NIDA Clinical Trials Network

Adverse Events (AD1)

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

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

The following AEs do not require reporting in the data system: Grade 1 (mild) and Grade 2 (moderate) Unrelated Events.

1. Adverse event name: *(A1DESCRI)*

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

3. Severity of event: *(A1SEVEVE)*
   - 1-Grade 1 - Mild
   - 2-Grade 2 - Moderate
   - 3-Grade 3 - Severe
   - 4-Grade 4 - Life-threatening
   - 5-Grade 5 - Death

4. Relationship to study intervention: *(A1RELTB)*
   - 1-Unrelated
   - 2-Possibly related
   - 3-Probably related
   - 4-Definitely related

   If "Unrelated" to study intervention, alternative etiology: *(A1ALTEB)*
   - 0-None apparent
   - 1-Study disease
   - 2-Concomitant medication
   - 3-Other pre-existing disease or condition
   - 4-Accident, trauma, or external factors
   - *Additional Options Listed Below

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

5. Action taken with study intervention: *(A1ACTBI)*
   - 0-None
   - 1-Decreased intervention
   - 2-Increased intervention
   - 3-Temporarily stopped intervention
   - 4-Permanently stopped intervention
   - *Additional Options Listed Below

6. Outcome of event: *(A1OUTCM)*
   - 1-Ongoing
   - 2-Resolved without sequelae
   - 3-Resolved with sequelae
   - 4-Resolved by convention
   - 5-Death

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

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

8. Was this event associated with: *(A1ASSOCI)*
   - 0-None of the following
   - 10-Hospitalization for a medical event
   - 1-Death
   - 2-Life-threatening event
   - 3-Inpatient admission to hospital
   - *Additional Options Listed Below

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

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

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

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

Comments: *(A1COMM)*

MedDRA:

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

Preferred Term: *(MEDRAPT)* Not Coded

System Organ Class: *(MEDRASOC)*

Additional Selection Options for AD1

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

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

Was this event associated with:
4-Prolongation of hospitalization
5-Persistent or significant disability or incapacity
6-Congenital anomaly or birth defect
7-Required significant intervention to prevent permanent impairment or damage
9-Important medical event

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Serious Adverse Event Summary (AD2)

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

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

1. Initial narrative description of serious adverse event:

(A2SUMM)

2. Relevant Past Medical History: *(A2SAEMHX)* ☐ No ☐ Yes ☐ Unknown
Allergies, pregnancy, smoking and alcohol use, hypertension, diabetes, epilepsy, depression, etc.

(A2MEDHX)

3. Medications at the Time of the Event: *(A2SAEMED)* ☐ No ☐ Yes ☐ Unknown

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

4. Treatments for the Event: *(A2SAETRT)* ☐ No ☐ Yes ☐ Unknown

Treatment	Indication	Date Treated
(A2_1TNME)	*(A2_1TIND)*	*(A2_1LTDT)* *(mm/dd/yyyy)*
(A2_2TNME)	*(A2_2TIND)*	*(A2_2LTDT)* *(mm/dd/yyyy)*

(A2_3TNME)	*(A2_3TIND)*	*(A2_3LTDT)* *(mm/dd/yyyy)*
(A2_4TNME)	*(A2_4TIND)*	*(A2_4LTDT)* *(mm/dd/yyyy)*
(A2_5TNME)	*(A2_5TIND)*	*(A2_5LTDT)* *(mm/dd/yyyy)*

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

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

6. Follow-Up:

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

(A2FOLLUP)

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7. Additional information requested by the Medical Monitor:

(A2ADDINF)

Have all Medical Monitor requests been addressed? *(A2RQADDR)* ☐ Yes

Additional Selection Options for AD2

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

Serious Adverse Event Medical Reviewer (AD3)

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

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

1. Was this determined to be a serious adverse event?*(A3DETER)*	☐ No ☐ Yes
2. Was this event considered associated with the study's behavioral intervention? *(A3BHINT)*	☐ No ☐ Yes
3. Was this event expected?*(A3EXPECT)*	☐ No ☐ Yes
4. Is this a standard expedited/reportable event? *(i.e., is it serious, unexpected and related to therapy)(A3EXPFDA)*	☐ No ☐ Yes
5. Is this an expedited/reportable event for other reasons?*(A3EXPOTH)*	☐ No ☐ Yes
6. Does the protocol need to be modified based on this event?*(A3EXPDSM)*	☐ No ☐ Yes
7. Does the consent form need to be modified based on this event? *(A3CONSEN)*	☐ No ☐ Yes
8. Is the review complete?*(A3REVDNE)*	☐ No ☐ Yes
If "No", what additional information is required:*(A3ADDINF)*	
Assessed by:*(A2ASRID)*	☐ Robert Lindblad ☐ Radhika Kondapaka
Reviewed by:*(A3REVID)*	☐ Robert Lindblad
Comments:*(A3COMM)*	

Additional Selection Options for AD3

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

NIDA Clinical Trials Network

Alcohol Breathalyzer (ALB)

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

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

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

Comments: *(ALBCOMM)*

NIDA Clinical Trials Network

Brief Screen (BFS)

Web Version: 1.0; 1.01; 09-14-11

Brief Screen ID *(BFSID)*:

Protocol 0044 is now closed to enrollment. No new Brief Screen Forms can be submitted.

1. Date of verbal consent: *(BFVCSNDT)* ____ *(mm/dd/yyyy)*
2. Date of screening: *(BFSCRNDT)* ____ *(mm/dd/yyyy)*
3. How did you hear about this research study? *(BFHEARST)*
   - 1-Treatment program staff
   - 2-Flyer/brochure
   - 3-Another client
   - 4-Research staff
   - 5-Other

   If "Other", specify: *(BFROTHSP)* ____
4. Age: *(BFAGE)* ____ *(xx)* years

   Note: If under 18: Ineligible
5. Sex: *(BFSEX)* ☐ Male ☐ Female
6. When did you start this treatment program? *(BFTRSTDT)* ____ *(mm/dd/yyyy)*

   (If this is client's intake appointment, enter screening date)

   If > 30 days since program start: Ineligible
7. How many days do you plan to attend this treatment program? *(BFPLTRDY)* ____ *(xxx)* days

   If < 90 days: Ineligible
8. What is your primary substance of abuse? *(BFPRISUB)*
   - 1-Alcohol
   - 2-Cocaine
   - 3-Cannabis
   - 4-Opiates
   - 5-Other

   If "Other", specify: *(BFSUABSP)* ____
9. When was the last time you used any illicit drug? *(BFLSTUSE)* ____ *(mm/dd/yyyy)*

   If > 30 days from screening, ask question 9a. Otherwise ask question 10.

   a. Have you been in a controlled environment within the last 30 days (including a detox unit, hospital or correctional facility)? *(BFCONENV)* ☐ No ☐ Yes

   If "No": Ineligible

   b. If "Yes", date of exit from controlled environment: *(BFENCTDT)* ____ *(mm/dd/yyyy)*

   If the last drug use was > 60 days prior to screening: Ineligible.
10. Are you currently receiving an opioid replacement medication? For example, are you prescribed methadone, buprenorphine, suboxone, or subutex from any provider or drug treatment program? *(BFOPIMED)* ☐ No ☐ Yes

    If "Yes": Ineligible

Thank you for your time in answering these questions!

11. Eligible? *(BFELIGIB)* ☐ No ☐ Yes

    If "No", STOP; do not complete questions 12, 13 and 14. Say: I am sorry, but based on the information you've given, it does not look like this study will be a good fit for you. Do you have any additional questions?

    If "Yes", say: It appears that you may be eligible to take part in this research study being conducted at this treatment program. If you are interested in participating, the next step is to attend an interview with study staff which will take about 90 minutes to complete and for which you will receive compensation for your time and effort. You will first complete a consent form where you will receive all the details about participation, have a chance to ask any questions, and decide whether or not you'd like to participate.
12. Are you interested in learning more about the study and possibly participating? *(BFINTERE)* ☐ No ☐ Yes

    If "Yes", complete question 13.

    If "No", why? (Check all that apply)

    a. Concerns about additional time or effort *(BFNOTIME)* ☐ No ☐ Yes

    b. Do not want treatment delivered via web *(BFNOWEB)* ☐ No ☐ Yes

    c. Not interested in participating in research *(BFNOINT)* ☐ No ☐ Yes

    d. Other *(BFNOOTHR)* ☐ No ☐ Yes

    If "Other", specify: *(BFOTHRSP)* ____
13. Scheduled baseline assessment date: *(BFBLASDT)* ____ *(mm/dd/yyyy)*

14. Did participant attend baseline interview? *(BFBASINT)* — ☐ No ☐ Yes

a. If "Yes", enter Participant ID: *(BFPATID)*

b. If "No", select reason: *(BFNOINRE)*

- 1-No-show/no additional contact
- 2-No longer interested
- 3-No longer enrolled at clinic
- 4-Other

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

Comments: *(BFSCOMM)*

NIDA Clinical Trials Network

Brief Symptom Inventory® 18 (BSI)

Web Version: 1.0; 2.00; 07-19-12

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

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

Instructions: The BSI 18 test consists of a list of problems people sometimes have. Read each one carefully and check the number of the response that best describes HOW MUCH THAT PROBLEM HAS DISTRESSED OR BOTHERED YOU DURING THE PAST 7 DAYS INCLUDING TODAY. Do not skip any items. Read the example before you begin. If you have any questions, please ask them now.

Example:

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

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

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

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NIDA Clinical Trials Network

Coping Strategies Scale-Brief Version (CSS)

Web Version: 1.0; 1.01; 08-25-11

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

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

Each statement below describes a strategy or thought that a person might use to help them not use drugs or alcohol. Please check the option that best describes how often you made use of each strategy or thought in the past 3 months to help you not use drugs or alcohol.

