSY)

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

Nights:(SBNGTPSY)

(xxx)

c. Drug/alcohol unit:(SBSPCDRG)

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

Nights:(SBNGTDRG)

(xxx)

5. What were the first three discharge diagnoses for this hospitalization?

a. (SBDISDX)

b. (SBDISDX2)

c. (SBDISDX3)

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6. Is the participant still inpatient at the time of this visit? (SBINPTNW)

☐ No ☐ Yes

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

☐ No ☐ Yes

Comments: (SDBCOMM)

Additional Selection Options for SDB

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

- 1-Self-report only
- 2-Abstracted medical record only

NIDA Clinical Trials Network

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

Web Version: 1.0; 2.00; 11-15-16

Segment (PROTSEG): A
Visit number (VISNO):
Facility name (FACPRLC):

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

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

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

- 1-Nursing home
2-Hospice
3-Rehabilitation Center
4-Respite care
5-Personal care home
*Additional Options Listed Below

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

Month	Year	Number of Nights
(SCMOV1) <input type="text"/>	(SCYRV1) <input type="text"/> (xxxx)	(SCNUMV1) <input type="text"/> (xx)
(SCMOV2) <input type="text"/>	(SCYRV2) <input type="text"/> (xxxx)	(SCNUMV2) <input type="text"/> (xx)
(SCMOV3) <input type="text"/>	(SCYRV3) <input type="text"/> (xxxx)	(SCNUMV3) <input type="text"/> (xx)
(SCMOV4) <input type="text"/>	(SCYRV4) <input type="text"/> (xxxx)	(SCNUMV4) <input type="text"/> (xx)
(SCMOV5) <input type="text"/>	(SCYRV5) <input type="text"/> (xxxx)	(SCNUMV5) <input type="text"/> (xx)
(SCMOV6) <input type="text"/>	(SCYRV6) <input type="text"/> (xxxx)	(SCNUMV6) <input type="text"/> (xx)
(SCMOV7) <input type="text"/>	(SCYRV7) <input type="text"/> (xxxx)	(SCNUMV7) <input type="text"/> (xx)
(SCMOV8) <input type="text"/>	(SCYRV8) <input type="text"/> (xxxx)	(SCNUMV8) <input type="text"/> (xx)
(SCMOV9) <input type="text"/>	(SCYRV9) <input type="text"/> (xxxx)	(SCNUMV9) <input type="text"/> (xx)
(SCMOV10) <input type="text"/>	(SCYRV10) <input type="text"/> (xxxx)	(SCNUMV10) <input type="text"/> (xx)
(SCMOV11) <input type="text"/>	(SCYRV11) <input type="text"/> (xxxx)	(SCNUMV11) <input type="text"/> (xx)
(SCMOV12) <input type="text"/>	(SCYRV12) <input type="text"/> (xxxx)	(SCNUMV12) <input type="text"/> (xx)

(SCMOV13) <input type="text"/>	(SCYRV13) <input type="text"/> (xxx)	(SCNUMV13) <input type="text"/> (xx)
(SCMOV14) <input type="text"/>	(SCYRV14) <input type="text"/> (xxx)	(SCNUMV14) <input type="text"/> (xx)
(SCMOV15) <input type="text"/>	(SCYRV15) <input type="text"/> (xxx)	(SCNUMV15) <input type="text"/> (xx)

Comments:(SDCCOMM)

Additional Selection Options for SDC

What type of facility was this:

97 -Don't know

98 -Refused

NIDA Clinical Trials Network

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

Web Version: 1.0; 2.00; 11-15-16

Segment (PROTSEG): A
Visit number (VISNO):
Facility name (FACPRLC):

Now I'm going to ask you to tell me about each of the day hospital/partial hospitalization programs and intensive outpatient programs that you mentioned visiting over the past 6 months.

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

	No	Yes	Don't Know	Refused
a. Medical care:	(SDMEDCAR) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. Mental health care:	(SDMNTLHT) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. Substance use treatment:	(SDSUBUSE) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. Housing assistance:	(SDHOUSNG) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e. Other:(SDOTHSP) <input type="text"/>	(SDOTHER) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments:(SDDCOMM)

NIDA Clinical Trials Network

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

Web Version: 1.0; 2.00; 11-15-16

Segment (PROTSEG): A

Visit number (VISNO):

Facility name (FACPRLC):

Now I'm going to ask you to tell me about each of the hospital clinic/outpatient departments or doctor's offices that you mentioned visiting over the past 6 months.

