NIDA Clinical	Trials	Networ	٢k
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Adverse Events (AD1)

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

	Adverse Events (ADT)
Adverse Event Onset Date (AEDATE): Select Sequence Number (AESEQNUM):	
The following AEs do not require reporting in the data system: Grade 1 (mild) and 0	Grade 2 (moderate) Unrelated Events.
1. Adverse event name:(A1DESCRI)	
2. Date site became aware of the event: (A1AWARDT)	(mm/dd/yyyy) Click here to view calendar
3. Severity of event:(A 1SEVEVE)	1-Grade 1 - Mild 2-Grade 2 - Moderate 3-Grade 3 - S evere 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:(A 1ALTEB)	O-None apparent 1-S tudy disease 2-C oncomitant medication 3-O ther pre-existing disease or condition 4-Accident, trauma, or external factors *Additional O ptions Listed Below
If "Other," specify: (A1AEBSP)	
5. Action taken with study intervention:(A1ACTBI)	O-None 1-Decreased intervention 2-Increased intervention 3-T emporarily stopped intervention 4-Permanent ys topped intervention *Additional O ptions Listed Below

6. Outcome of event: (A1 OUTCM)	1-Ongoing 2-Resolved without sequelae 3-Resolved with sequelae 4-Resolved by convention 5-Death
7. Date of resolution or medically stable: (A1RESDT)	(mm/dd/yyyy)
Except for "None of the following", all selections in the question below will designate the Adverse Events reported.	is as a Serious Adverse Event (SAE). The Serious Adverse Event Summary (AD2) form should be completed for all Serious
8. Was this event associated with: (A1ASSOCI)	O-None of the following 10-Hospitalization for a medical event 1-Death 2-Life-threatening event 3-Inpatient admission to hospital *Additional O ptions Listed Below
If "Death", date of death: (A1DTHDTE)	(mm/dd/yyyy)
If "Inpatient admission to hospital" or "Prolongation of hospitalization": Date of hospital admission: (A1HOSPAD)	(mm/d d/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 Advers Preferred Term: (MEDRAPT)	
System Organ Class: (MEDRASOC)	Not Coded

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-Prolon gation 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

		NIDA Clinical Trials Network
		Serious Adverse Event Summary (AD2)
s	Adverse Event Onset Date (AEDATE): Select Sequence Number (AESEQNUM):	
1	Initial narrative description of serious adverse event:	
	(A2 SUMM)	
2	2. Relevant Past Medical History: (A2SAEMHX) \(\square\) No	
	Allergies, pregnancy, smoking and alcohol use, hyperte	nsion, diabetes, epilepsy, depression, etc.
3	B. Medications at the Time of the Event: (A2SAEMED)	No Yes Unknown
	Medication (Generic Name)	Indication
	(A2_01DNM)	(A2_01DIN)
	(A2_02DNM)	(A2_02DIN)
	(A2_03DNM)	(A2_03DIN)
	(A2_04DNM)	(A2_04DIN)

(A2_05DIN)

(A2_05DNM)

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

(A2_06DNM)	(A2_06DIN)	_	
(A2_07DNM)	(A2_07DIN)		
(A2_08DNM)	(A2_08DIN)	_	
(A2_09DNM)	(A2_09DIN)		
(A2_10DNM)	(A2_10DIN)		
F. Treatments for the Event: (A2SAETRT) ☐ No ☐ Ye	es Unknown		
Treatment Treatment	Indication	Date Treated	\neg
(A2_1 TNME)	(A2_1 TIND)	(A2_1LTDT) (mm/dd/y)	
(A2_2 TNME)	(A2_2 TIND)	(A2_2LTDT) (mm/dd/y)	
(A2_3TNME)	(A2_3TIND)	(A2_3LTDT) (mm/dd/y)	
(A2_4TNME)	(A2_4TIND)	(A2_4LTDT) (mm/dd/y)	
(A2_5 TNME)	(A2_5TIND)	(A2_5LTDT) (mm/dd/y)	
5. Labs/Tests Performed in Conjunction with this Event: (A	2SAELAB) ☐ No ☐ Yes ☐ Unknown		_
Lab/Test Lab/Test	Findings		Date of Test
(A2_1LBNM)	(A2_1LBIN)		(A2_1LBDT) (mm/dd/yyyy)
(A2_2LBNM)	(A2_2LBIN)		(A2_2LBDT) (mm/dd/yyyy)
(A2_3LBNM)	(A2_3LBIN)		(A2_3LBDT) (mm/dd/yyyy)
(A2_4LBNM)	(A2_4LBIN)		(A2_4LBDT) (mm/dd/yyyy)
(A2_5LBNM)	(A2_5LBIN)		(A2_5LBDT) (mm/dd/yyyy)
	1, - 71		1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
 Follow-Up: Include labs/test results as they become available, clinic 	cal changes, consultant diagnosis, etc.		
(A2 FOLLUP)			

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

Additional Selection Options for AD2

Select Sequence Number (AESEQNUM) (key field): 01-1st Adverse Event of the day

02-2nd Adverse Event of the day

03-3rd Adverse Event of the day

04-4th Adverse Event of the day

05-5th Adverse Event of the day

06-6th Adverse Event of the day

07-7th Adverse Event of the day

08-8th Adverse Event of the day

09-9th Adverse Event of the day

10-10th Adverse Event of the day

NIDA Clinical Trials Network
Ondana Adama Franci Madiad Davissas (ADO)

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

Serious Advers	se Event Medical Reviewer (AD3)
Adverse Event Onset Date (AEDATE): Select Sequence Number (AESEQNUM):	
1. Was this determined to be a serious adverse event? (A3DETER) 2. Was this event considered associated with the study's behavioral intervention? (A3BHINT) 3. Was this event expected? (A3EXPECT) 4. Is this a standard expedited/reportable event? (i.e., is it serious, unexpected and related to therapy) (A3EXPFDA) 5. Is this an expedited/reportable event for other reasons? (A3EXPOTH) 6. Does the protocol need to be modified based on this event? (A3EXPDSM) 7. Does the consent form need to be modified based on this event? (A3CONSEN) 8. Is the review complete? (A3REVDNE) If "No", what additional information is required: (A3ADDINF)	No
Assessed by:(A2 ASRID) Reviewed by:(A3REVID) Comments: (A3COMM)	Robert Lindblad Radhika Kondapaka Robert Lindblad

Additional Selection Options for AD3

Select Sequence Number (AESEQNUM) (key field): 01-1st Adverse Event of the day

02-2nd Adverse Event of the day

03-3rd Adverse Event of the day

04-4th Adverse Event of the day

05-5th Adverse Event of the day

06-6th Adverse Event of the day

07-7th Adverse Event of the day

08-8th Adverse Event of the day

09-9th Adverse Event of the day

10-10th Adverse Event of the day

NIDA Clinical Trials Network

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

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

Segment (PROTSEG): Visit Number (VISNO):

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

Route of Administration:

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

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

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

Substance	A Past 30 (Days)	C Route of Administration	
D1 Alcohol (any use at all):	(ADALA 30D) (xx)	-	
D2 Alcohol (to intoxication):	(ADALI30D) (xx)	-	
D3 Heroin	(ADHER30D) (xx)	1-(1) Oral 2-(2) Nasal 3-(3) Smoking 4-(4) Non IV injection 5-(5) IV injection 96-(96) Notapplicable 97-(97) Notanswered	
D4 Methadone/LAAM (prescribed):	(ADMDP30D) (xx)	1-(1) O ral 2-(2) Nasal 3-(3) S moking 4-(4) Non IV injection 5-(5) IV injection 96-(96) Notapplicable 97-(97) Notanswered	
D4a Methadone/LAAM (illicit):	(ADMLI30D) (xx)	1-(1) Oral 2-(2) Nasal 3-(3) S moking 4-(4) Non IV injection 5-(5) IV injection 96-(96) Notapplicable 97-(97) Notanswered	