	Never	Seldom	Occasionally	Frequently
1. I engage in some physical activity when I get the urge to use drugs or alcohol.	*(CSPHYACT)* ☐	☐	☐	☐
2. I avoid people associated with my drug or alcohol use.	*(CSAVOID)* ☐	☐	☐	☐
3. I consider that feeling good about myself includes changing my drug or alcohol use behavior.	*(CSFEELGD)* ☐	☐	☐	☐
4. I remove things from my home or work that remind me of using drugs or alcohol.	*(CSREMOVE)* ☐	☐	☐	☐
5. I ask people not to offer me drugs or alcohol.	*(CSNOOFFR)* ☐	☐	☐	☐
6. I try to think about other things when I begin to think about using drugs or alcohol.	*(CSOTHTHG)* ☐	☐	☐	☐
7. I remind myself that I can choose to overcome my drug or alcohol use if I want to.	*(CSOVRCOM)* ☐	☐	☐	☐
8. I do something else instead of using drugs or alcohol when I need to deal with tension.	*(CSSOMELS)* ☐	☐	☐	☐
9. I tell myself that if I try hard enough I can keep from using drugs and alcohol.	*(CSTRYHRD)* ☐	☐	☐	☐
10. I leave places where people are using drugs or alcohol.	*(CSLEAVE)* ☐	☐	☐	☐
11. I seek out social situations where it is OK not to use drugs or alcohol.	*(CSSOCIAL)* ☐	☐	☐	☐
12. I stay away from places or situations associated with my drug or alcohol use.	*(CSSTAYAW)* ☐	☐	☐	☐
13. I find that doing things is a good substitute for using drugs or alcohol.	*(CSDOGOOD)* ☐	☐	☐	☐
14. I think about my physical reactions to drug or alcohol use and remember what a problem it is for me.	*(CSPHYREA)* ☐	☐	☐	☐
15. I am able to express emotions such as anger or affection without relying on drugs or alcohol.	*(CSEMOTIO)* ☐	☐	☐	☐
16. When I feel angry, I try first to calm myself down.	*(CSCALM)* ☐	☐	☐	☐
17. If someone offers me drugs or alcohol, I say "no" immediately.	*(CSSAYNO)* ☐	☐	☐	☐
18. I adopt a positive outlook that helps me not use drugs or alcohol.	*(CSPOSOUT)* ☐	☐	☐	☐
19. I try to remind myself of the good things I have accomplished.	*(CSACCOMP)* ☐	☐	☐	☐
20. When I feel upset, I try to stop or challenge my negative self-talk.	*(CSSTONEG)* ☐	☐	☐	☐
21. I think of the difficulties in my life as problems to be solved.	*(CSDIFFIC)* ☐	☐	☐	☐
22. I have a plan to deal with urges to use, if they occur.	*(CSDEAL)* ☐	☐	☐	☐
23. If I have the urge to use drugs or alcohol, I tell myself that it will go away if I just wait awhile.	*(CSWAIT)* ☐	☐	☐	☐

Comments:*(CSSCOMM)*

Demographics (DEM)

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

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

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

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

4. Race:

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

OR

Unknown*(DEUNKNOW)* ☐ Yes

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

Comments:*(DEMCOMM)*

NIDA Clinical Trials Network

DSM-IV Criteria - Substance Related Disorders (DSM)

Web Version: 1.0; 2.02; 06-18-12

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

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

Primary Drug:*(DSPRIMAR)*
1-Alcohol
2-Cocaine
3-Stimulants
4-Marijuana
5-Opiates
*Additional Options Listed Below

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

1. Have you used _____ in the past 12 months? (Continue the assessment only for drugs used within the past 12 months.)

Alcohol	Cocaine	Stimulants	Marijuana	Opiates	Other
(DSALCHOL) 0-No 1-Yes	*(DSCOCINE)* 0-No 1-Yes	*(DSOTHSTI)* 0-No 1-Yes	*(DSMARHAS)* 0-No 1-Yes	*(DSOPIATE)* 0-No 1-Yes	*(DSOTHER)* 0-No 1-Yes

Substance DEPENDENCE Criteria

A maladaptive pattern of substance use, leading to clinically significant impairment or distress, as manifested by **three** (or more) of the following, occurring at any time within the same 12-month period.

A1 Have you found that you needed to use a lot more (drug) in order to get high than you did when you first started using it? IF YES: How much more? IF NO: What about finding that when you used the same amount, it had much less effect than before? *Tolerance, as defined by either a need for markedly increased amounts of the substance in order to achieve intoxication or desired effect, or markedly diminished effect with continued use of the same amount of substance.*

Alcohol	Cocaine	Stimulants	Marijuana	Opiates	Other
(DSNDALCH) 0-Present 1-Absent 2-Uncertain	*(DSNDCOCA)* 0-Present 1-Absent 2-Uncertain	*(DSNDOTST)* 0-Present 1-Absent 2-Uncertain	*(DSNDMARH)* 0-Present 1-Absent 2-Uncertain	*(DSNDOPIA)* 0-Present 1-Absent 2-Uncertain	*(DSNDOTHR)* 0-Present 1-Absent 2-Uncertain

A2 Have you ever had withdrawal symptoms, that is felt sick when you cut down or stopped using (drug)? IF YES: What symptom have you had? *(Need to refer to withdrawal symptoms associated with each drug.)* Have you used (drug) to keep yourself from getting sick with (specific withdrawal symptom[s])? *Withdrawal, as manifested by either the characteristic withdrawal syndrome for the substance (see special criteria sets for withdrawal in p. 185 of DSM-IV manual) or the same (or closely related) substance is taken to relieve or avoid withdrawal symptoms.*

Alcohol	Cocaine	Stimulants	Marijuana	Opiates	Other
(DSWDALCH) 0-Present 1-Absent 2-Uncertain	*(DSWDCOCA)* 0-Present 1-Absent 2-Uncertain	*(DSWDOTST)* 0-Present 1-Absent 2-Uncertain	*(DSWDMARH)* 0-Present 1-Absent 2-Uncertain	*(DSWDOPIA)* 0-Present 1-Absent 2-Uncertain	*(DSWDOTHR)* 0-Present 1-Absent 2-Uncertain

A3 Have you often found that when you started using (drug), you ended up using more of it than you were planning to? IF NO: What about using it over a much longer period of time than you were planning to? *Substance often taken in larger amounts or over a longer period than subject intended.*

Alcohol	Cocaine	Stimulants	Marijuana	Opiates	Other
(DSSDALCH) 0-Present 1-Absent 2-Uncertain	*(DSSDCOCA)* 0-Present 1-Absent 2-Uncertain	*(DSSDOTST)* 0-Present 1-Absent 2-Uncertain	*(DSSDMARI)* 0-Present 1-Absent 2-Uncertain	*(DSSDOPIA)* 0-Present 1-Absent 2-Uncertain	*(DSSDOTHR)* 0-Present 1-Absent 2-Uncertain

A4 Have you tried to cut down or stop using (drug)? IF YES: Have you ever actually stopped using (drug) altogether? (How many times did you try to cut down or stop altogether?) IF UNCLEAR: Did you want to stop or cut down? IF NO: Is this something you kept worrying about? *Persistent desire or one or more unsuccessful efforts to cut down or control substance use.*

Alcohol	Cocaine	Stimulants	Marijuana	Opiates	Other
(DSCTALCH) 0-Present 1-Absent 2-Uncertain	*(DSCTCOCA)* 0-Present 1-Absent 2-Uncertain	*(DSCTOTHE)* 0-Present 1-Absent 2-Uncertain	*(DSCTMARI)* 0-Present 1-Absent 2-Uncertain	*(DSCTOPIA)* 0-Present 1-Absent 2-Uncertain	*(DSCTBENZ)* 0-Present 1-Absent 2-Uncertain

A5 Have you spent a lot of time using (drug) or doing whatever you had to do to get it? Did it take you a long time to get back to normal? (How much time?) *A great deal of time spent in activities necessary to get the substance (e.g., visiting multiple doctors or driving long distances), use the substance (e.g., chain smoking) or recover from its effects.*

Alcohol	Cocaine	Stimulants	Marijuana	Opiates	Other
(DSLTALCO) 0-Present 1-Absent 2-Uncertain	*(DSLTCOCA)* 0-Present 1-Absent 2-Uncertain	*(DSLTOTHS)* 0-Present 1-Absent 2-Uncertain	*(DSLTMARH)* 0-Present 1-Absent 2-Uncertain	*(DSLTOPIA)* 0-Present 1-Absent 2-Uncertain	*(DSLOTHR)* 0-Present 1-Absent 2-Uncertain

A6 Have you had times when you would use (drug) so often that you used (drug) instead of working or spending time in hobbies with your family or friends? *Important social, occupational, or recreational activities given up or reduced because of substance abuse.*

Alcohol	Cocaine	Stimulants	Marijuana	Opiates	Other
(DSOFALCO) 0-Present 1-Absent 2-Uncertain	*(DSOFCOCA)* 0-Present 1-Absent 2-Uncertain	*(DSOFOTHS)* 0-Present 1-Absent 2-Uncertain	*(DSOFMARH)* 0-Present 1-Absent 2-Uncertain	*(DSOFOPIA)* 0-Present 1-Absent 2-Uncertain	*(DSOFOTHR)* 0-Present 1-Absent 2-Uncertain

A7 IF NOT ALREADY KNOWN, has (drug) caused psychological problems, like making you depressed? IF NOT ALREADY KNOWN, has (drug) ever caused physical problems or made a physical problem worse? IF YES TO EITHER OF THE ABOVE, did you keep on using (drug) anyway? *Continued substance use despite knowledge of having persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the use of the substance (e.g., continued drinking despite worsening ulcer).*

Alcohol	Cocaine	Stimulants	Marijuana	Opiates	Other
(DSPPALCH) 0-Present 1-Absent 2-Uncertain	*(DSPPCOCA)* 0-Present 1-Absent 2-Uncertain	*(DSPPOTHS)* 0-Present 1-Absent 2-Uncertain	*(DSPPMARH)* 0-Present 1-Absent 2-Uncertain	*(DSPPOPIA)* 0-Present 1-Absent 2-Uncertain	*(DSPPOTHR)* 0-Present 1-Absent 2-Uncertain

	Alcohol	Cocaine	Stimulants	Marijuana	Opiates	Other
Number of "Present" responses for each column. Dependence is indicated by a total of 3 or more.	*(DSPREALC)* *(x)*	*(DSPRECOC)* *(x)*	*(DSPREOTH)* *(x)*	*(DSPREMAR)* *(x)*	*(DSPREOPI)* *(x)*	*(DSPREOTR)* *(x)*
How old were you the first time you experienced three or more of these symptoms?	*(DSDAGALC)* *(xx)*	*(DSDAGCOC)* *(xx)*	*(DSDAGOTR)* *(xx)*	*(DSDAGMAH)* *(xx)*	*(DSDAGOPI)* *(xx)*	*(DSDAGOTH)* *(xx)*

Substance ABUSE Criteria

Now I'd like to ask for a few more questions about your use of (drug)

A maladaptive pattern of substance use, leading to clinically significant impairment or distress, as manifested by **one** (or more) of the following, occurring at any time within the same 12-month period.