Date of assessment: (SDEASMDT)

 (mm/dd/yyyy)

1. Was the visit to a "Clinic/outpatient department" or "Doctor's office"? (SEVSTYPE)

☐ Clinic/outpatient department ☐ Doctor's office

If the facility is a hospital, what is the name of the clinic or outpatient department within the hospital or, if this is a doctor's office, what is the name of the doctor? (SEFACLT)

 - OR - (SEFACUNK) ☐ Unknown

2. How many times did you visit this facility during the past 6 months?

Month	Year	Number of Visits
(SEMOV1) <input type="text"/>	(SEYRV1) <input type="text"/> (xxxx)	(SENUMV1) <input type="text"/> (xx)
(SEMOV2) <input type="text"/>	(SEYRV2) <input type="text"/> (xxxx)	(SENUMV2) <input type="text"/> (xx)
(SEMOV3) <input type="text"/>	(SEYRV3) <input type="text"/> (xxxx)	(SENUMV3) <input type="text"/> (xx)
(SEMOV4) <input type="text"/>	(SEYRV4) <input type="text"/> (xxxx)	(SENUMV4) <input type="text"/> (xx)
(SEMOV5) <input type="text"/>	(SEYRV5) <input type="text"/> (xxxx)	(SENUMV5) <input type="text"/> (xx)
(SEMOV6) <input type="text"/>	(SEYRV6) <input type="text"/> (xxxx)	(SENUMV6) <input type="text"/> (xx)
(SEMOV7) <input type="text"/>	(SEYRV7) <input type="text"/> (xxxx)	(SENUMV7) <input type="text"/> (xx)
(SEMOV8) <input type="text"/>	(SEYRV8) <input type="text"/> (xxxx)	(SENUMV8) <input type="text"/> (xx)
(SEMOV9) <input type="text"/>	(SEYRV9) <input type="text"/> (xxxx)	(SENUMV9) <input type="text"/> (xx)
(SEMOV10) <input type="text"/>	(SEYRV10) <input type="text"/> (xxxx)	(SENUMV10) <input type="text"/> (xx)
(SEMOV11) <input type="text"/>	(SEYRV11) <input type="text"/> (xxxx)	(SENUMV11) <input type="text"/> (xx)
(SEMOV12) <input type="text"/>	(SEYRV12) <input type="text"/> (xxxx)	(SENUMV12) <input type="text"/> (xx)
(SEMOV13) <input type="text"/>	(SEYRV13) <input type="text"/> (xxxx)	(SENUMV13) <input type="text"/> (xx)
(SEMOV14) <input type="text"/>	(SEYRV14) <input type="text"/> (xxxx)	(SENUMV14) <input type="text"/> (xx)

(SEMOV15) <input type="text"/>	(SEYRV15) <input type="text"/> (xxxx)	(SENUMV15) <input type="text"/> (xx)
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3. Date of earliest visit in the past 6 months:(SEPRGDT)

(mm/dd/yyyy)

4. Date of most recent visit:(SELASTDT)

(mm/dd/yyyy)

Comments:(SDECOMM)

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

Web Version: 1.0; 1.01; 11-15-16

Segment (PROTSEG): B
Date of admission (ADMSNDT):

Was the date of admission exact or an approximation?(SIDATE) Exact Approximation

Now I'm going to ask you to tell me about each of the residential drug or alcohol treatment facility or detox hospital visits that you mentioned having since your last visit.

