

## 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):**

1. Adverse event name: (A1DESCR1)

2. Date site became aware of the event: (A1AWARDT)

 (mm/dd/yyyy) [Click here to view calendar](#)

3. Severity of event: (A1SEVR2)

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

4. Is there a reasonable possibility that Buspirone caused the event? (A1RBUSPR)

0-No  
1-Yes

Action taken with Buspirone: (A1ABUSPR)

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

5. If "Unrelated" to Buspirone, alternative etiology: (A1ALTSDG)

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: (A1AEPSP)

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", all selections in the question below will designate this as a Serious Adverse Event (SAE). The Serious Adverse Event Summary (AD2) form should be completed for all Serious Adverse Events reported.**

8. Was this event associated with: (A1ASSOC2)

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

If "Death", date of death: (A1DTHDTE)

 (mm/dd/yyyy)

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

Date of hospital admission: (A1HOSPAD)

 (mm/dd/yyyy)

Date of hospital discharge: (A1HOSPDC)

 (mm/dd/yyyy)

Comments:(A 1COMM)

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**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
- 

**If "Unrelated" to Buspirone, alternative etiology:**

- 5-Concurrent illness/condition (not pre-existing)
- 9-Other

**Was this event associated with:**

- 5-Prolongation of hospitalization
- 6-Persistent or significant incapacity
- 7-Congenital anomaly or birth defect
- 8-Important medical event that required intervention to prevent any of the above

## NIDA Clinical Trials Network

### Serious Adverse Event Summary (AD2)

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

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

1. Initial narrative description of serious adverse event:

(A2SUMM)

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

(A2MEDHX)

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

Medication (Generic Name)	Indication
(A2_01DNM) <input type="text"/>	(A2_01DIN) <input type="text"/>
(A2_02DNM) <input type="text"/>	(A2_02DIN) <input type="text"/>
(A2_03DNM) <input type="text"/>	(A2_03DIN) <input type="text"/>
(A2_04DNM) <input type="text"/>	(A2_04DIN) <input type="text"/>
(A2_05DNM) <input type="text"/>	(A2_05DIN) <input type="text"/>
(A2_06DNM) <input type="text"/>	(A2_06DIN) <input type="text"/>
(A2_07DNM) <input type="text"/>	(A2_07DIN) <input type="text"/>
(A2_08DNM) <input type="text"/>	(A2_08DIN) <input type="text"/>
(A2_09DNM) <input type="text"/>	(A2_09DIN) <input type="text"/>
(A2_10DNM) <input type="text"/>	(A2_10DIN) <input type="text"/>

4. Treatments for the Event: (A2SAETR)  No  Yes  Unknown

Treatment	Indication	Date Treated
(A2_1TNME) <input type="text"/>	(A2_1TIND) <input type="text"/>	(A2_1LTD) <input type="text"/> (mm/dd/yyyy)
(A2_2TNME) <input type="text"/>	(A2_2TIND) <input type="text"/>	(A2_2LTD) <input type="text"/> (mm/dd/yyyy)

(A2_3TNME) <input type="text"/>	(A2_3TIND) <input type="text"/>	(A2_3LTD) <input type="text"/> (mm/dd/yyyy)
(A2_4TNME) <input type="text"/>	(A2_4TIND) <input type="text"/>	(A2_4LTD) <input type="text"/> (mm/dd/yyyy)
(A2_5TNME) <input type="text"/>	(A2_5TIND) <input type="text"/>	(A2_5LTD) <input type="text"/> (mm/dd/yyyy)

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

Lab/Test	Findings	Date of Test
(A2_1LBNM) <input type="text"/>	(A2_1LBIN) <input type="text"/>	(A2_1LBDT) <input type="text"/> (mm/dd/yyyy)
(A2_2LBNM) <input type="text"/>	(A2_2LBIN) <input type="text"/>	(A2_2LBDT) <input type="text"/> (mm/dd/yyyy)
(A2_3LBNM) <input type="text"/>	(A2_3LBIN) <input type="text"/>	(A2_3LBDT) <input type="text"/> (mm/dd/yyyy)
(A2_4LBNM) <input type="text"/>	(A2_4LBIN) <input type="text"/>	(A2_4LBDT) <input type="text"/> (mm/dd/yyyy)
(A2_5LBNM) <input type="text"/>	(A2_5LBIN) <input type="text"/>	(A2_5LBDT) <input type="text"/> (mm/dd/yyyy)

6. Follow-Up:

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

(A2FOLLUP)

7. Additional information requested by the Medical Monitor:

(A2ADDINF)

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

## Additional Selection Options for AD2

Select Sequence Number (*AESQNUM*) (key field):

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

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NIDA Clinical Trials Network

Serious Adverse Event Medical Reviewer (AD3)

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

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

- 1. Was this determined to be a serious adverse event? (A3DETER)  No  Yes
- 2. Was this event considered associated with Buspirone? (A3BUSPR)  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)  
Reviewed by: (A3REVID)  
  
Comments: (A3COMM)

- Robert Lindblad  Radhika Kondapaka
- Robert Lindblad

## Additional Selection Options for AD3

Select Sequence Number (*AESQNUM*) (key field):

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

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**NIDA Clinical Trials Network**

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

Web Version: 1.0; 5.00; 06-18-12

Segment (PROTSEG):

Visit Number (VISNO):

**CTN-ASI Lite v. 1 Follow-Up: Drug/Alcohol Use**

**Route of Administration:**

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

*Note the usual or most recent route. For more than one route, choose the most severe.*

*The routes are listed from least severe to most severe. If Past 30 Days is zero, route should be "Not applicable".*

Substance	A Past 30 (Days)	D Route of Administration
<b>D1 Alcohol</b> (any use at all):	(ADALA30D) <input type="text"/> (xx)	-
<b>D2 Alcohol</b> (to intoxication):	(ADALI30D) <input type="text"/> (xx)	-
<b>D3 Heroin</b>	(ADHER30D) <input type="text"/> (xx)	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 (ADHERRTE)
<b>D4 Methadone/LAAM</b> (prescribed):	(ADM DP30D) <input type="text"/> (xx)	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 RTE)
<b>D4a Methadone/LAAM</b> (illicit):	(ADMLI30D) <input type="text"/> (xx)	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 (ADMLIRTE)
<b>D5 Other Opiates/Analgesics:</b>	(ADOPI30D) <input type="text"/> (xx)	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 (ADOPI RTE)
<b>D6 Barbiturates:</b>	(ADBAR30D) <input type="text"/> (xx)	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 (ADBARRTE)

<b>D7 Other Sedatives/ Hypnotics/Tranquilizers:</b>	(ADSH30D) <input type="text"/> (xx)	(ADSHRTE)	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
<b>D8 Cocaine:</b>	(ADCOC30D) <input type="text"/> (xx)	(ADCOCRTE)	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
<b>D9 Amphetamines:</b>	(ADAMP30D) <input type="text"/> (xx)	(ADAMP 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
<b>D10 Cannabis:</b>	(ADTHC30D) <input type="text"/> (xx)	(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
<b>D11 Hallucinogens:</b>	(ADHAL30D) <input type="text"/> (xx)	(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
<b>D12 Inhalants:</b>	(ADINH30D) <input type="text"/> (xx)	(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
<b>D36 Nicotine:</b>	(ADNIC30D) <input type="text"/> (xx)		
<b>D13 More than 1 substance per day (including alcohol, excluding nicotine):</b>	(ADGT130D) <input type="text"/> (xx)		-

**D14** According to the interviewer, which substance(s) is/are 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 (b intoxication)  
 3-03 - Heroin  
 4-04 - Methadone/LAAM (prescribed or illicit)  
 5-05 - Other Opiates/Analgesics  
 6-06 - Barbiturates  
 7-07 - Other Sedatives/Hypnotics/Tranquillizers  
 8-08 - Cocaine  
 9-09 - Amphetamines  
 9a-09a - Methamphetamine  
 10-10 - Cannabis  
 11-11 - Hallucinogens  
 12-12 - Inhalants  
 15-15 - Alcohol & one or more drugs  
 16-16 - More than one drug, but no alcohol

(ADMAJDRG)

OR

(ADMJGNA)  (97) Not Answered

**D17** How many times since your last ASI have you had Alcohol DTs?

- **Delirium Tremens (DTs):** Occur 24-48 hours after last drink, or significant decrease in alcohol intake. Characterized by shaking, severe disorientation, fever, hallucinations; they usually require medical attention.

(ADALCDT)  (xx)

OR

(ADALDTNA)  (97) Not Answered

**How many times since your last ASI have you been treated for:**

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

**D19** Alcohol abuse:

(ADALCTR)  (xx)

OR

(ADALTRNA)  (97) Not Answered

**D20** Drug abuse:

(ADDRGTR)  (xx)

OR

(ADDTRNA)  (97) Not Answered

**How many of these were detox only:**

**D21** Alcohol:

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

(ADADETOX)  (xx)

OR

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

**D22** Drugs:

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

(ADDETOX)  (xx)

OR

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

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

Max. = \$99999

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**D23 Alcohol:**

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

(ADALCMNY) \$  (xxxxx)

**OR**

(ADAMNYNA)  (97) Not Answered

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**D24 Drugs:**

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

(ADDRGMNY) \$  (xxxxx)

**OR**

(ADDMNYNA)  (97) Not Answered

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

- Include AA/NA

(ADOUPAT)  (xx) days

**OR**

(ADOPTNA)  (97) Not Answered

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**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.

(ADAP30D)  (xx) days

**OR**

(ADAP30NA)  (97) Not Answered

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

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**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

(ADAPB30D)

**OR**

(ADAB30NA)  (97) Not Answered

---

**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

(ADAPI30D)

**OR**

(ADAI30NA)  (97) Not Answered

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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.

(ADDP30D)  (xx) days

OR

(ADDP30NA)  (97) Not Answered

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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

(ADDPB30D)

OR

(ADDB30NA)  (97) Not Answered

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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

(ADDP130D)

OR

(ADD130NA)  (97) Not Answered

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

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D34 Participant's misrepresentation?

(ADMISREP)  (0) No  (1) Yes

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D35 Participant's inability to understand?

(ADUNDRST)  (0) No  (1) Yes

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Comments:(ASDCOMM)

# NIDA Clinical Trials Network

## CTN-ASI Lite v. 1: Employment/Support Status (ASE)

Web Version: 1.0; 4.01; 06-05-12

Segment (PROTSEG):

Visit Number (VISNO):

### CTN-ASI Lite v. 1 Follow-Up: Employment/Support Status

E1 Education completed since your last ASI:

- GED = 12 years
- Include formal education only.

(AEEDCPYR)  (xx) a. years

(AEEDCPMT)  (xx) b. months

OR

(AEEDCPNA)  (97) Not Answered

E2 Training or technical education completed since your last ASI:

- Formal/organized training only. For military training, only include training that can be used in civilian life, i.e., electronics or computers.

(AETECPMT)  (xx) months

OR

(AETECPNA)  (97) Not Answered

E4 Do you have a valid driver's license?

- Valid license; not suspended/revoked.

(AEDRVLSC) 

0-(0) No
1-(1) Yes
97-(97) Notanswered

E5 Do you have an automobile available?

- If answer to E4 is "No", then E5 must be "No". Does not require ownership, only requires availability on a regular basis.

(AEAUTOAV) 

0-(0) No
1-(1) Yes
97-(97) Not answered

E7 Usual (or last) occupation since your last ASI?

- Use Hollingshead Categories Reference Sheet.

- 1-(1) Higher Executive, Major Professionals, Owner of Large Business
- 2-(2) Business Manager, Owner (medium sized business), Other Professional
- 3-(3) Administrative Personnel, Manager, Owner/Proprietor of Small Business
- 4-(4) Clerical and Sales, Technician, Owner of Small Business
- 5-(5) Skilled Manual - usually having had training
- 6-(6) Semi-skilled
- 7-(7) Unskilled/Unemployed
- 8-(8) Homemaker
- 9-(9) Student/No Occupation/Disabled

(AEOCCUPT)

Specify:

(AEOCCPSP)

OR

(AEOCCPNA)  (97) Not Answered

**E9** Does someone contribute the majority of your support?

- Is participant receiving any regular support (i.e., cash, food, housing) from family/friend?
- Include spouse's contribution; exclude support by an institution.

- 0-(0) No
- 1-(1) Yes
- 96-(96) Not applicable
- 97-(97) Not answered

(AESUPPRT)

**E11** How many days were you paid for working in the past 30 days?

- Include "under the table" work, paid sick days, and vacation.

(AEPAID) | \_\_\_\_\_ (xx) days

OR

(AEPAIDNA)  (97) Not Answered

**For questions E12-E17: How much money did you receive from the following sources in the past 30 days?**  
**Max. = \$9999**

**E12** Employment (net income):

- Net or "take home" pay, include any "under the table" money.

(AEEMPMNY) \$ | \_\_\_\_\_ (xxxxx)

OR

(AEEMNYNA)  (97) Not Answered

**E13** Unemployment compensation:

(AEUNEMNY) \$ | \_\_\_\_\_ (xxxxx)

OR

(AEUMNYNA)  (97) Not Answered

**E14** Welfare:

- Include food stamps, transportation money provided by an agency to go to and from treatment.

(AEWLFMNY) \$  (xxxxx)

**OR**

(AEWMNYNA)  (97) Not Answered

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**E15** Pensions, benefits, or Social Security:

- Include disability, pensions, retirement, veteran's benefits, SSI & workers' compensation.

(AEPENMNY) \$  (xxxxx)

**OR**

(AEPMNYNA)  (97) Not Answered

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**E16** Mate, family or friends:

- Money for personal expenses, (i.e., clothing), include unreliable sources of income (e.g., gambling). Record **cash** payments only, include windfalls (unexpected), money from loans, gambling, inheritance, tax returns, etc.

(AEMATMNY) \$  (xxxxx)

**OR**

(AEMMNYNA)  (97) Not Answered

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**E17** Illegal:

- **Cash** obtained from drug dealing, stealing, fencing stolen goods, gambling, prostitution, etc.
- **Do not** attempt to convert drugs exchanged to a dollar value.

(AEILLMNY) \$  (xxxxx)

**OR**

(AEIMNYNA)  (97) Not Answered

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**E18** How many people depend on you for the majority of their food, shelter, etc.?

- Must be regularly depending on participant; do not include alimony/child support; do not include the participant or self-supporting spouse, etc.

(AEDEPEND)  (xx) max = 99

**OR**

(AEDPNDNA)  (97) Not Answered

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**E19** How many days have you experienced employment problems in the past 30 days?

- Include inability to find work, if they are actively looking for work, or problems with present job in which that job is jeopardized.

(AEEP30D)  (xx) days

**OR**

(AEEP30NA)  (96) Not applicable  (97) Not answered

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**For questions E20-E21: Please ask participant to use the Participant Rating Scale.**

The participant's ratings in questions E20 and E21 refer to question E19. Stress help in finding or preparing for a job, not giving them a job.

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**E20** How troubled or bothered have you been by these employment problems in the past 30 days?

- If the participant has been incarcerated or detained during the past 30 days, they cannot have employment problems.



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

(AEEBP30D)

OR

(AEEB30NA)  (96) Not applicable  (97) Not answered

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**E21** How important to you **now** is counseling for these employment problems?

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

(AEECI30D)

OR

(AEEC30NA)  (97) Not Answered

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

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**E23** Participant's misrepresentation?

(AEMISREP)  (0) No  (1) Yes

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**E24** Participant's inability to understand?

(AEUNDRST)  (0) No  (1) Yes

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Comments:(ASECOMM)

NIDA Clinical Trials Network

CTN-ASI Lite v. 1: Family/Social Relationships (ASF)

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

Segment (PROTSEG):

Visit Number (VISNO):

CTN-ASI Lite v. 1 Follow-Up: Family/Social Relationships

F1 Marital status:

- *Common-law marriage = 1: Specify in Comments.*

1-(1) Married  
2-(2) Remarried  
3-(3) Widowed  
4-(4) Separated  
5-(5) Divorced  
6-(6) Never married  
97-(97) Not answered

(AFMRTLST)

Comments: (AFMRTLST)

F3 Are you satisfied with this situation?

- *Satisfied = Generally liking the situation. Refers to question F1.*

0-(0) No  
1-(1) Indifferent  
2-(2) Yes  
97-(97) Not answered

(AFMSSAT)

Comments: (AFMSSAT)

F4 Usual living arrangements (*since your last ASI*):

- 1-(1) With sexual partner and children
- 2-(2) With sexual partner alone
- 3-(3) With children alone
- 4-(4) With parents
- 5-(5) With family
- 6-(6) With friends
- 7-(7) Alone
- 8-(8) Controlled environment
- 9-(9) No stable arrangements
- 97-(97) Not answered

(AFLIVARR)

Comments: (AFLVARCM)

**F6** Are you satisfied with these arrangements?

- Refers to response in question F4.

- 0-(0) No
- 1-(1) Indifferent
- 2-(2) Yes
- 97-(97) Not answered

(AFLSSAT)

Comments: (AFLSATCM)

**Do you live with anyone who:**

**F7** Has a current alcohol problem?

- 0-(0) No
- 1-(1) Yes
- 97-(97) Not answered

(AFLIVALC)

Comments: (AFLVALCM)

**F8** Uses non-prescribed drugs?

0-(0) No  
1-(1) Yes  
97-(97) Notanswered

(AFLIVDRG)

Comments:(AFLVDGCM)

**F9** With whom do you spend most of your free time?

- *If a girlfriend/boyfriend is considered as family by participant, then they must refer to them as family throughout this section, not as a friend. Family is not to be referred to as "friend."*

1-(1) Family  
2-(2) Friends  
3-(3) Alone  
97-(97) Notanswered

(AFFREETM)

Comments:(AFFREECM)

**F10** Are you satisfied with spending your free time this way?

- *A satisfied response must indicate that the person generally likes the situation. Refers to question F9.*

0-(0) No  
1-(1) Indifferent  
2-(2) Yes  
97-(97) Notanswered

(AFFTMSAT)

Comments:(AFSFRECM)

**Have you had significant periods in which you have experienced serious problems getting along with:**

- *"Serious problems" mean those that endangered the relationship.*
- *A "problem" requires contact of some sort, either by telephone or in person. Indicate "Not applicable" if there was no contact.*

	A Past 30 Days
--	----------------

<b>F18 Mother:</b>	<div style="border: 1px solid black; padding: 2px;"> 0-(0) No  1-(1) Yes  96-(96) Not applicable  97-(97) Not answered </div> (AFMT30D)
<b>F19 Father:</b>	<div style="border: 1px solid black; padding: 2px;"> 0-(0) No  1-(1) Yes  96-(96) Not applicable  97-(97) Not answered </div> (AFFT30D)
<b>F20 Brothers/sisters:</b>	<div style="border: 1px solid black; padding: 2px;"> 0-(0) No  1-(1) Yes  96-(96) Not applicable  97-(97) Not answered </div> (AFSIB30D)
<b>F21 Sexual partner/spouse:</b>	<div style="border: 1px solid black; padding: 2px;"> 0-(0) No  1-(1) Yes  96-(96) Not applicable  97-(97) Not answered </div> (AFSPS30D)
<b>F22 Children:</b>	<div style="border: 1px solid black; padding: 2px;"> 0-(0) No  1-(1) Yes  96-(96) Not applicable  97-(97) Not answered </div> (AFCHD30D)
<b>F23 Other significant family (specify):</b> <div style="border: 1px solid black; height: 150px; width: 100%; margin-top: 10px;"></div> (AFOSFMSP)	<div style="border: 1px solid black; padding: 2px;"> 0-(0) No  1-(1) Yes  96-(96) Not applicable  97-(97) Not answered </div> (AFOSF30D)
<b>F24 Close friends:</b>	<div style="border: 1px solid black; padding: 2px;"> 0-(0) No  1-(1) Yes  96-(96) Not applicable  97-(97) Not answered </div> (AFFRD30D)
<b>F25 Neighbors:</b>	<div style="border: 1px solid black; padding: 2px;"> 0-(0) No  1-(1) Yes  96-(96) Not applicable  97-(97) Not answered </div> (AFNBR30D)
<b>F26 Co-workers:</b>	<div style="border: 1px solid black; padding: 2px;"> 0-(0) No  1-(1) Yes  96-(96) Not applicable  97-(97) Not answered </div> (AFCWK30D)
<b>Did anyone abuse you?</b> (F18-F26)	<b>A Past 30 Days</b>
<b>F28 Physically (caused you physical harm)?</b>	<div style="border: 1px solid black; padding: 2px;"> 0-(0) No  1-(1) Yes  97-(97) Not answered </div> (AFPA B30D)
<b>F29 Sexually (forced sexual advances/acts)?</b>	<div style="border: 1px solid black; padding: 2px;"> 0-(0) No  1-(1) Yes  97-(97) Not answered </div> (AFSAB30D)