B1 Have you often been intoxicated or high or very hungover with (drug) while you were doing something important like being at school or work, or taking care of children? IF NO: What about missing something important, like staying away from school or work or missing an appointment because you were intoxicated, high, or very hungover? IF YES AND UNKNOWN, how often? (Over what period of time?) *Recurrent substance use resulting in a failure to fulfill major role obligations at work, school, or home (e.g., repeated absences or poor work performance related to substance use; substance-related absences, suspensions, or expulsions from school, neglect of children or household).*

Alcohol	Cocaine	Stimulants	Marijuana	Opiates	Other
(DSHOALCO) 0-Present 1-Absent 2-Uncertain	*(DSHOCOCA)* 0-Present 1-Absent 2-Uncertain	*(DSHOOTHS)* 0-Present 1-Absent 2-Uncertain	*(DSHOMARH)* 0-Present 1-Absent 2-Uncertain	*(DSHOOPIA)* 0-Present 1-Absent 2-Uncertain	*(DSHOOTHR)* 0-Present 1-Absent 2-Uncertain

B2 Have you ever used (drug) in a situation in which it might have been dangerous to use (drug) at all? (Have you ever driven while you were really too high to drive?) IF YES AND UNKNOWN: How often? (Over what period of time?) *Recurrent substance use in situations in which it is physically hazardous (e.g., driving an automobile or operating a machine when impaired by substance use).*

Alcohol	Cocaine	Stimulants	Marijuana	Opiates	Other
(DSDNALCO) 0-Present 1-Absent 2-Uncertain	*(DSDNCOCA)* 0-Present 1-Absent 2-Uncertain	*(DSDNOTHS)* 0-Present 1-Absent 2-Uncertain	*(DSDNMARH)* 0-Present 1-Absent 2-Uncertain	*(DSDNOPIA)* 0-Present 1-Absent 2-Uncertain	*(DSDNOTHR)* 0-Present 1-Absent 2-Uncertain

B3 Has your use of (drug) ever gotten you into trouble with the law? IF YES AND UNKNOWN: How often? (Over what period of time?) *Recurrent substance-related legal problems (e.g., arrests for substance-related disorderly conduct).*

Alcohol	Cocaine	Stimulants	Marijuana	Opiates	Other
(DSTLALCO) 0-Present 1-Absent 2-Uncertain	*(DSTLCOCA)* 0-Present 1-Absent 2-Uncertain	*(DSTLOTHS)* 0-Present 1-Absent 2-Uncertain	*(DSTLMARH)* 0-Present 1-Absent 2-Uncertain	*(DSTLOPIA)* 0-Present 1-Absent 2-Uncertain	*(DSTLOTHR)* 0-Present 1-Absent 2-Uncertain

B4 Has your use of (drug) caused problems with other people, such as with family members, friends, or people at work? (Did you ever get into physical fights or bad arguments about your drug use?) IF YES: Did you keep on using (drug) anyway? (Over what period of time?) *Continued substance use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of the substance (e.g., arguments with spouse about consequences of intoxication, physical fights).*

Alcohol	Cocaine	Stimulants	Marijuana	Opiates	Other
(DSPBALCO) 0-Present 1-Absent 2-Uncertain	*(DSPBCOCA)* 0-Present 1-Absent 2-Uncertain	*(DSPBOTHS)* 0-Present 1-Absent 2-Uncertain	*(DSPBMARH)* 0-Present 1-Absent 2-Uncertain	*(DSPBOPIA)* 0-Present 1-Absent 2-Uncertain	*(DSPBOTHR)* 0-Present 1-Absent 2-Uncertain

	Alcohol	Cocaine	Stimulants	Marijuana	Opiates	Other
Number of "Present" responses for each column. Abuse is indicated by a total of 1 or more.	*(DSPRAALC)* *(x)*	*(DSPRACOC)* *(x)*	*(DSPRAOTS)* *(x)*	*(DSPRAMAH)* *(x)*	*(DSPRAOPI)* *(x)*	*(DSPRABEN)* *(x)*
How old were you the first time you experienced one or more of these symptoms?	*(DSAAGALC)* *(xx)*	*(DSAAGCOC)* *(xx)*	*(DSAAGOTS)* *(xx)*	*(DSAAGMAH)* *(xx)*	*(DSAAGOPI)* *(xx)*	*(DSAAGOTH)* *(xx)*

Additional Selection Options for DSM

Primary Drug:
6-Other

NIDA Clinical Trials Network

0044A (ENR)

Web Version: 1.0; 1.00; 09-03-10

Baseline

1. Date informed consent signed: *(SCCNSTDT)* ____ *(mm/dd/yyyy)*
2. What is your highest level of education? *(SCLVLEDU)*
   - 1-High school not complete
   - 2-High school graduate or GED
   - 3-Associate's degree
   - 4-Bachelor's degree
   - 5-Master's degree
   - *Additional Options Listed Below

   If "High school not complete", provide last grade completed: *(SCLASTGR)* ____ *(xx)*
3. Marital status: *(SCMARITA)*
   - 1-Single, never married
   - 2-Married/remarried
   - 3-Separated/divorced/widowed
4. What has been your usual employment pattern over the past 3 years? (Answer represents the majority of the last 3 years, not just the most recent selection. If there are equal times for more than one category, select that which best represents the more current situation.) *(SCEMPLOY)*
   - 1-Full time (35+ hours/week)
   - 2-Part time (regular hours)
   - 3-Part time (irregular, day work)
   - 4-Student
   - 5-Military Service
   - *Additional Options Listed Below
5. What has been your usual living arrangement over the past three years? (Answer represents the majority of the last 3 years, not just the most recent selection. If there are equal times for more than one category, select that which best represents the more current situation.) *(SCLIVING)*
   - 1-With sexual partner and children
   - 2-With sexual partner alone
   - 3-With children alone
   - 4-With parents
   - 5-With family
   - *Additional Options Listed Below
6. How many miles do you travel to get to the treatment program from your home? *(SCMILES)* ____ *(xxx)* miles
7. About how long does the trip typically take (in hours and minutes): *(SCHOURS)* ____ *(x)* hours *(SCMINUTE)* ____ *(xx)* minutes

Comments: *(SCCOMM)*

Additional Selection Options for ENR

What is your highest level of education?
6-Doctorate/Medical degree

What has been your usual employment pattern over the past 3 years? (Answer represents the majority of the last 3 years, not just the most recent selection. If there are equal times for more than one category, select that which best represents the more current situation.)
6-Retired/disability
7-Unemployed
8-In controlled environment

What has been your usual living arrangement over the past three years? (Answer represents the majority of the last 3 years, not just the most recent selection. If there are equal times for more than one category, select that which best represents the more current situation.)
6-With friends
7-Alone
8-Controlled environment
9-No stable arrangement

NIDA Clinical Trials Network

Fagerstrom Test for Nicotine Dependence (FTN)

Web Version: 1.0; 1.02; 02-06-12

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

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

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

Are you currently using medication to help you stop smoking?*(FTCESS)*

- 0-None
- 1-Nicotine replacement (e.g., patch, lozenge, gum, nasal spray)
- 2-Bupropion (Wellbutrin, Zyban)
- 3-Varenicline (Chantix)
- 9-Other

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

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

1. How soon after you wake up do you smoke your first cigarette?*(FT1STCIG)*
   - 3-(3) Within 5 minutes
   - 2-(2) 6 - 30 minutes
   - 1-(1) 31 - 60 minutes
   - 0-(0) After 60 minutes
2. Do you find it difficult to refrain from smoking in places where it is forbidden, e.g., in church, at the library, in cinema, etc.?*(FTFORBID)*
   - 1-(1) Yes
   - 0-(0) No
3. Which cigarette would you hate most to give up?*(FTGIVEUP)*
   - 1-(1) The first one in the morning
   - 0-(0) All others
4. How many cigarettes/day do you smoke?*(FTPERDAY)*
   - 0-(0) 10 or less
   - 1-(1) 11-20
   - 2-(2) 21-30
   - 3-(3) 31 or more
5. Do you smoke more frequently during the first hours after waking than during the rest of the day?*(FTFREQ)*
   - 1-(1) Yes
   - 0-(0) No
6. Do you smoke if you are so ill that you are in bed most of the day?*(FTILL)*
   - 1-(1) Yes
   - 0-(0) No

Comments:*(FTNCOMM)*

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.

MicroCog Assessment (MCA)

Web Version: 1.0; 1.00; 04-09-10

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

1. Did the participant complete the MicroCog Assessment?*(MCCOMPLT)* ☐ No ☐ Yes

   If "Yes", date of assessment:*(MCASMTDT)* ____ *(mm/dd/yyyy)*

Comments:*(MCACOMM)*

NIDA Clinical Trials Network

Non-CTP/Study Medical and Other Services (NMS)

Web Version: 1.0; 1.04; 08-25-11

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

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

When did the participant last complete this form? *(NMLSTFDT)* *(mm/dd/yyyy)*

(For Baseline Visit, enter date 90 days ago.)

The following questions are about the services you've received in the past 90 days, besides what you've received in this substance abuse treatment program.

The following questions are about the services you've received ***since your last assessment****, besides what you've received in this substance abuse treatment program or in the research study.*

1. Are you currently receiving substance abuse treatment services from this substance abuse treatment program (CTP)? *If YES, skip to question 1b; if NO, proceed to question 1a.(NMABUTPR)* ☐ No ☐ Yes
   a. Have you received any outpatient substance abuse treatment from this substance abuse treatment program (CTP) since your last assessment? *If YES, proceed to question 1b; if NO, skip to question 2.(NMOUTPAT)* ☐ No ☐ Yes
   b. RESEARCH STAFF COMPLETES THE FOLLOWING USING CLINIC/CHART RECORDS: # of days of CTP treatment attended since the study intervention termination form (SIT) was completed: *(NM3MOTER)* *(xxx)* days
   c. RESEARCH STAFF COMPLETES THE FOLLOWING USING CLINIC/CHART RECORDS: # of days of CTP treatment attended since the 3-month follow-up assessment (or since study intervention termination form (SIT) was completed if the 3-month follow-up assessment was missed): *(NM6MOTER)* *(xxx)* days
2. Have you participated in an (other) outpatient treatment program for drug or alcohol problems? (Do not include your participation in this study or the services directly related to this study or services received from this substance abuse treatment program.) *(NMDRUGAL)* ☐ No ☐ Yes
   a. How many days have you participated? *(NMTRETDY)* *(xxx)* days
   b. How many days have you participated? *(NMTRETDY)* *(xxx)* days
   c. How many hours do you attend the program in a typical week? *(NMTRHOUR)* *(xx)* hours
   d. Are you, or have you been, required by the criminal justice system to attend treatment? *(NMREQCRJ)* ☐ No ☐ Yes
3. Have you been admitted into a residential program for detox or for other services? *(NMRESOTH)* ☐ No ☐ Yes
   a. How many admissions? *(NMRESADM)* *(xxx)* admissions
   b. How many admissions? *(NMRESADM)* *(xxx)* admissions
   c. How many nights altogether for all stays? *(NMRESNIG)* *(xxx)* nights
   d. How many nights altogether for all stays? *(NMRESNIG)* *(xxx)* nights
4. Have you been admitted into a hospital for detox? *(NMDETOX)* ☐ No ☐ Yes
   a. How many admissions? *(NMDETADM)* *(xxx)* admissions
   b. How many admissions? *(NMDETADM)* *(xxx)* admissions
   c. How many nights altogether for all stays? *(NMDETNIG)* *(xxx)* nights
   d. How many nights altogether for all stays? *(NMDETNIG)* *(xxx)* nights
5. Have you been admitted to the hospital for any other reason? *(NMOTHERR)* ☐ No ☐ Yes
   a. How many times were you admitted? *(NMOTHADM)* *(xxx)* admissions
   b. How many times were you admitted? *(NMOTHADM)* *(xxx)* admissions
   c. Were any admissions for psychiatric or emotional reasons? *(NMPSYADM)* ☐ No ☐ Yes
   d. How many nights altogether for all stays? *(NMOTHNIG)* *(xxx)* nights
   e. How many nights altogether for all stays? *(NMOTHNIG)* *(xxx)* nights
6. Have you visited an emergency room and not been admitted to the hospital? *(NMVSTEME)* ☐ No ☐ Yes
   a. How many times did you visit the emergency room? *(NMNMVTEM)* *(xxx)* visits
7. Outside of the services or programs mentioned above, have you seen a therapist, that is a psychiatrist, psychologist, counselor, or social worker for psychological or emotional problems? *(NMDOCEMO)* ☐ No ☐ Yes
   a. How many times did you see a psychiatrist, psychologist, counselor or social worker? *(NMVSTEMO)* *(xxx)* times
8. Outside of the services or programs mentioned above, have you seen a therapist, that is a psychiatrist, psychologist, counselor, or social worker for alcohol or drug problems? *(NMDOCDRU)* ☐ No ☐ Yes

a. How many times did you see a psychiatrist, psychologist, counselor or social worker?*(NMVSTDRU)* ☐ *(xxx)* times