- 1. Name of the residential drug or alcohol treatment facility or detox hospital:(SIPRLC01)
- 2. How many nights did you receive detox in this facility for this stay?(SIDTXNTS)
- 3. How many nights did you receive residential treatment in this facility for this stay?(SIRESNTS)
- 4. During this stay, what did you receive treatment for?(SIRCVTRT)

(xxx)

(xxx)

1-Alcohol abuse

2-Drug abuse

3-Both alcohol and drug abuse

4-Refused

5-Don't know

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

0-No

1-Yes

97-Don't know

98-Refused to answer

- 5. Is the participant still at the residential treatment facility at the time of this visit?(SIRESNW)
- 6. Is this residential treatment stay a continuation of a residential treatment stay from the previous visit?(SICONTVS)

No Yes
No Yes

Comments:(SDICOMM)

NIDA Clinical Trials Network

Short Form 12 (SF-12) Measure (SFM)

Web Version: 1.0; 1.00; 10-14-16

Segment (*PROTSEG*): AVisit number (*VISNO*):Date of assessment:(*SFMASMDT*)

(mm/dd/yyyy)

*RA Instruction: Provide participant with reference cards for each question that list all response options for his/her easy reference.**This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. Select the response that best describes your answer.*1. In general, would you say your health is:(*SFHEALTH*)

1-Excellent
2-Very good
3-Good
4-Fair
5-Poor

The following questions are about activities you might do during a typical day.

2. Does your health now limit you in these activities? If so, how much?

a. Moderate activities (such as moving a table, pushing a vacuum cleaner, bowling, or playing golf):
(*SFMODACT*)

1-Yes, limited a lot
2-Yes, limited little
3-No, not limited at all

b. Climbing several flights of stairs:(*SFSTAIRS*)

1-Yes, limited a lot
2-Yes, limited little
3-No, not limited at all

3. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?a. Accomplished less than you would like:(*SFPACCMP*)

1-All of the time
2-Most of the time
3-Some of the time
4-A little of the time
5-None of the time

b. Were limited in the kind of work or other activities:(*SFPKDWRK*)

1-All of the time
2-Most of the time
3-Some of the time
4-A little of the time
5-None of the time

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

a. Accomplished less than you would like:(*SFEACOMP*)

1-All of the time
2-Most of the time
3-Some of the time
4-A little of the time
5-None of the time

b. Did work or other activities less carefully than usual:(*SFEWORK*)

1-All of the time
2-Most of the time
3-Some of the time
4-A little of the time
5-None of the time

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

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

The following questions are about how you feel and how things have been with you during the past 4 weeks.

6. How much of the time during the past 4 weeks:

a. Have you felt calm and peaceful?(*SFCALM*)

1-All of the time
2-Most of the time
3-Some of the time
4-A little of the time
5-None of the time

b. Did you have a lot of energy?(*SFENERGY*)

1-All of the time
2-Most of the time
3-Some of the time
4-A little of the time
5-None of the time

c. Have you felt downhearted and depressed?(*SFDEPRSS*)

1-All of the time
2-Most of the time
3-Some of the time
4-A little of the time
5-None of the time

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

- 1-All of the time
- 2-Most of the time
- 3-Some of the time
- 4-A little of the time
- 5-None of the time

Comments:(*SF MCOMM*)

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Study Completion (STC)

Web Version: 1.0; 6.00; 03-28-18

Segment (PROTSEG): B

1. Did the participant complete the 12 month follow-up visit?(STCOMPLT)

If "No", select the primary reason for not completing the 12 month follow-up visit:(STEARLY)

No Yes

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

If "Participant terminated for other clinical reasons", "Participant terminated for administrative issues", or "Participant terminated for other reason", specify:(STCMPOSP)

2. Date of last data collection or date of withdrawn consent:(STCOMPDT)

(mm/dd/yyyy)

Comments:(STCOMM)

Investigator's Signature

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

Principal Investigator:(STPISIGN)

Date:(STPISGDT)

(mm/dd/yyyy)

Additional Selection Options for STC

- If "No", select the primary reason for not completing the 12 month follow-up visit:
- 6-Participant terminated for other clinical reasons
 - 7-Participant had a significant psychiatric risk (e.g., suicidal, homicidal, psychotic)
 - 8-Participant withdrew consent/assent
 - 9-Participant deceased
 - 10-Participant terminated for administrative issues
 - 11-Participant terminated due to pressure or advice from outsiders
 - 12-Participant feels treatment no longer necessary, cured
 - 13-Participant feels treatment no longer necessary, not working
 - 34-Participant was ineligible and should not have been enrolled in study
 - 99-Participant terminated for other reason

NIDA Clinical Trials Network

Substance Use (SUB)

Web Version: 1.0; 1.00; 10-14-16

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

Date of assessment (SUBASMDT) (mm/dd/yyyy)

The next several questions are about substance (drug) use.