Comments:(AFPRBLCM)

**F30** How many days in the past 30 have you had serious conflicts with your family?

(AFFMC30D)  (xx) days

**OR**

(AFFC30NA)  (97) Not Answered

Comments:(AFFC30CM)

**For questions F32 and F34, please ask participant to use the Participant Rating Scale.**

**F32** How troubled or bothered have you been in the past 30 days by these family problems?

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

(AFFCB30D)

**OR**

(AFFB30NA)  (97) Not Answered

Comments:(AFFB30CM)

**F34** How important to you now is treatment or counseling for these family problems?

*Participant is rating his/her need for counseling for family problems, not whether the family would be willing to attend.*

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

(AFFC30D)

**OR**

(AFFI30NA)  (97) Not Answered

Comments:(AFFI30CM)

---

**F31** How many days in the past 30 have you had serious conflicts with other people *(excluding family)*?

(AFSCC30D)  (xx) days

**OR**

(AFSC30NA)  (97) Not Answered

Comments:(AFSC30CM)

---

**For questions F33 and F35, please ask participant to use the Participant Rating Scale.**

**F33** How troubled or bothered have you been in the past 30 days by these social problems?

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

(AFSPB30D)

**OR**

(AFSB30NA)  (97) Not Answered

Comments:(AFSB30CM)

---

**F35** How important to you now is treatment or counseling for these social problems?

- *Include participant's need to seek treatment for such social problems as loneliness, inability to socialize, and dissatisfaction with friends. Participant rating should refer to dissatisfaction, conflicts, or other serious problems. Exclude problems that would be eliminated if participant had no substance abuse.*

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

(AFSPI30D)

**OR**

(AFS130NA)  (97) Not Answered

Comments:(AFS130CM)

---

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

---

**F37** Participant's misrepresentation?

(AFMISREP)  (0) No  (1) Yes

---

**F38** Participant's inability to understand?

(AFUNDRST)  (0) No  (1) Yes

Comments:(ASF COMM)



NIDA Clinical Trials Network

CTN-ASI Lite v. 1: General Information (ASG)

Web Version: 1.0; 3.00; 05-18-12

Segment (PROTSEG):  
Visit Number (VISNO):

CTN-ASI Lite v. 1 Follow-Up: General Information

G19 Have you been in a controlled environment in the past 30 days? (A place, theoretically, without access to drugs/alcohol)

- 1-(1) No
- 2-(2) Jail
- 3-(3) Alcohol or drug treatment
- 4-(4) Medical treatment
- 5-(5) Psychiatric treatment
- 6-(6) Other
- 97-(97) Not answered

(AGCNTENV)

Other (specify):(AGCENVSP)

G20 How many days? (Refers to total number of days detained in the past 30 days)

- Not applicable if question G19 is "No."

(AGCEDAYS)  (xx) days

OR

(AGCEDSNA)  (96) Not applicable  (97) Not answered

Comments:(ASGCOMM)

# NIDA Clinical Trials Network

## CTN-ASI Lite v. 1 (ASI)

Web Version: 1.0; 3.00; 05-16-12

Segment (*PROTSEG*):

Visit Number (*VISNO*):

### CTN-ASI Lite v. 1 Follow-Up

Date of assessment: (*ASASMTDT*)

(mm/dd/yyyy) [Click here to view calendar](#)

Date of birth: (*ASIBTHDT*)

(mm/dd/yyyy)

### Introducing the CTN-ASI Lite v. 1 Follow-Up

Seven potential problem areas: Medical, Employment/Support Status, Alcohol, Drug, Legal, Family/Social, and Psychological.

All clients receive this same **standard** interview. All information gathered is **confidential**.

There are **two time periods** we will discuss:

1. The past 30 days
2. Lifetime Data

**Participant Rating Scale:** Participant input is important. For each area, I will ask you to use this scale to let me know how bothered you have been by any problems in each section. I will also ask you how important treatment is for you for the area being discussed.

Please refer to the Participant Rating Scale in the adjacent key.

If you are uncomfortable giving an answer, then don't answer.

**Please do not give inaccurate information!**

Key: Participant Rating Scale
-------------------------------

0=Not at all
--------------

1=Slightly
------------

2=Moderately
--------------

3=Considerably
----------------

4=Extremely
-------------

### Interviewer Instructions

1. Leave no blanks.
2. Make plenty of comments (*if another person reads this ASI, they should have a relatively complete picture of the client's perceptions of his/her problems*).
3. Throughout the ASI, please note if not answered or not applicable in the appropriate box.
4. Terminate interview if client misrepresents two or more sections.
5. When noting comments, please write the question number.

#### HALF TIME RULE:

If a question asks the number of months, round up periods of 14 days or more to 1 month.  
Round up 6 months or more to 1 year.

#### CONFIDENCE RATINGS:

- Last two items in each section.
- Do not over interpret.
- Denial does not warrant misrepresentation.
- Misrepresentation = overt contradiction in information.

**Probe and make plenty of comments!**

### CTN-ASI Lite v. 1: Hollingshead Categories

**1 = Higher Executive, Major Professionals, Owner of Large Business**

**2 = Business Manager, Owner (medium sized business), Other Professional (nurse, optician, pharmacist, social worker, teacher)**

**3 = Administrative Personnel, Manager, Owner/Proprietor of Small Business (bakery, car dealership, engraving business, plumbing business, florist, decorator, actor, reporter, travel agent)**

**4 = Clerical and Sales, Technician, Owner of Small Business (bank teller, bookkeeper, clerk, draftsman, timekeeper, secretary, car salesperson)**

**5 = Skilled Manual - usually having had training (baker, barber, brakeman, chef, electrician, fireman, lineman, machinist, mechanic, paperhanger, painter, repairman, tailor, welder, police officer, plumber)**

6 = **Semi-skilled** (*hospital aide, painter, bartender, bus driver, cutter, cook, drill press, garage guard, checker, waiter, spot welder, machine operator*)

7 = **Unskilled** (*attendant, janitor, construction help, unspecified labor, porter*). **Include Unemployed.**

8 = **Homemaker**

9 = **Student/No Occupation/Disabled**

---

## List of Commonly Used Drugs

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

---

## Alcohol/Drug Section Instructions

The following questions look at two time periods: the past 30 days and lifetime. Lifetime refers to the time prior to the last 30 days. However, if the client has been incarcerated for more than 1 year, you would only gather lifetime information, unless the client admits to significant alcohol/drug use during incarceration. This guideline only applies to the Alcohol/Drug Section.

30 day questions only require the number of days used.

Lifetime use is asked to determine extended periods of use.

Regular use = 3+ times per week, binges, or problematic irregular use in which normal activities are compromised.

Alcohol to intoxication does not necessarily mean "drunk;" use the words "felt the effects," "got a buzz," "high," etc., instead of intoxication. As a rule of thumb, 3+ drinks in one setting, or within a brief period of time, or 5+ drinks in one day defines "intoxication."

How to ask these questions:

"How many days in the past 30 have you used...?"

"How many years in your life have you regularly used...?"

NIDA Clinical Trials Network

CTN-ASI Lite v. 1: Legal Status (ASL)

Web Version: 1.0; 4.01; 06-05-12

Segment (PROTSEG):

Visit Number (VISNO):

CTN-ASI Lite v. 1 Follow-Up: Legal Status

L2 Are you on parole or probation?

- Note duration and level in comments.

0-(0) No, neither  
1-(1) Yes, parole or post release supervision  
2-(2) Yes, probation or pre-sentencing diversion  
97-(97) Not answered

(ALPROBAT)

How many times since your last ASI have you been arrested and charged with the following:

Include total numbers of counts, not just convictions. Do not include juvenile [under age 18] crimes, unless they were charged as an adult. Include formal charges only.

Comments:

L3 Shoplifting/vandalism: (ALSHPLFT) \_\_\_\_\_ (xx)

OR (ALSLFTNA)  (97) Not Answered

(ALSLFTCM)

L4 Parole/probation violation: (ALPPVIOL) \_\_\_\_\_ (xx)

OR (ALPPVINA)  (97) Not Answered

(ALPPVLCM)

L5 Drug Charges: (ALDRGCHR) \_\_\_\_\_ (xx)

OR (ALDCHRNA)  (97) Not Answered

(ALDCHRCM)

L6 Forgery: (ALFORGER)  
| (xx)

OR (ALFORGNA)  (97)  
Not Answered

(ALFORGCM)

L7 Weapons offense: (ALWEAPON)  
| (xx)

OR (ALWEAPNA)  (97)  
Not Answered

(ALWEAPCM)

L8 Burglary/larceny/B&E: (ALBURGLR)  
| (xx)

OR (ALBURGNA)  (97)  
Not Answered

(ALBURGCM)

L9 Robbery: (ALROBBRY)  
| (xx)

OR (ALROBBNA)  (97)  
Not Answered

(ALROBBCM)

L10 Assault: (ALASLT)  
| (xx)

OR (ALASLTNA)  (97)  
Not Answered

(ALASLTCM)

L11 Arson: (ALARSON)  
| (xx)

OR (ALARSNNA)  (97)  
Not Answered

(ALARSNCM)

L12 Rape:

(ALRAPE)  
| (xx)

OR (ALRAPENA)  (97)  
Not Answered

(ALRAPECM)

L13 Homicide/manslaughter:

(ALMURDER)  
| (xx)

OR (ALMRDRNA)  (97)  
Not Answered

(ALMRDRCM)

L14 Prostitution:

(ALPROST)  
| (xx)

OR (ALPRSTNA)  (97)  
Not Answered

(ALPRSTCM)

L15 Contempt of court

(ALCONTMP)  
| (xx)

OR (ALCNTPNA)  (97)  
Not Answered

(ALCNTPCM)

L16 Other (specify):

(ALOTHARR)  
| (xx)

OR (ALOARRNA)  (97)  
Not Answered

(ALOARRCM)

If "Other", specify:(ALOTHASP)

Comments:(ALARSTCM)

**L17** How many of these charges resulted in convictions?

- Do not include misdemeanor offenses from questions L18-L20 below. Convictions include fines, probation, incarcerations, suspended sentences, and guilty pleas.
- If L3-L16 = 00, then L17 = Not applicable

(ALCONVCT)  (xx)

**OR**

(ALCNVTNA)  (96) Not applicable  (97) Not answered

**How many times since your last ASI have you been charged with the following:**

**L18** Disorderly conduct, vagrancy, public intoxication:

(ALDISCND)  (xx)

**OR**

(ALDCNDNA)  (97) Not Answered

**L19** Driving while intoxicated (DWI):

(ALDWI)  (xx)

**OR**

(ALDWINA)  (97) Not Answered

**L20** Major driving violations:

- Moving violations: speeding, reckless driving, no license, etc.

(ALDRVIOI)  (xx)

OR

(ALDRVLNA)  (97) Not Answered

**L21** How many months were you incarcerated since your last ASI?

- If incarcerated **2 weeks or more**, round this up to 1 month. List total number of months incarcerated (up to 99). If more than 99, code 99 and enter the number in comments.

(ALINCRMT)  (xx) months

OR

(ALINCRNA)  (97) Not Answered

**L24** Are you presently awaiting charges, trial, or sentence?

0-(0) No  
1-(1) Yes  
97-(97) Not answered

(ALCHTRSE)

**L25** What for (refers to L24)?

- Use code 03-16, 18-20. If more than one, choose most severe. Don't include civil cases, unless a criminal offense is involved.

03-03 = Shoplifting  
04-04 = Probation violation  
05-05 = Drug  
06-06 = Forgery  
07-07 = Weapons  
08-08 = Burglary  
09-09 = Robbery  
10-10 = Assault  
11-11 = Arson  
12-12 = Rape  
13-13 = Homicide  
14-14 = Prostitution  
15-15 = Contempt  
16-16 = Other  
18-18 = Disorderly conduct  
19-19 = DWI  
20-20 = Major driving violation

(ALCTSSP)

OR

(ALCTSPNA)  (96) Not applicable  (97) Not answered

**L26** How many days in the past 30 were you detained or incarcerated?

- Include being arrested and released on the same day.

(ALIN30D)  (xx) days

OR

(ALIN30NA)  (97) Not Answered

**L27** How many days in the past 30 have you engaged in illegal activities for profit?

- Exclude simple drug possession. Include drug dealing, prostitution, selling stolen goods, etc. May be cross checked with question E17 under Employment/Family Support section.

(ALIP30D)  (xx) days

OR

(ALIP30NA)  (97) Not Answered





NIDA Clinical Trials Network

CTN-ASI Lite v. 1: Medical Status (ASM)

Web Version: 1.0; 3.00; 05-29-12

Segment (PROTSEG):  
Visit Number (VISNO):

CTN-ASI Lite v. 1 Follow-Up: Medical Status

M1 Since your last ASI, how many times have you been hospitalized for medical problems?

- Include O.D.'s and D.T.'s. Exclude detox, alcohol/drug, psychiatric treatment and childbirth (if no complications).
- Enter the number of **overnight** hospitalizations for medical problems.

(AMHOSPTM)  (xx) times

OR

(AMHOSPNA)  (97) Not Answered

Comments: (AMHOSPCM)

M4 Are you taking any prescribed medication on a regular basis for a physical problem?

- Medication prescribed by a M.D. for medical conditions; **not psychiatric medicines**.
- Include medicines prescribed, whether or not the participant is currently taking them.
- The intent is to verify chronic medical problems.

0-(0) No  
1-(1) Yes  
97-(97) Not answered

(AMRXPHYS)

If "Yes", specify: (AMRXPHSP)

Comments: (AMRXP HCM)

**M5** Do you receive a pension for a physical disability?

- Include Workers' Compensation, exclude psychiatric disability.

0-(0) No  
1-(1) Yes  
97-(97) Not answered

(AMPENSPD)

If "Yes", specify: (AMPNDSP)

Comments: (AMPND CM)

**M6** How many days have you experienced medical problems in the past 30 days?

- Do not include ailments directly caused by drugs/alcohol.
- Include flu, colds, etc. Include serious ailments related to drugs/alcohol, which would continue even if the participant were abstinent (e.g., cirrhosis of liver, abscesses from needles, etc.).

(AMPRB30D)  (xx) days

**OR**

(AMPR30NA)  (97) Not Answered

Comments: (AMPR30CM)

For questions M7 & M8, please ask participant to use the Participant Rating Scale.

---

**M7** How troubled or bothered have you been by these medical problems in the past 30 days?

- *Restrict response to problem days of question M6.*

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

(AMPBR30D)

OR

(AMPB30NA)  (97) Not Answered

Comments: (AMPB30CM)

---

**M8** How important to you **now** is treatment for these medical problems?

- *Refers to the need for new or additional medical treatment by the participant.*

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

(AMMT130D)

OR

(AMMI30NA)  (97) Not Answered

Comments: (AMMI30CM)

---

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

---

**M10** Participant's misrepresentation?

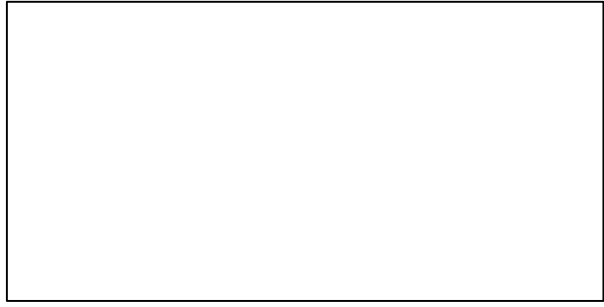
(AMMISREP)  (0) No  (1) Yes

---

**M11** Participant's inability to understand?

(AMUNDRST)  (0) No  (1) Yes

Comments:(AMCOMM)



NIDA Clinical Trials Network

CTN-ASI Lite v. 1: Psychiatric Status (ASP)

Web Version: 1.0; 3.00; 04-09-12

Segment (PROTSEG):  
Visit Number (VISNO):

CTN-ASI Lite v. 1 Follow-Up: Psychiatric Status

How many times since your last ASI have you been treated for any psychological or emotional problems?

- Do not include substance abuse, employment, or family counseling. Treatment episode = a series of more or less continuous visits or treatment days, not the number of visits or treatment days. Enter diagnosis in Comments if known.

P1 In a hospital or inpatient setting?

(APPIHSPX)  (xx)

OR

(APPIHPNA)  (97) Not Answered

Comments:(APPIHCM)

P2 Outpatient/private patient?

(APPOHSPX)  (xx)

OR

(APPOHPNA)  (97) Not Answered

Comments:(APPOHPCM)

P3 Do you receive a pension for a psychiatric disability?

(APPENPSY) 

0-(0) No
1-(1) Yes
97-(97) Notanswered

Comments:(APPENPCM)

---

**Have you had a significant period of time** (that was not a direct result of drug/alcohol use) **in which you have:**

---

	A Past 30 Days	Comments
<b>P4</b> Experienced serious depression-sadness, hopelessness, loss of interest, difficulty with daily function?	(APDEP30D) 0-(0) No 1-(1) Yes 97-(97) Not answered	(APDEPCM) <div style="border: 1px solid black; height: 140px;"></div>
<b>P5</b> Experienced serious anxiety/tension-uptight, unreasonably worried, inability to feel relaxed?	(APANX30D) 0-(0) No 1-(1) Yes 97-(97) Not answered	(APANXCM) <div style="border: 1px solid black; height: 140px;"></div>
<b>P6</b> Experienced hallucinations-saw things or heard voices that other people did not see or hear?	(APHLC30D) 0-(0) No 1-(1) Yes 97-(97) Not answered	(APHLCCM) <div style="border: 1px solid black; height: 140px;"></div>
<b>P7</b> Experienced trouble understanding, concentrating, or remembering?	(APCNC30D) 0-(0) No 1-(1) Yes 97-(97) Not answered	(APCNCCM) <div style="border: 1px solid black; height: 140px;"></div>

---

*For questions P8-P10, participant could have been under the influence of alcohol/drugs*

---

**A Past 30 Days**

**Comments**

**P8** Experienced trouble controlling violent behavior including episodes of rage, or violence?

(APVLT30D)

0-(0) No  
1-(1) Yes  
97-(97) Not answered

(APVLT30D)

- Participant can be under the influence of alcohol/drugs.

**P9** Experienced serious thoughts of suicide?

(APTOS30D)

0-(0) No  
1-(1) Yes  
97-(97) Not answered

(APTOS30D)

- Participant seriously considered a plan for taking his/her life.

**P10** Attempted suicide?

(APASU30D)

0-(0) No  
1-(1) Yes  
97-(97) Not answered

(APASU30D)

- Include actual suicidal gestures or attempts.

**P11** Been prescribed medications for any psychological/emotional problem?

(APMED30D)

0-(0) No  
1-(1) Yes  
97-(97) Not answered

(APMED30D)

- Prescribed for the participant by M.D. Record "Yes" if a medication was prescribed **even if** the participant is not taking it.

---

**P12** How many days in the past 30 have you experienced these psychological or emotional problems?

- This refers to problems noted in questions P4-P10.