9. Have you visited a medical office, not including your therapist? (Include all visits to a physician, nurse, nurse practitioner, or physician's assistant.)*(NMMEDOFF)* ☐ No ☐ Yes
   a. How many visits to a medical office have you had?*(NMVSTMED)* ☐ *(xxx)* visits
   b. How many of these visits did you see a doctor?*(NMMODOCT)* ☐ *(xxx)* visits
10. Have you attended AA, NA, or CA meetings?*(NMATDANC)* ☐ No ☐ Yes
   a. For how many days?*(NMATTDAY)* ☐ *(xxx)* days
   b. For how many days?*(NMATTDAY)* ☐ *(xxx)* days
11. Are you currently prescribed any medication for the treatment of substance abuse?*(NMPRMED)* ☐ No ☐ Yes
   a. Which medications have you been prescribed?
      Depot Naltrexone*(NMDPTNAL)* ☐ No ☐ Yes
      Naltrexone*(NMNALTRE)* ☐ No ☐ Yes
      Suboxone*(NMSBOXNE)* ☐ No ☐ Yes
      Subutex*(NMSBTEX)* ☐ No ☐ Yes
      Methadone*(NMMTHDON)* ☐ No ☐ Yes
      Buprenorphine*(NMBUHINE)* ☐ No ☐ Yes
      Acamprosate*(NMACSATE)* ☐ No ☐ Yes
      Antabuse/Disulfiram*(NMATBDLM)* ☐ No ☐ Yes
      Other*(NMOTHER)* ☐ No ☐ Yes
         If "Other", specify:*(NMOTHSPE)* ☐
   b. How many total days did you take this/these medications?*(NMMEDDAY)* ☐ *(xxx)* days
   c. How many total days did you take this/these medications?*(NMMEDDAY)* ☐ *(xxx)*
12. Have you had health insurance?*(NMHLTHIN)* ☐ No ☐ Yes
   a. Did you have Medicaid?*(NMMEDIAI)* ☐ No ☐ Yes
   b. Did you have other public insurance?*(NMPUBINS)* ☐ No ☐ Yes
   c. Do you have private health insurance?*(NMPRTINS)* ☐ No ☐ Yes
   d. Have you spent time uninsured?*(NMTNOINS)* ☐ No ☐ Yes
13. Have you had a job? This includes <u>any job for which you have been paid</u> (including under-the-table work.)*(NMWORKIN)* ☐ No ☐ Yes
   a. How many days have you been paid for working?*(NMDYSPAD)* ☐ *(xxx)* days
   b. How many days have you been paid for working?*(NMDYSPAD)* ☐ *(xxx)* days
   c. Including overtime, how many hours per week do you work on this job?*(NMHRSWK)* ☐ *(xxx)* hours
   d. Including tips and bonuses, what is your hourly rate on this job, before taxes? *(NMHRRATE)* ☐ *($$$.$$)* per hour
14. Have you accessed the internet/world wide web, besides any use related to this research study?*(NMACCWWW)* ☐ No ☐ Yes
   a. How often did you access the internet?*(NMACCFRQ)*
      1-Less than once a week
      2-One time per week
      3-A couple of times per week
      4-Once a day
      5-More than once per day
   b. What was the primary purpose of your internet use (select the option that best applies)?*(NMACCPRP)*
      1-Work or educational purposes
      2-Information gathering (e.g., directions, instructions)
      3-Recovery-oriented purposes
      4-Recreational (shopping, personal email, chat, games, music, etc.)

Now I would like to ask you some questions about your legal status. I want to remind you all information is kept strictly confidential. Legal information will not be available to anyone outside this research study.

15. Was your admission into substance abuse treatment prompted by the criminal justice system?*(NMCRMJUS)* ☐ No ☐ Mandated ☐ Referred/recommended
16. How many days have you participated in criminal activities (excluding drug use)?*(NMCRIACT)* ☐ *(xxx)* days
17. How many days have you participated in criminal activities (excluding drug use)?*(NMCRIACT)* ☐ *(xxx)* days
18. How many days were you detained or incarcerated (spent overnight in jail)? *(NMDETNED)* ☐ *(xxx)* days
19. How many days were you detained or incarcerated (spent overnight in jail)? *(NMDETNED)* ☐ *(xxx)* days

Have you committed, been charged with, or been convicted of (answer all questions below):

	Committed	**Charged**	**Convicted**
20. Drug charges (not drug dealing)		*(NMDCCHAR)* ☐ No ☐ Yes	*(NMDCCONV)* ☐ No ☐ Yes
21. Drug dealing	*(NMDDCOMT)* ☐ No ☐ Yes	*(NMDDCHAR)* ☐ No ☐ Yes	*(NMDDCONV)* ☐ No ☐ Yes

22. Shoplifting/retail theft	*(NMSLCOMT)* ☐ No ☐ Yes	*(NMSLCHAR)* ☐ No ☐ Yes	*(NMSLCONV)* ☐ No ☐ Yes
23. Theft/non-retail	*(NMTFCOMT)* ☐ No ☐ Yes	*(NMTFCHAR)* ☐ No ☐ Yes	*(NMTFCONV)* ☐ No ☐ Yes
24. Robbery	*(NMRBCOMT)* ☐ No ☐ Yes	*(NMRBCHAR)* ☐ No ☐ Yes	*(NMRBCONV)* ☐ No ☐ Yes
25. Household burglary	*(NMHHCOMT)* ☐ No ☐ Yes	*(NMHHCHAR)* ☐ No ☐ Yes	*(NMHHCONV)* ☐ No ☐ Yes
26. Auto theft	*(NMATCOMT)* ☐ No ☐ Yes	*(NMATCHAR)* ☐ No ☐ Yes	*(NMATCONV)* ☐ No ☐ Yes
27. Aggravated assault	*(NMAACOMT)* ☐ No ☐ Yes	*(NMAACHAR)* ☐ No ☐ Yes	*(NMAACONV)* ☐ No ☐ Yes
28. Sexual assault	*(NMSACOMT)* ☐ No ☐ Yes	*(NMSACHAR)* ☐ No ☐ Yes	*(NMSACONV)* ☐ No ☐ Yes
29. Driving while intoxicated	*(NMDICOMT)* ☐ No ☐ Yes	*(NMDICHAR)* ☐ No ☐ Yes	*(NMDICONV)* ☐ No ☐ Yes
30. Other	*(NMOTCOMT)* ☐ No ☐ Yes	*(NMOTCHAR)* ☐ No ☐ Yes	*(NMOTCONV)* ☐ No ☐ Yes

a. If "Other", specify: *(NMOTCRSP)*

Comments: *(NMSCOMM)*

NIDA Clinical Trials Network

Patient Health Questionnaire (PHQ)

Web Version: 1.0; 1.01; 08-25-11

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

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

Please answer each question to the best of your ability unless you are required to skip over a question.

1. Over the last two weeks, how often have you been bothered by any of the following problems?	Not at all	Several days	More than half the days	Nearly every day
a. Little interest or pleasure in doing things:	*(PHINTPLE)* ☐	☐	☐	☐
b. Feeling down, depressed or hopeless:	*(PHDEPRES)* ☐	☐	☐	☐
c. Trouble falling or staying asleep, or sleeping too much:	*(PH2SLEEP)* ☐	☐	☐	☐
d. Feeling tired or having little energy:	*(PH2TIRED)* ☐	☐	☐	☐
e. Poor appetite or overeating:	*(PHAPPEAT)* ☐	☐	☐	☐
f. Feeling bad about yourself or that you are a failure or have let yourself or your family down:	*(PHFAILUR)* ☐	☐	☐	☐
g. Trouble concentrating on things, such as reading the newspaper or watching television:	*(PH2CONC)* ☐	☐	☐	☐
h. Moving or speaking so slowly that other people could have noticed or the opposite, being so fidgety or restless that you have been moving around a lot more than usual:	*(PHMOVSPK)* ☐	☐	☐	☐
i. Thoughts that you would be better off dead or of hurting yourself in some way:	*(PHDEADHU)* ☐	☐	☐	☐

2. Over the last 4 weeks, to what extent did you experience the following?	Not at all	A little bit	Some-what	Very Much	Extremely
a. Fear of embarrassment causes me to avoid doing things or speaking to people:	*(PHEMBARR)* ☐	☐	☐	☐	☐
b. I avoid activities in which I am the center of attention:	*(PHAVDACT)* ☐	☐	☐	☐	☐
c. Being embarrassed or looking stupid are among my worse fears:	*(PHWORSE)* ☐	☐	☐	☐	☐

3. Questions about anxiety:	No	Yes
a. In the last 4 weeks, have you had an anxiety attack, suddenly feeling fear or panic?	*(PHANXIET)* ☐	☐
If you checked "No", go to question #5.		
b. Has this ever happened before?	*(PHHAPBEF)* ☐	☐
c. Do some of these attacks come suddenly out of the blue--that is, in situations where you don't expect to be nervous or uncomfortable?	*(PHSUDDEN)* ☐	☐
d. Do these attacks bother you a lot or are you worried about having another attack?	*(PHBOTHER)* ☐	☐

4. Think about your last bad anxiety attack:	No	Yes
a. Were you short of breath?	*(PHBREATH)* ☐	☐
b. Did your heart race, pound, or skip?	*(PHHEARTR)* ☐	☐
c. Did you have chest pain or pressure?	*(PHCHESTP)* ☐	☐
d. Did you sweat?	*(PHSWEAT)* ☐	☐
e. Did you feel as though you were choking?	*(PHCHOKE)* ☐	☐
f. Did you have hot flashes or chills?	*(PHCHILLS)* ☐	☐

g. Did you have nausea or an upset stomach, or the feeling that you were going to have diarrhea?	(PHNAUSEA) ☐	☐
h. Did you feel dizzy, unsteady, or faint?	(PHDIZZY) ☐	☐
i. Did you have tingling or numbness in parts of your body?	(PHTINGLE) ☐	☐
j. Did you tremble or shake?	(PHTREMBL) ☐	☐
k. Were you afraid of dying?	(PHAFRAID) ☐	☐

5. Over the last 4 weeks, how often have you been bothered by any of the following problems?	Not at all	Several days	More than half the days
a. Feeling nervous, anxious, on edge, or worrying a lot about different things:	(PHNERVES) ☐	☐	☐
If you checked "Not at all", skip to question #6.			
b. Feeling restless so that it is hard to sit still:	(PHRESTLS) ☐	☐	☐
c. Getting tired very easily:	(PH4TIRED) ☐	☐	☐
d. Muscle tension, aches, or soreness:	(PHMUSCLE) ☐	☐	☐
e. Trouble falling asleep or staying asleep:	(PH4SLEEP) ☐	☐	☐
f. Trouble concentrating on things, such as reading a book or watching television:	(PH4CONC) ☐	☐	☐
g. Becoming easily annoyed or irritable:	(PHANNOY) ☐	☐	☐