1. How many times in the **past 12 months** have you used an illegal drug or used a prescription medication for nonmedical reasons? (SUTIMES) (xxxx) times

2. Were any of the following used for non-medical purposes?

No Yes

- a. Ecstasy (also known as E, X, or MDMA):

(SUECSTAS) ☐ ☐
- b. GHB (also known as gamma hydroxybutyric acid, G, or GBL):

(SUGHB) ☐ ☐
- c. Heroin:

(SUHEROIN) ☐ ☐
- d. Marijuana:

(SUTHC) ☐ ☐
- e. Medical marijuana:

If "Yes", do you have a prescription for medical marijuana?

(SUMEDTHC) ☐ ☐

(SUMEDRX) ☐ ☐
- f. Methamphetamine (also known as crystal meth, speed, or tina):

(SUMETHA) ☐ ☐
- g. Hallucinogens (such as LSD, mushrooms, peyote, or mescaline):

(SUHALLU) ☐ ☐
- h. PCP (also known as angel dust, wet, or wicky sticks):

(SUPCP) ☐ ☐
- i. Poppers (also known as amyl nitrate):

(SUPOPPER) ☐ ☐
- j. Powdered cocaine:

(SUCOCAIN) ☐ ☐
- k. Rock or crack cocaine:

(SUROCKCO) ☐ ☐
- l. Ketamine (also known as special K or K):

(SUKETAMI) ☐ ☐
- m. Recreational use of prescription drugs or pain killers to get high (such as codeine, Vicodin (hydrocodone), Percocet, Darvon, Oxycontin (oxycodone), Demerol, or Dilaudid):

(SURECDRU) ☐ ☐
- n. Tranquilizers or barbiturates (such as Valium, Librium, Seconal, Xanax, Ambien, lorazepam, or Rohypnol--also known as Roofies):

(SUTRANQU) ☐ ☐
- o. Fentanyl:

(SUFNTNYL) ☐ ☐
- p. Synthetic stimulants (such as Flakka (also known as gravel), bath salts, methylene or cat):

(SUSYNTHS) ☐ ☐

Comments: (SUBCOMM)

NIDA Clinical Trials Network

Service Utilization Detail (SUD)

Web Version: 1.0; 2.00; 11-15-16

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

RA Instruction: This is a participant self report form and should reflect only the information provided by the participant. Provide participant with a reference card that lists all response options for his/her easy reference.

The next questions ask about your use of medical and social services since your last CTN-0049 visit.
The next questions ask about your use of medical and social services since your last visit.

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

1. 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.(SUER)

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

a. If "Yes", how many different visits did you have to a hospital emergency room for emergency care, including psychiatric hospitals?(SUERVS)

(xxx) visits

How many of these visits were in the last 6 months?(SUERVS6M)

(xxx) visits

b. If "Yes", how many different emergency departments have you attended?(SUERDEPT)

(xxx) departments

How many different emergency departments were visited in the last 6 months?(SUERDP6M)

(xxx) departments

2. Were you a patient in any hospital overnight or longer?
Include psychiatric hospitals.(SUOVHS)

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

If "Yes", how many separate overnight hospital stays did you have, including psychiatric hospital stays?(SUOVHVS)

(xxx) stays

If "Yes", how many separate overnight hospital stays did you have, including psychiatric hospital stays?(SUOVHVS)

(xxx) stays

How many of these overnight hospital stays were in the last 6 months?(SUOVHS6M)

(xxx) stays

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

3. Did you spend one or more nights in a respite care facility, personal care home, nursing home, rehabilitation center or hospice facility?(SUCARE)

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

If "Yes", how many separate stays in a respite care facility, personal care home, nursing home, rehabilitation center or hospice facility did you have? (SUCAREVS)

(xxx) stays

If "Yes", how many separate stays in a respite care facility, personal care home, nursing home, rehabilitation center or hospice facility did you have? (SUCAREVS)

(xxx) stays

4. Did you attend any medical program where you spent the day there but went home at night?

Include day hospitals, partial hospitalizations or intensive outpatient programs for reasons other than substance abuse. (SUDAYH)

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

If "Yes", how many different programs like this did you go to? (SUDAYHVS)

(xx) programs

5. Did you go to any hospital clinics, hospital outpatient departments, community clinics or neighborhood health centers for medical care (for example, to care for your HIV/AIDS) or other physical problems?