(APPRB30D)  (xx) days

**OR**

(APPR30NA)  (97) Not Answered



Comments:(APPR30CM)

---

**For questions P13-P14, please ask participant to use the Participant Rating Scale.**

---

**P13** How much have you been troubled or bothered by these psychological or emotional problems in the past 30 days?

- Participant should be rating the problem days from question P12.

(APPR30D) 

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

OR

(APPB30NA)  (97) Not Answered

Comments:(APPB30CM)

---

**P14** How important to you **now** is treatment for these psychological or emotional problems?

(APPTI30D) 

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

OR

(APP130NA)  (97) Not Answered

Comments:(APP130CM)

---

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

---

**P22** Participant's misrepresentation?

(APMISREP)  (0) No  (1) Yes

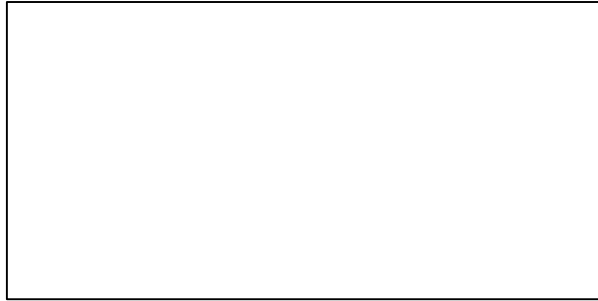
---

**P23** Participant's inability to understand?

(APUNDRST)  (0) No  (1) Yes

---

Comments:(APCOMM)



NIDA Clinical Trials Network

Cocaine Craving Questionnaire - Now Brief (CCQ)

Web Version: 1.0; 1.00; 06-18-12

Segment (PROTSEG):

Visit Number (VISNO):

Date of assessment:(CCQASMDT)

(mm/dd/yyyy) [Click here for calendar](#)

Indicate how much you agree or disagree with each of the following statements by clicking a single check mark along each line between STRONGLY DISAGREE and STRONGLY AGREE. The closer you place your check mark to one end or the other indicates the strength of your disagreement or agreement. Please complete every item. We are interested in how you are thinking or feeling right now as you are filling out the questionnaire.

1. I want cocaine so bad I can almost taste it.

STRONGLY DISAGREE (CC\_TASTE)        STRONGLY AGREE

2. I have an urge for cocaine.

STRONGLY DISAGREE (CC\_URGE)        STRONGLY AGREE

3. I am going to use cocaine as soon as possible.

STRONGLY DISAGREE (CC\_USASAP)        STRONGLY AGREE

4. I think that I could resist using "coke" now.

STRONGLY DISAGREE (CC\_RESIST)        STRONGLY AGREE

5. I crave "coke" right now.

STRONGLY DISAGREE (CC\_CRAVE)        STRONGLY AGREE

6. All I want to use now is cocaine.

STRONGLY DISAGREE (CC\_USENOW)        STRONGLY AGREE

7. I have no desire for cocaine right now.

STRONGLY DISAGREE (CC\_DESIRE)        STRONGLY AGREE

8. Using cocaine now would make things seem just perfect.

STRONGLY DISAGREE (CC\_PERFCT)        STRONGLY AGREE

9. I will use cocaine as soon as I get the chance.

STRONGLY DISAGREE (CC\_USOON)        STRONGLY AGREE

10. Nothing would be better than using "coke" right now.

STRONGLY DISAGREE (CC\_BEST)        STRONGLY AGREE

Comments:(CCQCOMM)

NIDA Clinical Trials Network

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

Web Version: 1.0; 1.00; 05-31-13

Segment (PROTSEG):

Visit Number (VISNO):

Date of assessment:(CHASMTDT)

(mm/dd/yyyy) [Click here for calendar](#)

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

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

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

# NIDA Clinical Trials Network

## Concise Health Risk Tracking (CHRT) Clinician Rated Module (CHT)

Web Version: 1.0; 1.00; 08-09-12

Segment (*PROTSEG*):

Visit Number (*VISNO*):

Date of assessment:(*CHTASMDT*)

(mm/dd/yyyy) [Click here for calendar](#)

1. **Suicidal Ideation** - Passive (i.e. wanting to be dead) and/or active (i.e. method,  No  Yes intent, plan) SI present.(*CHSCIDTN*)

**This last week did you think you might be better off dead or wish you were dead?  
Did you have any thoughts of harming or injuring yourself in any way?**

If "Yes": **Have you thought about how you might do this?**

**Have there been times when you seriously considered harming or injuring yourself?**

**Do you intend to kill yourself or harm yourself in any way? Do you have a plan?**

**How often have you had these thoughts? How long do they last?**

2. **Suicide Attempt** - Patient made a suicide attempt (i.e. they engaged in a  No  Yes potentially self-injurious behavior associated with intent to die. Intent can be stated by patient or inferred by rater).( *CHSCA TMP* )

**This last week did you attempt to harm or injure yourself in any way?**

If "Yes": **Can you tell me what happened? Was this an accident or on purpose?**

If On Purpose: **Why did you \_\_\_\_\_? Were you trying to kill yourself when you \_\_\_\_\_?**

If "Yes", list method: (*CHMETHOD*)

3. **Self-injurious Behavior - No Intent to Die** - Purposeful self-injurious behavior  No  Yes with no intent to die.(*CHSIBDIE*)

**This last week, have you done anything to prepare yourself for suicide or take any steps towards killing yourself?**

If "Yes": **What did you do? Were you thinking about killing yourself when you \_\_\_\_\_?**

**Did you stop yourself, or did someone else stop you before you harmed yourself?**

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

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

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

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

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

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

Comments:(*CHTCOMM*)

# NIDA Clinical Trials Network

## Cocaine Related Adverse Consequences (CRC)

Web Version: 1.0; 1.00; 05-11-12

Segment (PROTSEG):

Visit Number (VISNO):

Date of assessment:(CRCASMDT)

(mm/dd/yyyy) [Click here for calendar](#)

This survey asks about the impact that your cocaine/crack use has had on your life. All of your answers are confidential.

Some people who use cocaine/crack have times of regular use and times when they don't use. Think about your times of regular use in the past year and answer the following:

1. How do you usually use cocaine/crack?(CRROUTE)

1-Snort it (intranasal)  
2-Smoke it (i.e. crack)  
3-Shoot it up (intravenous)

2. During times of regular use do you usually use cocaine/crack at least once a week?(CR1XWEEK)

No  Yes

a. If "Yes", how many days a week do you usually use cocaine/crack?

[If your pattern of use has changed within the past few months, describe how many days a week you were using cocaine/crack before this change.] (CRDYWEEK)

1-1 - 2 days  
2-3 - 4 days  
3-5 - 6 days  
4-7 days

b. If "No", how many days a month do you usually use cocaine/crack? (CRDYMNTM)

(xx) days/month

3. On a typical day of cocaine/crack use, how many hours **total** are you involved in obtaining cocaine/crack, using, and recovering from using?

[Include the time you start seeking cocaine/crack through the time the effect from the final amount used has worn off.](CRHRACTY)

1-1 hour  
2-2 - 3 hours  
3-4 - 5 hours  
4-6 - 7 hours  
5-8 - 9 hours  
\*Additional Options Listed Below

### Recent Use

4. During the past 4 weeks (28 days), how many days did you use cocaine/crack?(CRDY4WK)

(xx) days

a. If you did not use in the last 28 days, when is the last time that you used?(CRLASTUS)

1-1 - 2 months ago  
2-3 - 4 months ago  
3-More than 4 months ago

### Impact of Use

Think about the ways your use of cocaine/crack impacts your life now, even if you haven't used recently.

In the past 28 days:

5. How much has your cocaine/crack use interfered with your ability to carry out your responsibilities at home, work, and/or school?(CRRESPBL)

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

a. Did your use of cocaine/crack cause you to get in trouble or do a bad job at work (or school)?(CRTRBLE)

No  Yes  NA - Not working or attending school

b. Did your use of cocaine/crack interfere with taking care of your children or elderly relatives?(CRCLDCRE)

No  Yes  NA - No dependent children or elderly relatives

c. Did your use of cocaine/crack interfere with you taking care of yourself or your home?(CRSELCR)

No  Yes

6. How much has your cocaine/crack use put you in situations where you could get hurt?(CRHURT)

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

a. Did you drive when you were high on cocaine/crack, even if you weren't caught?(CRDRVEHI)

No  Yes  NA - Do not drive

- b. Did you go to a dangerous place to buy or use cocaine/crack?  
(CRDANGPL)  No  Yes
- c. When walking, did you take risks to get where you were going faster (such as walking in front of traffic, taking dangerous short cuts, etc.) while you were high on cocaine/crack?(CRRISKWK)  No  Yes

7. How much has your cocaine/crack use caused social or relationship problems?(CRSOCIAL)

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

- a. Did your use of cocaine/crack cause you to get into arguments/fights with other people?(CRFIGHT)  No  Yes
- b. Besides using an illegal drug or carrying paraphernalia, did your use of cocaine/crack cause you to do other things that could have gotten you in trouble with the law?(CRLAWTBL)  No  Yes
- c. Did you go hungry or not have a place to stay because you used your money for cocaine/crack rather than for groceries or rent?(CRSPEND)  No  Yes

8. How much have you had trouble controlling the amount of cocaine/crack or the length of time you use?(CRTRAMT)

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

- a. Did you buy cocaine/crack with money you had set aside for bills or other important purchases?(CRUSBILL)  No  Yes
- b. Did you miss important appointments or events because you didn't stop using cocaine/crack in time?(CRAPPTS)  No  Yes
- c. Did you find that you used up your cocaine/crack purchases faster than you planned?(CRPURFST)  No  Yes

9. How much have you wanted to stop or cut down on your cocaine/crack use?(CRSTPWNT)

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

- a. Did you try to stop or cut down on your cocaine/crack use but found that you went back to using within a month or less?(CRSTPMTH)  No  Yes
- b. Did you want to stop or cut down, but were unable to even try?(CRSTPTRY)  No  Yes
- c. Did you spend time on three or more days thinking about reasons to stop or cut down?(CR3DYRSN)  No  Yes

10. To what degree was your time spent in activities necessary to obtain, use, or recover from cocaine/crack?(CRTMACVY)

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

- a. Did you spend a lot of time doing what was needed to get money and buy your cocaine/crack?(CRTMMONY)  No  Yes
- b. Did you spend a lot of time getting and staying high (such as smoking several rocks over a period of several hours)?(CRTMHIGH)  No  Yes
- c. Did you spend a lot of time getting over your high, including time sleeping it off or time feeling blue?(CRTMRCVR)  No  Yes

11. How much did using cocaine/crack interfere with or replace other important activities?(CRINACTY)

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

- a. Did your use of cocaine/crack interfere with activities to improve your job situation such as training, job-seeking, or clearing up issues related to employment?(CRINJOB)  No  Yes  NA - Not trying to improve job situation
- b. Did your use of cocaine/crack interfere with spending time with your family/spouse/children or non-using friends?(CRINSOCL)  No  Yes
- c. Did your use of cocaine/crack cause you to reduce time spent in activities you usually enjoy, such as hobbies, sports, or spiritual activities?(CRINHOB Y)  No  Yes

12. How much did using cocaine/crack cause you physical or emotional problems or make them worse? (CRWSPRBM)

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

- a. Did your use of cocaine/crack cause you to feel depressed, anxious, or paranoid or make those feelings worse? (CRWSSAD)  No  Yes
- b. Did your use of cocaine/crack cause you any medical problems or make any medical problems worse, like asthma, high blood pressure, seizures, or heart problems? (CRWSMED)  No  Yes
- c. Did your use of cocaine/crack negatively impact your sexual desire or performance? (CRWSSEX)  No  Yes

13. How much have you been bothered by craving or urges to use cocaine/crack? (CRCRAVE)

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

- a. Did you think about or want cocaine/crack so much that it interfered with your ability to concentrate? (CRCNCRTE)  No  Yes
- b. Did you think about or want cocaine/crack so much that it made you irritable (easily upset or aggravated)? (CRIRRTBL)  No  Yes
- c. Did you want cocaine/crack so much you couldn't stop thinking about it until you used? (CRTHINK)  No  Yes

**Overall Quality of Life**

14. In general, would you say your physical health now is: (CRPHYSCL)

1-Excellent
2-Very good
3-Good
4-Fair
5-Poor

15. In general, would you say your mental health now is: (CRMENTAL)

1-Excellent
2-Very good
3-Good
4-Fair
5-Poor

In the past 4 weeks (28 days):

16. On average, about how many hours did you usually work for pay each week? (CR4WORK)

5-32 - 40 hours per week; or more
4-19 - 31 hours per week
3-9 - 18 hours per week
2-1 - 8 hours per week
1-0: did not work at all

17. Have you had enough money to provide yourself with food, shelter, and basic needs? (CR4WNEED)  No  Yes

18. How many times have you gone to an emergency room for treatment? (CR4WER)  (xxx) ER visits

19. Has your appetite been significantly different from usual? (CR4WAPTE)  No  Yes  
 If "Yes", has your appetite been significantly more or less than usual? (CRAPTEDF)  More  Less

20. Has your sleep pattern been significantly different from usual? (CR4WSLEP)  No  Yes  
 If "Yes", have you been sleeping significantly more or less than usual? (CRSLEPDF)  More  Less

Comments: (CRCCOMM)

--



## **Additional Selection Options for CRC**

On a typical day of cocaine/crack use, how many hours total are you involved in obtaining cocaine/crack, using, and recovering from using?

*[Include the time you start seeking cocaine/crack through the time the effect from the final amount used has worn off.]*

6-10 - 12 hours

7-More than 12 hours

# NIDA Clinical Trials Network

## Demographics (DEM)

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

1. Date of birth: (DEBRTHDT)

(mm/dd/yyyy)

2. Sex: (DEGENDER)

Male  Female  Participant chooses not to answer

3. Ethnicity: (DEETHNIC)

Hispanic or Latino  Not Hispanic or Latino  Participant chooses not to answer

4. Race:

American Indian or Alaska Native (DEAMEIND)

No  Yes

Asian (DEASIAN)

No  Yes

Black or African American (DEBLACK)

No  Yes

Native Hawaiian or Pacific Islander (DEHAWAII)

No  Yes

White (DEWHITE)

No  Yes

Other (DEOTHER)

No  Yes

If "Yes", specify: (DEOTHRSP)

**OR**

Unknown (DEUNKNOWN)

Yes

Participant chooses not to provide their race (DENORACE)

Yes

Comments: (DEMCOMM)

# NIDA Clinical Trials Network

## Drug Stroop Summary (DSS)

Web Version: 1.0; 1.00; 05-23-12

Segment (*PROTSEG*):

Visit Number (*VISNO*):

Date of assessment:(*DSSASMDT*)

(mm/dd/yyyy) [Click here to view calendar](#)

Word Category	Average Response Time
1. Marijuana	( <i>DSMARJU</i> ) <input type="text"/> (xxxx) Milliseconds
2. Heroin	( <i>DSHEROIN</i> ) <input type="text"/> (xxxx) Milliseconds
3. Mixed	( <i>DSMIXED</i> ) <input type="text"/> (xxxx) Milliseconds
4. Neutral	( <i>DSNEUTRL</i> ) <input type="text"/> (xxxx) Milliseconds
5. Cocaine	( <i>DSCOCAIN</i> ) <input type="text"/> (xxxx) Milliseconds
6. Cocaine interference score	( <i>DSCOCNIS</i> ) <input type="text"/> (xxxxx) Milliseconds
7. Marijuana interference score	( <i>DSMARJIS</i> ) <input type="text"/> (xxxxx) Milliseconds
8. Heroin interference score	( <i>DSHERNIS</i> ) <input type="text"/> (xxxxx) Milliseconds
9. Mixed interference score	( <i>DSMIXDIS</i> ) <input type="text"/> (xxxxx) Milliseconds

Comments(*DSSCOMM*)

NIDA Clinical Trials Network

End of Medication (EOM)

Web Version: 1.0; 2.00; 07-10-12

Segment (PROTSEG):

Date of assessment:(EOASMTDT)

(mm/dd/yyyy) [Click here for calendar](#)

1. Did the participant discontinue study medication early?(EOMEDERL)

No  Yes

Primary reason for not completing study medication:(EOSTP52)

- 1-Participant became pregnant
- 2-Participant unable to tolerate side effects
- 3-Participant continued to experience intolerable side effects after a dose reduction
- 4-Contraindicated concomitant medication
- 5-Participant refused, non-specific
- \*Additional Options Listed Below

If "Other", specify:(EOSTPMSP)

2. Date of last dose taken:(EOLASTDT)

(mm/dd/yyyy) [Click here for calendar](#)

Comments:(EOMCOMM)

## **Additional Selection Options for EOM**

### **Primary reason for not completing study medication:**

- 6-Participant left study and never returned
- 7-Clinical deterioration: new onset of psychiatric or medical condition
- 8-Physical illness or condition that precludes taking study medication
- 9-Participant feels study treatment no longer necessary, cured
- 10-Participant feels study treatment no longer necessary, not working
- 11-Participant became incarcerated
- 12-Participant withdrew consent
- 13-Participant moved from area
- 14-Participant deceased
- 99-Other

# NIDA Clinical Trials Network

## 0052B (ENR)

Web Version: 1.0; 1.00; 07-27-12

Date of assessment: (R7ASMDT)

(mm/dd/yyyy) [Click here for calendar](#)

### Inclusion Criteria

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

1. Is the individual 18 years of age or older? (See 5209 - Demographics, Q1)(R7PTAGE)  No  Yes  Not assessed
2. Is the individual able to understand the study, and having understood, provided written informed consent in English? (See SIGNED Informed Consent Form)(R7ENGLISH)  No  Yes  Not assessed
3. Is the individual currently (within the last 12 months) cocaine dependent (See MindLinc CIDI Diagnostic Report), self-reporting having used crack cocaine a minimum of four times in the 28 days prior to inpatient/residential admission (See 5233 - TLFB Screening/Baseline), and reporting that their typical pattern of use is at least once a week (See 5206 - CRAC, Q2)?(R7COCDEP)  No  Yes  Not assessed
4. Does the individual have a willingness to comply with all study procedures and medication instructions? (Based on the judgment of the study investigator and inherent in the SIGNED Informed Consent Form)(R7COMPLY)  No  Yes  Not assessed
5. Is the individual enrolled in an inpatient/residential program at a participating CTP, scheduled to be in inpatient/residential treatment for 12-19 days when randomized, and planning to enroll in local outpatient treatment through the end of the active treatment phase (i.e., study week 15)?(See 5230 - Substance Abuse Treatment Status)(R7RSDNTL)  No  Yes  Not assessed
6. If female, and of child bearing potential, does the individual agree to use an acceptable form of birth control? (See 5222 - Pregnancy, and Birth Control Assessment, Q2)(R7BCUSE)  No  Yes  Not assessed  Not applicable (male)

### Exclusion Criteria

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

7. Is the individual currently (within the last 12 months) opioid dependent according to the DSM-IV-TR diagnostic criteria? (See MindLinc CIDI Diagnostic Report)(R7OPDDEP)  No  Yes  Not assessed
8. Does the individual have a medical or psychiatric condition that, in the judgment of the study medical clinician, would make study participation unsafe or which would make treatment compliance difficult? (See 5204 - Blood Chemistry, 5214 - Medical History)(R7MEDCDN)
  - a. If "Yes", does the individual have AIDS according to the current CDC criteria for AIDS? (See 5214 - Medical History, Q19)(R7AIDS)  No  Yes  Not assessed
  - b. If "Yes", does the individual have liver function tests greater than 3x the upper limit of normal? (See 5204 - Blood Chemistry, Q3-5)(R7LIVER3)  No  Yes  Not assessed
  - c. If "Yes", is the individual's serum creatinine greater than 2 mg/dL? (See 5204 - Blood Chemistry, Q2)(R7CRTNE)  No  Yes  Not assessed
  - d. If "Yes", other?(R7MEDOTH)  No  Yes  Unknown  If "Other", specify:(R7MDOTSP)
9. Does the individual have a psychiatric disorder requiring continued treatment with a psychotropic medication? (See 5223 - Prior and Concomitant Medication and 5214 - Medical History)(R7PSYCH)  No  Yes  Not assessed
10. Does the individual have a known or suspected hypersensitivity to Buspirone? (See 5214 - Medical History, Q20)(R7SENBUP)  No  Yes  Not assessed
11. Is the individual pregnant or breastfeeding? (See 5222 - Pregnancy, and Birth Control Assessment, Q3b and Q1)(R7PREGNT)  No  Yes  Not assessed  Not applicable (male)
12. Has the individual used any of the following medications within 14 days of randomization: monoamine oxidase (MAO) inhibitors such as phenelzine (Nardil), selegiline (Eldepryl), isocarboxazid (Marplan), or tranylcypromine (Parnate)? (See 5223 - Prior and Concomitant Medications)(R7MED14D)  No  Yes  Not assessed
13. Is the individual taking any medications, which in the judgment of the study medical clinician, may produce interactions with buspirone that are sufficiently dangerous so as to exclude the patient from participating in the study? (See 5223 - Prior and Concomitant Medications)(R7MEDINT)  No  Yes  Not assessed
14. Is the individual anyone who would not be expected to complete the study protocol? (Based on 5210 - Drop-Out Risk Assessment and the judgment of the study investigator)(R7CMPLTE)  No  Yes  Not assessed
15. Is the individual a significant suicidal/homicidal risk? (Based on the judgment of the study investigator and 5224 - PRISM)(R7SUICDE)  No  Yes  Not assessed

**Eligibility**

16. Is the individual eligible for the study as defined by the inclusion/exclusion criteria? (R7ELGSTY)  No  Yes

How many days did the participant report using cocaine in the 28 days prior to residential admission? (See 5233 - Timeline Follow-Back - Screening/Baseline, Q1-28)(R7COCFRQ)  Less than 10 days  10 days of use or more

**Randomization**

17. If Participant is eligible, will they be randomized? (R7ELGRDM)  No  Yes

If "No", specify: (R7NORSP)

1-No longer interested in participating in the study  
2-Left prior to randomization and failed to return  
99-Other

If "Other", specify: (R7OTHERSP)

Comments: (R7COMM)

## NIDA Clinical Trials Network

### Fagerstrom Test for Nicotine Dependence (FNA)

Web Version: 1.0; 1.00; 05-16-12

Segment (PROTSEG):

Visit Number (VISNO):

Date of assessment:(FNASMTDT)

(mm/dd/yyyy) [Click here for calendar](#)

Do you currently smoke cigarettes?(FNASMOKE)

No  Yes

If "Yes", please read each question below. For each question enter the answer choice which best describes your responses.