6.	No	Yes
a. Are you often distracted?	(PHDISTRA) ☐	☐
b. Are you often unable to organize your daily activities?	(PHORGACT) ☐	☐
c. Are you always "on the go"?	(PHONTHGO) ☐	☐
d. Do people often complain that you interrupt people when they are talking?	(PHINTRUP) ☐	☐
e. Is it hard for you to be quiet in situations where you are expected to be quiet?	(PHQUIET) ☐	☐

7. Do you often...	No	Yes
a. ...make careless mistakes while working/studying or taking care of your personal business?	(PHCARELS) ☐	☐
b. ...find it hard to pay attention when someone talks to you?	(PHATTENT) ☐	☐
c. ...lose necessary things for your work/study/personal business?	(PHLOSETH) ☐	☐
d. ...avoid doing things that require a lot of concentration?	(PHAVCONC) ☐	☐
e. ...not finish work/study because you didn't follow the instructions?	(PHINSTRC) ☐	☐
f. ...forget to do things that you had planned to do?	(PHFORGET) ☐	☐
g. ...find it hard to stay seated?	(PHSEATED) ☐	☐

8.	No	Yes
Due to these problems (questions 7a-g) has it been hard for you to work/go to school/do your chores?	(PHCHORES) ☐	☐

9.	No	Yes
Have you ever been exposed to, witnessed or been confronted with a horrible event that caused you intense fear and helplessness?	(PHEVENT) ☐	☐
If you checked "No," you are finished with this assessment. *If you checked "Yes," please go to question 10.*		

10.	No	Yes
Did it involve death or threat to your physical integrity, such as being physically or sexually assaulted, being under attack, or experiencing combat or a severe accident?	(PHSEVACC) ☐	☐
If you checked "No," you are finished with this assessment. *If you checked "Yes," please name the event(s) and go to question 11.*		

If "Yes", please name the event(s):	(PHEVNTSP)

11.	No	Yes
a. Do you relive the event(s) through recurrent memories, dreams, or feelings as if the event is happening again?	*(PHRELIVE)* ☐	☐
b. Do you get emotionally upset when you are reminded of the event(s) (e.g., scared, angry, sad, guilty)?	*(PHUPSET)* ☐	☐
c. Do you have a physical reaction when you are reminded of the event(s) (e.g., sweat, faster heart beat)?	*(PHPHYSIC)* ☐	☐
d. Do you avoid thoughts, activities or places that remind you of the event(s)?	*(PHAVTHOU)* ☐	☐
e. Do you seem less interested in important things, in people around you, or do you feel emotionally numb since the event(s)?	*(PHNUMB)* ☐	☐
f. Do you have problems sleeping, concentrating, being alert or have you become short tempered since the event(s)?	*(PHPRBSLE)* ☐	☐

12.	No	Yes
Have you had the above problems (questions 11a–f) for at least the past month?	*(PHPROBLM)* ☐	☐

Comments:*(PHQCOMM)*

NIDA Clinical Trials Network

Protocol Violation Log (PVL)

Web Version: 1.0; 3.04; 08-29-12

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

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

1. Violation type: *(PVTYPE44)*

Z01-INFORMED CONSENT PROCEDURES
01A - No consent/assent obtained
01C - Invalid/incomplete informed consent
01D - Unauthorized assessments and/or procedures conducted prior to obtaining informed consent
01Z - Other (specify)
*Additional Options Listed Below

If "Other" is indicated, provide the specification: *(PVTPSP44)*

2. Description of violation: *(PVDESC)*

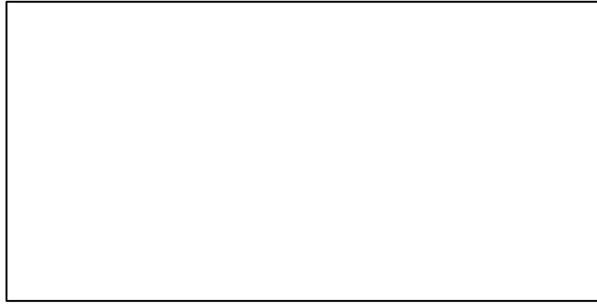
3. Has this protocol violation been resolved? *(PVRESOL)* ☐ No ☐ Yes

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

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

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

Comments:*(PVLCOMM)*



Additional Selection Options for PVL

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

Violation type:
02-INCLUSION/EXCLUSION CRITERIA
Z04-LABORATORY ASSESSMENTS/PROCEDURES
04A- Required testing not obtained
04B- Testing completed outside window
04D- Unauthorized test/procedure obtained
04Z- Other (specify)
Z05-STUDY PROCEDURES/ASSESSMENTS
05A- Protocol required procedures not obtained
05C- Procedures/Assessments obtained outside the visit timeframes
05Z- Other (specify)
Z06-ADVERSE EVENT
06A- SAE not reported
06B- SAE reported out of time window
06Z- Other (specify)
Z07-RANDOMIZATION PROCEDURES
07A- Randomization procedures not followed (e.g., outside window, out of sequence, etc.)
07B- Ineligible participant randomized
07C- Improper un-blinding procedures
07E- Incorrect treatment assignment
07Z- Other (specify)
Z09-BEHAVIORAL INTERVENTION
09A- Intervention not provided per protocol schedule or visit window timeframe
09Z- Other (specify)
Z99-OTHER SIGNIFICANT VIOLATIONS
99C- Using advertising materials or brochures without prior IRB approval
99Z- Other (specify)

NIDA Clinical Trials Network

EuroQoL Questionnaire (QOL)

Web Version: 1.0; 1.01; 08-25-11

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

1. Date of assessment:*(QOASMTDT)* (mm/dd/yyyy)

Please check the answer that best describes your current health state today.

2. Mobility:*(QOMOBIL)*
   - 1-I have no problems in walking about
   - 2-I have some problems in walking about
   - 3-I am confined to bed
3. Self-care:*(QOSLFCAR)*
   - 1-I have no problems with self-care
   - 2-I have some problems washing or dressing myself
   - 3-I am unable to wash or dress myself
4. Usual activities (e.g., work, study, housework, family or leisure activities): *(QOACTIVE)*
   - 1-I have no problems with performing my usual activities
   - 2-I have some problems with performing my usual activities
   - 3-I am unable to perform my usual activities
5. Pain/discomfort:*(QOPAIN)*
   - 1-I have no pain or discomfort
   - 2-I have some pain or discomfort
   - 3-I have extreme pain or discomfort
6. Anxiety/depression:*(QOANXDEP)*
   - 1-I am not anxious or depressed
   - 2-I am moderately anxious or depressed
   - 3-I am extremely anxious or depressed

Use the EuroQol Questionnaire Thermometer paper form to indicate how good or bad your health is currently.

7. Health state today:*(QOHLTHST)* (xxx)

Comments:*(QOLCOMM)*

NIDA Clinical Trials Network

Risk Behaviors Survey (RBS)

Web Version: 1.0; 1.02; 12-12-11

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

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

Interviewer: *The RBS contains sensitive information about sexual behavior. Please ensure that you have developed a rapport with the participant before asking these questions.*

C Sexual Activity

Now I'm going to ask you some questions about sex. I'm referring here to anybody you've had sex with in the last 30 days.

1. During the last 30 days, with how many people did you have vaginal, oral, or anal sex?*(RBNBSXPT)* *(xxx)*
   If none, enter 0 and end questionnaire
2. How many of your partners were female?*(RBNBFEPT)* *(xxx)*
   Number cannot exceed total number of people [question C1]
3. How many of your partners were male?*(RBNBMAPT)* *(xxx)*
   Number cannot exceed total number of people [question C1]
4. **Interviewer:** Code gender of respondent:*(RBRGNDR)* ☐ Male ☐ Female ☐ Don't know
   If Male, complete sections D, E, F, G and I.
   If Female, complete sections D, G, H, and I.
   If Don't Know, ask ALL sex/gender specific questions and allow client to answer as they like.

D Ask Male/Female/Gender Unknown Clients who had Female Partners

1. How many women performed oral sex ("went down") on you?*(RBNBORFW)* *(xxx)*
   If 0, then skip to question D4. Number cannot exceed total number of female partners [question C2]
2. How often did your partner(s) perform oral sex ("go down") on you?*(RBFQORFW)*
   1-Once or irregularly
   2-Less than once a week
   3-About once a week
   4-2-6 times a week
   5-About once a day
   *Additional Options Listed Below
3. How often did you use condoms/dental dams when your partner(s) performed oral sex ("went down") on you?*(RBFQOCFW)*
   0-Never
   1-Less than half the time
   2-About half the time
   3-More than half the time
   4-Always
   *Additional Options Listed Below
4. How many women did you perform oral sex ("go down") on?*(RBNBOROW)* *(xxx)*
   If 0, then skip to the next section appropriate for the sex of this client. Number cannot exceed total number of female partners [question C2]
5. How often did you perform oral sex ("go down") on your partner(s)? *(RBFQOROW)*
   1-Once or irregularly
   2-Less than once a week
   3-About once a week
   4-2-6 times a week
   5-About once a day
   *Additional Options Listed Below
6. How often did you use condoms/dental dams when you performed oral sex ("went down") on your partner(s)?*(RBFQOCOW)*
   0-Never
   1-Less than half the time
   2-About half the time
   3-More than half the time
   4-Always
   *Additional Options Listed Below

E Ask Male/Gender Unknown Clients who had Female Partners

1. How many women have you had vaginal sex with?*(RBNBVAWW)* *(xxx)*
   If 0, then skip to question E4. Number cannot exceed total number of female partners [question C2]

2. How often did you have vaginal sex? *(RBFQVAWW)*

1-Once or irregularly
2-Less than once a week
3-About once a week
4-2-6 times a week
5-About once a day
*Additional Options Listed Below

3. How often did you use a condom? *(RBFQVCWW)*

0-Never
1-Less than half the time
2-About half the time
3-More than half the time
4-Always
*Additional Options Listed Below

4. How many women did you have (insertive) anal sex with? *(RBNBANWW)* *(xxx)*

If 0, then skip to next section appropriate for the sex of this client. Number cannot exceed total number of female partners [question C2]

5. How often did you have (insertive) anal sex? *(RBFQANWW)*

1-Once or irregularly
2-Less than once a week
3-About once a week
4-2-6 times a week
5-About once a day
*Additional Options Listed Below

6. How often did you use a condom? *(RBFQACWW)*

0-Never
1-Less than half the time
2-About half the time
3-More than half the time
4-Always
*Additional Options Listed Below

F Ask Male/Gender Unknown Clients who had Male Partners

1. How many men did you have (insertive) anal sex with? *(RBNBANOM)* *(xxx)*

If 0, then skip to next section appropriate for the sex of this client. Number cannot exceed total number of male partners [question C3]

2. How often did you have (insertive) anal sex? *(RBFQANOM)*

1-Once or irregularly
2-Less than once a week
3-About once a week
4-2-6 times a week
5-About once a day
*Additional Options Listed Below