D5 Other Opiates/Analgesics:	(ADOPI30D) (3	α) (AD	1-(1) Oral 2-(2) Nasal 3-(3) Smoking 4-(4) Non IV injection 5-(5) IV injection 96-(96) Not applicable 97-(97) Not answered
D6 Barbiturates:	(ADBAR30D) ((AD	1-(1) O ral 2-(2) Nasal 3-(3) Smoking 4-(4) Non IV injection 5-(5) IV injection 96-(96) Notapplicable 97-(97) Notanswered
D7 Other Sedatives/ Hypnotics/Tranquilizers:	(ADSHT30D) ((AD	1-(1) Oral 2-(2) Nasal 3-(3) Smoking 4-(4) Non IV injection 5-(5) IV injection 96-(96) Not applicable 97-(97) Not answered
D8 Cocaine:	(ADCOC30D)	(AD	1-(1) Oral 2-(2) Nasal 3-(3) S moking 4-(4) Non IV injection 5-(5) IV injection 96-(96) Notapplicable 97-(97) Notanswered
D9 Amphetamines:	(ADAMP30D)	(xx)	1-(1) Oral 2-(2) Nasal 3-(3) S moking 4-(4) Non IV injection 5-(5) IV injection 96-(96) Notapplicable 97-(97) Notanswered
D9 a Methamphetamine:	(ADMET30D)	(xx)	1-(1) O ral 2-(2) N asal 3-(3) S moking 4-(4) N on IV injection 5-(5) IV injection 96-(96) Notapplicable 97-(97) Notans wered

D10 Cannabis:	(ADTHC30D)	(xx)		1-(1) O ral 2-(2) Nasal 3-(3) Smoking 4-(4) Non IV injection 5-(5) IV injection 96-(96) Notapplicable 97-(97) Notanswered
D11 Halluc in ogens:	(ADHAL30D) ((xx)	:	1-(1) Oral 2-(2) Nasal 3-(3) S moking 4-(4) Non IV injection 5-(5) IV injection 96-(96) Notapplicable 97-(97) Notanswered
D1 2 Inhalants :	(ADINH30D)	(xx)	2 2 2 5	I-(1) Oral 2-(2) Nasal 3-(3) S moking 4-(4) Non IV injection 5-(5) IV injection 96-(96) Notapplicable 97-(97) Notanswered
D13 More than 1 substance per day (including alcohol, excluding nicotine):	(ADGT130D)	(xx)		-

D14 According to the interviewer, which substance(s) is/are the major problem?

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

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

OR

(ADMJDGNA) (97) Not Answered

D17	How many times have you had Alcohol DT's? • <u>Delirium Tremens</u> (DT's): Occur 24-48 hours after last drink, or significant decrease in alcohol intake. Characterized by shaking, severe disorientation, fever, hallucinations; they usually require medical attention.
	(ADALCDT) (xx)
	OR
	(ADALDTNA) (97) Not Answered
	nany times in your life have you been treated for: e detoxification, halfway houses, in/outpatient counseling and AA or NA (if 3+ meetings within one month period).
D19	Alcohol abuse:
	(ADALCTRT) (xx)
	OR
	(ADATRTNA) (97) Not Answered
D20	Drug abuse:
	(ADDRGTRT) (xx)
	OR
	(ADDTRTNA) (97) Not Answered
How n	nany of these were detox only:
D21	Alcohol:
	• If D19 = 00, then question D21 is Not applicable.
	(ADADETOX) (xx)
	OR
	(ADADTXNA) (96) Not applicable (97) Not answered
D22	Drugs:
	• If D20 = 00, then question D22 is Not applicable.
	(ADDDETOX) (xx)
	OR
	(ADDDTXNA) (96) Not applicable (97) Not answered
	nuch money would you say you spent during the past 30 days on: \$99999

D23	Alcohol:
	Only count actual money spent. What is the financial burden caused by alcohol?
	(ADALCMNY) \$ (xxxxx)
	OR
	(ADAMNYNA) (97) Not Answered
D24	Drugs:
	Only count actual money spent. What is the financial burden caused by drugs?
	(ADDRGMNY) \$ (xxxxx)
	OR
	(ADDMNYNA) (97) Not Answered
D25	How many days have you been treated in an outpatient setting for alcohol or drugs in the past 30 days?
	• Include A A/NA
	(ADOUTPAT) (xx) days
	OR
	(ADOPTNA) (97) Not Answered
D26	How many days in the past 30 have you experienced alcohol problems?
	• Include: Craving, withdrawal symptoms, disturbing effects of use, or wanting to stop and being unable to.
	(ADAP30D) (xx) days
	OR
	(ADAP30NA) (97) Not Answered
For q	uestions D28-D31, please ask participant to use the Participant Rating Scale. The participant is rating the need for additional substance abuse treatment.
D28	How troubled or bothered have you been in the past 30 days by these alcohol problems?
	O-(O) Notatall
	1-(1) Slightly 2-(2) Moderately
	3-(3) Considerably
	4-(4) Extremely (ADAPB30D)
	OR
	(ADAB30NA) (97) Not Answered

D30	How important to you now is treatment for these alcohol problems?
	O-(O) Not at all 1-(1) S lightly 2-(2) Moderately 3-(3) C onsiderably 4-(4) Extremely
	OR .
	(ADAI30NA) (97) Not Answered
D27	How many days in the past 30 have you experienced drug problems?
	 Include: Craving, withdrawal symptoms, disturbing effects of use, or wanting to stop and being unable to.
	(ADDP30D) (xx) days
	OR
	(ADDP30NA) (97) Not Answered
D29	How troubled or bothered have you been in the past 30 days by these drug problems?
	C-(0) Notatall 1-(1) Slighty 2-(2) Moderately 3-(3) Considerably 4-(4) Externely
	OR
	(ADDB30NA) (97) Not Answered
D31	How important to you now is treatment for these drug problems?
	O-(0) Notatall 1-(1) Slightly 2-(2) Moderately 3-(3) Considerably 4-(4) Extremely
	OR
	(ADDI30NA) (97) Not Answered
Confi	dence Ratings: Is the above information significantly distorted by:
D34	Participant's misrep resentation?
D34	(ADMISREP) (0) No (1) Yes
	$p_{\text{TMONLE}} = p_{\text{TMONLE}} = p_{\text{TMONLE}}$

D35 Participant's inability to understand? (ADUNDRST) (0) No (1) Yes	
Comme nts: (ASDCOMM)	

	NIDA Clinical Trials Network	
	CTN-ASI Lite v. 1: Employment/Support Status (ASE)	
		Web Version: 1.0; 4.01; 06-05-12
Segment (<i>PROTSEG</i>): Visit Number (<i>VISNO</i>):		

CTN-ASI Lite v. 1 Follow-Up: Employment/Support Status
E1 Education completed since your last ASI:
● GED = 12 years ● Include formal education only.
(AEEDCPYR) (xx) a. years
(AEEDCPMT) (xx) b. months
OR
(AEEDCPNA) (97) Not Answered
E2 Training or technical education completed since your last ASI:
 Formal/organized training only. For military training, only include training that can be used in civilian life, i.e., electronics or computers.
(AETECPMT) (xx) months
OR
(AETECPNA) (97) Not Answered
E4 Do you have a valid driver's license?
Valid license: not suspended/revoked

- E4

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

- E5 Do you have an automobile available?
 - If answer to E4 is "No", then E5 must be "No". Does not require own ership, only requires availability on a regular basis.

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

		occupation since your la	

• Use Hollingshead Categories Reference Sheet.

1-(1) Higher Executive, Major Professionals, Owner of Large Business

2-(2) Business Manager, Owner (medium sized business), Other Professional

3-(3) A dministrative Personnel, Manager, Owner/Proprietor of Small Business

4-(4) Clerical and Sales, Technician, Owner of Small Business

5-(5) S killed Manual - usually having had training

6-(6) S emi-skilled

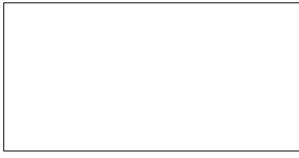
7-(7) Unskilled/Unemployed

8-(8) Homemaker

9-(9) S tudent/No Occupation/Disabled

(AEOCCUPT)

Specify:



(AEOCCPSP)

OR

(AEOCCPNA) (97) Not Answered

- **E9** Does someone contribute the majority of your support?
 - Is participant receiving any regular support (i.e., cash, food, housing) from family/friend?
 - Include spouse's contribution; exclude support by an institution.

