

NIDA Clinical Trials Network

Adverse Events (AD1)

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

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

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

1. Adverse event name: (A1DESCR1)

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

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

3. Severity of event: (A1SEVEVE)

1-Grade 1 - Mild
2-Grade 2 - Moderate
3-Grade 3 - Severe
4-Grade 4 - Life-threatening
5-Grade 5 - Death

4. Relationship to study intervention: (A1RELTB)

1-Unrelated
2-Possibly related
3-Probably related
4-Definitely related

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

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

If "Other," specify: (A1AEBSP)

5. Action taken with study intervention: (A1ACTBI)

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

6. Outcome of event: (A1OUTCM)

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

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

 (mm/dd/yyyy)

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

8. Was this event associated with: (A1ASSOCI)

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

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

 (mm/dd/yyyy)

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

Date of hospital admission:(A1HOSPAD)

(mm/dd/yyyy)

Date of hospital discharge:(A1HOSPDC)

(mm/dd/yyyy)

Comments:(A1COMM)

MedDRA:

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

Preferred Term:(MEDRAPT)

Not Coded

System Organ Class:(MEDRASOC)

Additional Selection Options for AD1

Select Sequence Number (AESEQNUM) (key field):

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

Action taken with study intervention:

- 5- Participant terminated from study

Was this event associated with:

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

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Serious Adverse Event Summary (AD2)

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

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

1. Initial narrative description of serious adverse event:

(A2SUMM)

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

(A2MEDHX)

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

Medication (Generic Name)	Indication
(A2_01DNM) <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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Serious Adverse Event Medical Reviewer (AD3)

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

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

- 1. Was this determined to be a serious adverse event?(A3DETER) No Yes
- 2. Was this event considered associated with the study's behavioral intervention? (A3BHINT) No Yes
- 3. Was this event expected?(A3EXPECT) No Yes
- 4. Is this a standard expedited/reportable event? (i.e., is it serious, unexpected and related to therapy)(A3EXPFDA) No Yes
- 5. Is this an expedited/reportable event for other reasons?(A3EXPO TH) 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

Alcohol Breathalyzer (ALB)

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

Segment (PROTSEG):

Visit Number (VISNO):

1. Was an Alcohol Breathalyzer performed? (ABPERFRM)

If "No", specify reason: (ABREASON)

If "Other", specify (AB1OTHSP)

No Yes

Participant refused to provide sample Study staff error Other

2. Date of assessment: (ABASMTDT)

(mm/dd/yyyy)

3. Alcohol Breathalyzer result: (ABRESULT)

(.xxx) mg/mL

4. Is a repeat test required? (ABREPTST)

No Yes

If "Yes", complete the questions below.

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

No Yes

If "No", specify reason: (ABREASN)

Participant refused to provide sample Study staff error Other

If "Other", specify (AB2OTHSP)

b. Repeat test date: (ABREPDT)

(mm/dd/yyyy)

c. Repeat Alcohol Breathalyzer result: (ABREPRES)

(.xxx) mg/mL

Comments: (ALBCOMM)

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Assessment Location Form (ALO)

Web Version: 1.0; 1.00; 07-26-11

Segment (PROTSEG):

Did This Visit Occur?	Visit Location	Comments:
Week 1 Visit 1 (ALVIOCA) 1-Yes 2-Missed Visit 3-Participant terminated from the study	1-Onsite atCTP/Research Office 2-Offsite atParticipants Residence 3-Offsite - OtherLocation 4-Telephone 5-Prison/Jail *Additional Options Listed Below (ALVISA)	(ALVISASP)
Specify Locations: (ALCOMASP)		
Week 1 Visit 2 (ALVIOCB) 1-Yes 2-Missed Visit 3-Participant terminated from the study	1-Onsite atCTP/Research Office 2-Offsite atParticipants Residence 3-Offsite - OtherLocation 4-Telephone 5-Prison/Jail *Additional Options Listed Below (ALVISB)	(ALVISBSP)
Specify Locations: (ALCOMBSP)		
Week 2 Visit 1 (ALVIOCC) 1-Yes 2-Missed Visit 3-Participant terminated from the study	1-Onsite atCTP/Research Office 2-Offsite atParticipant's Residence 3-Offsite - Other Location 4-Telephone 5-Prison/Jail *Additional Options Listed Below (ALVISC)	(ALVISCSP)
Specify Locations: (ALCOMCSP)		
Week 2 Visit 2 (ALVIOCD) 1-Yes 2-Missed Visit 3-Participant terminated from the study	1-Onsite atCTP/Research Office 2-Offsite atParticipant's Residence 3-Offsite - Other Location 4-Telephone 5-Prison/Jail *Additional Options Listed Below (ALVSD)	(ALVSDSP)
Specify Locations: (ALCOMDSP)		
Week 3 Visit 1 (ALVIOCE) 1-Yes 2-Missed Visit 3-Participant terminated from the study	1-Onsite atCTP/Research Office 2-Offsite atParticipants Residence 3-Offsite - OtherLocation 4-Telephone 5-Prison/Jail *Additional Options Listed Below (ALVISE)	(ALVISESP)
Specify Locations: (ALCOMESP)		
Week 3 Visit 2 (ALVIOCF) 1-Yes 2-Missed Visit 3-Participant terminated from the study	1-Onsite atCTP/Research Office 2-Offsite atParticipant's Residence 3-Offsite - Other Location 4-Telephone 5-Prison/Jail *Additional Options Listed Below (ALVISF)	(ALVISFSP)