3. How often did you use a condom? *(RBFQACOM)*

0-Never
1-Less than half the time
2-About half the time
3-More than half the time
4-Always
*Additional Options Listed Below

G Ask Male/Female/Gender Unknown Clients who had Male Partners

1. How many men performed oral sex ("went down") on you? *(RBNBORFM)* *(xxx)*

If 0, then skip to question G4. Number cannot exceed total number of male partners [question C3]

2. How often did your partner(s) perform oral sex ("go down") on you? *(RBFQORFM)*

1-Once or irregularly
2-Less than once a week
3-About once a week
4-2-6 times a week
5-About once a day
*Additional Options Listed Below

3. How often did you use condoms/dental dams when your partner(s) performed oral sex ("went down") on you? *(RBFQOCFM)*

0-Never
1-Less than half the time
2-About half the time
3-More than half the time
4-Always
*Additional Options Listed Below

4. How many men did you perform oral sex ("go down") on? *(RBNBOROM)* *(xxx)*

If 0, then skip to next section appropriate for the sex of this client. Number cannot exceed total number of male partners [question C3]

5. How often did you perform oral sex ("go down") on your partner(s)? *(RBFQOROM)*

1-Once or irregularly
2-Less than once a week
3-About once a week
4-2-6 times a week
5-About once a day
*Additional Options Listed Below

6. How often did you use condoms/dental dams when you performed oral sex ("went down") on your partner(s)? *(RBFQOCOM)*

0-Never
1-Less than half the time
2-About half the time
3-More than half the time
4-Always
*Additional Options Listed Below

H Ask Female/Gender Unknown Clients who had Male Partners

1. How many men have you had vaginal sex with? *(RBNBVAWM)* *(xxx)*

If 0, then skip to next question appropriate for the sex of this client. Number cannot exceed total number of male partners [question C3]

2. How often did you have vaginal sex? *(RBFQVAWM)*

1-Once or irregularly
2-Less than once a week
3-About once a week
4-2-6 times a week
5-About once a day
*Additional Options Listed Below

3. How often did you use a condom? *(RBFQVCWM)*

0-Never
1-Less than half the time
2-About half the time
3-More than half the time
4-Always
*Additional Options Listed Below

I Ask Male/Female/Gender Unknown Clients who had Male Partners

1. How many men did you have (receptive) anal sex with? *(RBNBANFM)* *(xxx)*

If 0, end questionnaire. Number cannot exceed total number of male partners [question C3]

2. How often did you have (receptive) anal sex? *(RBFQANFM)*

1-Once or irregularly
2-Less than once a week
3-About once a week
4-2-6 times a week
5-About once a day
*Additional Options Listed Below

3. How often did you use a condom? *(RBFQACFM)*

0-Never
1-Less than half the time
2-About half the time
3-More than half the time
4-Always
*Additional Options Listed Below

Comments: *(RBSCOMM)*

Additional Selection Options for RBS

How often did your partner(s) perform oral sex ("go down") on you?
6-2-3 times a day
7-4 or more times a day
99-Don't know/unsure
98-Refused

How often did you use condoms/dental dams when your partner(s) performed oral sex ("went down") on you?
99-Don't know/unsure
98-Refused

NIDA Clinical Trials Network

Social Adjustment Scale-Self Report (SAS)

Web Version: 1.0; 1.01; 11-18-11

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

We are interested in finding out how you have been doing in the last two weeks. We would like you to answer some questions about your work, your spare time, and your family life. There are no right or wrong answers to these questions.

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

A. Work for Pay

Do you work 15 hours or more per week for pay?*(SAWRK15H)* ☐ No ☐ Yes

*If **YES**, please answer question 1. If **NO**, skip to section B. Housework (unpaid).*

1. How many days did you miss from work in the past 2 weeks? *(SADAYMIS)*
   - 1-I didn't miss any days
   - 2-I missed one day
   - 3-I missed about half the time
   - 4-I missed more than half the time but did work at least 1 day
   - 5-I did not work any days
   - *Additional Options Listed Below

Did you work any days in the last 2 weeks?
*If **YES**, please answer questions 2 through 6. If **NO**, skip to section B. Housework (unpaid).*

2. How well have you been able to do your work in the last 2 weeks? *(SAABLWRK)*
   - 1-I did my work very well
   - 2-I did my work well but had some minor problems
   - 3-I needed help with work and did not do well about half the time
   - 4-I did my work poorly most of the time
   - 5-I did my work poorly all of the time
3. How often have you been ashamed of how you did your work in the last 2 weeks?*(SAASHWRK)*
   - 1-I have never felt ashamed
   - 2-Once or twice I felt a little ashamed
   - 3-About half the time I felt ashamed
   - 4-I felt ashamed most of the time
   - 5-I felt ashamed all of the time
4. Have you had any arguments with people at work in the last 2 weeks? *(SAARGWRK)*
   - 1-I had no arguments and got along very well
   - 2-I usually got along well but had minor arguments
   - 3-I had more than one argument
   - 4-I had many arguments
   - 5-I was constantly having arguments
5. How often have you felt upset, worried, or uncomfortable while doing your work during the last 2 weeks?*(SAUPSWRK)*
   - 1-I never felt upset
   - 2-Once or twice I felt upset
   - 3-Half the time I felt upset
   - 4-I felt upset most of the time
   - 5-I felt upset all the time
6. How often have you found your work interesting these last 2 weeks? *(SAINTWRK)*
   - 1-My work was almost always interesting
   - 2-Once or twice my work was uninteresting
   - 3-Half the time my work was uninteresting
   - 4-Most of the time my work was uninteresting
   - 5-My work was always uninteresting

B. Housework (unpaid)

Is unpaid housework a significant activity in your life? *(SAHHUPAD)* ☐ No ☐ Yes

*If **YES**, please answer question 7. If **NO**, skip to section C. Student.*

7. How often did you do some unpaid housework (e.g., cooking, cleaning, laundry, grocery shopping, and errands) in the past 2 weeks? *(SAHSWKDY)*

- 1-I did the housework every day
- 2-I did the housework almost every day
- 3-I did the housework about half the time
- 4-I did not usually do the housework
- 5-I was completely unable to do the housework
- *Additional Options Listed Below

Were you away from home all of the last 2 weeks?

*If **YES**, skip to section C. Student. If **NO**, please answer questions 8 through 12.*

8. During the last 2 weeks, how well did you do your housework? *(SAUPKPHW)*

- 1-I did my work very well
- 2-I did my work well but had some minor problems
- 3-I needed help with work and did not do well about half the time
- 4-I did my work poorly most of the time
- 5-I did my work poorly all of the time

9. How often have you been ashamed of how you did your housework in the last 2 weeks? *(SAASHHWK)*

- 1-I have never felt ashamed
- 2-Once or twice I felt a little ashamed
- 3-About half the time I felt ashamed
- 4-I felt ashamed most of the time
- 5-I felt ashamed all of the time

10. Have you had any arguments with salespeople, repair persons, or neighbors in the last 2 weeks? *(SAARGNBR)*

- 1-I had no arguments and got along very well
- 2-I usually got along well but had minor arguments
- 3-I had more than one argument
- 4-I had many arguments
- 5-I was constantly having arguments

11. How often have you felt upset while doing your housework during the last 2 weeks? *(SAUPSHWK)*

- 1-I never felt upset
- 2-Once or twice I felt upset
- 3-Half the time I felt upset
- 4-I felt upset most of the time
- 5-I felt upset all the time

12. How often have you found your housework interesting these last 2 weeks? *(SAINTHWK)*

- 1-My work was almost always interesting
- 2-Once or twice my work was uninteresting
- 3-Half the time my work was uninteresting
- 4-Most of the time my work was uninteresting
- 5-My work was always uninteresting

C. Student

Do you attend school at least half-time? *(SASCATHT)* ☐ No ☐ Yes

*If **YES**, please answer questions 13 through 18. If **NO**, skip to section D. Social and Leisure.*

13. How many days of classes did you miss in the past 2 weeks? *(SACLASS)*

- 1-I didn't miss any days
- 2-I missed 1 day
- 3-I missed about half the time
- 4-I missed more than half the time but did attend class at least 1 day
- 5-I did not go to classes at all
- *Additional Options Listed Below

14. How well have you been able to keep up with your schoolwork in the last 2 weeks? *(SAUPKPCL)*

- 1-I did my schoolwork very well
- 2-I did my schoolwork well but had some minor problems
- 3-I needed help with schoolwork and did not do well about half the time
- 4-I did my schoolwork poorly most of the time
- 5-I did my schoolwork poorly all the time

15. During the last 2 weeks, how often have you been ashamed of how you did your schoolwork? *(SAASHSW)*

- 1-I have never felt ashamed
- 2-Once or twice I felt a little ashamed
- 3-About half the time I felt ashamed
- 4-I felt ashamed most of the time
- 5-I felt ashamed all of the time

16. Have you had any arguments with people at school in the last 2 weeks? *(SAARGSCH)*

- 1-I had no arguments and got along very well
- 2-I usually got along well but had minor arguments
- 3-I had more than one argument
- 4-I had many arguments
- 5-I was constantly having arguments
- *Additional Options Listed Below

17. How often have you felt upset at school during the last 2 weeks? *(SAUPSSW)*

1-I never felt upset
2-Once or twice I felt upset
3-Half the time I felt upset
4-I felt upset most of the time
5-I felt upset all the time
*Additional Options Listed Below

18. How often have you found your schoolwork interesting these last 2 weeks? *(SAINTSW)*

1-My schoolwork was almost always interesting
2-Once or twice my schoolwork was uninteresting
3-Half the time my schoolwork was uninteresting
4-Most of the time my schoolwork was uninteresting
5-My schoolwork was always uninteresting

D. Social and Leisure

Everyone please answer questions 19 through 27.