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

(AESUPPRT)

- E11 How many days were you paid for working in the past 30 days?
 - Include "under the table" work, paid sick days, and vacation.

(AEPAID) (xx) days	
OR	
(AEPAIDNA) (97) Not Answered	
For questions E12-E17: How much money did you receive from the following sources in the past 30 days? Max. = \$99999	
E12 Employment (net income):	
• Net or "take home" pay, include any "under the table" money.	
(AEEMPMNY) \$ (xxxxx)	
OR	
(AEEMNYNA) [(97) Not Answered	
E13 Unemployment compensation:	
(AEUNEMNY) \$ (xxxxx)	
OR	
(AEUMNYNA) (97) Not Answered	
E14 Welfare:	
 Include food stamps, transportation money provided by an agency to go to and from treatment. 	
(AEWLFMNY) \$ (xxxxx)	
OR	
(AEWMNYNA) (97) Not Answered	
E15 Pensions, benefits, or Social Security:	
 Include disability, pensions, retirement, veteran's benefits, SSI & workers' compensation. 	
(AEPENMNY) \$ (xxxxx)	
OR	
(A EPMNYNA) (97) Not Answered	
E16 Mate, family or friends:	
 Money for personal expenses, (i.e., clothing), include unreliable sources of income (e.g., gambling). Record cash payments only, include windfalls (unexpected), money from loans, gambling, inheritance, tax refc. 	eturns,
(AEMATMNY) \$ (xxxxx)	

OR .	
(AEMMNYNA) [(97) Not Answered	
E17 Illegal:	
 Cash obtained from drug dealing, stealing, fencing stolen goods, gambling, prostitution, etc. Do not attempt to convert drugs exchanged to a dollar value. 	
(AEILLMNY) \$ (xxxxx)	
OR	
(AEIMNYNA) [(97) Not Answered	
E18 How many people depend on you for the majority of their food, shelter, etc.?	
 Must be regularly depending on participant; do include alimony/child support; do not include the participant or self-supporting spouse, etc. 	
(AEDEPEND) (xx) max = 99	
OR .	
(AEDPNDNA) (97) Not Answered	
E19 How many days have you experienced employment problems in the past 30 days?	
 Include inability to find work, if they are actively looking for work, or problems with present job in which that job is jeopardized. 	
(AEEP30D) (xx) days	
OR	
(AEEP30NA) (96) Not applicable (97) Not answered	
For questions E20-E21: Please ask participant to use the Participant Rating Scale. The participant's ratings in questions E20 and E21 refer to question E19. Stress help in finding or preparing for a job, not giving them a job.	
E20 How troubled or bothered have you been by these employment problems in the past 30 days?	
• If the participant has been incarcerated or detained during the past 30 days, they cannot have employment problems.	
O-(0) Notatall 1-(1) Slightly 2-(2) Modera tely 3-(3) Considerably 4-(4) Extremely	
OR	
(AEEB30NA) (96) Not applicable (97) Not answered	

E21 How important to you now is counseling for these employment problems?	21 How important to you now is counseling for these employment problems?			
O-(O) Notatall 1-(1) Slightly 2-(2) Moderately 3-(3) Considerably 4-(4) Extremely				
OR				
(AEEC30NA) (97) Not Answered				
Confidence Ratings: Is the above information significantly distorted by:				
E23 Participant's misrepresentation?				
(AEMISREP) (0) No (1) Yes				
E24 Participant's inability to understand?				
(AEUNDRST) (0) No (1) Yes				
Comments: (ASECOMM)				

NIDA Clinical Trials Network

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

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

Segment (PROTSEG): Visit Number (VISNO):

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

- F1 Marital status:
 - Common-law marriage = 1: Specify in Comments.

1-(1) Married

2-(2) Remarried

3-(3) Widowed

4-(4) Separated

5-(5) Divorced

6-(6) Never married

97-(97) Not answered

(AFMRTLST)

- F3 Are you satisfied with this situation?
 - Satisfied = Generally liking the situation. Refers to question F1.

0-(0) No

1-(1) Indifferent

2-(2) Yes

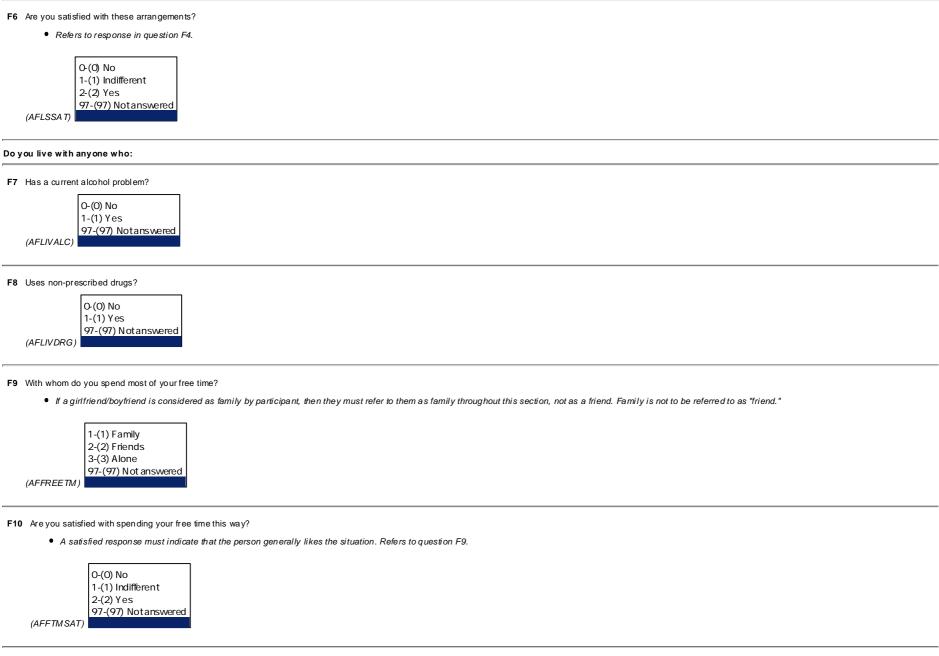
97-(97) Notanswered

(AFMSSAT)

- F4 Usual living arrangements (since your last ASI):
 - 1-(1) With sexual partner and children
 - 2-(2) With sexual partner alone
 - 3-(3) With children alone
 - 4-(4) With parents

 - 5-(5) With family 6-(6) With friends
 - 7-(7) Alone
 - 8-(8) Controlled environment
 - 9-(9) No stable arrangements
 - 97-(97) Notanswered

(AFLIVARR)



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

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

	A Past 30 Days
F18 Mother:	O-(0) No 1-(1) Yes 96-(96) Notapplicable 97-(97) Notanswered
F19 Father:	(AFFTR30D) O-(O) No 1-(1) Yes 96-(96) Not applicable 97-(97) Not answered
F20 B rothers/siste rs:	0-(0) No 1-(1) Yes 96-(96) Not applicable 97-(97) Not answered
F21 Sexual partner/spouse:	0-(0) No 1-(1) Yes 96-(96) Notapplicable 97-(97) Notanswered
F22 Children:	O-(0) No 1-(1) Yes 96-(96) Notapplicable 97-(97) Notanswered
F23 Other significant family (specify): (AFOSFMSP)	(AFO SF30D) O-(0) No 1-(1) Yes 96-(96) Not applicable 97-(97) Not answered
F24 Close friends:	0-(0) No 1-(1) Yes 96-(96) Not applicable 97-(97) Not answered