	Specify Locations: (ALCOMFSP)	
Week 4 Visit 1 (ALVIOCG) 1-Yes 2-Missed Visit 3-Participant terminated from the study	1- Onsite at CTP/Research Office 2- Offsite at Participant's Residence 3- Offsite - Other Location 4- Telephone 5- Prison/Jail *Additional Options Listed Below (ALVISG)	(ALVISGSP)
	Specify Locations: (ALCOMGSP)	
Week 4 Visit 2 (ALVIOCH) 1-Yes 2-Missed Visit 3-Participant terminated from the study	1- Onsite at CTP/Research Office 2- Offsite at Participant's Residence 3- Offsite - Other Location 4- Telephone 5- Prison/Jail *Additional Options Listed Below (ALVISH)	(ALVISHSP)
	Specify Locations: (ALCOMHSP)	
Week 5 Visit 1 (ALVIOCI) 1-Yes 2-Missed Visit 3-Participant terminated from the study	1- Onsite at CTP/Research Office 2- Offsite at Participant's Residence 3- Offsite - Other Location 4- Telephone 5- Prison/Jail *Additional Options Listed Below (ALVISI)	(ALVISISP)
	Specify Locations: (ALCOMISP)	
Week 5 Visit 2 (ALVIOCIJ) 1-Yes 2-Missed Visit 3-Participant terminated from the study	1- Onsite at CTP/Research Office 2- Offsite at Participant's Residence 3- Offsite - Other Location 4- Telephone 5- Prison/Jail *Additional Options Listed Below (ALVISJ)	(ALVISJSP)
	Specify Locations: (ALCOMJSP)	
Week 6 Visit 1 (ALVIOCK) 1-Yes 2-Missed Visit 3-Participant terminated from the study	1- Onsite at CTP/Research Office 2- Offsite at Participant's Residence 3- Offsite - Other Location 4- Telephone 5- Prison/Jail *Additional Options Listed Below (ALVISK)	(ALVISKSP)
	Specify Locations: (ALCOMKSP)	
Week 6 Visit 2 (ALVIOCL) 1-Yes 2-Missed Visit 3-Participant terminated from the study	1- Onsite at CTP/Research Office 2- Offsite at Participant's Residence 3- Offsite - Other Location 4- Telephone 5- Prison/Jail *Additional Options Listed Below (ALVISL)	(ALVISLSP)
	Specify Locations: (ALCOMLSP)	
Week 7 Visit 1 (ALVIOCM) 1-Yes 2-Missed Visit 3-Participant terminated from the study	1- Onsite at CTP/Research Office 2- Offsite at Participant's Residence 3- Offsite - Other Location 4- Telephone 5- Prison/Jail *Additional Options Listed Below (ALVISM)	(ALVISMSP)

	Specify Locations: (ALCOM MSP)	
Week 7 Visit 2 (ALVIOCN) 1-Yes 2-Missed Visit 3-Participant terminated from the study	1-Onsite at CTP/Research Office 2-Offsite at Participant's Residence 3-Offsite - Other Location 4-Telephone 5-Prison/Jail *Additional Options Listed Below (ALVISN)	(ALVISNSP)
	Specify Locations: (ALCOM NSP)	
Week 8 Visit 1 (ALVIOCO) 1-Yes 2-Missed Visit 3-Participant terminated from the study	1-Onsite at CTP/Research Office 2-Offsite at Participant's Residence 3-Offsite - Other Location 4-Telephone 5-Prison/Jail *Additional Options Listed Below (ALVISO)	(ALVISOSP)
	Specify Locations: (ALCOM OSP)	
Week 8 Visit 2 (ALVIOCP) 1-Yes 2-Missed Visit 3-Participant terminated from the study	1-Onsite at CTP/Research Office 2-Offsite at Participant's Residence 3-Offsite - Other Location 4-Telephone 5-Prison/Jail *Additional Options Listed Below (ALVISP)	(ALVISPSP)
	Specify Locations: (ALCOM PSP)	
Week 9 Visit 1 (ALVIOCQ) 1-Yes 2-Missed Visit 3-Participant terminated from the study	1-Onsite at CTP/Research Office 2-Offsite at Participant's Residence 3-Offsite - Other Location 4-Telephone 5-Prison/Jail *Additional Options Listed Below (ALVISQ)	(ALVISQSP)
	Specify Locations: (ALCOM QSP)	
Week 9 Visit 2 (ALVIOCR) 1-Yes 2-Missed Visit 3-Participant terminated from the study	1-Onsite at CTP/Research Office 2-Offsite at Participant's Residence 3-Offsite - Other Location 4-Telephone 5-Prison/Jail *Additional Options Listed Below (ALVISR)	(ALVISRSP)
	Specify Locations: (ALCOM RSP)	
Week 10 Visit 1 (ALVIOCS) 1-Yes 2-Missed Visit 3-Participant terminated from the study	1-Onsite at CTP/Research Office 2-Offsite at Participant's Residence 3-Offsite - Other Location 4-Telephone 5-Prison/Jail *Additional Options Listed Below (ALVISS)	(ALVISSSP)
	Specify Locations: (ALCOM SSP)	
Week 10 Visit 2 (ALVIOCT) 1-Yes 2-Missed Visit 3-Participant terminated from the study	1-Onsite at CTP/Research Office 2-Offsite at Participant's Residence 3-Offsite - Other Location 4-Telephone 5-Prison/Jail *Additional Options Listed Below (ALVIST)	(ALVISTSP)