19. How many friends have you seen or been in contact with (e.g., on the telephone, via e-mail, etc.) in the last 2 weeks? *(SASPOKEN)*

1-Nine or more friends
2-Five to eight friends
3-Two to four friends
4-One friend
5-No friends

20. How often have you been able to talk about your feelings and problems with one of your friends during the last 2 weeks? *(SATALK)*

1-I was always able to talk about my innermost feelings
2-I was usually able to talk about my feelings
3-About half the time I was able to talk about my feelings
4-I was not usually able to talk about my feelings
5-I was never able to talk about my feelings
*Additional Options Listed Below

21. How many times in the last 2 weeks have you gone out socially with other people, for example, visited friends; gone to movies, bowling, church, or restaurants; or invited friends to your home? *(SASOCIAL)*

1-More than three times
2-Three times
3-Twice
4-Once
5-None

22. How much time have you spent on hobbies or spare-time interests during the last 2 weeks? For example, have you been gardening, playing sports, listening to music, reading, or using the computer? *(SAHOBBY)*

1-I spent most of my spare time on hobbies every day
2-I spent some of my spare time on hobbies some of the days
3-I spent a little of my spare time on hobbies
4-I did not usually spend any time on hobbies but did watch TV
5-I did not spend any spare time on hobbies or watching TV

23. Have you had any open arguments with your friends in the last 2 weeks? *(SAARGFRD)*

1-I had no arguments and got along very well
2-I usually got along well but had minor arguments
3-I had more than one argument
4-I had many arguments
5-I was constantly having arguments
*Additional Options Listed Below

24. If your feelings were hurt or offended by a friend during the last 2 weeks, how did you take it? *(SAFEELIN)*

1-It did not affect me or it did not happen
2-I got over it in a few hours
3-I got over it in a few days
4-I got over it in a week
5-It will take me months to recover
*Additional Options Listed Below

25. How often have you felt shy or uncomfortable with people in the last 2 weeks? *(SASHY)*

1-I always felt comfortable
2-Sometimes I felt uncomfortable but I could relax after a while
3-About half the time I felt uncomfortable
4-I usually felt uncomfortable
5-I always felt uncomfortable
*Additional Options Listed Below

26. How often have you felt lonely and wished for more friends during the last 2 weeks? *(SALONELY)*

1-I have not felt lonely
2-I have felt lonely a few times
3-I felt lonely about half the time
4-I usually felt lonely
5-I always felt lonely and wished for more friends

27. How often have you felt bored in your spare time during the last 2 weeks? *(SABORED)*

1-I never felt bored
2-I did not usually feel bored
3-About half the time I felt bored
4-Most of the time I felt bored
5-I was constantly bored

Are you a single, separated, or divorced person not living with a partner? *(SANOPART)*

☐ No ☐ Yes

*If **YES**, please answer questions 28 and 29. If **NO**, skip to section E. Family Outside the Home.*

28. How many times have you been on a date these past two weeks? *(SADATING)*

1-More than three times
2-Three times
3-Twice
4-Once
5-Never

29. Have you been interested in dating during the last 2 weeks? If you have not dated, would you have liked to? *(SAINTDAT)*

1-I was always interested in dating
2-Most of the time I was interested
3-About half the time I was interested
4-Most of the time I was not interested
5-I was completely uninterested

E. Family Outside the Home

Answer questions 30 through 37 about your parents, brothers, sisters, in-laws, and children not living at home.

Have you been in contact with any of them in the last 2 weeks? *(SACTCFAM)*

☐ No ☐ Yes

*If **YES**, please answer questions 30 through 37. If **NO**, skip to question 36.*

30. Have you had any open arguments with your relatives in the last two weeks? *(SAARGREL)*

1-We always got along very well
2-We usually got along very well but had some minor arguments
3-I had more than one argument with at least one relative
4-I had many arguments
5-I was constantly having arguments

31. How often have you been able to talk about your feelings and problems with one of your relatives in the last 2 weeks? *(SAFEELRL)*

1-I was always able to talk about my feeling with at least one relative
2-I was usually able to talk about my feelings
3-About half the time I was able to talk about my feelings
4-I was not usually able to talk about my feelings
5-I was never able to talk about my feelings

32. Have you avoided contact with your relatives these last 2 weeks? *(SAAVDCNT)*

1-I have contacted relatives regularly
2-I have contacted a relative at least once
3-I have waited for my relatives to contact me
4-I have avoided my relatives, but they contacted me
5-I have had no contact with any relatives

33. Did you depend on your relatives for help, advice, money, or friendship during the last 2 weeks? *(SADPNDRL)*

1-I never needed to depend on them
2-I did not usually need to depend on them
3-About half the time I needed to depend on them
4-Most of the time I depended on them
5-I depended completely on them

34. During the last 2 weeks, how often have you wanted to do the opposite of what your relatives wanted in order to make them angry? *(SAOPPREL)*

1-I never wanted to oppose them
2-Once or twice I wanted to oppose them
3-About half the time I wanted to oppose them
4-Most of the time I wanted to oppose them
5-I always opposed them

35. How often have you been worried about things happening to your relatives without good reason in the last 2 weeks? *(SAWORRY)*

1-I have not worried without reason
2-Once or twice I worried
3-About half the time I worried
4-Most of the time I worried
5-I have worried the entire time

Everyone answer questions 36 and 37, even if your relatives are not living.

36. During the last 2 weeks, have you been thinking that you have let any of your relatives down or been unfair to them at any time?*(SAYOUNFR)*

1-I did not feel that I let them down at all
2-I usually did not feel that I let them down
3-About half the time I felt that I let them down
4-Most of the time I felt that I let them down
5-I always felt that I let them down

37. During the last 2 weeks, have you been thinking that any of your relatives have let you down or have been unfair to you at any time?*(SAUNFREL)*

1-I never felt that they let me down
2-I felt that they usually did not let me down
3-About half the time I felt they let me down
4-I usually felt that they let me down
5-I feel bitter that they let me down

F. Primary Relationship

Are you living with your spouse or have you been living with a partner in an intimate relationship?*(SALIVPRT)*

☐ No ☐ Yes

*If **YES**, please answer questions 38 through 46. If **NO**, skip to section G. Parental.*

38. Have you had any open arguments with your partner in the last 2 weeks? *(SAARGPRT)*

1-We had no arguments, and we got along well
2-We usually got along well but had minor arguments
3-We had more than one argument
4-We had many arguments
5-We were constantly having arguments

39. How often have you been able to talk about your feelings and problems with your partner during the last 2 weeks?*(SAFELPRT)*

1-I could always talk freely about my feelings
2-I could usually talk about my feelings
3-About half the time I felt able to talk about my feelings
4-I was not usually able to talk about my feelings
5-I was never able to talk about my feelings

40. How often have you been demanding to have you own way at home during the last 2 weeks?*(SAOWNWAY)*

1-I have not insisted on always having my own way
2-I have not usually insisted on having my own way
3-About half the time I insisted on having my own way
4-I usually insisted on having my own way
5-I always insisted on having my own way

41. How often have you been bossed around by your partner these last 2 weeks? *(SAPRTBOS)*

1-Almost never
2-Once in a while
3-About half the time
4-Most of the time
5-Always

42. How much have you felt dependent on your partner these last 2 weeks? *(SADEPEND)*

1-I was independent
2-I was usually independent
3-I was somewhat dependent
4-I was usually dependent
5-I depended on my partner for everything

43. How have you felt about your partner during the last 2 weeks?*(SAFELT)*

1-I always felt affection
2-I usually felt affection
3-About half the time I felt dislike and half the time affection
4-I usually felt dislike
5-I always felt dislike

44. How many times have you and your partner had sex?*(SASEXPRT)*

1-More than twice a week
2-Once or twice a week
3-Once every 2 weeks
4-Less than once every 2 weeks, but at least once in the last month
5-Not at all in a month or longer

45. Have you had any problems during sex, such as pain, these last 2 weeks? *(SASEXPRB)*

1-None
2-Once or twice
3-About half the time
4-Most of the time
5-Always
*Additional Options Listed Below

46. How have you felt about sex during the last 2 weeks? *(SAFELSEX)*

1-I always enjoyed it
2-I usually enjoyed it
3-About half the time I enjoyed it, and half the time I did not
4-I usually did not enjoy it
5-I never enjoyed it
*Additional Options Listed Below

G. Parental

Have you had unmarried children, stepchildren, or foster children living at home during the last 2 weeks? *(SACHILDN)* ☐ No ☐ Yes

*If **YES**, please answer questions 47 through 50. If **NO**, skip to section H. Famliy Unit.*

47. How often have you been interested in what your children are doing- school, play, or hobbies-during the last 2 weeks? *(SACHINTS)*

1-I was always interested and actively involved
2-I was usually interested and involved
3-I was interested about half the time and uninterested half the time
4-I was usually uninterested
5-I was always uninterested

48. Have you been able to talk and listen to your children during the last 2 weeks? (Include only children over the age of 2.) *(SACHTALK)*

1-I always was able to communicate with them
2-I was usually able to communicate with them
3-About half the time I could communicate
4-I was not usually able to communicate
5-I was completely unable to communicate
*Additional Options Listed Below

49. How have you been getting along with your children during the last 2 weeks? *(SACHALNG)*

1-I had no arguments and got along very well
2-I usually got along well but had minor arguments
3-I had more than one argument
4-I had many arguments
5-I was constantly having arguments

50. How have you felt toward your children during the last 2 weeks? *(SACHFELT)*

1-I always felt affection
2-I usually felt affection
3-About half the time I felt affection
4-Most of the time I did not feel affection
5-I never felt affection toward them

H. Family Unit

Have you ever been married, ever lived with a partner in an intimate relationship, or ever had children? *(SAMARCLD)* ☐ No ☐ Yes

*If **YES**, please answer questions 51 through 53. If **NO**, skip to question 54.*

51. Have you worried about your partner or any of your children without any reason during the last 2 weeks, even if you are not living together now? *(SAWORPRT)*

1-I never worried
2-Once or twice I worried
3-About half the time I worried
4-Most of the time I worried
5-I always worried
*Additional Options Listed Below

52. During the last 2 weeks, have you been thinking that you have let down your partner or any of your children at any time? *(SALETDWN)*

1-I did not feel I let them down at all
2-I did not usually feel that I let them down
3-About half the time I felt I let them down
4-Most of the time I felt that I let them down
5-I let them down completely

53. During the last 2 weeks, have you been thinking that your partner or any of your children have let you down at any time? *(SAPRTLTD)*

1-I never felt that they let me down
2-I did not usually feel that they let me down
3-About half the time I felt that they let me down
4-I usually felt that they let me down
5-I feel bitter that they have let me down

Everyone please answer question 54.

54. Have you had enough money to take care of your own and your immediate family's financial needs during the last 2 weeks? *(SAFINANC)*

1-I had enough money for needs
2-I usually had enough money with minor problems
3-About half the time I did not have enough money but did not have to borrow money
4-I usually did not have enough money and had to borrow from others
5-I had great financial difficulty

Thank you for your participation.
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Additional Selection Options for SAS

How many days did you miss from work in the past 2 weeks?
8-I did not work any days because of scheduled vacation

How often did you do some unpaid housework (e.g., cooking, cleaning, laundry, grocery shopping, and errands) in the past 2 weeks?
8-I was away from home all of the last 2 weeks

How many days of classes did you miss in the past 2 weeks?
6-I was on vacation all of the last 2 weeks

Have you had any arguments with people at school in the last 2 weeks?
99-Not applicable: I did not attend school

How often have you felt upset at school during the last 2 weeks?
99-Not applicable: I did not attend school

How often have you been able to talk about your feelings and problems with one of your friends during the last 2 weeks?
99-Not applicable: I have no friends

Have you had any open arguments with your friends in the last 2 weeks?
99-Not applicable: I have no friends

If your feelings were hurt or offended by a friend during the last 2 weeks, how did you take it?
99-Not applicable: I have no friends

How often have you felt shy or uncomfortable with people in the last 2 weeks?
99-Not applicable: I was never with people during the last two weeks

Have you had any problems during sex, such as pain, these last 2 weeks?
99-Not applicable: No sex in the last 2 weeks

How have you felt about sex during the last 2 weeks?
99-Not applicable: No sex in the last 2 weeks

Have you been able to talk and listen to your children during the last 2 weeks? (Include only children over the age of 2.)
99-Not applicable: No children over the age of 2

Have you worried about your partner or any of your children without any reason during the last 2 weeks, even if you are not living together now?
99-Not applicable: Partner and children not living