		- 1	
F25 Neighbors:	O-(O) No 1-(1) Yes 96-(96) Notapplicable 97-(97) Notanswered		
F26 Co-workers:	O-(0) No 1-(1) Yes 96-(96) Notapplicable 97-(97) Notanswered		
Did a nyone abuse you? (F18-F26)	A Past 30 Days		
F28 Physically (caused you physical harm)?	0-(0) No 1-(1) Yes 97-(97) Notanswered		
F29 S exually (forced sexual advances/acts)?	0-(0) No 1-(1) Yes 97-(97) Notanswered		
F30 How many days in the past 30 have you had serious conflicts with your family?			
(AFFMC30D) (xx) days			
OR			
(AFFC30NA) (97) Not Answered			
For questions F32 and F34, please ask participant to use the Participant Rating Scale	٠.		
F32 How troubled or bothered have you been in the past 30 days by these family problems	s?		
O-(0) Notatall 1-(1) S lightly 2-(2) Modera tely 3-(3) C onsiderably 4-(4) E xtremely			
OR			
(AFFB30NA) (97) Not Answered			

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

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

O-(O) Not at all 1-(1) S lightly
2-(2) Moderately 3-(3) Considerably
4-(4) Extremely (AFFCI30D)
OR
(AFFI30NA) (97) Not Answered
F31 How many days in the past 30 have you had serious conflicts with other people (excluding family)?
(AFSCC30D) (xx) days
OR
(AFSC30NA) (97) Not Answered
For questions F33 and F35, please ask participant to use the Participant Rating Scale.
F33 How troubled or bothered have you been in the past 30 days by these social problems?
O-(O) Notatall
1-(1) Slightly 2-(2) Moderately
3-(3) Considerably
4-(4) Extremely (AFSPB30D)
OR
(AFSB30NA) (97) Not Answered
F35 How important to you now is treatment or counseling for these social problems?
• Include participant's need to seek treatment for such social problems as loneliness, inability to socialize, and dissatisfaction with friends. Participant rating should refer to dissatisfaction, conflicts, or other serious problems. Exclude problems that would be eliminated if participant had no substance abuse.
O-(O) N ot at all 1-(1) S lightly
2-(2) Moderately 3-(3) Considerably
4-(4) Extremely
(AFSPI30D)
OR
(AFSI30NA) (97) Not Answered
Confidence Ratings: Is the above information significantly distorted by:
F37 Participant's misrepresentation?
(AFMISREP) (0) No (1) Yes

F38 Participant's inability to understand?	
(AFUNDRST) (0) No (1) Yes	
Comme nts: (ASFCOMM)	

NIDA Clinical Trials Network

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

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

Segment (PROTSEG): Visit Number (VISNO):

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

G9 Contact code:

1-(1) In person

2-(2) Telephone (Intake ASI must be in person)

3-(3) Mail

97-(97) NotAnswered

(AGCONTCT)

G12 Special:

1-(1) Participant terminated

2-(2) Participant refused

3-(3) Participant unable to respond

96-(96) Not Applicable

(AGSPCIAL)

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

1-(1) No

2-(2) Jail

3-(3) Alcohol or drug treatment

4-(4) Medical treatment

5-(5) Psychiatric treatment

6-(6) Other

97-(97) Notanswered

(AGCNTENV)

Other (specify): (AGCENVSP)	
Outer (specify). (AOOENVOI)	
COO Have many days 2 (Parties to total assertion of days detained in the most 20 days)	
G20 How many days? (Refers to total number of days detained in the past 30 days)	
 Not applicable if question G 19 is "No." 	
(AGCEDAYS) (xx) days	
OR	
(AGCEDSNA) (96) Not applicable (97) Not answered	
2	
Comments: (ASG CO MM)	

NIDA Clinical Trials Network
CTN-ASI Lite v. 1 (ASI)

Segment (PROTSEG): Visit Number (VISNO):

CTN-ASI Lite v. 1 Follow-l

Date of assessment: (ASASMTDT)

(mm/dd/yyyy) Click here to view calendar

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

Seven potential problem are as: Medical, Employment/Support Status, Alcohol, Drug, Legal, Family/Social, and Psychological. All clients receive this same standard interview. All information gathered is confidential.

There are two time periods we will discuss:

- 1. The past 30 days
- 2. Lifetime Data

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

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

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

Please do not give inaccurate information!

Key: Participant Rating Scale

0=Not at all

1=Slightly

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

2=Moderately

3=Considerably

4=Extremely

Interviewer Instructions

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

HALF TIME RULE:

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

Round up 6 months or more to 1 year.

CONFIDENCE RATINGS:

Last two items in each section.

Do not over interpret.

Denial does not warrant misrepresentation.

Misrepresentation = overt contradiction in information.

CTN-ASI Lite v. 1: Hollingshead Categories

- 1 = Higher Executive, Major Professionals, Owner of Large Business
- 2 = Business Manager, Owner (medium sized business), Other Professional (nurse, optician, pharmacist, social worker, teacher)
- 3 = Administrative Personnel, Manager, Owner/Proprietor of Small Business (bakery, car dealership, engraving business, plumbing business, florist, decorator, actor, reporter, travel agent)
- 4 = Clerical and Sales, Technician, Owner of Small Business (bank teller, bookkeeper, clerk, draftsman, timekeeper, secretary, car salesperson)
- 5 = Skilled Manual usually having had training (baker, barber, brakeman, chef, electrician, fireman, lineman, machinist, mechanic, paperhanger, painter, repairman, tailor, welder, police officer, plumber)
- 6 = Semi-skilled (hospital aide, painter, bartender, bus driver, cutter, cook, drill press, garage guard, checker, waiter, spot welder, machine operator)
- 7 = Unskilled (attendant, janitor, construction help, unspecified labor, porter). Include Unemployed.
- 8 = Homemaker
- 9 = Student/No Occupation/Disabled

List of Commonly Used Drugs

Alcohol: Beer, wine, liquor

Methadone: Dolophine, LAAM

Opiates: Pain killers = Morphine, Diluaudid, Demerol, Percocet, Darvon, Talwin, Codeine, Tylenol 2, 3, 4 Syrups = Robitussin, Fentanyl

Barb itur ate s: Nemb uta I, Secona I, Tui nol, Amytal, Pen to barbital, Secobarb ital, Phen obarb ital, Fi orinol

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

Cocaine: Cocaine Crystal, Free-Base Cocaine or "Crack", and "Rock Cocaine"

Amphetamines: Monster, Crank, Benzedrine, Dexedrine, Ritalin, Preludin

Methamphetamine: Speed, Ice, Crystal

Cannabis: Marijuana, Hashish

Hallucinogens: LSD (Acid), Mescaline, Mushrooms (Psilocybin), Peyote, Green, PCP (Phencyclidine), Angel Dust, Ecstacy

Inhalants: Nitrous Oxide, Amyl Nitrate (Whippits, Poppers), Glue, Solvents, Gasoline, Toluene, etc.

Just note if these are used: Antidepressants.

Ulcer Meds = Zantac, Tagamet

Asthma Meds = Ventoline Inhaler, Theodur Other meds = Antipsychotics, Lithium

Alcohol/Drug Section Instructions

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

30 day questions only require the number of days used

Lifetime use is asked to determine extended periods of use.