Include visits for urgent care. (SUOUTP)

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

If "Yes", how many different hospital clinics, hospital outpatient departments, community clinics or neighborhood health centers did you visit for medical care? (SUOUTPVS)

(xx) clinics, departments and/or centers

6. Did you get medical care in any private doctor's offices? (SUDR)

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

If "Yes", how many different private doctor's offices did you visit for medical care? (SUDRVS)

(xx) different doctor's offices

7. Did you see any professional for the primary purpose of getting help for a psychological or emotional issue?

These professionals could include a 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, other religious/spiritual advisors or healers. (SUPSYC)

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

Thinking about all the mental health care professionals you visited:

a. How many times did you visit any of these professionals to talk about psychological or emotional issues? (SUPSYEM)

(xxx) times

b. How many times did you visit any of these professionals to discuss your use of prescribed medications for psychological and emotional issues? (SUPSYMED)

(xxx) times

8. Did you see any professional for the primary purpose of getting alcohol or drug treatment, including methadone maintenance, or getting help for an alcohol or drug problem?

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, other religious/spiritual advisors or healers. (SUDRUG)

☐ No ☐ Yes

a. If "Yes", were you in a residential drug or alcohol treatment facility or detox hospital in which you stayed overnight? (SUDRUGOV)

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

How many separate stays did you have? (SUDRUGVS)

(xxx) stays

Answer the following questions for all outpatient substance abuse treatment that you received.

b. How many different alcohol or drug treatment providers in an outpatient setting did you visit? (SUDRGOPT)

(xx) different providers

1. How many days did you attend intensive outpatient substance abuse treatment? (SUINTOPT)

(xxx) days

2. How many days did you attend regular outpatient substance abuse treatment? (SUREGOPT)

(xxx) days

Answer the following questions for all outpatient substance abuse service providers that you met with.

c. How many times did you meet one-on-one with an outpatient substance abuse service provider to discuss substance use issues? (SUDGIND)

(xxx) times

d. How many times did you meet in group sessions with an outpatient substance abuse service provider to discuss substance use issues? (SUGRPSES)

(xxx) times

Answer the following questions for all substance abuse providers or medical providers.

e. Are you taking any of the following medications for opioid treatments?

1. Methadone: (SUOUTMET)

☐ No ☐ Yes Methadone treatment center: (SUMETHTX)

2. Buprenorphine (Suboxone): (SUOUTSBX)

☐ No ☐ Yes

3. Naltrexone oral: (SUOUTONX)

☐ No ☐ Yes

4. Naltrexone depot (intramuscular): (SUOUTINJ)

☐ No ☐ Yes

f. How many times did you pick up opioid replacement medications? (SUOUTOPI)

(xxx) times

9. 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 provider.
(SUGR)

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

a. If "Yes", how many group sessions did you attend with one of these providers to discuss substance use issues? (SUGRVS)

(xxx) group sessions

b. Which best describes the group you attend or attended?

1. Mental health self-help or support group: (SUGRMN)

☐ No ☐ Yes

How many times did you attend? (SUGRMNTM)

(xxx) times

2. Substance abuse self-help or support group: (SUGRSB)

☐ No ☐ Yes

How many times did you attend? (SUGRSBTM)

(xxx) times

3. HIV/AIDS self-help or support group: (SUGRHI)

☐ No ☐ Yes

How many times did you attend? (SUGRHITM)

(xxx) times

4. HCV self-help or support group: (SUGRHC)

☐ No ☐ Yes

How many times did you attend? (SUGRHCTM)

(xxx) times

5. Other self-help or support group: (SUGROT)

☐ No ☐ Yes

If "Other", specify (SUGROTSP)

How many times did you attend? (SUGROTTM)

(xxx) times

- OR -

Refused: (SUGRRF)

Don't know: (SUGRDK)

10. Did you get any dental care? (SUDENTAL)

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

11. Did you receive any help at home from professional health care providers, such as nurses, aides or therapists sent by a home health agency, or from other home-based services, such as Meals on Wheels? (SUHOME)

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

a. If "Yes", how many different professional home health care providers assisted you? (SUHOMEVPV)

(xx) providers

b. If "Yes", how many different home visits occurred? (SUHOMEVS)

(xxx) home visits

c. What kind of professional home health care providers have visited you?