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

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.?(FNAFORBI)

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

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

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

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

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?(FNAFREQ)

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

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

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

Comments:(FNACOMM)



## NIDA Clinical Trials Network

### FrSBe - Frontal Systems Behavior Assessment (FSB)

Web Version: 1.0; 1.00; 06-18-12

Segment (PROTSEG):

Visit Number (VISNO):

Date of assessment:(FSBASMDT)

(mm/dd/yyyy) [Click here for calendar](#)

Inside this form is a list of phrases that can be used to describe a person's behavior. Please read each phrase carefully. Using the rating scale below, circle the number under each column that corresponds to how often you have engaged in the behavior described. Rate your behavior for each point in time - **Before the illness or injury, which refers to the time before you started using crack/cocaine and At the present time.** Please try to provide a rating for all the statements.

1	2	3	4	5
Almost never	Seldom	Sometimes	Frequently	Almost Always

**Example**

If during the time before your illness or injury you almost never felt confused, then you would click the **1** in the column labeled **Before illness or injury**. If at the present time you frequently feel confused, then you would click the **4** in the column labeled **At the present time**. See the example below showing how these answers would be checked on the form.

	Before Illness or Injury	At the Present Time
1. I feel confused.	(FSEXAMPB) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	(FSEXAMPP) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5

a. How old were you when you first started using crack/cocaine? (FSAGECOC)  (xx)

b. How old were you when you began having problems with crack/cocaine? (FSPROBCC)  (xx)

1	2	3	4	5
Almost never	Seldom	Sometimes	Frequently	Almost Always

**Before the illness or injury refers to the time before you started using crack/cocaine.**

	Before Illness or Injury	At the Present Time
1. I speak only when spoken to.	(FSSPOKNB) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	(FSSPOKNP) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
2. I am easily angered or irritated; I have emotional outbursts without good reason.	(FSANGRYB) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	(FSANGRYP) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
3. Repeat certain actions or get stuck on certain ideas.	(FSSTUCKB) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	(FSSTUCKP) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
4. I do things impulsively.	(FSIMPLSB) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	(FSIMPLSP) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
5. Mix up a sequence, get confused when doing several things in a row.	(FSCONFSB) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	(FSCONFSP) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
6. Laugh or cry too easily.	(FSCRYB) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	(FSCRYP) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
7. Make the same mistakes over and over, do not learn from past experience.	(FSMISTKB) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	(FSMISTKP) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
8. Have difficulty starting an activity, lack initiative, motivation.	(FSMOTIVB) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	(FSMOTIVP) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
9. Make inappropriate sexual comments and advances, am too flirtatious.	(FSSEXSB) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	(FSSEXSP) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
10. Do or say embarrassing things.	(FSEMBRSB) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	(FSEMBRSP) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5

	Before Illness or Injury	At the Present Time
11. Neglect my personal hygiene.	(FSHYGENB) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	(FSHYGENP) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
12. Can't sit still, am hyperactive.	(FSHYPERB) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	(FSHYPERP) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
13. Am unaware of my problems or when I make mistakes.	(FSUNAWRB) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	(FSUNAWRP) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
14. Sit around doing nothing.	(FSLAZYB) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	(FSLAZYP) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
15. Am disorganized.	(FSDISORB) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	(FSDISORP) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
16. Lose control of my urine or bowels and it doesn't seem to bother me.	(FSPEEB) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	(FSPEEP) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
17. Cannot do two things at once (for example, talk and prepare a meal).	(FS2THNGB) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	(FS2THNGP) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
18. Talk out of turn, interrupt others in conversations.	(FSINTRPB) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	(FSINTRPP) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
19. Show poor judgment, poor problem solver.	(FSJUDGMB) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	(FSJUDGMP) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
20. Make up fantastic stories when unable to remember something.	(FSLIEB) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	(FSLIEP) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
21. Have lost interest in things that used to be fun or important to me.	(FSFUNB) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	(FSFUNP) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5

1	2	3	4	5
Almost never	Seldom	Sometimes	Frequently	Almost Always

**Before the illness or injury refers to the time before you started using crack/cocaine.**

	Before Illness or Injury	At the Present Time
22. Say one thing, then do another thing.	(FSSAYB) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	(FSSAYP) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
23. Start things but fail to finish them, "peter out."	(FSFINSHB) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	(FSFINSHP) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
24. Show little emotion, am unconcerned and unresponsive.	(FSEMOTNB) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	(FSEMOTNP) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
25. Forget to do things but then remember when prompted or when it is too late.	(FSFORGTB) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	(FSFORGTP) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
26. Am inflexible, unable to change routines.	(FSSTUBNB) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	(FSSTUBNP) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
27. Get in trouble with the law or authorities.	(FSLAWB) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	(FSLAWP) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
28. Do risky things just for the heck of it.	(FSRISKB) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	(FSRISKP) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
29. Am slow moving, lack energy, inactive.	(FSINATVB) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	(FSINATVP) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
30. Am overly silly, have a childish sense of humor.	(FSSILLYB) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	(FSSILLYP) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
31. Find that food has no taste or smell.	(FSFOODB) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	(FSFOODP) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
32. Swear.	(FSSWEARB) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	(FSSWEARP) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5

Read each of the following items carefully before responding.			
		Before Illness or Injury	At the Present Time
33. Apologize for misbehavior (for example, apologize for swearing).	(FSAPOLGB) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	(FSAPOLGP) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	
34. Pay attention, concentrate even when there are distractions.	(FSCONCTB) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	(FSCONCTP) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	
35. Think things through before acting (for example, consider finances before spending money).	(FSTHINKB) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	(FSTHINKP) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	
36. Use strategies to remember important things (for example, write notes to myself).	(FSNOTESB) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	(FSNOTESP) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	
37. Am able to plan ahead.	(FSPLANB) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	(FSPLANP) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	
38. Am interested in sex.	(FSLKSEXB) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	(FSLKSEXP) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	
39. Care about my appearance (for example, daily grooming).	(FSLOOKSB) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	(FSLOOKSP) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	
40. Benefit from feedback, accept constructive criticism from others.	(FSFDBCKB) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	(FSFDBCKP) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	

1	2	3	4	5
Almost never	Seldom	Sometimes	Frequently	Almost Always

**Before the illness or injury refers to the time before you started using crack/cocaine.**

	Before Illness or Injury	At the Present Time
41. Get involved with activities spontaneously (such as hobbies).	(FSSPORTB) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	(FSSPORTP) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
42. Do things without being requested to do so.	(FSINTATB) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	(FSINTATP) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
43. Am sensitive to the needs of other people.	(FSEMPTHB) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	(FSEMPTHP) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
44. Get along well with others.	(FSALONGB) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	(FSALONGP) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
45. Act appropriately for my age.	(FSAGEB) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	(FSAGEP) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5
46. Can start conversations easily.	(FSCONVSB) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5	(FSCONVSP) <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5

Comments:(FSBCOMM)

## NIDA Clinical Trials Network

### Hospital Anxiety Depression Scale (HAD)

Web Version: 1.0; 1.00; 04-09-12

Segment (PROTSEG):

Visit Number (VISNO):

Date of assessment:(HADASMDT)

(mm/dd/yyyy) [Click here for calendar](#)

*This questionnaire will help your physician to know how you are feeling. Read every sentence. Pick an answer that best describes how you have been feeling during the **LAST WEEK**. You do not have to think too much to answer. In this questionnaire, spontaneous answers are more important.*

1. I feel tense or wound up:(HATENSE)

3-Most of the time  
2-A lot of the time  
1-From time to time  
0-Not at all

2. I still enjoy the things I used to enjoy:(HAENJOY)

3-Definitely as much  
2-Not quite so much  
1-Only a little  
0-Hardly at all

3. I get a sort of frightened feeling as if something awful is about to happen:  
(HAAWFUL)

3-Very definitely and quite badly  
2-Yes, but not too badly  
1-A little, but it doesn't worry me  
0-Not at all

4. I can laugh and see the funny side of things:(HALAUGH)

3-As much as I always could  
2-Not quite as much now  
1-Definitely not so much  
0-Not at all

5. Worrying thoughts go through my mind:(HAWORRY)

3-A great deal of the time  
2-A lot of the time  
1-From time to time but not too often  
0-Only occasionally

6. I feel cheerful:(HACHERFL)

0-Not at all  
1-Not often  
2-Sometimes  
3-Most of the time

7. I can sit at ease and feel relaxed:(HARELXD)

3-Definitely  
2-Usually  
1-Not often  
0-Not at all

8. I feel as if I am slowed down:(HASLOWDN)

3-Nearly all the time  
2-Very often  
1-Sometimes  
0-Not at all

9. I get a sort of frightened feeling like "butterflies" in the stomach:(HABTRFLY)

0-Not at all  
1-Occasionally  
2-Quite often  
3-Very often

10. I have lost interest in my appearance: (HALOOKS)

3-Definitely  
2-I don't take so much care as I should  
1-I may not take quite as much care  
0-I take just as much care as ever

11. I feel restless, as if I have to be on the move: (HARS TLS)

3-Very much indeed  
2-Quite a lot  
1-Not very much  
0-Not at all

12. I look forward with enjoyment to things: (HAFORWRD)

3-As much as I ever did  
2-Rather less than I used to  
1-Definitely less than I used to  
0-Hardly at all

13. I get sudden feelings of panic: (HAPANIC)

3-Very often indeed  
2-Quite often  
1-Not very often  
0-Not at all

14. I can enjoy a good book or radio or TV program: (HALIKETV)

3-Often  
2-Sometimes  
1-Not often  
0-Very seldom

Comments: (HADCOMM)



1-A 2-B 3-C 4-D2 5-D3 *Additional Options Listed Below									
(MABOT08) 1-A 2-B 3-C 4-D2 5-D3 *Additional Options Listed Below	(MADSDT08) <a href="#">Calendar</a>	(MARXSW08)	(MARPLC08) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MAPDSP08)	(MARTDT08) <a href="#">Calendar</a>	(MARTNA08) <input type="checkbox"/>	(MAREXP08)	(MARACT08)	(I 
(MABOT09) 1-A 2-B 3-C 4-D2 5-D3 *Additional Options Listed Below	(MADSDT09) <a href="#">Calendar</a>	(MARXSW09)	(MARPLC09) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MAPDSP09)	(MARTDT09) <a href="#">Calendar</a>	(MARTNA09) <input type="checkbox"/>	(MAREXP09)	(MARACT09)	(I 
<b>Bottle ID</b>	<b>Date Dispensed/ Re-Dispensed (mm/dd/yyyy)</b>	<b>Prescribed for Study Week? (xx)</b>	<b>Is this Replacement Medication?</b>	<b># Pills Dispensed (xx)</b>	<b>Date Bottle Returned (mm/dd/yyyy)</b>	<b>Date Bottle Returned N/A</b>	<b># Pills Returned - Expected (xx)</b>	<b># Pills Returned - Actual (xx)</b>	
(MABOT10) 1-A 2-B 3-C 4-D2 5-D3 *Additional Options Listed Below	(MADSDT10) <a href="#">Calendar</a>	(MARXSW10)	(MARPLC10) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MAPDSP10)	(MARTDT10) <a href="#">Calendar</a>	(MARTNA10) <input type="checkbox"/>	(MAREXP10)	(MARACT10)	(I 
(MABOT11) 1-A 2-B 3-C 4-D2 5-D3 *Additional Options Listed Below	(MADSDT11) <a href="#">Calendar</a>	(MARXSW11)	(MARPLC11) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MAPDSP11)	(MARTDT11) <a href="#">Calendar</a>	(MARTNA11) <input type="checkbox"/>	(MAREXP11)	(MARACT11)	(I 
(MABOT12) 1-A 2-B 3-C 4-D2 5-D3 *Additional Options Listed Below	(MADSDT12) <a href="#">Calendar</a>	(MARXSW12)	(MARPLC12) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MAPDSP12)	(MARTDT12) <a href="#">Calendar</a>	(MARTNA12) <input type="checkbox"/>	(MAREXP12)	(MARACT12)	(I 
(MABOT13) 1-A 2-B 3-C 4-D2 5-D3 *Additional Options Listed Below	(MADSDT13) <a href="#">Calendar</a>	(MARXSW13)	(MARPLC13) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MAPDSP13)	(MARTDT13) <a href="#">Calendar</a>	(MARTNA13) <input type="checkbox"/>	(MAREXP13)	(MARACT13)	(I 
(MABOT14) 1-A 2-B 3-C 4-D2 5-D3 *Additional Options Listed Below	(MADSDT14) <a href="#">Calendar</a>	(MARXSW14)	(MARPLC14) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MAPDSP14)	(MARTDT14) <a href="#">Calendar</a>	(MARTNA14) <input type="checkbox"/>	(MAREXP14)	(MARACT14)	(I 

(MABOT15) 1-A 2-B 3-C 4-D2 5-D3 *Additional Options Listed Below	(MADSDT15) <a href="#">Calendar</a>	(MARXSW15)	(MARPLC15) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MAPDSP15)	(MARTDT15) <a href="#">Calendar</a>	(MARTNA15) <input type="checkbox"/>	(MAREXP15)	(MARACT15)	(/)
(MABOT16) 1-A 2-B 3-C 4-D2 5-D3 *Additional Options Listed Below	(MADSDT16) <a href="#">Calendar</a>	(MARXSW16)	(MARPLC16) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MAPDSP16)	(MARTDT16) <a href="#">Calendar</a>	(MARTNA16) <input type="checkbox"/>	(MAREXP16)	(MARACT16)	(/)
(MABOT17) 1-A 2-B 3-C 4-D2 5-D3 *Additional Options Listed Below	(MADSDT17) <a href="#">Calendar</a>	(MARXSW17)	(MARPLC17) <input type="checkbox"/> No <input type="checkbox"/> Yes	(MAPDSP17)	(MARTDT17) <a href="#">Calendar</a>	(MARTNA17) <input type="checkbox"/>	(MAREXP17)	(MARACT17)	(/)

Comments:(MACCOMM)



## Additional Selection Options for MAC

Record Number (*RECNUMB*) (key field):

1-1

2-2

### 01 bottle ID

6-D4

7-D5

8-D6

9-D7

10-D8

11-D9

12-D10

13-D11

14-D12

15-D13

16-D14

17-D15

18-Replacement

**NIDA Clinical Trials Network**

**Medication Adherence - Participant Report (MAP)**

Web Version: 1.0; 1.02; 11-28-12

Segment (PROTSEG):  
Study Week (STYWK52):

**Study Week 1**  
**Study Week 6**  
**Study Week 11**

Study Day	Study Day	Study Day	Date (mm/dd/yyyy)	Mgs. Prescribed (XX)	Mgs. Prescribed	Mgs. Taken (XX)	Mgs. Taken	C
Day 1	Day 36	Day 71	(MADTD01)	(MARX_D1) (xx)	(MARXD01) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *A dditional Options Listed Below	(MATKN_D1)	(MATKND01) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *A dditional Options Listed Below	(MACOMD01)
Day 2	Day 37	Day 72	(MADTD02)	(MARX_D2) (xx)	(MARXD02) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *A dditional Options Listed Below	(MATKN_D2)	(MATKND02) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *A dditional Options Listed Below	(MACOMD02)
Day 3	Day 38	Day 73	(MADTD03)	(MARX_D3) (xx)	(MARXD03) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *A dditional Options Listed Below	(MATKN_D3)	(MATKND03) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *A dditional Options Listed Below	(MACOMD03)
Day 4	Day 39	Day 74	(MADTD04)	(MARX_D4) (xx)	(MARXD04) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *A dditional Options Listed Below	(MATKN_D4)	(MATKND04) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *A dditional Options Listed Below	(MACOMD04)
Day 5	Day 40	Day 75	(MADTD05)	(MARX_D5) (xx)	(MARXD05) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *A dditional Options Listed Below	(MATKN_D5)	(MATKND05) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *A dditional Options Listed Below	(MACOMD05)
Day 6	Day 41	Day 76	(MADTD06)	(MARX_D6) (xx)	(MARXD06) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *A dditional Options Listed Below	(MATKN_D6)	(MATKND06) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *A dditional Options Listed Below	(MACOMD06)

Day 7	Day 42	Day 77	(MADTD07)	(MARX_D7) (xx)	(MARXD07) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *A dditional Options Listed Below	(MATKN_D7)	(MATKND07) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *A dditional Options Listed Below	(MACOMD07)
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**Study Week 2**  
**Study Week 7**  
**Study Week 12**

Study Day	Study Day	Study Day	Date (mm/dd/yyyy)	Mgs. Prescribed (XX)	Mgs. Prescribed	Mgs. Taken (XX)	Mgs. Taken	C
Day 8	Day 43	Day 78	(MADTD08)	(MARX_D8) (xx)	(MARXD08) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *A dditional Options Listed Below	(MATKN_D8)	(MATKND08) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *Additional Options Listed Below	(MACOMD08)
Day 9	Day 44	Day 79	(MADTD09)	(MARX_D9) (xx)	(MARXD09) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *A dditional Options Listed Below	(MATKN_D9)	(MATKND09) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *Additional Options Listed Below	(MACOMD09)
Day 10	Day 45	Day 80	(MADTD10)	(MARX_D10) (xx)	(MARXD10) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *A dditional Options Listed Below	(MATK_D10)	(MATKND10) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *Additional Options Listed Below	(MACOMD10)
Day 11	Day 46	Day 81	(MADTD11)	(MARX_D11) (xx)	(MARXD11) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *A dditional Options Listed Below	(MATK_D11)	(MATKND11) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *Additional Options Listed Below	(MACOMD11)
Day 12	Day 47	Day 82	(MADTD12)	(MARX_D12) (xx)	(MARXD12) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *A dditional Options Listed Below	(MATK_D12)	(MATKND12) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *Additional Options Listed Below	(MACOMD12)
Day 13	Day 48	Day 83	(MADTD13)	(MARX_D13) (xx)	(MARXD13) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *A dditional Options Listed Below	(MATK_D13)	(MATKND13) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *Additional Options Listed Below	(MACOMD13)
Day 14	Day 49	Day 84	(MADTD14)	(MARX_D14) (xx)	(MARXD14)	(MATK_D14)	(MATKND14)	(MACOMD14)