	Specify Locations: (ALCOM TSP)	
Week 11 Visit 1 (ALVIOCU) 1-Yes 2-Missed Visit 3-Participant terminated from the study	1-Onsite at CTP/Research Office 2-Offsite at Participant's Residence 3-Offsite - Other Location 4-Telephone 5-Prison/Jail *Additional Options Listed Below (ALVISU)	(ALVISUSP)
	Specify Locations: (ALCOM USP)	
Week 11 Visit 2 (ALVIOC V) 1-Yes 2-Missed Visit 3-Participant terminated from the study	1-Onsite at CTP/Research Office 2-Offsite at Participant's Residence 3-Offsite - Other Location 4-Telephone 5-Prison/Jail *Additional Options Listed Below (ALVISV)	(ALVISVSP)
	Specify Locations: (ALCOM VSP)	
Week 12 Visit 1 (ALVIOCW) 1-Yes 2-Missed Visit 3-Participant terminated from the study	1-Onsite at CTP/Research Office 2-Offsite at Participant's Residence 3-Offsite - Other Location 4-Telephone 5-Prison/Jail *Additional Options Listed Below (ALVISW)	(ALVISWSP)
	Specify Locations: (ALCOM WSP)	
Week 12 Visit 2 (ALVIOCX) 1-Yes 2-Missed Visit 3-Participant terminated from the study	1-Onsite at CTP/Research Office 2-Offsite at Participant's Residence 3-Offsite - Other Location 4-Telephone 5-Prison/Jail *Additional Options Listed Below (ALVISX)	(ALVISXSP)
	Specify Locations: (ALCOM XSP)	
Week 12 Monthly Assessment (ALVIOCY) 1-Yes 2-Missed Visit 3-Participant terminated from the study	1-Onsite at CTP/Research Office 2-Offsite at Participant's Residence 3-Offsite - Other Location 4-Telephone 5-Prison/Jail *Additional Options Listed Below (ALVISY)	(ALVISYSP)
	Specify Locations: (ALCOM YSP)	
3MFU (ALVIO CZ) 1-Yes 2-Missed Visit 3-Participant terminated from the study	1-Onsite at CTP/Research Office 2-Offsite at Participant's Residence 3-Offsite - Other Location 4-Telephone 5-Prison/Jail *Additional Options Listed Below (ALVISZ)	(ALVISZSP)
	Specify Locations: (ALCOM ZSP)	
6MFU (ALVIOC1A) 1-Yes 2-Missed Visit 3-Participant terminated from the study	1-Onsite at CTP/Research Office 2-Offsite at Participant's Residence 3-Offsite - Other Location 4-Telephone 5-Prison/Jail *Additional Options Listed Below (ALVIS1A)	(ALVIS1ASP)

	Specify Locations: (ALCO1ASP)	
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	Specify Locations: (ALCO1ASP)	
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Additional Selection Options for ALO

Week 1 Visit 1
6-Combination

NIDA Clinical Trials Network

Brief Symptom Inventory[®] 18 (BSI)

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

Segment (PROTSEG):

Visit Number (VISNO):

Date of assessment:(BSASM TDT)

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

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

Example:

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

How much were you distressed by:

Body aches(BSEXAMPL) 0 = Not at all 1 = A little bit 2 = Moderately 3 = Quite a bit 4 = Extremely

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

NIDA Clinical Trials Network

Counselor Checklist (CCL)

Web Version: 1.0; 1.00; 02-01-10

Segment (PROTSEG):

Date of Assessment (CCASMTDT):

This checklist should be completed each time you meet with a CTN-0044 study participant who is receiving the TES web-based psychosocial intervention. Please answer each question below and return to CTN-0044 study staff.

1. Counselor staff ID: (CCSTFFID)

2. Did you ask this participant about the TES intervention during this session? (CCASKTES)

No Yes

If "No", skip all other questions.