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

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

How to ask these questions:

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

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

Comments: (ASCOMM)	

	NIDA Clinical Trials	s Network	
	CTN-ASI Lite v. 1: Lega	al Status (ASL)	
Segment (PROTSEG): Visit Number (VISNO):			Web Version: 1.0; 4.01; 06-05-12
CTN-ASI Lite v. 1 Follow-Up: Legal Status			
L2 Are you on parole or probation?			
• Note duration and level in comments.			
O-(0) No, neither 1-(1) Yes, parole or post release supervision 2-(2) Yes, probation or pre-sentencing diversion			
(ALPROBAT) 97-(97) Not answered			
How many times since your last ASI have you been arrested and charged Include total numbers of counts, not just convictions. Do not include juvenile [un		ged as an adult. Include formal charges only.	
L3 Shoplifting/vandalism:	(ALSHPLFT) (xx)	OR (ALSLFTNA) [(97) Not Answered	
L4 Parole/probation violations:	(ALPP VIOL) (xx)	OR (ALPPVLNA) [(97) Not Answered	
L5 Drug Charges:	(ALDRGCHR) (xx,	OR (ALDCHRNA) [(97) Not Answered	
L6 Forgery:	(ALFORGER) (xx,	OR (ALFORGNA) [(97) Not Answered	
L7 Weapons offense:	(ALWEA PON) (xx	OR (ALWEAPNA) [(97) Not Answered	
L8 Burglary/larceny/B&E:	(ALBURGLR) (xx)	OR (ALBURGNA) [(97) Not Answered	
L9 Robbery:	(ALROBBRY) (xx)	OR (ALROBBNA) (97) Not Answered	
L10 Assault:	(ALASSLT) (xx)	OR (ALA SLTNA) [(97) Not Answered	
L11 Arson:	(ALARSON) (xx)	OR (ALARSNNA) (97) Not Answered	
L12 Rape:	(ALRAPE) (xx)	OR (ALRAPENA) [(97) Not Answered	
L13 Homicide/manslaughter:	(ALMURDER) (xx	OR (ALMRDRNA) [(97) Not Answered	
L14 Prostitution:	(ALPROST) (xx)	OR (ALPRSTNA) [(97) Not Answered	
L15 Contempt of court:	(ALCONTMP) (xx,	OR (ALCNTPNA) (97) Not Answered	

L16 Other (specify):	(ALOTHARR) (xx) OR (ALOARRNA) (97) Not Answered
(ALOTHASP)	
L17 How many of these charges resulted in convictions?	
 Do not include misdemeanor offenses from questions L18-L20 below. Convid 	ctions include fines, probation, incarcerations, suspended sentences, and guilty pleas.
• If L3-L16 = 00, then L17 = Not applicable	
(ALCONVCT) (xx)	
OR	
(ALCNVTNA) (96) Not applicable (97) Not answered	
How many times since your last ASI have you been charged with the following:	
L18 Disorderly conduct, vagrancy, public intoxication:	
(ALDISCND) (xx)	
OR	
(ALDCNDNA) (97) Not Answered	
L19 Driving while intoxicated (DWI):	
(ALDWI) (xx)	
OR	
(ALDWINA) (97) Not Answered	
L20 Major driving violations:	
 Moving violations: speeding, reckless driving, no license, etc. 	
(ALDRVIOL) (xx)	
OR	
(ALDRVLNA) (97) Not Answered	

L21	low many months were you incarcerated since your last ASI?	
	• If incarcerated 2 weeks or more, round this up to 1 month. List total number of months incarcerated (up to 99). If more than 99, code 99 and enter the number in comments.	
	ALINCRMT) (xx) months	
	OR .	
	ALINCRNA) (97) Not Answered	
L24	re you presently awaiting charges, trial, or sentence?	
	0-(0) No 1-(1) Y es 97-(97) Notanswered	
L25	What for (refers to L24)?	
	• Use code 03-16, 18-20. If more than one, choose most severe. Don't include civil cases, unless a criminal offense is involved.	
	03-03 = Shoplifting 04-04 = Probation violation 05-05 = Drug 06-06 = Forgery 07-07 = Weapons 08-08 = Burglary 09-09 = Robbery 10-10 = Assault 11-11 = Arson 12-12 = Rape 13-13 = Homicide 14-14 = Prosttution 15-15 = Contempt 16-16 = Other 18-18 = Disorderly conduct 19-19 = DWI 20-20 = Major driving violation	
	ALCTSPNA) (96) Not applicable (97) Not answered	
L26	low many days in the past 30 were you detained or incarce rated?	_
	Include being arrested and released on the same day.	
	ALIN30D) (xx) days	
	OR .	
	ALIN30NA) [(97) Not Answered	

L27 How many days in the past 30 have you engaged in illegal activities for profit?
• Exclude simple drug possession. Include drug dealing, prostitution, selling stolen goods, etc. May be cross checked with question E17 under Employment/Family Support section.
(ALIP30D) (xx) days
OR .
(ALIP30NA) [(97) Not Answered
For questions L28-29: Please ask participant to use the Participant Rating Scale.
L28 How serious do you feel your present legal problems are?
Exclude civil problems
O-(O) Not at all
1-(1) S lightly
2-(2) Moderately 3-(3) Considerably
4-(4) Extremely (ALL PS30D)
OR
(ALL P30NA) [(97) Not Answered
VIEL CONTY = (a) Not his word
L29 How important to you now is counseling or referral for these legal problems?
• Participant is rating a need for additional referral to legal counsel for defense against criminal charges.
O-(O) Not atall 1-(1) S lightly
2-(2) Modera tely
3-(3) Considerably 4-(4) Extremely
(ALL CI30D)
OR .
(ALLI30NA) [(97) Not Answered
Confidence Ratings: Is the above information significantly distorted by:
L31 Participant's misrepresentation?
(ALMISREP) (0) No (1) Yes
L32 Participant's inability to understand?
(ALUNDRST) (0) No (1) Yes

Comments: (ALCOMM)	

NIDA Clinical Trials Network		
CTN-ASI Lite v. 1: Medical Status (ASM)		
Segment (PROTSEG): Visit Number (VISNO):	Web Version: 1.0; 3.00; 05-29-12	
CTN-ASI Lite v. 1 Follow-Up: Medical Status		
M1 Since your last ASI, how many times have you been hospitalized for medical problems?		
 Include O.D.'s and D.T.'s. Exclude detox, alcohol/drug, psychiatric treatment and childbirth (if no complications). Enter the number of overnight hospitalizations for medical problems. 		
(AMHOSPTM) (xx) times		
OR		
(AMHOSPNA) (97) Not Answered		
 M4 Are you taking any prescribed medication on a regular basis for a physical problem? Medication prescribed by a M.D. for medical conditions; not psychiatric medicines. Include medicines prescribed, whether or not the participant is currently taking them. The intent is to verify chronic medical problems. O-(O) No 1-(1) Yes 97-(97) Notanswered (AMRXPHYS)		
If "Yes", specify:(AMRXPHSP)		

	• Include Workers' Compensation, exclude psychiatric disability.
	0-(0) No 1-(1) Yes 97-(97) Notanswered
	If "Yes", specify:(AMPNPDSP)
М6	How many days have you experienced medical problems in the past 30 days? • Do not include a ilments directly caused by drugs/alcohol. • Include flu, colds, etc. Include serious ailments related to drugs/alcohol, which would continue even if the participant were abstinent (e.g., cirrhosis of liver, abscesses from needles, etc.). (AMPRB30D) (xx) days OR (AMPR30NA) (97) Not Answered
For o	questions M7 & M8, please ask participant to use the Participant Rating Scale.
М7	How troubled or bothered have you been by the se medical problems in the past 30 days? • Restrict response to problem days of question M6. O-(O) Notatall 1-(1) S lightly 2-(2) Modera tely 3-(3) C onsiderably 4-(4) E xtremely OR (AMPB30NA) (97) Not Answered

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

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

O-(0) Not at all 1-(1) S lightly 2-(2) Moderately 3-(3) C onsiderably	
(AMM TI30D) 4-(4) Extremely	
OR .	
(AMMI30NA) (97) Not Answered	
Confidence Ratings: Is the above information significantly distorted by:	
M10 Participant's misrepresentation?	
(AMMISREP) (0) No (1) Yes	
M11 Participant's inability to understand?	
(AMUNDRST) (0) No (1) Yes	
Comments: (AMCOMM)	7

NIDA Clinical Trials Network

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

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

Segment (PROTSEG): Visit Number (VISNO):

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

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

• Do not include substance abuse, employment, or family counseling. Treatment episode = a series of more or less continuous visits or treatment days, not the number of visits or treatment days. Enter disknown.	agnosis in Comments it
In a hospital or inpatient setting?	
(APPIHSPX) (xx)	
OR	
(APPIHPNA) [(97) Not Answered	
2 Outpatient/private patient?	
(APPOHSPX) (xx)	
OR	

P3 Do you receive a pension for a psychiatric disability?

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

(APPOHPNA) (97) Not Answered

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

P4 Experienced serious depression-sadness, hopelessness, loss of interest, difficulty with daily function?