					0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *Additional Options Listed Below		0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *Additional Options Listed Below	
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**Study Week 3**  
**Study Week 8**  
**Study Week 13**

Study Day	Study Day	Study Day	Date (mm/dd/yyyy)	Mgs. Prescribed (XX)	Mgs. Prescribed (XX)	Mgs. Taken (XX)	Mgs. Taken (XX)	C
Day 15	Day 50	Day 85	(MADTD15)	(MARX_D15) (xx)	(MARXD15) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *Additional Options Listed Below	(MATKND15) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *Additional Options Listed Below	(MATKN_15)	(MACOMD15)
Day 16	Day 51	Day 86	(MADTD16)	(MARX_D16) (xx)	(MARXD16) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *Additional Options Listed Below	(MATKND16) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *Additional Options Listed Below	(MATKN_16)	(MACOMD16)
Day 17	Day 52	Day 87	(MADTD17)	(MARX_D17) (xx)	(MARXD17) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *Additional Options Listed Below	(MATKND17) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *Additional Options Listed Below	(MATKN_17)	(MACOMD17)
Day 18	Day 53	Day 88	(MADTD18)	(MARX_D18) (xx)	(MARXD18) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *Additional Options Listed Below	(MATKND18) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *Additional Options Listed Below	(MATKN_18)	(MACOMD18)
Day 19	Day 54	Day 89	(MADTD19)	(MARX_D19) (xx)	(MARXD19) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *Additional Options Listed Below	(MATKND19) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *Additional Options Listed Below	(MATKN_19)	(MACOMD19)
Day 20	Day 55	Day 90	(MADTD20)	(MARX_D20) (xx)	(MARXD20) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *Additional Options Listed Below	(MATKND20) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *Additional Options Listed Below	(MATKN_20)	(MACOMD20)
Day 21	Day 56	Day 91	(MADTD21)	(MARX_D21) (xx)	(MARXD21)	(MATKND21)	(MATKN_21)	(MACOMD21)

					0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *Additional Options Listed Below	0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *Additional Options Listed Below		
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**Study Week 4**  
**Study Week 9**  
**Study Week 14**

Study Day	Study Day	Study Day	Date (mm/dd/yyyy)	Mgs. Prescribed	Mgs. Taken	Com
Day 22	Day 57	Day 92	(MADTD22) <input type="text"/>	(MARXD22) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *Additional Options Listed Below	(MATKND22) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *Additional Options Listed Below	(MACOMD22) <input type="text"/>
Day 23	Day 58	Day 93	(MADTD23) <input type="text"/>	(MARXD23) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *Additional Options Listed Below	(MATKND23) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *Additional Options Listed Below	(MACOMD23) <input type="text"/>
Day 24	Day 59	Day 94	(MADTD24) <input type="text"/>	(MARXD24) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *Additional Options Listed Below	(MATKND24) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *Additional Options Listed Below	(MACOMD24) <input type="text"/>
Day 25	Day 60	Day 95	(MADTD25) <input type="text"/>	(MARXD25) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *Additional Options Listed Below	(MATKND25) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *Additional Options Listed Below	(MACOMD25) <input type="text"/>
Day 26	Day 61	Day 96	(MADTD26) <input type="text"/>	(MARXD26) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *Additional Options Listed Below	(MATKND26) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *Additional Options Listed Below	(MACOMD26) <input type="text"/>
Day 27	Day 62	Day 97	(MADTD27) <input type="text"/>	(MARXD27) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *Additional Options Listed Below	(MATKND27) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *Additional Options Listed Below	(MACOMD27) <input type="text"/>
Day 28	Day 63	Day 98	(MADTD28) <input type="text"/>	(MARXD28)	(MATKND28)	(MACOMD28) <input type="text"/>

				0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *Additional Options Listed Below	0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *Additional Options Listed Below	
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**Study Week 5**

**Study Week 10**

**Study Week 15**

Study Day	Study Day	Study Day	Date (mm/dd/yyyy)	Mgs. Prescribed	Mgs. Taken	Com
Day 29	Day 64	Day 99	(MADTD29) <input type="text"/>	(MARXD29) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *Additional Options Listed Below	(MATKND29) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *Additional Options Listed Below	(MACOMD29) <input type="text"/>
Day 30	Day 65	Day 100	(MADTD30) <input type="text"/>	(MARXD30) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *Additional Options Listed Below	(MATKND30) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *Additional Options Listed Below	(MACOMD30) <input type="text"/>
Day 31	Day 66	Day 101	(MADTD31) <input type="text"/>	(MARXD31) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *Additional Options Listed Below	(MATKND31) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *Additional Options Listed Below	(MACOMD31) <input type="text"/>
Day 32	Day 67	Day 102	(MADTD32) <input type="text"/>	(MARXD32) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *Additional Options Listed Below	(MATKND32) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *Additional Options Listed Below	(MACOMD32) <input type="text"/>
Day 33	Day 68	Day 103	(MADTD33) <input type="text"/>	(MARXD33) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *Additional Options Listed Below	(MATKND33) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *Additional Options Listed Below	(MACOMD33) <input type="text"/>
Day 34	Day 69	Day 104	(MADTD34) <input type="text"/>	(MARXD34) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *Additional Options Listed Below	(MATKND34) 0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *Additional Options Listed Below	(MACOMD34) <input type="text"/>
Day 35	Day 70	Day 105	(MADTD35) <input type="text"/>	(MARXD35)	(MATKND35)	(MACOMD35) <input type="text"/>

				0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *Additional Options Listed Below	0-0mgs 1-15mgs 2-30mgs 3-45mgs 4-60mgs *Additional Options Listed Below	
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Comments:(MAPCOMM)

## Additional Selection Options for MAP

### Study Week (STYWK52) (key field):

- 1-Study Weeks 1-5
- 2-Study Weeks 6-10
- 3-Study Weeks 11-15

### D36,71 Mgs prescribed

- 5-Greater than 60mgs
- 6-10mgs



**NIDA Clinical Trials Network**

**Medication Destruction Log (MDL)**

Web Version: 1.0; 2.00; 01-28-13

Destroy Date (mm/dd/yyyy)	Bottle ID	Number of Pills (XX)	Lot Number (XXBXXX/XX)	Reason	Staff Initials	Comments
(MDDSDT01) <a href="#">Calendar</a>	(MDBOTL01) 1-A 2-B 3-C 4-D2 5-D3 *Additional Options Listed Below	(MDPILL01)	(MDLOT01)	(MDRESN01) 1-Weekly return 2-Termination 3-Expired 4-Other (specify in comments)	(MDSTAF01)	(MDCOMM01)
(MDDSDT02) <a href="#">Calendar</a>	(MDBOTL02) 1-A 2-B 3-C 4-D2 5-D3 *Additional Options Listed Below	(MDPILL02)	(MDLOT02)	(MDRESN02) 1-Weekly return 2-Termination 3-Expired 4-Other (specify in comments)	(MDSTAF02)	(MDCOMM02)
(MDDSDT03) <a href="#">Calendar</a>	(MDBOTL03) 1-A 2-B 3-C 4-D2 5-D3 *Additional Options Listed Below	(MDPILL03)	(MDLOT03)	(MDRESN03) 1-Weekly return 2-Termination 3-Expired 4-Other (specify in comments)	(MDSTAF03)	(MDCOMM03)
(MDDSDT04) <a href="#">Calendar</a>	(MDBOTL04) 1-A 2-B 3-C 4-D2 5-D3 *Additional Options Listed Below	(MDPILL04)	(MDLOT04)	(MDRESN04) 1-Weekly return 2-Termination 3-Expired 4-Other (specify in comments)	(MDSTAF04)	(MDCOMM04)
(MDDSDT05) <a href="#">Calendar</a>	(MDBOTL05) 1-A 2-B 3-C 4-D2 5-D3 *Additional Options Listed Below	(MDPILL05)	(MDLOT05)	(MDRESN05) 1-Weekly return 2-Termination 3-Expired 4-Other (specify in comments)	(MDSTAF05)	(MDCOMM05)
(MDDSDT06) <a href="#">Calendar</a>	(MDBOTL06) 1-A 2-B 3-C 4-D2 5-D3 *Additional Options Listed Below	(MDPILL06)	(MDLOT06)	(MDRESN06) 1-Weekly return 2-Termination 3-Expired 4-Other (specify in comments)	(MDSTAF06)	(MDCOMM06)
(MDDSDT07) <a href="#">Calendar</a>	(MDBOTL07)	(MDPILL07)	(MDLOT07)	(MDRESN07) 1-Weekly return 2-Termination 3-Expired 4-Other (specify in comments)	(MDSTAF07)	(MDCOMM07)

	1-A 2-B 3-C 4-D2 5-D3 <b>*Additional Options Listed Below</b>					
(MDDS DT08) <a href="#">Calendar</a>	(MDBO TL 08) 1-A 2-B 3-C 4-D2 5-D3 <b>*Additional Options Listed Below</b>	(MDPILL08)	(MDLOT08)	(MDRESN08) 1-Weekly return 2-Termination 3-Expired <b>4-Other (specify in comments)</b>	(MDSTAF08)	(MDCOMM08)
(MDDS DT09) <a href="#">Calendar</a>	(MDBO TL 09) 1-A 2-B 3-C 4-D2 5-D3 <b>*Additional Options Listed Below</b>	(MDPILL09)	(MDLOT09)	(MDRESN09) 1-Weekly return 2-Termination 3-Expired <b>4-Other (specify in comments)</b>	(MDSTAF09)	(MDCOMM09)
(MDDS DT10) <a href="#">Calendar</a>	(MDBO TL 10) 1-A 2-B 3-C 4-D2 5-D3 <b>*Additional Options Listed Below</b>	(MDPILL10)	(MDLOT10)	(MDRESN10) 1-Weekly return 2-Termination 3-Expired <b>4-Other (specify in comments)</b>	(MDSTAF10)	(MDCOMM10)
(MDDS DT11) <a href="#">Calendar</a>	(MDBO TL 11) 1-A 2-B 3-C 4-D2 5-D3 <b>*Additional Options Listed Below</b>	(MDPILL11)	(MDLOT11)	(MDRESN11) 1-Weekly return 2-Termination 3-Expired <b>4-Other (specify in comments)</b>	(MDSTAF11)	(MDCOMM11)
(MDDS DT12) <a href="#">Calendar</a>	(MDBO TL 12) 1-A 2-B 3-C 4-D2 5-D3 <b>*Additional Options Listed Below</b>	(MDPILL12)	(MDLOT12)	(MDRESN12) 1-Weekly return 2-Termination 3-Expired <b>4-Other (specify in comments)</b>	(MDSTAF12)	(MDCOMM12)
(MDDS DT13) <a href="#">Calendar</a>	(MDBO TL 13) 1-A 2-B 3-C 4-D2 5-D3 <b>*Additional Options Listed Below</b>	(MDPILL13)	(MDLOT13)	(MDRESN13) 1-Weekly return 2-Termination 3-Expired <b>4-Other (specify in comments)</b>	(MDSTAF13)	(MDCOMM13)
(MDDS DT14) <a href="#">Calendar</a>	(MDBO TL 14) 1-A 2-B 3-C 4-D2 5-D3 <b>*Additional Options Listed Below</b>	(MDPILL14)	(MDLOT14)	(MDRESN14) 1-Weekly return 2-Termination 3-Expired <b>4-Other (specify in comments)</b>	(MDSTAF14)	(MDCOMM14)
(MDDS DT15) <a href="#">Calendar</a>	(MDBO TL 15)	(MDPILL15)	(MDLOT15)	(MDRESN15) 1-Weekly return 2-Termination 3-Expired <b>4-Other (specify in comments)</b>	(MDSTAF15)	(MDCOMM15)

	1-A 2-B 3-C 4-D2 5-D3 *Additional Options Listed Below					
(MDDS DT16) <a href="#">Calendar</a>	(MDBO TL 16) 1-A 2-B 3-C 4-D2 5-D3 *Additional Options Listed Below	(MDPILL16)	(MDLOT16)	(MDRESN16) 1-Weekly return 2-T ermination 3-E xpired 4-O ther (specify in comments)	(MDSTAF16)	(MDCOMM16)
(MDDS DT17) <a href="#">Calendar</a>	(MDBO TL 17) 1-A 2-B 3-C 4-D2 5-D3 *Additional Options Listed Below	(MDPILL17)	(MDLOT17)	(MDRESN17) 1-Weekly return 2-T ermination 3-E xpired 4-O ther (specify in comments)	(MDSTAF17)	(MDCOMM17)
(MDDS DT18) <a href="#">Calendar</a>	(MDBO TL 18) 1-A 2-B 3-C 4-D2 5-D3 *Additional Options Listed Below	(MDPILL18)	(MDLOT18)	(MDRESN18) 1-Weekly return 2-T ermination 3-E xpired 4-O ther (specify in comments)	(MDSTAF18)	(MDCOMM18)
(MDDS DT19) <a href="#">Calendar</a>	(MDBO TL 19) 1-A 2-B 3-C 4-D2 5-D3 *Additional Options Listed Below	(MDPILL19)	(MDLOT19)	(MDRESN19) 1-Weekly return 2-T ermination 3-E xpired 4-O ther (specify in comments)	(MDSTAF19)	(MDCOMM19)
(MDDS DT20) <a href="#">Calendar</a>	(MDBO TL 20) 1-A 2-B 3-C 4-D2 5-D3 *Additional Options Listed Below	(MDPILL20)	(MDLOT20)	(MDRESN20) 1-Weekly return 2-T ermination 3-E xpired 4-O ther (specify in comments)	(MDSTAF20)	(MDCOMM20)

Comments:(MDLCOMM)

## Additional Selection Options for MDL

### 01 bottle ID

6-D4  
7-D5  
8-D6  
9-D7  
10-D8  
11-D9  
12-D10  
13-D11  
14-D12  
15-D13  
16-D14  
17-D15  
18-Replacement  
99-Unknown

**NIDA Clinical Trials Network**

**Medication Adherence - Mems/Contingency Management Tracking (MEM)**

Web Version: 1.0; 1.00; 06-20-12

Segment (PROTSEG):  
Study Weeks (WK52MEM):

Week 1	Week 4	Week 7	Week 13	Week 10				
Date (mm/dd/yyyy)	Date (mm/dd/yyyy)	Date (mm/dd/yyyy)	Date (mm/dd/yyyy)	Date (mm/dd/yyyy)	Adherence Level	Incentive Earned (\$XX.XX)	Paid	Comm
1. (MEDTD01)	22.(MEDTD01)	43.(MEDTD01)	85.(MEDTD01)	64.(MEDTD01)	(MEADHD01) <input type="checkbox"/> Full <input type="checkbox"/> Partial <input type="checkbox"/> Not compliant	(MEINCD01) \$ _____	(MEPAYD01) <input type="checkbox"/>	(MECOMD01)
2. (MEDTD02)	23.(MEDTD02)	44.(MEDTD02)	86.(MEDTD02)	65.(MEDTD02)	(MEADHD02) <input type="checkbox"/> Full <input type="checkbox"/> Partial <input type="checkbox"/> Not compliant	(MEINCD02) \$ _____	(MEPAYD02) <input type="checkbox"/>	(MECOMD02)
3. (MEDTD03)	24.(MEDTD03)	45.(MEDTD03)	87.(MEDTD03)	66.(MEDTD03)	(MEADHD03) <input type="checkbox"/> Full <input type="checkbox"/> Partial <input type="checkbox"/> Not compliant	(MEINCD03) \$ _____	(MEPAYD03) <input type="checkbox"/>	(MECOMD03)
4. (MEDTD04)	25.(MEDTD04)	46.(MEDTD04)	88.(MEDTD04)	67.(MEDTD04)	(MEADHD04) <input type="checkbox"/> Full <input type="checkbox"/> Partial <input type="checkbox"/> Not compliant	(MEINCD04) \$ _____	(MEPAYD04) <input type="checkbox"/>	(MECOMD04)
5. (MEDTD05)	26.(MEDTD05)	47.(MEDTD05)	89.(MEDTD05)	68.(MEDTD05)	(MEADHD05) <input type="checkbox"/> Full <input type="checkbox"/> Partial <input type="checkbox"/> Not compliant	(MEINCD05) \$ _____	(MEPAYD05) <input type="checkbox"/>	(MECOMD05)
6. (MEDTD06)	27.(MEDTD06)	48.(MEDTD06)	90.(MEDTD06)	69.(MEDTD06)	(MEADHD06) <input type="checkbox"/> Full <input type="checkbox"/> Partial <input type="checkbox"/> Not compliant	(MEINCD06) \$ _____	(MEPAYD06) <input type="checkbox"/>	(MECOMD06)
7. (MEDTD07)	28.(MEDTD07)	49.(MEDTD07)	91.(MEDTD07)	70.(MEDTD07)	(MEADHD07) <input type="checkbox"/> Full <input type="checkbox"/> Partial <input type="checkbox"/> Not compliant	(MEINCD07) \$ _____	(MEPAYD07) <input type="checkbox"/>	(MECOMD07)
Week 2	Week 5	Week 8	Week 14	Week 11				
Date (mm/dd/yyyy)	Date (mm/dd/yyyy)	Date (mm/dd/yyyy)	Date (mm/dd/yyyy)	Date (mm/dd/yyyy)	Adherence Level	Incentive Earned (\$XX.X)	Paid	Comm