3. Did you discuss specific TES modules with this participant during this session? (CCMODTES)

No Yes

4. Did you discuss or recommend additional TES modules that this participant might complete? (CCADDTES)

No Yes

5. Approximately how many minutes did you discuss the TES intervention with this participant during this session? (CCMINTES)

 (xx) minutes

6. Did you discuss the TES intervention with this participant since your last session (i.e., outside of this individual session)? (CCLSTTES)

No Yes

7. How useful do you think the TES intervention has been to this participant in the past week?

Not useful												Very useful
(CCUSETES)	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7	<input type="checkbox"/> 8	<input type="checkbox"/> 9	<input type="checkbox"/> 10	

Comments/issues: (CCLCOMM)

NIDA Clinical Trials Network

Coping Strategies Scale-Brief Version (CSS)

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

Segment (PROTSEG):

Visit Number (VISNO):

Date of assessment:(CSASMTDT)

(mm/dd/yyyy)

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

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

Comments:(CSSCOMM)

NIDA Clinical Trials Network

0044B (ENR)

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

Randomization

Date of assessment: (RAASMTDT)

(mm/dd/yyyy)

Inclusion Criteria

Check the appropriate response. If any of the inclusion criteria have been answered "No" or "Unknown," the participant is not eligible and cannot be enrolled or randomized into the study.

1. Participant is 18 years or older: (RAPTAGE) No Yes Unknown
2. Participant is enrolled in treatment at the participating CTP: (RAENRTRE) No Yes Unknown
3. Participant has been in the current treatment episode 30 days or less (as of baseline date): (RATRE30D) No Yes Unknown
4. Participant self-reports a substance use problem (alcohol or drugs): (RASRSUB) No Yes Unknown
5. Participant has used drugs within 30 days prior to screening or has exited a controlled environment within 30 days of screening and has used drugs within 60 days prior to screening: (RAUSE30D) No Yes Unknown
6. Participant plans to attend substance abuse treatment at the participating CTP for at least 90 days (as of screening date): (RAPTR90D) No Yes Unknown

Exclusion Criteria

Check the appropriate response. If any of the exclusion criteria have been answered "Yes" or "Unknown," the participant is not eligible and cannot be enrolled or randomized into the study.

7. Participant is prescribed an opioid replacement medication: (RAOPIREP) No Yes Unknown
8. Participant plans to move out of the area in the next 90 days: (RAMOV90D) No Yes Unknown
9. Participant has insufficient ability to provide informed consent: (RAINCSNT) No Yes Unknown
10. Participant lacks sufficient ability to use English to participate in the consent process, the intervention or assessments: (RANOENG) No Yes Unknown

Eligibility for Randomization

11. Is the participant eligible for the study? (RAPTELIG) No Yes
12. Is the participant eligible for randomization? (RAPTRAND) No Yes

a. If "No", please specify: (RANORASP)

1-Failed to return to clinic
2-Declined study participation
3-Death
4-Judgment of CTP/research staff
5-Other

b. If "Judgment of CTP/research staff", please specify: (RAJUDGSP)

c. If "Other", please specify: (RAOTHRSP)

13. Primary substance of abuse: (RAPRIMSU) Stimulant Non-stimulant
14. Baseline urine/breath screen: (RABLURBR) Negative Positive (drugs or alcohol)

Comments: (RACOMM)

NIDA Clinical Trials Network

Fagerstrom Test for Nicotine Dependence (FTN)

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

Segment (PROTSEG):

Visit Number (VISNO):

Date of assessment:(FTASMTDT)

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

Do you currently smoke cigarettes?(FTSMOKE)

No Yes

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

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

If "Other", specify:(FTCESSSP)

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

1. How soon after you wake up do you smoke your first cigarette?(FT1STCIG)

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

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

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

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

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

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

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

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

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

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

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

Comments:(FTNCOMM)

NIDA Clinical Trials Network

Missed Visit Form (MVF)

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

Segment (*PROTSEG*):

Visit Number (*VISNO*):

Missed visit target date: (*MVTRGDT*)

Reason for missed visit: (*MVREASON*)

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

- 1-Participant refused test
- 2-Participant too ill
- 3-Participant missed the study visit
- 4-Unable to contact participant
- 5-Information or sample not obtained
- *Additional Options Listed Below

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

Additional Selection Options for MVF

Reason for missed visit:

6- Procedure or assessment not performed

9- Other

NIDA Clinical Trials Network

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

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

Segment (PROTSEG):

Visit Number (VISNO):

Date of assessment: (NMASTM TDT)

(mm/dd/yyyy)

When did the participant last complete this form? (NMLSTFDT)

(mm/dd/yyyy)