A Past 30 Days

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

(APDEP 30D)

Po	Experienced serious anxiety/lension-uplight, unreasonably worried, inability to lee1relaxed?	(ΔΡ	0-(0) No 1-(1) Yes 97-(97) Not answered
P6	Experienced hallucinations-saw things or heard voices that other people did not see or hear?	,	0-(0) No 1-(1) Yes 97-(97) Notanswered
P7	Experienced trouble understanding, concentrating, or remembering?	·	O-(0) No 1-(1) Yes 97-(97) Not answered
For	questions P8-P10, participant could have been under the influence of alcohol/drugs		
		А	A Past 30 Days
P8	Experienced trouble controlling violent behavior including episodes of rage, or violence?		O-(O) No
	 Participant can be under the influence of alcohol/drugs. 	(APVLT30D)	1-(1) Yes 97-(97) Not answered
P9	Experienced serious thoughts of suicide?		O-(O) No
	 Participant seriously considered a plan for taking his/her life. 	(APTOS 30D)	1-(1) Yes 97-(97) Not answered
P10	Attempted suicide?		O-(O) No
	 Include actual suicidal gestures or attempts. 	(APASU30D)	1-(1) Yes 97-(97) Not answered
P11	Been prescribed medications for any psychological/emotional problem?		O-(O) No
	 Prescribed for the participant by MD. Record "Yes" if a medication was prescribed even if the participant is not taking it. 	(APM ED30D)	1-(1) Yes 97-(97) Not answered
P12	2 How many days in the past 30 have you experienced these psychological or emotional problem.	lems?	
	 This refers to problems noted in questions P4-P10. 		
	(APPRB30D) (xx) days		
	OR		
	(APPR30NA) [(97) Not Answered		
For	questions P13-P14, please ask participant to use the Participant Rating Scale.		

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

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

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

O-(O) Notatall 1-(1) Slightly 2-(2) Moderately 3-(3) Considerably 4-(4) Extremely	
OR	
(APPB30NA) (97) Not Answered	
P14 How important to you now is treatment for these psychological or emotional problems? O-(0) Notatall 1-(1) Slighty 2-(2) Moderately 3-(3) C onsiderably 4-(4) Extremely OR (APPI30NA) (97) Not Answered	
Confidence Ratings: Is the above information significantly distorted by:	
P22 Participant's misrepresentation?	
(APMISREP) (0) No (1) Yes	
P23 Participant's inability to understand?	
(APUNDRST) (0) No (1) Yes	
Comme nts: (APCOMM)	

NIDA Clinical Trials Network

Concise Associated Symptoms Tracking - Self-Report (CAST-SR) (CAS)

Web Version: 1.0; 1.00; 05-06-10
Segment (PROTSEG):

Date of assessment: (CAASMTDT)	(mm/dd/yyyy) (CATODAY) ☐ Click here for today's date

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

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

	Strongly Disagree	Disagree	Neither Agree nor Disagree	Agree	Strongly Agree
1. I feel anxious all the time.	(CAANXTM)				
2. I have been feeling really good lately.	(CAFLGOOD)				
3. I feel as if I am going to have a heart attack.	(CAHEARTA)				
4. I wish people would just leave me alone.	(CALVEALN)				
5. I have been having more trouble sleeping than usual.	(CATRBSLP)				
6. I am feeling restless, as if I have to move constantly.	(CARESTLS)				
7. I suddenly feel very confident.	(CACONDNT)				
8. I am more talkative than normal.	(CATALKNM)				
9. I feel very uptight.	(CAUPTTE)				
10. I find myself saying or doing things without thinking.	(CATHINK)				
11. I feel very tense and I cannot relax.	(CANOTRLX)				
12. I can feel my heart racing.	(CAHRTRAC)				
13. Lately everything seems to be annoying me.	(CAANOYME)				
14. I slept very little last night.	(CA SLPL TL)				
15. I cannot sit still.	(CACNTSIT)				
16. I find people get on my nerves easily.	(CANERVES)				
17. I have been having lots of great ideas.	(CAIDEAS)				

Visit Number (VISNO):

NIDA Clinical Trials Network

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

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

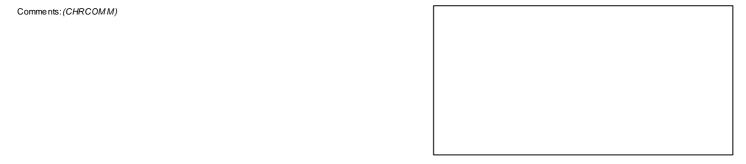
Se gr	nent <i>(PR</i> 0	OTSEG):
V is it	Number	(VISNO):

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

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

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

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



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NIDA Clinical Trials Network	

	Massachusetts	General Hospital C	ognitive and Phys	sical Functioning (Questionnaire (CPFC	
Segment (PROTSEG):						Web Version: 1.0; 1.00; 05-06-10
Visit Number (VISNO):						
Date of assessment: (CPASMT	DT)			(mm/dd/yyyy) (CPTODAY)	Click here for today's date	
Please answer all questions b most satisfied with your cogni			vhich seems the most ap	ppropriate to you (conside	er "Normal" the time in your	life prior to the past month when you were
a. How has your motivation/inter	rest/enthusiasm been	over the past month?				
(CPINTMTH)						
1	2	3	4	5	6	
Greater Than Normal	Normal	Minimally Diminished	Moderately Diminished	Markedly Diminished	Totally Absent	
b. How has your wakefulness/ale	ertness been over the	past month?				
(CPWKEMTH)						
1	2	3	4	5	6	
Greater Than Normal	Normal	Minimally Diminished	Moderately Diminished	Markedly Diminished	Totally Absent	
c. How has your energy been ov	ver the past month?					
(CPENGMTH)						
1	2	3	4	5	6	
Greater Than Normal	Normal	Minimally Diminished	Moderately Diminished	Markedly Diminished	Totally Absent	
d. How has your ability to focus/	sustain attention been	over the past month?				
(CPFCSMTH)						
1	2	3	4	5	6	
Greater Than Normal	Normal	Minimally Diminished	Moderately Diminished	Markedly Diminished	Totally Absent	
e. How has your ability to remen	nber/recall information	been over the past month	n?			
(CPREMMTH)						
1	2	3	4	5	6	

٦	Greater Fhan Normal	Normal	Minimally Diminished	Moderately Diminished	Markedly Diminished	Totally Absent
f. How has y	our ability to find words	been over the past mo	onth?			
(CPW	'DSMTH)					
	1	2	3	4	5	6
٦	Greater Fhan Normal	Normal	Minimally Diminished	Moderately Diminished	Markedly Diminished	Totally Absent
g. How has y	our sharpness/mental a	cuity been over the pas	st month?			
(CPA	түмтн) 🗆					
	1	2	3	4	5	6
7	Greater Than Normal	Normal	Minimally Diminished	Moderately Diminished	Markedly Diminished	Totally Absent

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NIDA Clinical Trials Network

Demographics (DEM)

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

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

	NIDA Clinical Trials Network
	Exercise Readiness Form (ERF)
Segment (PROTSEG): Visit Number (VISNO):	Web Version: 1.0; 1.01; 02-01-
Date of assessment: (ERDATE)	(mm/dd/yyyy)
1. Heart Rate	
Reading 1: (ERHR1) (xxx) beats per minute	
Reading 2: (ERHR2) (xxx) beats per minute	
*If HR reading 1 or reading 2 is 100 or greater, remeasure.	
Reading 3: (ERHR3) (xxx) beats per minute	
*If HR reading 3 is 100 or greater, participant not allowed to exercise this session.	
2. Blood Pressure (sitting)	
Reading 1: (ERBPSYS1) (xxx) / (ERBPDIA1) (xxx) mml	lg
Reading 2: (ERBPSYS2) (xxx) / (ERBPDIA2) (xxx) mml	
*If BP reading 1 or reading 2 exceeds 160/100, remeasure.	9
Reading 3: (ERBPSYS3) (xxx) / (ERBPDIA3) (xxx) mml	lg
*If BP reading 3 exceeds 160/100, participant not allowed to exercise this session.	previous visits were also greater than 140/90. If so, refer to appropriate medical care and obtain clearance before continuing with exercise.
3. Participant cleared to exercise this session: (ERCLEAR)	□ No □ Yes
Comments: (ERCOMM)	