8. (MEDTD08)	29.(MEDTD08)	50.(MEDTD08)	92.(MEDTD08)	71.(MEDTD08)	(MEADHD08) <input type="checkbox"/> Full <input type="checkbox"/> Partial <input type="checkbox"/> Not compliant	(MEINCD08) \$ _____	(MEPAYD08) <input type="checkbox"/>	(MECOMD08)
9. (MEDTD09)	30.(MEDTD09)	51.(MEDTD09)	93.(MEDTD09)	72.(MEDTD09)	(MEADHD09) <input type="checkbox"/> Full <input type="checkbox"/> Partial <input type="checkbox"/> Not compliant	(MEINCD09) \$ _____	(MEPAYD09) <input type="checkbox"/>	(MECOMD09)
10. (MEDTD10)	31.(MEDTD10)	52.(MEDTD10)	94.(MEDTD10)	73.(MEDTD10)	(MEADHD10) <input type="checkbox"/> Full <input type="checkbox"/> Partial <input type="checkbox"/> Not compliant	(MEINCD10) \$ _____	(MEPAYD10) <input type="checkbox"/>	(MECOMD10)
11. (MEDTD11)	32.(MEDTD11)	53.(MEDTD11)	95.(MEDTD11)	74.(MEDTD11)	(MEADHD11) <input type="checkbox"/> Full <input type="checkbox"/> Partial <input type="checkbox"/> Not compliant	(MEINCD11) \$ _____	(MEPAYD11) <input type="checkbox"/>	(MECOMD11)
12. (MEDTD12)	33.(MEDTD12)	54.(MEDTD12)	96.(MEDTD12)	75.(MEDTD12)	(MEADHD12) <input type="checkbox"/> Full <input type="checkbox"/> Partial <input type="checkbox"/> Not compliant	(MEINCD12) \$ _____	(MEPAYD12) <input type="checkbox"/>	(MECOMD12)
13. (MEDTD13)	34.(MEDTD13)	55.(MEDTD13)	97.(MEDTD13)	76.(MEDTD13)	(MEADHD13) <input type="checkbox"/> Full <input type="checkbox"/> Partial <input type="checkbox"/> Not compliant	(MEINCD13) \$ _____	(MEPAYD13) <input type="checkbox"/>	(MECOMD13)
14. (MEDTD14)	35.(MEDTD14)	56.(MEDTD14)	98.(MEDTD14)	77.(MEDTD14)	(MEADHD14) <input type="checkbox"/> Full <input type="checkbox"/> Partial <input type="checkbox"/> Not compliant	(MEINCD14) \$ _____	(MEPAYD14) <input type="checkbox"/>	(MECOMD14)
<b>Week 3</b>	<b>Week 6</b>	<b>Week 9</b>	<b>Week 15</b>	<b>Week 12</b>				
<b>Date</b> (mm/dd/yyyy)	<b>Date</b> (mm/dd/yyyy)	<b>Date</b> (mm/dd/yyyy)	<b>Date</b> (mm/dd/yyyy)	<b>Date</b> (mm/dd/yyyy)	<b>Adherence Level</b>	<b>Incentive Earned</b> (\$XX.X)	<b>Paid</b>	<b>Comm</b>
15. (MEDTD15)	36.(MEDTD15)	57.(MEDTD15)	99.(MEDTD15)	78.(MEDTD15)	(MEADHD15) <input type="checkbox"/> Full <input type="checkbox"/> Partial <input type="checkbox"/> Not compliant	(MEINCD15) \$ _____	(MEPAYD15) <input type="checkbox"/>	(MECOMD15)
16. (MEDTD16)	37.(MEDTD16)	58.(MEDTD16)	100.(MEDTD16)	79.(MEDTD16)	(MEADHD16) <input type="checkbox"/> Full <input type="checkbox"/> Partial <input type="checkbox"/> Not compliant	(MEINCD16) \$ _____	(MEPAYD16) <input type="checkbox"/>	(MECOMD16)
17. (MEDTD17)	38.(MEDTD17)	59.(MEDTD17)	101.(MEDTD17)	80.(MEDTD17)	(MEADHD17) <input type="checkbox"/> Full <input type="checkbox"/> Partial <input type="checkbox"/> Not compliant	(MEINCD17) \$ _____	(MEPAYD17) <input type="checkbox"/>	(MECOMD17)

18. (MEDTD18)	39.(MEDTD18)	60.(MEDTD18)	102.(MEDTD18)	81.(MEDTD18)	(MEADHD18) <input type="checkbox"/> Full <input type="checkbox"/> Partial <input type="checkbox"/> Not compliant	(MEINCD18) \$	(MEPAYD18) <input type="checkbox"/>	(MECOMD18)
19. (MEDTD19)	40.(MEDTD19)	61.(MEDTD19)	103.(MEDTD19)	82.(MEDTD19)	(MEADHD19) <input type="checkbox"/> Full <input type="checkbox"/> Partial <input type="checkbox"/> Not compliant	(MEINCD19) \$	(MEPAYD19) <input type="checkbox"/>	(MECOMD19)
20. (MEDTD20)	41.(MEDTD20)	62.(MEDTD20)	104.(MEDTD20)	83.(MEDTD20)	(MEADHD20) <input type="checkbox"/> Full <input type="checkbox"/> Partial <input type="checkbox"/> Not compliant	(MEINCD20) \$	(MEPAYD20) <input type="checkbox"/>	(MECOMD20)
21. (MEDTD21)	42.(MEDTD21)	63.(MEDTD21)	105.(MEDTD21)	84.(MEDTD21)	(MEADHD21) <input type="checkbox"/> Full <input type="checkbox"/> Partial <input type="checkbox"/> Not compliant	(MEINCD21) \$	(MEPAYD21) <input type="checkbox"/>	(MECOMD21)

Comments:(MEMCOMM)

## Additional Selection Options for MEM

Study Weeks (*WK52MEM*) (key field):

1-1-3  
2-4-6  
3-7-9  
4-10-12  
5-13-15



NIDA Clinical Trials Network

Missed Visit Form (MVF)

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

Segment (PROTSEG):

Visit Number (VISNO):

Reason for missed visit:(M VRESN52)

Z01-PARTICIPANT MISSED SCHEDULED APPOINTMENT BECAUSE  
01a- 1a - Participant illness  
01b- 1b - Participant incarceration  
01c- 1c - Participant family issues  
01d- 1d - Participant employment issues  
\*Additional Options Listed Below

If "Other", specify:(MVO THRSP)

4. Staff Response to missed visit:

- a. Phone contact with participant:(MVSTFPHN)  No  Yes
- b. Phone contact with locator contacts:(MVSTFLOC)  No  Yes
- c. Missed visit form letter sent to participant at primary residence:(MVSTFLPR)  No  Yes
- d. Missed visit form letter sent to participant at locator contact location:  
(MVSTFLLC)  No  Yes
- e. Electronic message via Text:(MVSTFTXT)  No  Yes
- f. Electronic message via E-mail:(MVSTFEML)  No  Yes
- g. Electronic message via other electronic social media (e.g., Facebook, T witter,  
etc):(MVSTFSOC)  No  Yes
- h. Home visit:(MVS TFHME)  No  Yes
- i. Visit to locator contact location:(MVSTFVLC)  No  Yes
- j. Other response not listed above:(MVSTFOTH)  No  Yes

If "Other response not listed above", specify:(MVSTFSP)

## Additional Selection Options for MVF

### Reason for missed visit:

01e- 1e - Reason unknown

01f- 1f - Participant refused

01g- 1g - Participant death

Z02-PARTICIPANT UNSCHEDULED FOR STUDY VISIT BECAUSE

02a- 2a - Missing; unable to contact

02b- 2b - Participant incarceration

02c- 2c - Participant refused

02d- 2d - Staff error

Z03-OTHER

03a- 3 - Other reason not included above

# NIDA Clinical Trials Network

## Obsessive Compulsive Drug Use Scale (OCDUS) (OCD)

Web Version: 1.0; 1.00; 06-18-12

Segment (PROTSEG):

Visit Number (VISNO):

Date of assessment:(OCDASMDT)

(mm/dd/yyyy) [Click here for calendar](#)

The questions below ask you about your cocaine use and your attempts to control your use. For each question, indicate the statement that best applies to you.

1. How much of your time when you are not using is occupied by ideas, thoughts, impulses, or images related to the use of cocaine?

- 0-(0) None
- 1-(1) Less than 1 hour a day
- 2-(2) 1-3 hours a day
- 3-(3) 4-8 hours a day
- 4-(4) Greater than 8 hours a day

(OCTKTIME)

2. How frequently do these thoughts related to cocaine occur?

(OCTKFREQ)

- 0-(0) Never
- 1-(1) Less than 8 times a day and most hours of the day are free of these thoughts.
- 2-(2) 8 or more times a day but most hours of the day are free of these thoughts.
- 3-(3) 8 or more times a day and during most hours of the day.
- 4-(4) Thoughts are too numerous to count and an hour rarely passes without several such thoughts occur

3. How much do these thoughts related to cocaine interfere with your social or work functioning?

(OCTKSOCL)

- 0-(0) Thoughts of cocaine never interfere - I can function normally.
- 1-(1) Thoughts of cocaine slightly interfere with my social activities and work performance, but my ov
- 2-(2) Thoughts of cocaine definitely interfere with my social activities and work performance, but I c
- 3-(3) Thoughts of cocaine cause substantial impairment in my social activities or work performance.
- 4-(4) Thoughts of cocaine interfere completely with my social activities or work performance.

4. How much distress or disturbances do these ideas, thoughts, impulses or images related to cocaine cause you when you are not taking cocaine?

- 0-(0) None
- 1-(1) Mild, infrequent and not too disturbing.
- 2-(2) Moderate, frequent, and disturbing, but still manageable.
- 3-(3) Severe, very frequent and very disturbing.
- 4-(4) Extreme, nearly constant, and disabling distress.

(OCDISTR)

5. How much of an effort do you make to resist these thoughts related to cocaine or try to disregard or turn your attention away from these thoughts?

(OCRESIST)

- 0-(0) My thoughts are so minimal, I don't need to actively resist. If I have thoughts, I make an effort
- 1-(1) I try to resist most of the time.
- 2-(2) I make some effort to resist
- 3-(3) I give in to all such thoughts without attempting to control them, but I do so with some relucta
- 4-(4) I completely and willingly give in to all such thoughts.

(Rate your efforts to resist these thoughts, not your success in controlling them)

6. How successful are you in stopping or diverting these thoughts related to cocaine?

(OCDIVERT)

- 0-(0) I am completely successful in stopping or diverting such thoughts.
- 1-(1) I am usually able to stop or divert such thoughts with some effort and concentration.
- 2-(2) I am sometimes able to stop or divert such thoughts.
- 3-(3) I am rarely successful in stopping such thoughts and can only divert such thoughts with difficul
- 4-(4) I completely and willingly give in to all such thoughts.

7. If you do not use, how often do you feel the urge or drive to use cocaine?

- 0-(0) Never
- 1-(1) Less than once per day.
- 2-(2) Once or twice per day.
- 3-(3) 3-7 times per day.
- 4-(4) 8 or more times per day.

(OCURGEOF)

8. If you do not use, how much time of the day do you feel the urge or drive to use cocaine?

- 0-(0) None
- 1-(1) Less than 1 hour a day
- 2-(2) 1-3 hours a day
- 3-(3) 4-8 hours a day
- 4-(4) Greater than 8 hours a day

(OCURGETM)

9. How much does the urge to use cocaine interfere with your social life or your occupational activities?

(OCURGESC)

- 0-(0) Urges to use cocaine never interfere - I can function normally.
- 1-(1) Urges to use cocaine slightly interfere with social activities and work performance, but my over
- 2-(2) Urges to use cocaine definitely interfere with social activities and work performance, but I can
- 3-(3) Urges to use cocaine cause substantial impairment in social activities and work performance.
- 4-(4) Urges to use cocaine interfere completely with my social or work performance.

10. If you were prevented from using cocaine when you desired to use it, how anxious or upset would you become?

(OCUPSET)

- 0-(0) I would not experience any anxiety or irritation.
- 1-(1) I would become only slightly anxious or irritated.
- 2-(2) The anxiety or irritation would mount, but remain manageable.
- 3-(3) I would experience a prominent and very disturbing increase in anxiety or irritation.
- 4-(4) I would experience incapacitating anxiety or irritation.

11. How much of an effort do you make to resist the use of cocaine?

(OCEFFORT)

- 0-(0) My thoughts are so minimal, I don't need to actively resist. If I have thoughts, I make an effort
- 1-(1) I try to resist most of the time.
- 2-(2) I make some effort to resist.
- 3-(3) I give in to all such thoughts without attempting to control them, but I do so with some reluctance.
- 4-(4) I completely and willingly give in to all such thoughts.

12. How strong was the drive to use cocaine in the past week?

- 0-(0) No drive.
- 1-(1) Some pressure to take cocaine.
- 2-(2) Strong pressure to take cocaine.
- 3-(3) Very strong drive to take cocaine.
- 4-(4) The drive to take cocaine is completely involuntary and overpowering.

(OCSTRONG)

13. How much control do you have over your cocaine use?

- 0-(0) I have complete control.
- 1-(1) I am usually able to exercise voluntary control over it.
- 2-(2) I can control it only with difficulty.
- 3-(3) I must use and can only delay using with difficulty.
- 4-(4) I am rarely able to delay using even momentarily.

(OCCONTRL)

Comments:(OCDCOMM)

NIDA Clinical Trials Network

Pregnancy and Birth Control Assessment (PBC)

Web Version: 1.0; 3.00; 06-13-12

Segment (PROTSEG):

Visit Number (VISNO):

Complete this form only for females.

Date of assessment:(PBASMDT)

Calendar input field (mm/dd/yyyy) with a link to a calendar.

- 1. Is the participant breastfeeding?(PBBSTFED)
2. Does the participant agree to use an acceptable method of birth control? (PBBCUSE)
a. Abstinence:(PBABSTIN)
b. Barrier:(PBBARRIR)
c. IUD:(PBIUD)
d. Levonorgestrel implant:(PBLEVIMP)
e. Medroxyprogesterone acetate injection:(PBMEDINJ)
f. Oral contraceptives:(PBORALCN)
g. Hormonal vaginal contraceptive ring:(PBRING)
h. Contraceptive transdermal patch (PBPATCH)
i. Surgical sterilization:(PBSURGSZ)
j. Other(PBBCOTH)
If "Other", specify:(PBBCOSP)

- 3. Was a pregnancy test performed?(PBPRGTST)
a. Date of pregnancy test:(PBPTS TDT)
b. Result of pregnancy test:(PBRESULT)
c. If pregnancy test was not performed, does the female participant have a documented hysterectomy?(PBHYS TMY)

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

Comments:(PBCCOMM)

Large empty rectangular box for entering comments.

NIDA Clinical Trials Network

Pregnancy Outcome 1 (PO1)

Web Version: 1.0; 1.01; 01-29-13

Pregnancy Number (PREGNO):

Newborn Information

- 1. Gender:(PO1GENDR)  Male  Female  Unknown
- 2. Gestational age at delivery:(PO1GESWK)  (xx) Weeks (PO1GESDY)  (x) Days (PO1GESUN)OR  Unknown
- 3. Weight at delivery:(PO1WTLBS)  (xx) Lbs (PO1WTOZ)  (xx) Oz (PO1WTUNK)OR  Unknown
- 4. Apgar score at 1 minute:(PO1APG1M)  (xx) (PO11APUK)OR  Unknown
- 5. Apgar score at 5 minutes:(PO1APG5M)  (xx) (PO15APUK)OR  Unknown
- 6. Normal infant?(PO1NORML)  No  Yes  
If "No", is there a congenital anomaly?(PO1CONAN)  No  Yes  Unknown  
If "Yes", specify abnormality and contributing factors:(PO1ABNSP)

Comments:(PO1COMM)

## Additional Selection Options for PO1

Pregnancy Number (*PREGNO*) (key field):

1-1

2-2

3-3

NIDA Clinical Trials Network

Pregnancy Outcome 2 (PO2)

Web Version: 1.0; 2.01; 01-29-13

Pregnancy Number (PREGNO):

Newborn Information

1. Gender:(PO2GENDR)

Male  Female  Unknown

2. Gestational age at delivery:(PO2GESWK)

(xx) Weeks (PO2GESDY)  (x) Days (PO2GESUN)OR  Unknown

3. Weight at delivery:(PO2WTLBS)

(xx) Lbs (PO2WTOZ)  (xx) Oz (PO2WTUNK)OR  Unknown

4. Apgar score at 1 minute:(PO2APG1M)

(xx) (PO21APUK)OR  Unknown

5. Apgar score at 5 minutes:(PO2APG5M)

(xx) (PO25APUK)OR  Unknown

6. Normal infant?(PO2NORML)

No  Yes

If "No", is there a congenital anomaly?(PO2CONAN)

No  Yes  Unknown

If "Yes", specify abnormality and contributing factors:(P02ABNSP)

Comments:(PO2COMM)



## Additional Selection Options for PO2

Pregnancy Number (*PREGNO*) (key field):

1-1

2-2

3-3

NIDA Clinical Trials Network

Pregnancy Outcome 3 (PO3)

Web Version: 1.0; 2.01; 01-29-13

Pregnancy Number (PREGNO):

Newborn Information

1. Gender:(PO3GENDR)

Male  Female  Unknown

2. Gestational age at delivery:(PO3GESWK)

(xx) Weeks (PO3GESDY)  (x) Days (PO3GESUN)OR  Unknown

3. Weight at delivery:(PO3WTLBS)

(xx) Lbs (PO3WTOZ)  (xx) Oz (PO3WTUNK)OR  Unknown

4. Apgar score at 1 minute:(PO3APG1M)

(xx) (PO31APUK)OR  Unknown

5. Apgar score at 5 minutes:(PO3APG5M)

(xx) (PO35APUK)OR  Unknown

6. Normal infant?(PO3NORML)

No  Yes

If "No", is there a congenital anomaly?(PO3CONAN)

No  Yes  Unknown

If "Yes", specify abnormality and contributing factors:(PO3ABNSP)

Comments:(PO3COMM)

## Additional Selection Options for PO3

Pregnancy Number (*PREGNO*) (key field):

1-1

2-2

3-3

NIDA Clinical Trials Network

Pregnancy Outcome 4 (PO4)

Web Version: 1.0; 2.01; 01-29-13

Pregnancy Number (PREGNO):

Newborn Information

1. Gender:(PO4GENDR)

Male  Female  Unknown

2. Gestational age at delivery:(PO4GESWK)

(xx) Weeks (PO4GESDY)  (x) Days (PO4GESUN)OR  Unknown

3. Weight at delivery:(PO4WTLBS)

(xx) Lbs (PO4WTOZ)  (xx) Oz (PO4WTUNK)OR  Unknown

4. Apgar score at 1 minute:(PO4APG1M)

(xx) (PO41APUK)OR  Unknown

5. Apgar score at 5 minutes:(PO4APG5M)

(xx) (PO45APUK)OR  Unknown

6. Normal infant?(PO4NORML)

No  Yes

If "No", is there a congenital anomaly?(PO4CONAN)

No  Yes  Unknown

If "Yes", specify abnormality and contributing factors:(PO4ABNSP)

Comments:(PO4COMM)

## Additional Selection Options for PO4

Pregnancy Number (*PREGNO*) (key field):

1-1

2-2

3-3

# NIDA Clinical Trials Network

## Confirmed Pregnancy and Outcome (PRG)

Web Version: 1.0; 3.00; 01-29-13

Pregnancy Number (PREGNO):

### Information About Pregnancy

Date of assessment:(PRASMTDT)

(mm/dd/yyyy) [Click here for calendar](#)

1. Date on which study staff became aware of pregnancy:(PRAWARDT)

(mm/dd/yyyy) [Click here for calendar](#)

2. How was the pregnancy confirmed (select all that apply)?

a. Urine pregnancy test result:(PRURICNF)

No  Yes

b. Serum pregnancy test result:(PRSERCNF)

No  Yes

c. Ultrasound result:(PRULTCNF)

No  Yes

d. Other:(PROTHCNF)

No  Yes

If "Other", specify:(PROTCNSP)

3. Date on which the pregnancy was confirmed:(PRCNFMDT)

(mm/dd/yyyy) [Click here for calendar](#)

4. Action taken with study intervention:(PRACTIND)

1-None  
2-Temporarily stopped intervention  
3-Permanently stopped intervention  
4-Participant terminated from study

5. Approximate due date:(PRADUEDT)

(mm/dd/yyyy) (PRDDTUNK)OR  Unknown

6. Outcome of pregnancy:(PROUTCME)

1-Vaginal delivery  
2-Cesarean delivery  
3-Miscarriage  
4-Termination  
98-Other  
\*Additional Options Listed Below

If "Other", specify:(PROTCMSP)

7. Date of pregnancy outcome:(PROTCMDT)

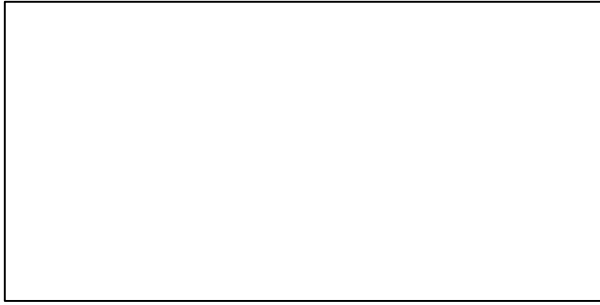
(mm/dd/yyyy) (PRODTUNK)OR  Unknown

8. Number of live births:(PRNMLIVB)

0-0  
1-1  
2-2  
3-3  
4-4  
\*Additional Options Listed Below

If "0" live births, please indicate reason:(PRRS0BSP)