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

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

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

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

- a. How many times did you see a psychiatrist, psychologist, counselor or social worker? (NMVSTDRU) (xxx) times
9. Have you visited a medical office, not including your therapist? (Include all visits to a physician, nurse, nurse practitioner, or physician's assistant.) (NMMEOFF) No Yes
- a. How many visits to a medical office have you had? (NMVSTMED) (xxx) visits
- b. How many of these visits did you see a doctor? (NMMDOCT) (xxx) visits
10. Have you attended AA, NA, or CA meetings? (NMATDANC) No Yes
- a. For how many days? (NMATTDAY) (xxx) days
- b. For how many days? (NMATTDAY) (xxx) days
11. Are you currently prescribed any medication for the treatment of substance abuse? (NMPRMED) No Yes
- a. Which medications have you been prescribed?
- Depot Naltrexone (NMDPTNAL) No Yes
 - Naltrexone (NMNAL TRE) No Yes
 - Suboxone (NMSBOXNE) No Yes
 - Subutex (NMSBTEX) No Yes
 - Methadone (NMMTHDON) No Yes
 - Buprenorphine (NMBUHINE) No Yes
 - Acamprosate (NMACSATE) No Yes
 - Antabuse/Disulfiram (NMA TBDLM) No Yes
 - Other (NMOTHER) No Yes
- If "Other", specify: (NMOTHSPE) _____
- b. How many total days did you take this/these medications? (NMMEDDAY) (xxx) days
- c. How many total days did you take this/these medications? (NMMEDDAY) (xxx)
12. Have you had health insurance? (NMHLTHIN) No Yes
- a. Did you have Medicaid? (NMEDIAI) No Yes
- b. Did you have other public insurance? (NMPUBINS) No Yes
- c. Do you have private health insurance? (NMPRTINS) No Yes
- d. Have you spent time uninsured? (NMTNOINS) No Yes
13. Have you had a job? This includes any job for which you have been paid (including under-the-table work.) (NMWORKIN) No Yes
- a. How many days have you been paid for working? (NMDYSPAD) (xxx) days
- b. How many days have you been paid for working? (NMDYSPAD) (xxx) days
- c. Including overtime, how many hours per week do you work on this job? (NMHRWK) (xxx) hours
- d. Including tips and bonuses, what is your hourly rate on this job, before taxes? (NMHRRATE) (\$\$\$.\$\$) per hour
14. Have you accessed the internet/world wide web, besides any use related to this research study? (NMACCWWW) No Yes
- a. How often did you access the internet? (NMACCFRQ)

- 1-Less than once a week
 2-Once per week
 3-A couple of times per week
 4-Once a day
 5-More than once per day

b. What was the primary purpose of your internet use (select the option that best applies)? (NMACCPRP)

- 1-Work or educational purposes
 2-Information gathering (e.g., directions, instructions)
 3-Recovery-oriented purposes
 4-Recreational (shopping, personal email, chat, games, music, etc.)

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

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

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

	Committed	Charged	Convicted
20. Drug charges (not drug dealing)		(NMDCCCHAR) <input type="checkbox"/> No <input type="checkbox"/> Yes	(NMDCCCONV) <input type="checkbox"/> No <input type="checkbox"/> Yes
21. Drug dealing	(NMDDCOMT) <input type="checkbox"/> No <input type="checkbox"/> Yes	(NMDDCHAR) <input type="checkbox"/> No <input type="checkbox"/> Yes	(NMDDCONV) <input type="checkbox"/> No <input type="checkbox"/> Yes

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

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

Comments: (NMSCOMM)

NIDA Clinical Trials Network

Participant Feedback (PFB)

Web Version: 1.0; 1.00; 08-04-10

Segment (PROTSEG):

Visit Number (VISNO):

Date of assessment:(PFASMTDT)

(mm/dd/yyyy)

Please check one number along the scale that you think most **honestly** answers the question. When answering these questions, please think about the counseling and education you are receiving from **this substance abuse treatment program** (do not include anything you've received as part of the research study).

1. How **interesting** are the counseling and education that you are receiving from this substance abuse treatment program?

Not interesting											Very interesting
(PFINTPRG)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7	<input type="checkbox"/> 8	<input type="checkbox"/> 9	<input type="checkbox"/> 10	

2. How **useful** are the counseling and education that you are receiving from this substance abuse treatment program?

Not useful											Very useful
(PFUSEPRG)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7	<input type="checkbox"/> 8	<input type="checkbox"/> 9	<input type="checkbox"/> 10	

3. How much **new information** are you learning as a result of the counseling and education that you are receiving from this substance abuse treatment program?

None											A great deal
(PFNEWPRG)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7	<input type="checkbox"/> 8	<input type="checkbox"/> 9	<input type="checkbox"/> 10	

4. How **easy to understand** are the counseling and education that you are receiving from this substance abuse treatment program?

Very easy											Very difficult
(PFESYPRG)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7	<input type="checkbox"/> 8	<input type="checkbox"/> 9	<input type="checkbox"/> 10	

5. How **satisfied are you** with the substance abuse treatment you are receiving from this program?

Not at all satisfied											Very satisfied
(PFSA TPRG)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7	<input type="checkbox"/> 8	<input type="checkbox"/> 9	<input type="checkbox"/> 10	

Please provide any additional **comments** you have about the counseling and education you are receiving from this substance abuse treatment program:
(PFCOMPRG)

--

Please list any **suggestions** you might have for how to improve the counseling and education you are receiving from this substance abuse treatment program:
(PFSUGPRG)

--

Please check one number along the scale that you think most **honestly** answers the question. When answering these questions, please think about the counseling and education you are receiving only from **the computerized system (TES)** that is part of this research study.