NIDA Clinical Trials Network

TLFB Assessment Period (TAP)

Web Version: 1.0; 1.04; 08-20-12

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

1. Date of assessment:*(TAASMTDT)* — ☐ *(mm/dd/yyyy)* Click here to view calendar
2. Assessment period:*(TATFSTDT)* — From: ☐ *(mm/dd/yyyy)* Click here to view calendar
   (TATFENDT) — To: ☐ *(mm/dd/yyyy)* Click here to view calendar
3. Was this assessment period reconstructed due to a missed visit? *(TARECON)* — ☐ No ☐ Yes
4. Have any illicit substances or alcohol been taken during this assessment period? *(TASUBALC)* — ☐ No ☐ Yes
5. Number of days within the past week on which urge, desire, or craving for any substance (drugs or alcohol) occurred:*(TANMURDY)* — ☐ *(x)*
6. How strong was the urge? How hard was it to resist? (Select only one):*(TAURGSTR)*
   - 0-None
   - 1-Mild urges, easily resisted
   - 2-Moderate urges, requiring effort to resist
   - 3-Strong urges to use, difficult to resist
   - 4-Severe, usually impossible to resist urges

NIDA Clinical Trials Network

Time Line Follow Back (TFB)

Web Version: 1.0; 2.00; 08-20-12

Segment *(PROTSEG)*:
TLFB Date *(TFASMTDT)*:

1. Have any illicit substances or alcohol been taken on this day?*(TFSUBALC)* ☐ No ☐ Yes

2. Alcohol:*(TFALCOHL)* ☐ No ☐ Yes
   a. Number of standard drinks:*(TFNMDRNK)* ____ *(xx)*

3. Cannabinoids/Marijuana:*(TFCANNAB)* ☐ No ☐ Yes
   a. Route:*(TFCANROU)*
   1-01-Oral
   2-02-Nasal
   3-03-Smoking
   4-04-Non-IV Injection
   5-05-IV Injection
   *Additional Options Listed Below

4. Cocaine:*(TFCOCAIN)* ☐ No ☐ Yes
   a. Route:*(TFCOCROU)*
   1-01-Oral
   2-02-Nasal
   3-03-Smoking
   4-04-Non-IV Injection
   5-05-IV Injection
   *Additional Options Listed Below

5. Amphetamines:*(TFAMPHET)* ☐ No ☐ Yes
   a. Route:*(TFAMPROU)*
   1-01-Oral
   2-02-Nasal
   3-03-Smoking
   4-04-Non-IV Injection
   5-05-IV Injection
   *Additional Options Listed Below

6. Methamphetamine:*(TFMETAMP)* ☐ No ☐ Yes
   a. Route:*(TFMETROU)*
   1-01-Oral
   2-02-Nasal
   3-03-Smoking
   4-04-Non-IV Injection
   5-05-IV Injection
   *Additional Options Listed Below

7. Oxycodone/Oxycontin:*(TFOXYCOD)* ☐ No ☐ Yes
   a. Route:*(TFOXYROU)*
   1-01-Oral
   2-02-Nasal
   3-03-Smoking
   4-04-Non-IV Injection
   5-05-IV Injection
   *Additional Options Listed Below

8. Methadone:*(TFMETHAD)* ☐ No ☐ Yes
   a. Route:*(TFMTHROU)*
   1-01-Oral
   2-02-Nasal
   3-03-Smoking
   4-04-Non-IV Injection
   5-05-IV Injection
   *Additional Options Listed Below

9. Opiates: *(TFOPIATE)*

☐ No ☐ Yes

a. Route: *(TFOPIROU)*

1-01-Oral
2-02-Nasal
3-03-Smoking
4-04-Non-IV Injection
5-05-IV Injection
*Additional Options Listed Below

10. Ecstasy (MDMA): *(TFECSTAS)*

☐ No ☐ Yes

a. Route: *(TFECSROU)*

1-01-Oral
2-02-Nasal
3-03-Smoking
4-04-Non-IV Injection
5-05-IV Injection
*Additional Options Listed Below

11. Barbiturates: *(TFBARBIT)*

☐ No ☐ Yes

a. Route: *(TFBARROU)*

1-01-Oral
2-02-Nasal
3-03-Smoking
4-04-Non-IV Injection
5-05-IV Injection
*Additional Options Listed Below

12. Benzodiazepines: *(TFBENZOD)*

☐ No ☐ Yes

a. Route: *(TFBENROU)*

1-01-Oral
2-02-Nasal
3-03-Smoking
4-04-Non-IV Injection
5-05-IV Injection
*Additional Options Listed Below

13. Other drugs: *(TFOTHDRG)*

☐ No ☐ Yes

a. Number of other drugs (up to 9): *(TFNMOTH)*

(x)

Other Drug 1

b. Specify Other Drug 1: *(TFOTH1SP)*

c. Route Other Drug 1: *(TFOTH1RT)*

1-01-Oral
2-02-Nasal
3-03-Smoking
4-04-Non-IV Injection
5-05-IV Injection
*Additional Options Listed Below

Other Drug 2

d. Specify Other Drug 2: *(TFOTH2SP)*

e. Route Other Drug 2: *(TFOTH2RT)*

1-01-Oral
2-02-Nasal
3-03-Smoking
4-04-Non-IV Injection
5-05-IV Injection
*Additional Options Listed Below

Other Drug 3

f. Specify Other Drug 3: *(TFOTH3SP)*

g. Route Other Drug 3: *(TFOTH3RT)*

1-01-Oral
2-02-Nasal
3-03-Smoking
4-04-Non-IV Injection
5-05-IV Injection
*Additional Options Listed Below

Other Drug 4

h. Specify Other Drug 4: *(TFOTH4SP)*

i. Route Other Drug 4: *(TFOTH4RT)*

1-01-Oral
2-02-Nasal
3-03-Smoking
4-04-Non-IV Injection
5-05-IV Injection
*Additional Options Listed Below

Other Drug 5

j. Specify Other Drug 5: *(TFOTH5SP)*

k. Route Other Drug 5: *(TFOTH5RT)*

1-01-Oral
2-02-Nasal
3-03-Smoking
4-04-Non-IV Injection
5-05-IV Injection
*Additional Options Listed Below

Other Drug 6

l. Specify Other Drug 6: *(TFOTH6SP)*

m. Route Other Drug 6: *(TFOTH6RT)*

1-01-Oral
2-02-Nasal
3-03-Smoking
4-04-Non-IV Injection
5-05-IV Injection
*Additional Options Listed Below

Other Drug 7

n. Specify Other Drug 7: *(TFOTH7SP)*

o. Route Other Drug 7: *(TFOTH7RT)*

1-01-Oral
2-02-Nasal
3-03-Smoking
4-04-Non-IV Injection
5-05-IV Injection
*Additional Options Listed Below

Other Drug 8

p. Specify Other Drug 8: *(TFOTH8SP)*

q. Route Other Drug 8: *(TFOTH8RT)*

1-01-Oral
2-02-Nasal
3-03-Smoking
4-04-Non-IV Injection
5-05-IV Injection
*Additional Options Listed Below

Other Drug 9

r. Specify Other Drug 9: *(TFOTH9SP)*

s. Route Other Drug 9: *(TFOTH9RT)*

1-01-Oral
2-02-Nasal
3-03-Smoking
4-04-Non-IV Injection
5-05-IV Injection
*Additional Options Listed Below

Comments: *(TFBCOMM)*

Additional Selection Options for TFB

Route:
99-99-Other

NIDA Clinical Trials Network

Urine Drug Screen (UDS)

Web Version: 1.0; 5.00; 05-10-12

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

1. Was a urine drug screen performed? *(UDTSTPRF)* ☐ No ☐ Yes
   a. If "No", provide reason: *(UD1NCLRS)*
   1-Participant reported being unable to provide sample
   2-Participant refused to provide sample
   3-Study staff error
   9-Other
   b. If "Other", specify: *(UD1NOCSP)*

1st Urine Drug Screen

2. Date 1st urine specimen collected: *(UDCOLDT)* *(mm/dd/yyyy)* Click here for calendar
3. Time 1st urine specimen collected (24 hour format): *(UD1COLTM)* *(hh:mm)*
4. Was the 1st urine drug screen observed? *(UD1OBS)* ☐ No ☐ Yes
5. Was the 1st urine temperature within range? (90 - 100 °F) *(UD1TMP)* ☐ No ☐ Yes
6. Was the 1st urine specimen determined to be adulterated? *(UD1ADULT)* ☐ No ☐ Yes

1st Urine Drug Screen Results

7.

Drug Name (Abbreviation)	Negative	Positive	Invalid
Benzodiazepines (BZO):	*(UD1BZO)* ☐	☐	☐
Amphetamine (AMP):	*(UD1AMP)* ☐	☐	☐
Marijuana (THC):	*(UD1THC)* ☐	☐	☐
Methamphetamine (MET):	*(UD1MET)* ☐	☐	☐
Opiates (2000 ng) (OPI):	*(UD1OPI)* ☐	☐	☐
Cocaine (COC):	*(UD1COC)* ☐	☐	☐
Ecstasy (MDMA):	*(UD1MDMA)* ☐	☐	☐
Oxycodone (OXY):	*(UD1OXY)* ☐	☐	☐
Methadone (MTD):	*(UD1MTD)* ☐	☐	☐
Barbiturate (BAR):	*(UD1BAR)* ☐	☐	☐

2nd Urine Drug Screen

8. If the 1st urine specimen was determined to be adulterated, was a second specimen collected? *(UD2COLNY)* ☐ No ☐ Yes
   a. If "No", provide reason: *(UD2NCLRS)*
   1-Participant reported being unable to provide sample
   2-Participant refused to provide sample
   3-Study staff error
   9-Other
   b. If "Other", specify: *(UD2NOCSP)*
9. Time 2nd urine specimen collected (24 hour format): *(UD2COLTM)* *(hh:mm)*

10. Was the 2nd urine drug screen observed?*(UD2OBS)* ☐ No ☐ Yes

11. Was the 2nd urine temperature within range? (90 - 100 °F)*(UD2TMP)* ☐ No ☐ Yes

12. Was the 2nd urine specimen determined to be adulterated?*(UD2ADULT)* ☐ No ☐ Yes

2nd Urine Drug Screen Results

13.

Drug Name (Abbreviation)	Negative	Positive	Invalid
Benzodiazepines (BZO):	*(UD2BZO)* ☐	☐	☐
Amphetamine (AMP):	*(UD2AMP)* ☐	☐	☐
Marijuana (THC):	*(UD2THC)* ☐	☐	☐
Methamphetamine (MET):	*(UD2MET)* ☐	☐	☐
Opiates (2000 ng) (OPI):	*(UD2OPI)* ☐	☐	☐
Cocaine (COC):	*(UD2COC)* ☐	☐	☐
Ecstasy (MDMA):	*(UD2MDMA)* ☐	☐	☐
Oxycodone (OXY):	*(UD2OXY)* ☐	☐	☐
Methadone (MTD):	*(UD2MTD)* ☐	☐	☐
Barbiturate (BAR):	*(UD2BAR)* ☐	☐	☐

Comments:*(UDSCOMM)*