Comments:(*PRGCOMM*)



## Additional Selection Options for PRG

**Pregnancy Number (*PREGNO*) (key field):**

1-1

2-2

3-3

**Outcome of pregnancy:**

99-Unknown

**Number of live births:**

99-Other

98-Unknown



## NIDA Clinical Trials Network

### Participant Self-Report Measures (PRM)

Web Version: 1.0; 1.00; 04-26-12

Segment (*PROTSEG*):

Visit Number (*VISNO*):

#### Welcome!

You are about to answer some questions using this computer by clicking on checkboxes like this: (*PSBOX1*)

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

*Try it out!*

Click this checkbox and then click on the "Save" button: (*PSBOX2*)

NIDA Clinical Trials Network

Protocol Violation Log (PVL)

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

Date of Violation (PVDATE):

Protocol Violation Number (PVSEQNUM):

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

1. Violation type: (PVTYPE52)

Z01-INFORMED CONSENT PROCEDURES  
O1A - O1A - No consent/assent obtained  
O1C - O1C - Invalid/incomplete informed decision  
O1D - O1D - Unauthorized assessments and/or procedures conducted prior to obtaining informed consent  
O1Z - O1E - Other  
\*Additional Options Listed Below

If "Other" is indicated, provide the specification:  
(PVTPSP52)

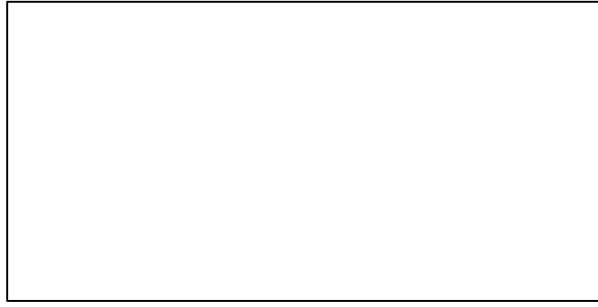
2. Description of violation: (PVDESC)

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

No  Yes

Protocol violation resolution and corrective action:  
(PVRSCASP)

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:

02-02 - INCLUSION/EXCLUSION CRITERIA  
03-03 - CONCOMITANT MEDICATION / THERAPY  
Z04-LABORATORY ASSESSMENTS / PROCEDURES  
04A- 04A - Required testing not obtained  
04B- 04B - Testing completed outside window  
04D- 04D - Unauthorized test/procedure obtained  
04Z- 04E - Other  
Z05-STUDY PROCEDURES/ASSESSMENTS  
05A- 05A - Protocol required procedures not obtained  
05C- 05C - Procedures/Assessments obtained outside the visit timeframes  
05Z- 05D - Other  
Z06-ADVERSE EVENT  
06A- 06A - SAE not reported  
06B- 06B - SAE reported out of time window  
06Z- 06C - Other  
Z07-RANDOMIZATION PROCEDURES  
07A- 07A - Randomization procedures not followed (e.g., outside window, out of sequence, etc.)  
07B- 07B - Ineligible participant randomized  
07C- 07C - Improper un-blinding procedures  
07Z- 07D - Other  
07E- 07E - Incorrect treatment assignment  
Z08-STUDY DRUG DOSING  
08A- 08A - Ineligible participant dispensed medication  
08B- 08B - Incorrect medication dispensed  
08C- 08C - Incorrect medication dosage or amount of medication dispensed  
08Z- 08D - Other  
Z09-BEHAVORAL INTERVENTION  
09A- 09A - Intervention not provided per protocol schedule or visit window timeframe  
09Z- 09C - Other  
Z99-OTHER SIGNIFICANT VIOLATIONS  
99C- 99C - Using advertising materials or brochures without prior IRB approval  
99Z- 99D - Other

NIDA Clinical Trials Network

Protocol Violation Review (PVR)

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

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

1. Is this event considered to be:(PVSEVER)  Major  Minor

2. What section of the protocol does this event refer to?(PVSECTN)

3. Does this event require retraining?(PVTRAIN)  No  Yes

4. Does the protocol need to be modified based on this event?(PVPRTMOD)  No  Yes

5. Does the consent need to be modified based on this event?(PVCNTMOD)  No  Yes

6. Is the review of this event complete?(PVREVCMP)  No  Yes

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

Assessed by:(PVREVBY)

- 2-RoShauna Rothwell
- 3-Dikla (Dee) Blumberg
- 5-Maria Campanella
- 6-Matthew Wright

Comments:(PVCOMM)

## Additional Selection Options for PVR

### Protocol Violation Number (*PVSEQNUM*) (key field):

- 01 -1st Protocol Violation of the day
- 02-2nd Protocol Violation of the day
- 03-3rd Protocol Violation of the day
- 04-4th Protocol Violation of the day
- 05-5th Protocol Violation of the day
- 06-6th Protocol Violation of the day
- 07-7th Protocol Violation of the day
- 08-8th Protocol Violation of the day
- 09-9th Protocol Violation of the day
- 10-10th Protocol Violation of the day

## NIDA Clinical Trials Network

### Risk Assessment Battery (RIS)

Web Version: 1.0; 1.00; 04-23-12

Segment (PROTSEG):

Visit Number (VISNO):

Date of assessment: (RISASMDT)

(mm/dd/yyyy) [Click here for calendar](#)

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

#### A. Past Month Drug and Alcohol Use

	Not At All	A Few Times	A Few Times Each Week	Everyday
1. In the past month, how often have you <u>Injected</u> cocaine and heroin together (Speedball)?	(RASPEDBL) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. In the past month, how often have you <u>Injected</u> heroin (not mixed)?	(RAHERINJ) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. In the past month, how often have you <u>Snorted</u> heroin (not mixed)?	(RASNRTHR) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. In the past month, how often have you <u>Smoked</u> heroin (not mixed)?	(RASMOKHR) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. In the past month, how often have you <u>Injected</u> cocaine (not mixed)?	(RACOCINJ) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. In the past month, how often have you <u>Snorted</u> cocaine (not mixed)?	(RASNRTCO) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. In the past month, how often have you <u>Smoked</u> crack, rock, or freebase cocaine?	(RASMOKCO) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. In the past month, how often have you <u>Injected</u> amphetamines, methamphetamine, speed, crank, or crystal?	(RASPDINJ) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. In the past month, how often have you <u>Snorted</u> amphetamines, methamphetamine, speed, crank, or crystal?	(RASNRTSP) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. In the past month, how often have you <u>Smoked</u> amphetamines, methamphetamine, speed, crank, or crystal?	(RASMOKSP) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. In the past month, how often have you used benzodiazepines (benzos, benzies) such as Xanax, Valium, Klonopin, or Ativan?	(RAUSEDPZ) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. In the past month, how often have you taken painkillers [pills such as Percodan, Percocet, Vicodin, Demerol, Dilaudid, Darvon, Darvocet, or syrup (Codeine)]?	(RAUSEDPK) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Which types of painkillers did you use? (RAPKSP) <input style="width: 200px;" type="text"/>				
13. In the past month, how often have you injected Dilaudid?	(RADILINJ) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. In the past month, how often have you used acid, LSD, or other hallucinogens?	(RAUSDLSD) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. In the past month, how often have you used marijuana?	(RAUSDCAN) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. In the past month, how often have you used beer, wine, or liquor?	(RADRANK) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

#### B. Needle Use

17. In the past month, have you injected drugs? (RADRGINJ)

No  Yes

18. In the past month, have you shared needles or works? (RASHNDLE)

No or I have not shot up in the past month  Yes

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

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

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

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

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

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

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

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

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

- a. I have not shot up in the past month (RANDLNOT)  No  Yes
- b. From a diabetic (RANDLDBT)  No  Yes
- c. On the street (RANDLSRT)  No  Yes
- d. Drugstore (RANDLDST)  No  Yes
- e. Shooting gallery or other place where users go to shoot up (RANDLSGY)  No  Yes
- f. Needle Exchange Program (RANLDEXC)  No  Yes
- g. Other (RANLOTH)  No  Yes

If "Other", specify: (RANLOSP)

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

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

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

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

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

- 0- I have not shot up in the past month
- 1- ALWAYS use new needles
- 2- ALWAYS clean my needle just BEFORE I shoot up
- 3- After I shoot up, I ALWAYS clean my needle
- 4- SOMETIMES I clean my needle, sometimes I don't
- \*Additional Options Listed Below

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

- a. I have not shot up in the past month (RANLNOT)  No  Yes
- b. Soap and water only (RANLSOAP)  No  Yes
- c. Alcohol (RANLALCH)  No  Yes
- d. Bleach (RANLBLCH)  No  Yes
- e. Boiling water (RANDLWTR)  No  Yes
- f. Other (RANLOTHC)  No  Yes

If "Other", specify (RANLCOSP)

- g. I did not clean my needles in the past month (RISNOTCL)  No  Yes
- h. I ALWAYS used new needles in the past month (RISALWAY)  No  Yes



	Never or I have not shot up or shared in the past month.	A Few Times (1 or 2 Times)	About Once a Week (3 or 4 Times)	More Than Once a Week (5 or More Times)
28. In the past month, how often have you shared rinse-water?	(RARH20SH) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
29. In the past month, how often have you shared a cooker?	(RACOKRSH) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
30. In the past month, how often have you shared cotton?	(RACTNSH) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
31. In the past month, how often have you divided or shared drugs with others by using one syringe (yours or someone else's) to squirt or load the drugs into the other syringe(s) (backloading, for example)?	(RISCKLD) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

### C. Sexual Practices

32. How would you describe yourself?(RASEXPRF)  Straight or Heterosexual  Gay or Homosexual  Bisexual

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

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

- 0-0 men
- 1-1 man
- 2-2 or 3 men
- 3-4 or more men

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

- 0-0 women
- 1-1 woman
- 2-2 or 3 women
- 3-4 or more women

	Never	A Few Times (1 or 2 Times)	About Once a Week (3 or 4 Times)	More Than Once a Week (5 or More Times)
35. In the past month, how often have you had sex so you could get drugs?	(RASEX4DG) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
36. In the past month, how often have you given drugs to someone so you could have sex with them?	(RADG4SEX) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
37. In the past month, how often were you paid money to have sex with someone?	(RAPOSTUT) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
38. In the past month, how often did you give money to someone so you could have sex with them?	(RAPD4SEX) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
39. In the past month, how often have you had sex with someone you knew (or later found out) had AIDS or was positive for HIV, the AIDS virus?	(RASEXHIV) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

40. In the past month, how often did you use condoms when you had sex?(RASEXSFE)

- 0-I have not had sex in the past month
- 1-All the time
- 2-Most of the time
- 3-Some of the time
- 4-None of the time

### D. Concerns About HIV and Testing

*If you know that you are HIV positive, skip to question 44.*

41. How worried are you about getting HIV or AIDS?(RAGETHIV)

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

42. How worried are you that you may have already been exposed to the HIV or AIDS virus?*(RAEXPHIV)*

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

43. How many times have you had a blood test for the AIDS virus (HIV)?*(RATSTHIV)*

- 0-Never
- 1-1
- 2-2
- 3-3
- 4-4
- \*Additional Options Listed Below

44. When were you last tested for HIV?*(RALTMHIV)*

(mm) / *(RALTYHIV)*  (yyyy)

45. Were you ever told that you had HIV, the AIDS virus?*(RAHIVYES)*

- No    Yes    I never got the results

Comments:*(RISCOMM)*

## Additional Selection Options for RIS

Which statement best describes the way you cleaned your needles during the past month?

5- I NEVER clean my needle

How many times have you had a blood test for the AIDS virus (HIV)?

5-5

6-6

7-7

8-8

9-9

10-10 or more times

## NIDA Clinical Trials Network

### Short Index of Problems - Drug (SIP)

Web Version: 1.0; 1.00; 04-16-12

Segment (PROTSEG):

Visit Number (VISNO):

Date of assessment:(SIPASMDT)

(mm/dd/yyyy) [Click here for calendar](#)

Here are a number of events that people sometimes experience. Read each one carefully, and indicate how often each one of them has happened to you DURING THE PAST 3 MONTHS. If an item does not apply to you, check Never.

**DURING THE PAST 3 MONTHS (Never, Once or a Few times, etc.), about how often has this happened to you?**

	Never	Once or a few times	Once or twice a week	Daily or almost daily
1. I have been unhappy because of my drug use.	(SIUNHAPY) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Because of my drug use, I have not eaten properly.	(SIFOOD) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. I have failed to do what is expected of me because of my drug use.	(SIDOEXPD) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. I have felt guilty or ashamed because of my drug use.	(SIGUILTY) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. I have taken foolish risks when I have been using drugs.	(SIRISKS) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. When using drugs, I have done impulsive things that I regretted later.	(SIMPULS) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. My physical health has been harmed because of my drug use.	(SIHEALTH) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. I have had money problems because of my drug use.	(SIMONEY) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. My physical appearance has been harmed because of my drug use.	(SILOOKS) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. My family has been hurt because of my drug use.	(SIFAMILY) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. A friendship or a close relationship has been damaged because of my drug use.	(SIFRIEND) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. My drug use has gotten in the way of my growth as a person.	(SIGROWTH) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. My drug use has damaged my social life, popularity, or reputation.	(SISOCIAL) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. I have spent too much or lost a lot of money because of my drug use.	(SISPEND) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. I have had an accident while using drugs or intoxicated.	(SIACCDNT) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments:(SIPCOMM)

NIDA Clinical Trials Network

Study Termination (STT)

Web Version: 1.0; 3.00; 05-10-12

1. Date of study completion or last attended study visit:  (mm/dd/yyyy) [Click here for calendar](#)  
(TRTRMDT)

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

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

- 07-Significant psychiatric risk (suicidal, homicidal, psychotic)
- 08-Death
- 09-Administrative discharge
- 10-Other type of clinical deterioration
- 11-Withdrew consent
- \*Additional Options Listed Below

b. Specify type of administrative discharge or other clinical deterioration:(TRTCLNDT)

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

3. Comments:(STTCOMM)

Investigator's Signature

I have reviewed all the data recorded on all CRF pages and certify that they are accurate and complete to the best of my knowledge.

Principal Investigator or designee:(TRPISIGN)

Date:(TRPISGDT)

(mm/dd/yyyy) [Click here for calendar](#)

## **Additional Selection Options for STT**

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

12-Moving from area

13-Practical problems (no childcare, transportation, other)

14-Medical problems (hospitalization, other)

15-Incarceration

16-Pressure or advice from outsiders

17-Feels treatment no longer necessary, cured

18-Feels treatment no longer necessary, not working

19-Failed to return to clinic and unable to contact

99-Participant terminated for other reason

## NIDA Clinical Trials Network

### Thoughts About Abstinence - Alcohol (TAA)

Web Version: 1.0; 1.00; 05-10-12

Segment (PROTSEG):

Visit Number (VISNO):

Date of assessment:(TAAASMDT)

(mm/dd/yyyy) [Click here for calendar](#)

#### Section I

This section asks about how you feel about **stopping all alcohol use** at this time in your life. On the scales below, check the number that best represents how you feel about **stopping**, how **successful** you will be, and **how you will do** after you quit.

1. Have you consumed alcohol in the past 90 days?(TAUSAL90)  No  Yes

2. Using the scale below, how would you describe your **desire to quit using alcohol** at this time in your life?

<b>No Desire to Quit</b>										<b>Greatest Desire to Quit</b>
0	1	2	3	4	5	6	7	8	9	
(TADESRT) <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. Using the scale below, how would you describe **how successful you expect** to be in quitting?

<b>Very Low Chance of Success</b>										<b>Very High Chance of Success</b>
0	1	2	3	4	5	6	7	8	9	
(TASUFLQT) <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. Using the scale below, how would you describe how **difficult** it will be **to keep from using alcohol** at this time in your life?

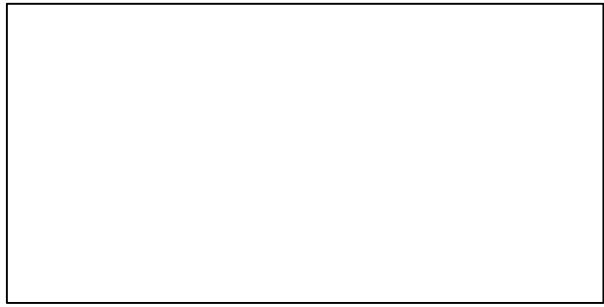
<b>Very EASY</b>										<b>Very DIFFICULT</b>
0	1	2	3	4	5	6	7	8	9	
(TADFCLQT) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

#### Section II

Please read the goals listed below, and choose which goal represents your own goal at this time. Please read all of them before you pick one. What is the **GOAL** you have chosen for yourself about using alcohol at this time?

- (TAAUB1) **No clear goal** I really don't have a clear goal in mind.
- (TAAUB2) **Controlled use** I want to use in a controlled manner - to be able to be in control of how often I use and how much I use.
- (TAAUB3) **New decision** I want to be totally abstinent from all use for a period of time, after which I will make a new decision about whether or not I will use again in any way.
- (TAAUB4) **Occasional use** I don't want using to be a habit for me, but I would like to be able to occasionally use when I really have the urge.
- (TAAUB5) **I may slip** I want to quit using once and for all, even though I realize I may slip and use once in a while.
- (TAAUB6) **Quit completely** I want to quit using once and for all, to be totally abstinent, and never use ever again for the rest of my life.
- (TAAUB7) **None of the above** None of the above applies exactly to me. My own goal is:(TAGOALSP) \_\_\_\_\_

Comments (TAACOMM)





## 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. Have any illicit substances or alcohol been taken during this assessment period? (*TASUBALC*)

No  Yes

4. Have any nicotine products been used during this assessment period? (*TANICOTN*)

No  Yes

## NIDA Clinical Trials Network

### Thoughts About Abstinence - Drugs (TDR)

Web Version: 1.0; 1.00; 05-11-12

Segment (PROTSEG):

Visit Number (VISNO):

Date of assessment:(TDRASMDT)

(mm/dd/yyyy) [Click here for calendar](#)

#### Section I

This section asks about how you feel about **stopping all drug use** at this time in your life. On the scales below, check the number that best represents how you feel about **stopping**, how **successful** you will be, and **how you will do** after you quit.

1. Have you used drugs in the past 90 days?(TDUSDR90)  No  Yes

2. Using the scale below, how would you describe your **desire to quit using drugs** at this time in your life?

<b>No Desire to Quit</b>											<b>Greatest Desire to Quit</b>
0	1	2	3	4	5	6	7	8	9		
(TDESRQT) <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"/>	<input type="checkbox"/>

3. Using the scale below, how would you describe **how successful you expect** to be in quitting?

<b>Very Low Chance of Success</b>											<b>Very High Chance of Success</b>
0	1	2	3	4	5	6	7	8	9		
(TDSUFLQT) <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"/>	<input type="checkbox"/>

4. Using the scale below, how would you describe how **difficult** it will be **to keep from using drugs** at this time in your life?

<b>Very EASY</b>											<b>Very DIFFICULT</b>
0	1	2	3	4	5	6	7	8	9		
(TDDFCLQT) <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"/>	<input type="checkbox"/>

#### Section II

Please read the goals listed below, and choose which goal represents your own goal at this time. Please read all of them before you pick one.

What is the **GOAL** you have chosen for yourself about using drugs at this time?

(TDUB1) **No clear goal** I really don't have a clear goal in mind.

(TDUB2) **Controlled use** I want to use in a controlled manner - to be able to be in control of how often I use and how much I use.

(TDUB3) **New decision** I want to be totally abstinent from all use for a period of time, after which I will make a new decision about whether or not I will use again in any way.