1. How **interesting** are the counseling and education that you are receiving from the computerized system?

Not interesting												Very interesting
(PFINTTES)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7	<input type="checkbox"/> 8	<input type="checkbox"/> 9	<input type="checkbox"/> 10		

2. How **useful** are the counseling and education that you are receiving from the computerized system?

Not useful												Very useful
(PFUSETES)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7	<input type="checkbox"/> 8	<input type="checkbox"/> 9	<input type="checkbox"/> 10		

3. How much **new information** are you learning as a result of the counseling and education that you are receiving from the computerized system?

None												A great deal
(PFNEWTES)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7	<input type="checkbox"/> 8	<input type="checkbox"/> 9	<input type="checkbox"/> 10		

4. How **easy to understand** are the counseling and education that you are receiving from the computerized system?

Very easy												Very difficult
(PFESYTES)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7	<input type="checkbox"/> 8	<input type="checkbox"/> 9	<input type="checkbox"/> 10		

5. How **satisfied are you** with the computerized system you are receiving as part of this research study?

Not at all satisfied												Very satisfied
(PFSATTES)	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7	<input type="checkbox"/> 8	<input type="checkbox"/> 9	<input type="checkbox"/> 10		

Please provide any additional **comments** you have about the counseling and education you are receiving from the computerized system as part of this research study:(PFCOMTES)

Please list any **suggestions** you might have for how to improve the counseling and education you are receiving from this computerized system:(PFSUGTES)

Comments:(PFBCOMM)

NIDA Clinical Trials Network

Protocol Violation Log (PVL)

Web Version: 1.0; 3.03; 08-29-12

Date of Violation (PVDATE):

Protocol Violation Number (PVSEQNUM):

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

1. Violation type: (PVTYPE44)

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

If "Other" is indicated, provide the specification: (PVTSP44)

2. Description of violation: (PVDESC)

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

No Yes

Protocol violation resolution and corrective action:
(PVRSCASP)

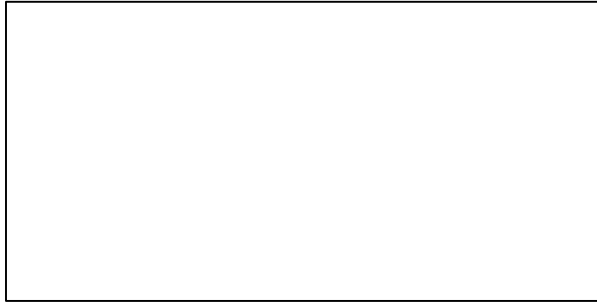
4. Does this protocol violation require IRB reporting? (PVIRB)

No Yes

If "Yes", provide date reported: (PVIRBDT)

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

Comments:(PVLCOMM)



Additional Selection Options for PVL

Protocol Violation Number (PVSEQNUM) (key field):

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

Violation type:

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

NIDA Clinical Trials Network

EuroQoL Questionnaire (QOL)

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

Segment (PROTSEG):

Visit Number (VISNO):

1. Date of assessment:(QOASMTDT)

(mm/dd/yyyy)

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

2. Mobility:(QOMOBIL)

1-I have no problems in walking about
2-I have some problems in walking about
3-I am confined to bed

3. Self-care:(QOSLFCAR)

1-I have no problems with self-care
2-I have some problems washing or dressing myself
3-I am unable to wash or dress myself

4. Usual activities (e.g., work, study, housework, family or leisure activities):
(QOACTIVE)

1-I have no problems with performing my usual activities
2-I have some problems with performing my usual activities
3-I am unable to perform my usual activities

5. Pain/discomfort:(QOPAIN)

1-I have no pain or discomfort
2-I have some pain or discomfort
3-I have extreme pain or discomfort

6. Anxiety/depression:(QOANXDEP)

1-I am not anxious or depressed
2-I am moderately anxious or depressed
3-I am extremely anxious or depressed

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

7. Health state today:(QOHLTHST)

(xxx)

Comments:(QOLCOMM)

NIDA Clinical Trials Network

Risk Behaviors Survey (RBS)

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

Segment (PROTSEG):

Visit Number (VISNO):

Date of assessment:(RBASMTDT)

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

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

C Sexual Activity

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

1. During the last 30 days, with how many people did you have vaginal, oral, or anal sex?(RBNBSXPT) (xxx)

If none, enter 0 and end questionnaire

2. How many of your partners were female?(RBNBFEPT) (xxx)

Number cannot exceed total number of people [question C1]

3. How many of your partners were male?(RBNBMAPT) (xxx)

Number cannot exceed total number of people [question C1]

4. **Interviewer:** Code gender of respondent.(RBRGNDR) Male Female Don't know

If Male, complete sections D, E, F, G and I.

If Female, complete sections D, G, H, and I.

If Don't Know, ask ALL sex/gender specific questions and allow client to answer as they like.