RA Instruction: Let participant give open-ended answer and mark appropriate response category. Read categories only if participant cannot answer question.

1. Visiting nurse: (SUNURSE)

☐ No ☐ Yes

2. Home health aide: (SUHMAID)

☐ No ☐ Yes

3. Homemaker: (SUHMMKR)

☐ No ☐ Yes

4. Physical, occupational or respiratory therapist: (SUTHRPST)

☐ No ☐ Yes

5. Counselor or social worker: (SUSOCIAL)

☐ No ☐ Yes

6. Babysitter: (SUBABYST)

☐ No ☐ Yes

7. Meals on wheels worker: (SUMEALS)

☐ No ☐ Yes

8. Other: (SUHOMEOT)

☐ No ☐ Yes

If "Other", specify: (SUHOMESP)

12. Did you receive any help because of a health problem or other disability from family members, friends or neighbors?

This help could be for medical problems, taking care of yourself, housekeeping, shopping, or any other assistance you might need, including transportation. (SUFAMILY)

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

13. Did you receive any help from case managers or social service workers with things like obtaining health care or legal services, housing or easing money problems? (SUCASE)

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

- a. How many different people have been your case manager or social service worker?(SUCASENM)

(xx) people
- b. How many times did you have face-to-face meetings with one of your case managers or social service workers?(SUCASEVS)

(xxx) times
- c. How often did you talk to one of your case managers or social service workers on the telephone?(SUCASEPH)

1-More than once a week
2-About once a week
3-Every other week
4-Once a month
5-A few times but less than monthly
*Additional Options Listed Below

14. Did you receive any health care from providers or social service agencies we have not yet discussed?
(SUCAREOT)

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

If "Yes", specify each additional provider and/or social service agencies from which you have received health care :

1. (SUCAREO1)
2. (SUCAREO2)
3. (SUCAREO3)
4. (SUCAREO4)
5. (SUCAREO5)

Additional Selection Options for SUD

How often did you talk to one of your case managers or social service workers on the telephone?

6-Once

7-No phone contact

97 -Don't know

98 -Refused

Urine Drug Screen (UDS)

Web Version: 1.0; 3.00; 03-08-17

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

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

If "No", reason:(UDNORSN1)

If "Other", specify:(UDNOSP1)

☐ No ☐ Yes

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

1st Urine Drug Screen

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

3. Was the 1st urine specimen temperature within range? (90 - 100 °F)(UDTEMP1)

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

5. 1st Urine Drug Screen Result(s):

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

 (mm/dd/yyyy)

☐ No ☐ Yes

☐ No ☐ Yes

2nd Urine Drug Screen

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

☐ No ☐ Yes

If "No", reason: (UDNORSN2)

If "Other", specify: (UDNOSP2)

7. Was the 2nd urine specimen temperature within range? (90 - 100 °F) (UDTEMP2)

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

9. 2nd Urine Drug Screen Result(s):

Drug Name (Abbreviation)	Negative	Positive	Invalid
Benzodiazepines (BZO):	(UDBZO2) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Amphetamine (AMP):	(UDAMP2) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Marijuana (THC):	(UDTHC2) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Methamphetamine (MET):	(UDMET2) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Opiates (2000 ng) (OPI):	(UDOPI2) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cocaine (COC):	(UDCOC2) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ecstasy (MDMA):	(UDMDA2) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Oxycodone (OXY):	(UDOXY2) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Methadone (MTD):	(UDMTD2) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Barbiturate (BAR):	(UDBAR2) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments: (UDSCOMM)

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

☐ No ☐ Yes

☐ No ☐ Yes