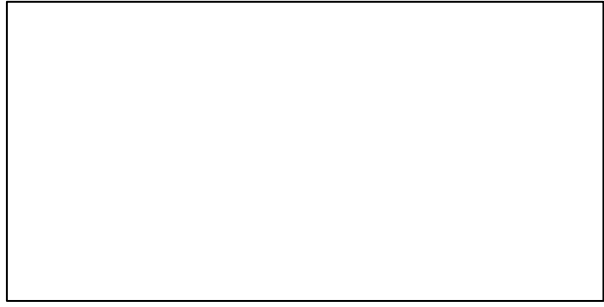
(TDUB4) **Occasional use** I don't want using to be a habit for me, but I would like to be able to occasionally use when I really have the urge.

(TDUB5) **I may slip** I want to quit using once and for all, even though I realize I may slip and use once in a while.

(TDUB6) **Quit completely** I want to quit using once and for all, to be totally abstinent, and never use ever again for the rest of my life.

(TDUB7) **None of the above** None of the above applies exactly to me. My own goal is:(TDGOALSP)

Comments(*TDRCOMM*)



# 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 nicotine products been used on this day?(TFNICOTN)  No  Yes

2. Cigarettes:(TFCIGRTS)  No  Yes

a. Number of cigarettes per day:(TFNMCIGS)  (xx)

3. Other Tobacco:(TFOTHTOB)  No  Yes

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

5. Alcohol:(TFALCOHL)  No  Yes

a. Number of standard drinks:(TFNMDRINK)  (xx)

6. Cannabinoids/Marijuana:(TFCANNAB)  No  Yes

a. Number of joints or joint equivalents smoked:(TFNMJNTS)  (xx)

7. Cocaine:(TFCOCAIN)  No  Yes

a. Route 1:(TFCOCROU)

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

b. Amount used 1:(TFCOCUS1)

(xxxx) Units:(TFCOCUNT)

- 1-01- 1 hour
- 2-02- 2-3 hours
- 3-03- 4-5 hours
- 4-04- 6-7 hours
- 5-05- 8-9 hours
- \*Additional Options Listed Below

- 1-01-Rocks (\$10)
- 2-02-Grams
- 3-03-Milligrams

Length:(TFCOCLN1)

c. Route 2:(TFCOCRO2)

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

d. Amount used 2:(TFCOCUS2)

(xxxx) Units:(TFCOCUN2)

- 1-01- 1 hour
- 2-02- 2-3 hours
- 3-03- 4-5 hours
- 4-04- 6-7 hours
- 5-05- 8-9 hours
- \*Additional Options Listed Below

- 1-01-Rocks (\$10)
- 2-02-Grams
- 3-03-Milligrams

Length:(TFCOCLN2)

8. 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
---

9. Methamphetamine: (TFMETAMP)

a. Route: (TFMETROU)

No  Yes

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

10. Oxycodone/Oxycontin: (TFOXYCOD)

a. Route: (TFOXYROU)

No  Yes

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

11. Methadone: (TFMETHAD)

a. Route: (TFMTHROU)

No  Yes

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

12. Opiates: (TFOPIATE)

a. Route: (TFOPIROU)

No  Yes

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

13. Ecstasy (MDMA): (TFECSTAS)

a. Route: (TFECSROU)

No  Yes

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

14. Barbiturates: (TFBARBIT)

a. Route: (TFBARROU)

No  Yes

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

15. Benzodiazepines: (TFBENZOD)

a. Route: (TFBENROU)

No  Yes

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

16. Other drugs: (TFO THDRG)

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**

**Length:**

6-06- 10-12 hours

7-07- more than 12 hours



## NIDA Clinical Trials Network

### Treatment Tracking (TTR)

Web Version: 1.0; 2.00; 02-13-13

**Segment (PROTSEG):**

**Study week number (TTRWKNM):**

Week start date: (TTWKSTDT)  (mm/dd/yyyy) Week end date: (TTWENDDT)  (mm/dd/yyyy)

Please record the number of hours that the participant was scheduled to attend treatment and the number of treatment hours actually attended during the study week.

**INPATIENT/RESIDENTIAL SERVICES:**

1. Did the participant utilize inpatient/residential services?(TTRESDNT)  No  Yes

Service Type	Scheduled Hours	Actual Hours
Detox	a. (TTIDTSCH) <input type="text"/> (xxx.x)	b. (TTIDTACT) <input type="text"/> (xxx.x)
Individual	c. (TTIIDSCH) <input type="text"/> (xxx.x)	d. (TTIIDACT) <input type="text"/> (xxx.x)
Group	e. (TTIGPSCH) <input type="text"/> (xxx.x)	f. (TTIGPACT) <input type="text"/> (xxx.x)
Case management	g. (TTICMSCH) <input type="text"/> (xxx.x)	h. (TTICMACT) <input type="text"/> (xxx.x)
Total inpatient/residential services	i. (TTINPSCH) <input type="text"/> (xxx.x)	j. (TTINPACT) <input type="text"/> (xxx.x)

k. Were non-study substance abuse treatment medications provided? (TTIMEDS)  No  Yes

If "Yes", complete the prior and concomitant medication form.

If "Yes", specify:(TTIMEDSP)

Complete the following questions **once for each inpatient/residential treatment stay:**

l. Date of admission to inpatient/residential program:(TTINADDT)  (mm/dd/yyyy) [Click here for calendar](#)

m. Date of discharge from inpatient/residential program:(TTINDSDT)  (mm/dd/yyyy) [Click here for calendar](#)

**OUTPATIENT/IOP SERVICES:**

2. Did the participant utilize outpatient/IOP services?(TTOUPAT)  No  Yes

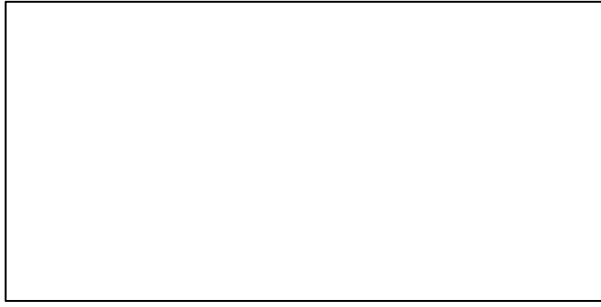
Service Type	Scheduled Hours	Actual Hours
Detox	a. (TTOOTSCH) <input type="text"/> (xxx.x)	b. (TTOOTACT) <input type="text"/> (xxx.x)
Individual	c. (TTOIDSCH) <input type="text"/> (xxx.x)	d. (TTOIDACT) <input type="text"/> (xxx.x)
Group	e. (TTOGPSCH) <input type="text"/> (xxx.x)	f. (TTOGPACT) <input type="text"/> (xxx.x)
Case management	g. (TTOCMSCH) <input type="text"/> (xxx.x)	h. (TTOCMACT) <input type="text"/> (xxx.x)
Total outpatient/IOP services	i. (TTOOTSCH) <input type="text"/> (xxx.x)	j. (TTOOUTACT) <input type="text"/> (xxx.x)

k. Were non-study substance abuse treatment medications provided? (TTOMEDS)  No  Yes

If "Yes", complete the prior and concomitant medication form.

If "Yes", specify:(TTOMEDSP)

Comments:(TTRCOMM)



## Additional Selection Options for TTR

Study week number (*TTRWKNM*) (key field):

1-1  
2-2  
3-3  
4-4  
5-5  
6-6  
7-7  
8-8  
9-9  
10-10  
11-11  
12-12  
13-13  
14-14  
15-15

**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. Was the 1st urine temperature within range? (90 - 100 °F)(UD1TMP)

No  Yes

4. Was the 1st urine specimen determined to be adulterated?(UD1ADULT)

No  Yes

**1st Urine Drug Screen Results**

5.	Drug Name (Abbreviation)	Negative	Positive	Invalid	TLFB Agreement Status
	Benzodiazepines (BZO):	(UD1BZO) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	(UD1BZOAG) 1-UDS agrees with initial TLFB data 2-UDS disagrees with initial TLFB data; pptchallenged; pptchanged TLFB 3-UDS disagrees with initial TLFB data; pptchallenged; pptdid notchange TLFB 4-UDS disagrees with initial TLFB data; pptwas NOT challenged
	Amphetamine (AMP):	(UD1AMP) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	(UD1AMPAG) 1-UDS agrees with initial TLFB data 2-UDS disagrees with initial TLFB data; pptchallenged; pptchanged TLFB 3-UDS disagrees with initial TLFB data; pptchallenged; pptdid notchange TLFB 4-UDS disagrees with initial TLFB data; pptwas NOT challenged
	Marijuana (THC):	(UD1THC) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	(UD1THCAG) 1-UDS agrees with initial TLFB data 2-UDS disagrees with initial TLFB data; pptchallenged; pptchanged TLFB 3-UDS disagrees with initial TLFB data; pptchallenged; pptdid notchange TLFB 4-UDS disagrees with initial TLFB data; pptwas NOT challenged
	Methamphetamine (MET):	(UD1MET) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	(UD1METAG) 1-UDS agrees with initial TLFB data 2-UDS disagrees with initial TLFB data; pptchallenged; pptchanged TLFB 3-UDS disagrees with initial TLFB data; pptchallenged; pptdid notchange TLFB 4-UDS disagrees with initial TLFB data; pptwas NOT challenged
	Opiates (2000 ng) (OPI):	(UD1OPI) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	(UD1OPIAG) 1-UDS agrees with initial TLFB data 2-UDS disagrees with initial TLFB data; pptchallenged; pptchanged TLFB 3-UDS disagrees with initial TLFB data; pptchallenged; pptdid notchange TLFB 4-UDS disagrees with initial TLFB data; pptwas NOT challenged
	Cocaine (COC):	(UD1COC) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	(UD1COCAG)

				1-UJS agrees with initial T L F B data 2-UJS disagrees with initial T L F B data; pptchallenged; pptchanged T LFB 3-UJS disagrees with initial T L F B data; pptchallenged; pptdid notchange T LFB 4-UJS disagrees with initial T L F B data; pptwas NOT challenged
Ecstasy (MDMA):	(UD1MDMA) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	(UD1MDMAG) 1-UJS agrees with initial T L F B data 2-UJS disagrees with initial T L F B data; pptchallenged; pptchanged T LFB 3-UJS disagrees with initial T L F B data; pptchallenged; pptdid notchange T LFB 4-UJS disagrees with initial T L F B data; pptwas NOT challenged
Oxycodone (OXY):	(UD1OXY) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	(UD1OXYAG) 1-UJS agrees with initial T L F B data 2-UJS disagrees with initial T L F B data; pptchallenged; pptchanged T LFB 3-UJS disagrees with initial T L F B data; pptchallenged; pptdid notchange T LFB 4-UJS disagrees with initial T L F B data; pptwas NOT challenged
Methadone (MTD):	(UD1MTD) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	(UD1MTDAG) 1-UJS agrees with initial T L F B data 2-UJS disagrees with initial T L F B data; pptchallenged; pptchanged T LFB 3-UJS disagrees with initial T L F B data; pptchallenged; pptdid notchange T LFB 4-UJS disagrees with initial T L F B data; pptwas NOT challenged
Barbiturate (BAR):	(UD1BAR) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	(UD1BARAG) 1-UJS agrees with initial T L F B data 2-UJS disagrees with initial T L F B data; pptchallenged; pptchanged T LFB 3-UJS disagrees with initial T L F B data; pptchallenged; pptdid notchange T LFB 4-UJS disagrees with initial T L F B data; pptwas NOT challenged

## 2nd Urine Drug Screen

6. 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)

7. Was the 2nd urine temperature within range? (90 - 100 °F)(UD2TMP)

No  Yes

8. Was the 2nd urine specimen determined to be adulterated?(UD2ADULT)

No  Yes

## 2nd Urine Drug Screen Results

Drug Name (Abbreviation)	Negative	Positive	Invalid	TLFB Agreement Status
Benzodiazepines (BZO):	(UD2BZO) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	(UD2BZOAG) 1-UJS agrees with initial T L F B data 2-UJS disagrees with initial T L F B data; pptchallenged; pptchanged T LFB 3-UJS disagrees with initial T L F B data; pptchallenged; pptdid notchange T LFB 4-UJS disagrees with initial T L F B data; pptwas NOT challenged
Amphetamine (AMP):	(UD2AMP) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	(UD2AMPAG) 1-UJS agrees with initial T L F B data 2-UJS disagrees with initial T L F B data; pptchallenged; pptchanged T LFB 3-UJS disagrees with initial T L F B data; pptchallenged; pptdid notchange T LFB 4-UJS disagrees with initial T L F B data; pptwas NOT challenged
Marijuana (THC):	(UD2THC) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	(UD2THCAG) 1-UJS agrees with initial T L F B data 2-UJS disagrees with initial T L F B data; pptchallenged; pptchanged T LFB 3-UJS disagrees with initial T L F B data; pptchallenged; pptdid notchange T LFB 4-UJS disagrees with initial T L F B data; pptwas NOT challenged

Methamphetamine (MET):	(UD2MET) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	(UD2METAG) 1-UDS agrees with initial T L F B data 2-UDS disagrees with initial T L F B data; pptchallenged; pptchanged T L F B 3-UDS disagrees with initial T L F B data; pptchallenged; pptdid notchange T L F B 4-UDS disagrees with initial T L F B data; pptwas NOT challenged
Opiates (2000 ng) (OPI):	(UD2OPI) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	(UD2OPIAG) 1-UDS agrees with initial T L F B data 2-UDS disagrees with initial T L F B data; pptchallenged; pptchanged T L F B 3-UDS disagrees with initial T L F B data; pptchallenged; pptdid notchange T L F B 4-UDS disagrees with initial T L F B data; pptwas NOT challenged
Cocaine (COC):	(UD2COC) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	(UD2COCAG) 1-UDS agrees with initial T L F B data 2-UDS disagrees with initial T L F B data; pptchallenged; pptchanged T L F B 3-UDS disagrees with initial T L F B data; pptchallenged; pptdid notchange T L F B 4-UDS disagrees with initial T L F B data; pptwas NOT challenged
Ecstasy (MDMA):	(UD2MDMA) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	(UD2MDMAG) 1-UDS agrees with initial T L F B data 2-UDS disagrees with initial T L F B data; pptchallenged; pptchanged T L F B 3-UDS disagrees with initial T L F B data; pptchallenged; pptdid notchange T L F B 4-UDS disagrees with initial T L F B data; pptwas NOT challenged
Oxycodone (OXY):	(UD2OXY) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	(UD2OXYAG) 1-UDS agrees with initial T L F B data 2-UDS disagrees with initial T L F B data; pptchallenged; pptchanged T L F B 3-UDS disagrees with initial T L F B data; pptchallenged; pptdid notchange T L F B 4-UDS disagrees with initial T L F B data; pptwas NOT challenged
Methadone (MTD):	(UD2MTD) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	(UD2MTDAG) 1-UDS agrees with initial T L F B data 2-UDS disagrees with initial T L F B data; pptchallenged; pptchanged T L F B 3-UDS disagrees with initial T L F B data; pptchallenged; pptdid notchange T L F B 4-UDS disagrees with initial T L F B data; pptwas NOT challenged
Barbiturate (BAR):	(UD2BAR) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	(UD2BARAG) 1-UDS agrees with initial T L F B data 2-UDS disagrees with initial T L F B data; pptchallenged; pptchanged T L F B 3-UDS disagrees with initial T L F B data; pptchallenged; pptdid notchange T L F B 4-UDS disagrees with initial T L F B data; pptwas NOT challenged

Comments:(UDSCOMM)

# NIDA Clinical Trials Network

## Vital Signs (VIS)

Web Version: 1.0; 3.01; 03-12-13

Segment (PROTSEG):

Visit Number (VISNO):

Date of assessment:(VISASMDT)

(mm/dd/yyyy) [Click here to view calendar](#)

1. Blood pressure (reading 1):(VIBPYS1)

Systolic / (VIBPDIS1)  Diastolic mmHg

2. Heart rate:(VIHEART)

(xxx) BPM

3. Weight:(VIWTLBS)

(xxx) lbs:

4. Height:(VIHIINCH)

in:  (xx)

**If the systolic blood pressure for the first reading is => 140 or <90 OR  
the diastolic blood pressure for the first reading is => 90 or <65  
then wait for five minutes and then repeat the assessment.**

5. Blood pressure (reading 2):(VIBPYS2)

Systolic / (VIBPDIS2)  Diastolic mmHg

*If two blood pressure readings were completed then average the systolic readings and average the diastolic readings and record the averages in the appropriate fields below.*

6. Average blood pressure:(VIBPSYAV)

Systolic / (VIBPDSAV)  Diastolic mmHg

Comments:(VISCOMM)

## NIDA Clinical Trials Network

### WHO Quality of Life - BREF (WQB)

Web Version: 1.0; 1.00; 06-29-12

Segment (*PROTSEG*):

Visit Number (*VISNO*):

Date of assessment: (*WQBASMDT*)

(mm/dd/yyyy) [Click here to view calendar](#)

The following questions ask how you feel about your quality of life, health, or other areas of your life. Please choose the answer that appears most appropriate. If you are unsure about which response to give to a question, the first response you think of is often the best one.

Please keep in mind your standards, hopes, pleasures, and concerns. We ask that you think about your life in the last four weeks.

	Very Poor	Poor	Neither Poor Nor Good	Good	Very Good
1. How would you rate your quality of life?	( <i>WQQUALLF</i> ) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Very Dissatisfied	Dissatisfied	Neither Satisfied Nor Dissatisfied	Satisfied	Very Satisfied
2. How satisfied are you with your health?	( <i>WQHEALTH</i> ) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

The following questions ask about **how much** you have experienced certain things in the last four weeks.

	Not At All	A Little	A Moderate Amount	Very Much	An Extreme Amount
3. To what extent do you feel that physical pain prevents you from doing what you needed to do?	( <i>WQPAINPV</i> ) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. How much do you need medical treatment to function in your daily life?	( <i>WQMEDFACT</i> ) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. How much do you enjoy your life?	( <i>WQENJYLF</i> ) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. To what extent do you feel your life to be meaningful?	( <i>WQMEANLF</i> ) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Not At All	A Little	A Moderate Amount	Very Much	Extremely
7. How well are you able to concentrate?	( <i>WQCONCEN</i> ) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. How safe do you feel in your daily life?	( <i>WQSAFE</i> ) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. How healthy is your physical environment?	( <i>WQENVIRO</i> ) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

The following questions ask about how completely you experience or were able to do certain things in the last four weeks.

	Not At All	A Little	Moderately	Mostly	Completely
10. Do you have enough energy for everyday life?	( <i>WQENERGY</i> ) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Are you able to accept your bodily appearance?	( <i>WQBODYOK</i> ) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Have you enough money to meet your needs?	( <i>WQMONEYK</i> ) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. How available to you is the information that you need in your day-to-day life?	( <i>WQINFOAV</i> ) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. To what extent do you have the opportunity for leisure activities?	( <i>WQBEISUR</i> ) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

	Very Poor	Poor	Neither Poor Nor Good	Good	Very Good
15. How well are you able to get around?	( <i>WQGETARN</i> ) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



	<b>Very Dissatisfied</b>	<b>Dissatisfied</b>	<b>Neither Satisfied Nor Dissatisfied</b>	<b>Satisfied</b>	<b>Very Satisfied</b>
16. How satisfied are you with your sleep?	(WQSLEEPK) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. How satisfied are you with your ability to perform your daily living activities?	(WQACTVOK) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. How satisfied are you with your capacity to work?	(WQWORKOK) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. How satisfied are you with yourself?	(WQSELFOK) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20. How satisfied are you with your personal relationships?	(WQRELATK) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21. How satisfied are you with your sex life?	(WQSEXOK) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22. How satisfied are you with the support you get from your friends?	(WQFRIEND) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23. How satisfied are you with the conditions of your living place?	(WQHOMEOK) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
24. How satisfied are you with your access to health services?	(WQAXSMED) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
25. How satisfied are you with your transport?	(WQTRANSK) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

The following question refers to how often you have felt or experienced certain things in the last four weeks.

	<b>Never</b>	<b>Seldom</b>	<b>Quite Often</b>	<b>Very Often</b>	<b>Always</b>
26. How often do you have negative feelings such as blue mood, despair, anxiety, depression?	(WQNGTFEL) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Comments:(WQBCOMM)