NIDA Clinical Trials Network

☐ No ☐ Yes ☐ Unknown/Not Assessed

Web Version: 1.0; 1.02; 09-23-11

	0037	B (EN	IR)
Eligibility			
Date of assessment: (R2 ASMTDT)			(mm/dd/yyyy)
Inclusion Criteria Check the appropriate response. If any of the inclusion criteria have been answered "No" or "Unknown,	," the parti	cipant is	s not eligible and cannot be enrolled or randomized into the study.
1. Male or female age 18-65:(R2PTAGE)	□No	☐ Ye	es Unknown/Not Assessed
2. Admitted to residential setting and receiving substance use treatment:(R2RESTRT)	□No	☐ Ye	
3. Ability to understand and willingness to provide written informed consent: (R2INFCNS)	□ No	☐ Ye	_
4. Agree to remain in facility for authorized treatment of about 21-30 days: (R2REMAIN)	□ No	☐ Ye	_
5. Agree to remain in facility for authorized treatment:(R2 REMAIN)	□ No	☐ Ye	_
6. Willing to provide contact information: (R2CONTCT)	□ No	☐ Ye	
 Self-reported use of stimulant drug (occaine, methamphetamine, amphetamine, or other stimulant, excluding caffeine and nicotine) within the 30 days prior to admission for treatment: (R2STM30D) 	□ No	☐ Ye	
8. Meets DSM-IV criteria (per CIDI) for substance abuse or dependence for stimulants (cocaine, methamphetamine, amphetamine, or other stimulant, excluding caffeine and nicotine) within the last 12 months:(R2STM6M)	□ No	☐ Ye	es Unknown/Not Assessed
Medical clearance with protocol-defined stress testing (in accordance with American College of Sports Medicine (ACSM) guidelines) from protocol approved medical personnel: (R2MEDCLR)	□ No	☐ Ye	es Unknown/Not Assessed
O. Body mass index (BMI) 40 kg/m ² or BMI > 40 kg/m ² and cleared by medical personnel to exercise: (R2BMI)	□ No	☐ Ye	es Unknown/Not Assessed
1. Able to comprehend and communicate in English: (R2ENGLSH)	□ No	☐ Ye	es Unknown/Not Assessed
Exclusion Criteria			
Check the appropriate response. If any of the exclusion criteria have been answered "Yes" or "Unknow	n," the pai	rticipant	is not eligible and cannot be enrolled or randomized into the study.
Evidence of general medical condition or other abnormality that contraindicates use of exercise, based on the Medical Screening Visit: (R2MCNTRA)	□ No	☐ Ye	es Unknown/Not Assessed
2. Current opiate dependence: (R20PIATE)	☐ No	☐ Ye	es Unknown/Not Assessed
3. Current opiate dependence (i.e., within the last 12 months): (R2OPIATE)	□ No	☐ Ye	es Unknown/Not Assessed
4. Currently considered a high suicide risk and/or high risk for being unable to complete the study due to the need for psychiatric hospitalization, suicide attempts or suicidality, significant self-mutilation, or other self-injurious or destructive behavior based on the judgment of the site PI, medical personnel, or designee:(R2SUICID)	r No	☐ Ye	es Unknown/Not Assessed
5. Pregnancy: (R2PREG)	☐ No	☐ Ye	es Unknown/Not Assessed
 Significant physical activity, defined as aerobic exercise more than 3 times per week for 20 minutes or more, completed consistently for the three months prior to study enrollment: (R2ACTIVE) 	□ No	☐ Ye	es Unknown/Not Assessed
 Current psychotic disorder. Other comorbid psychiatric diagnosis that, in the investigator's judgment, will pose a safety issue or make it difficult for the participant to understand or complete the intervention: (R2PSYCH) 	I 🗆 No	☐ Ye	es Unknown/Not Assessed

8. Concomitant treatments: beta blockers, methadone, buprenorphine or any other opioid replacement therapies: (R2CONMED)

 Anticipated circumstances over the 9-month course of the trial that would render the participant unlikely to complete the study in the judgment of the site PI or designee: (R2COMPLT) 	□ No □ Yes □ Unknown/Not Assessed			
10. Anticipated living arrangements after the first month of the study that are likely to restrict exposure to substance use in the judgment of the site PI or designee: (R2 EXPOSE)	□ No □ Yes □ Unknown/Not Assessed			
11. Any reason not listed herein yet, determined by the site PI, medical personnel, or designee that constitutes good clinical practice and that would in the opinion of the site PI, medical personnel, or designee make participation in the study hazardous: (R2HAZARD)	□ No □ Yes □ Unknown/Not Assessed			
Randomization				
1. Is the participant eligible for the study?(R2PTELIG)	□ No □ Yes			
2. Is the participant eligible for the study and able to be randomized?(R2 PTRA ND)	□ No □ Yes			
a. If "No", please specify:(R2NORASP)	☐ Drop ped out of treatment ☐ Declined study participation ☐ Death ☐ Other			
b. If "Other", please specify: (R2OTHRSP)				
3. What is the participant's score on the QIDS-C ₁₆ ?(R2DEPRES)	□ 10 □ 11			
4. What is the quantity of the participant's stimulant use in the 30 days prior to admission for treatment? (R2DRG SEV)	18 days of use >18 days of use			
Comments:(R2COMM)				

NIDA Clinical Trials Network

Acute Phase Assessment Location Form (LOA)

Segment (PROTSEG):

Web Version: 1.0; 1.00; 08-25-11

Did This Visit Occur?	Visit Location	Comments:
Week 1 Visit 1 (LAVOC1A) 1-Yes 2-Missed V isit 3-Participant terminated from the study	1-Onsite at CTP/Research Office 2-Offsite at Participant's Residence 3-Offsite - Other Location 4-T elephone 5-Prison/J ail *Additional O ptions Listed Below (LAVIS1A)	(LAVI1ASP)
	Specify Locations:(LACO1ASP)	
Week 1 Visit 2 (LAVOC1B) 1-Yes 2-Missed V isit 3-Participant terminated from the study	1-Onsite at CTP/Research Office 2-Offsite at Participant's Residence 3-Offsite - Other Location 4-T elephone 5-Prison/J ail *Additional Options Listed Below (LAVIS1B)	(LAVI1BSP)
	Specify Locations:(LACO1BSP)	
Week 1 Visit 3 (LAVOC1C) 1-Yes 2-Missed V isit 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/J ail *A dditional Options Listed Below (LAVIS1C)	(LAVI1CSP)
	Specify Locations:(LACO1CSP)	
Week 2 Visit1 (LAVOC2A) 1-Yes 2-Missed V isit 3-Participant terminated from the study	1-Onsite at CTP/Research Office 2-Offsite at Participant's Residence 3-Offsite - Other Location 4-T elephone 5-Prison/J ail *Additional Options Listed Below	(LAVI2A SP)
	Specify Locations:(LACO2ASP)	

Week 2 Visit 2 (LAVOC2B) 1-Yes 2-Missed V isit 3-Participant terminated from the study	1-Onsite at CTP/Research Office 2-Offsite at Participants Residence 3-Offsite - Other Location 4-T elephone 5-Prison/J ail *Additional Options Listed Below (LAV/S2B) Specify Locations:(LACO2BSP)	(LAVI2BSP)
Week 2 Visit 3 (LAVOC2C) 1-Yes 2-Missed V isit 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 *A dditional Options Listed Below	(LAVI2CSP)
Week 3 Visit 1 (LAVOC3A) 1-Yes 2-Missed V isit 3-Participant terminated from the study	1-Onsite at CTP/Research Office 2-Offsite at Participants Residence 3-Offsite - Other Location 4-T elephone 5-Prison/J ail *Additional Options Listed Below	(LAVI3A SP)
	Specify Locations:(LACO3ASP)	
Week 3 Visit 2 (LAVO C3B) 1-Yes 2-Missed V isit 3-Participant terminated from the study	1-Onsite at CTP/Research Office 2-Offsite at Participants Residence 3-Offsite - Other Location 4-T elephone 5-Prison/J ail *Additional Options Listed Below	(LAVI3BSP)
	Specify Locations:(LACO3BSP)	
Week 3 Visit 3 (LAVOC3C) 1-Yes 2-Missed V isit 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/J ail *A dditional Options Listed Below	(LAVI3CSP)
	Specify Locations:(LACO3CSP)	