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

1. How many women performed oral sex ("went down") on you?(RBNBORFW) (xxx)

If 0, then skip to question D4. Number cannot exceed total number of female partners [question C2]

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

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

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

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

4. How many women did you perform oral sex ("go down") on?(RBNBOROW) (xxx)

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

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

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

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

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

E Ask Male/Gender Unknown Clients who had Female Partners

1. How many women have you had vaginal sex with?(RBNBVAWW) (xxx)

If 0, then skip to question E4. Number cannot exceed total number of female partners [question C2]

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

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

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

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

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

(xxx)

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

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

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

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

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

F Ask Male/Gender Unknown Clients who had Male Partners

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

(xxx)

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

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

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

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

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

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

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

(xxx)

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

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

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

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

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

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

(xxx)

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

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

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

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

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

H Ask Female/Gender Unknown Clients who had Male Partners

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

(xxx)

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

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

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

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

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

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

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

(xxx)

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

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

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

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

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

Comments:(RBSCOMM)

Additional Selection Options for RBS

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

6-2-3 times a day

7-4 or more times a day

99-Don't know/unsure

98-Refused

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

99-Don't know/unsure

98-Refused

NIDA Clinical Trials Network

Social Adjustment Scale-Self Report (SAS)

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

Segment (PROTSEG):

Visit Number (VISNO):

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

Date of assessment:(SAASMTDT)

(mm/dd/yyyy)

A. Work for Pay

Do you work 15 hours or more per week for pay?(SAWRK15H)

No Yes

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

1. How many days did you miss from work in the past 2 weeks? (SADAYMIS)

1-I didn't miss any days
2-I missed one day
3-I missed about half the time
4-I missed more than half the time but did work at least 1 day
5-I did not work any days
*Additional Options Listed Below

Did you work any days in the last 2 weeks?

If **YES**, please answer questions 2 through 6. If **NO**, skip to section B. Housework (unpaid).

2. How well have you been able to do your work in the last 2 weeks?
(SAABLWRK)

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

3. How often have you been ashamed of how you did your work in the last 2 weeks?
(SAASHWRK)

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

4. Have you had any arguments with people at work in the last 2 weeks?
(SAARGWRK)

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

5. How often have you felt upset, worried, or uncomfortable while doing your work during the last 2 weeks?
(SAUPSWRK)

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

6. How often have you found your work interesting these last 2 weeks?
(SAINTWRK)

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

B. Housework (unpaid)

Is unpaid housework a significant activity in your life? (SAHHUPAD)

No Yes

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

C. Student

Do you attend school at least half-time?(SASCATHT)

No Yes

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

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

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

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

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

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

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

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

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

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

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

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

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

D. Social and Leisure

Everyone please answer questions 19 through 27.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

No Yes

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

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

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

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

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

E. Family Outside the Home

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

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

No Yes

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

F. Primary Relationship

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

No Yes

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

G. Parental

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

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

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

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

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

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

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

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

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

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

H. Family Unit

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

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

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

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

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

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

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

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

Everyone please answer question 54.

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

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

Thank you for your participation.

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Additional Selection Options for SAS

How many days did you miss from work in the past 2 weeks?

8-I did not work any days because of scheduled vacation

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

8-I was away from home all of the last 2 weeks

How many days of classes did you miss in the past 2 weeks?

6-I was on vacation all of the last 2 weeks

Have you had any arguments with people at school in the last 2 weeks?

99-Not applicable: I did not attend school

How often have you felt upset at school during the last 2 weeks?

99-Not applicable: I did not attend school

How often have you been able to talk about your feelings and problems with one of your friends during the last 2 weeks?

99-Not applicable: I have no friends

Have you had any open arguments with your friends in the last 2 weeks?

99-Not applicable: I have no friends

If your feelings were hurt or offended by a friend during the last 2 weeks, how did you take it?

99-Not applicable: I have no friends

How often have you felt shy or uncomfortable with people in the last 2 weeks?

99-Not applicable: I was never with people during the last two weeks

Have you had any problems during sex, such as pain, these last 2 weeks?

99-Not applicable: No sex in the last 2 weeks

How have you felt about sex during the last 2 weeks?

99-Not applicable: No sex in the last 2 weeks

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

99-Not applicable: No children over the age of 2

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

99-Not applicable: Partner and children not living

NIDA Clinical Trials Network

Study Intervention Termination (SIT)

Web Version: 1.0; 1.00; 02-18-11

1. Date of assessment:(*SIASMTDT*)

 (mm/dd/yyyy)

2. Did the participant complete the study intervention (i.e., did not drop out/terminate early)?(*SISTYINT*)

 No Yes

a. Reason for not completing study intervention (please answer all questions):

1. Was the participant incarcerated?(*SIINCARC*)

 No Yes

2. Was the participant discharged from the treatment program, not due to incarceration?(*SIDISCHA*)

 No Yes

3. Did the participant withdraw consent?(*SICONSNT*)

 No Yes

4. Did the participant die?(*SIDEATH*)

 No Yes

5. Did the participant terminate for some other reason?(*SITERMIN*)

 No Yes

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

Comments:(*SITCOMM*)

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)

- 01-Participant incarcerated for duration of study
- 02-Participant terminated for clinical reasons
- 03-Participant terminated due to AE/SAE
- 04-Participant withdrew consent
- 05-Participant died
- *Additional Options Listed Below

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:

06-Participant terminated due to protocol violation

99-Participant terminated for other reason

NIDA Clinical Trials Network

TLFB Assessment Period (TAP)

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

Segment (*PROTSEG*):

Visit Number (*VISNO*):

1. Date of assessment: (*TAASMTDT*)

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

2. Assessment period: (*TATFSTDT*)

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

(*TATFENDT*)

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

3. Was this assessment period reconstructed due to a missed visit? (*TARECON*)

No Yes

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

No Yes

5. Number of days within the past week on which urge, desire, or craving for any substance (drugs or alcohol) occurred: (*TANMURDY*)

(x)

6. How strong was the urge? How hard was it to resist? (Select only one): (*TAURGSTR*)

- 0-None
- 1-Mild urges, easily resisted
- 2-Moderate urges, requiring effort to resist
- 3-Strong urges to use, difficult to resist
- 4-Severe, usually impossible to resist urges

NIDA Clinical Trials Network

Time Line Follow Back (TFB)

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

Segment (PROTSEG):
TLFB Date (TFASMTDT):

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

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

3. Cannabinoids/Marijuana:(TFCANNAB)
a. Route:(TFCANROU) No Yes

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

4. Cocaine:(TFCOCAIN)
a. Route:(TFCOCROU) No Yes

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

5. Amphetamines:(TFAMPHET)
a. Route:(TFAMPROU) No Yes

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

6. Methamphetamine:(TFMETAMP)
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

7. 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

8. 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

9. 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

10. 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

11. 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

12. 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

13. Other drugs:(TFOTHDRG)

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

No Yes

(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)

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Additional Selection Options for TFB

Route:
99-99-Other

NIDA Clinical Trials Network

Treatment-as-Usual Tracking Form (TTF)

Web Version: 1.0; 2.00; 09-15-10

Segment (PROTSEG):

Visit Number (VISNO):

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

This form should be completed by research staff for each participant at the end of each visit week during the treatment phase. Use documentation from the participant's CTP Clinical Chart. Only document attendance considered treatment-as-usual within the CTP (do not include participation in TES).

2. Treatment week (inclusive dates): (TTTRSTDY) (mm/dd/yyyy) to (TTTRENDY) (mm/dd/yyyy)

3. Total days of treatment attendance: (TTNMTRAT) (xx) day(s)

4. Number of group sessions attended: (TTNMGRAT) (xx.xx) group(s)

a. How many of these groups were related to HIV prevention education? (TTNMHIV) (xx) group(s)

b. How many of these groups were related primarily to mental health issues/co-occurring disorders? (TTNMHLTH) (xx) group(s)

c. Total hours of group session(s) attendance: (TTHRSGRP) (xx.xx) hours

5. Number of on-site 12-step meetings attended as part of TAU: (TTNM12ST) (xx) meeting(s)

6. Number of individual sessions with clinical staff attended: (TTNMCLIN) (xx) session(s)

a. How many of these individual sessions were related primarily to mental health? (TTNMIMH) (xx) session(s)

b. How many of these individual sessions were related primarily to medication management/psychopharmacology? (TTNMIPPP) (xx) session(s)

c. Total hours of individual session(s) attendance: (TTHRSIND) (xx.xx) hours

7. Date of last face-to-face contact: (TTLS TCDT) (mm/dd/yyyy)

Comments: (TTFCOMM)

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)

a. If "No", provide reason:(UD1NCLRS)

b. If "Other", specify:(UD1NOCSP)

No Yes

- 1-Participant reported being unable to provide sample
- 2-Participant refused to provide sample
- 3-Staff error
- 9-Other

1st Urine Drug Screen

2. Date 1st urine specimen collected:(UDCOLDT)

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

3. Time 1st urine specimen collected (24 hour format):(UD1COLTM)

(hh:mm)

4. Was the 1st urine drug screen observed?(UD1OBS)

No Yes

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

No Yes

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

No Yes

1st Urine Drug Screen Results

7. Drug Name (Abbreviation)	Negative	Positive	Invalid
Benzodiazepines (BZO):	(UD1BZO) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Amphetamine (AMP):	(UD1AMP) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Marijuana (THC):	(UD1THC) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Methamphetamine (MET):	(UD1MET) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Opiates (2000 ng) (OPI):	(UD1OPI) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cocaine (COC):	(UD1COC) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ecstasy (MDMA):	(UD1MDMA) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Oxycodone (OXY):	(UD1OXY) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Methadone (MTD):	(UD1MTD) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Barbiturate (BAR):	(UD1BAR) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2nd Urine Drug Screen

8. If the 1st urine specimen was determined to be adulterated, was a second specimen collected?(UD2COLNY)

No Yes

a. If "No", provide reason:(UD2NCLRS)

- 1-Participant reported being unable to provide sample
- 2-Participant refused to provide sample
- 3-Staff error
- 9-Other

b. If "Other", specify:(UD2NOCSP)

9. Time 2nd urine specimen collected (24 hour format):(UD2COLTM)

(hh:mm)

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

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

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

2nd Urine Drug Screen Results

13.

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

Comments:(UDSCOMM)