	T.	
Week 4 Visit 1 (LAVO C4A) 1-Yes 2-Missed V isit 3-Participant terminated from the study	1-Onsite at CTP/Research Office 2-Offsite at Participants Residence 3-Offsite - Other Location 4-T elephone 5-Prison/J ail *Additional Options Listed Below (LAVIS4A) Specify Locations:(LACO4ASP)	(LAVI4A SP)
Week 4 Visit 2 (LAVOC4B) 1-Yes 2-Missed V isit 3-Participant terminated from the study	1-Onsite at CTP/Research Office 2-Offsite at Participants Residence 3-Offsite - Other Location 4-T elephone 5-Prison/J ail *Additional Options Listed Below (LAVIS4B)	(LAVI4BSP)
Week 4 Visit 3 (LAVOC4C) 1-Yes 2-Missed V isit 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 /J ail *A dditional Options Listed Below	(LAVI4CSP)
	Specify Locations:(LACO4CSP)	
Week 5 Visit 1 (LAVO C5A) 1-Yes 2-Missed V isit 3-Participant terminated from the study	1-Onsite at CTP/Research Office 2-Offsite at Participants Residence 3-Offsite - Other Location 4-T elephone 5-Prison/J ail *Additional Options Listed Below	(LAVI5ASP)
	Specify Locations:(LACO5ASP)	
Week 5 Visit 2 (LAVOC5B) 1-Yes 2-Missed V isit 3-Participant terminated from the study	1-Onsite at CTP/Research Office 2-Offsite at Participants Residence 3-Offsite - Other Location 4-T elephone 5-Prison/J ail *Additional Options Listed Below (LAVIS5B)	(LAVI5BSP)
	Specify Locations:(LACO5BSP)	

Week 5 Visit 3 (LAVOC5C) 1-Yes 2-Missed V isit 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 *A dditional Options Listed Below (LAVISSC) Specify Locations:(LACO5CSP)	(LAVI5CSP)
Week 6 Visit 1 (LAVOC6A) 1-Yes 2-Missed V isit 3-Participant terminated from the study	1-Onsite at CTP/Research Office 2-Offsite at Participants Residence 3-Offsite - Other Location 4-T elephone 5-Prison/Jail *Additional Options Listed Below (LAVIS6A) Specify Locations:(LACO6ASP)	(LAVI6ASP)
Week 6 Visit 2 (LAVOC6B) 1-Yes 2-Missed V isit 3-Participant terminated from the study	1-Onsite at CTP/Research Office 2-Offsite at Participants Residence 3-Offsite - Other Location 4-T elephone 5-Prison/J ail *Additional Options Listed Below	(LAVI6BSP)
	Specify Locations:(LACO6BSP)	
Week 6 Visit 3 (LAVOC6C) 1-Yes 2-Missed V isit 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	(LAVI6CSP)
	Specify Locations:(LACO6CSP)	
Week 7 Visit 1 (LAVOC7A) 1-Yes 2-Missed V isit 3-Participant terminated from the study	1-Onsite at CTP /Research Office 2-Offsite at Participants Residence 3-Offsite - Other Location 4-T elephone 5-Prison /J ail *Additional Options Listed Below (LAVISTA)	(LAVI7ASP)
	Specify Locations:(LACO7ASP)	

Week 7 Visit 2 (LAVOC7B) 1-Yes 2-Missed V isit 3-Participant terminated from the study	1-Onsite at CTP/Research Office 2-Offsite at Participants Residence 3-Offsite - Other Location 4-T elephone 5-Prison/J ail *Additional Options Listed Below (LAVIS7B) Specify Locations:(LACO7BSP)	(LAVI7BSP)
Week 7 Visit 3 (LAVOC7C) 1-Yes 2-Missed V isit 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 *A dditional Options Listed Below (LAVISTC) Specify Locations:(LACOTCSP)	(LAVI7CSP)
Week 8 Visit 1 (LAVOC8A) 1-Yes 2-Missed V isit 3-Participant terminated from the study	1-Onsite at CTP/Research Office 2-Offsite at Participants Residence 3-Offsite - Other Location 4-T elephone 5-Prison/J ail *Additional Options Listed Below	(LAVI8ASP)
	Specify Locations:(LACO8ASP)	
Week 8 Visit 2 (LAVO C8B) 1-Yes 2-Missed V isit 3-Participant terminated from the study	1-Onsite at CTP/Research Office 2-Offsite at Participants Residence 3-Offsite - Other Location 4-T elephone 5-Prison/J ail *Additional O ptions Listed Below (LAVIS8B)	(LAVI8BSP)
	Specify Locations:(LACO8BSP)	
Week 8 Visit 3 (LAVOC8C) 1-Yes 2-Missed V isit 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/J ail *A dditional Options Listed Below (LAVIS8C)	(LAVI8CSP)
	Specify Locations:(LACO8CSP)	

Week 9 Visit 1 (LAVOC9A) 1-Yes 2-Missed V isit 3-Participant terminated from the study	1-Onsite at CTP/Research Office 2-Offsite at Participants Residence 3-Offsite - Other Location 4-T elephone 5-Prison/J ail *Additional O ptions Listed Below (LAVIS9A) Specify Locations:(LACO9ASP)	(LAVI9ASP)
Week 9 Visit 2 (LAVOC9B) 1-Yes 2-Missed V isit 3-Participant terminated from the study	1-Onsite at CTP/Research Office 2-Offsite at Participants Residence 3-Offsite - Other Location 4-T elephone 5-Prison/J ail *Additional O ptions Listed Below (LAVIS9B) Specify Locations:(LACO9BSP)	(LAVI9BSP)
Week 9 Visit 3 (LAVOC9C) 1-Yes 2-Missed V isit 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/J ail *A dditional Options Listed Below (LAV/S9C)	(LAVI9CSP)
	Specify Locations:(LACO9CSP)	
Week 10 Visit 1 (LAVOC10A) 1-Yes 2-Missed V isit 3-Participant terminated from the study	1-O nsite at CTP/Research Office 2-O ffsite at Participants Residence 3-O ffsite - O ther Location 4-T elephone 5-Prison/J ail *Additional O ptions Listed Below (LAVIS10A)	(LAV10ASP)
	Specify Locations:(LAC10ASP)	
Week 10 Visit 2(LAVOC10B) 1-Yes 2-Missed V isit 3-Participant terminated from the study	1-O nsite at CTP/Research Office 2-O ffsite at Participant's Residence 3-O ffsite - O ther Location 4-T elephone 5-Prison/J ail *Additional O ptions Listed Below (LAVIS10B)	(LAV10BSP)
	Specify Locations:(LAC10BSP)	

W 1 40 W 1/2 0/400 (00)		(4.414.0000)
Week 10 Visit 3(LAVOC10C) 1-Yes 2-Missed V isit 3-Participant terminated from the study	1-Onsite at CTP/Research Office 2-Offsite at Participant's Residence 3-Offsite - Other Location 4-T elephone 5-Prison/Jail *Additional Options Listed Below (LAVIS10C) Specify Locations:(LAC10CSP)	(LAV10CSP)
	Specify Locations.(LAC to CSF)	
Week 11 Visit 1(LAVOC11A) 1-Yes 2-Missed V isit 3-Participant terminated from the study	1-O nsite at CTP/Research Office 2-O ffsite at Participant's Residence 3-O ffsite - O ther Location 4-T elephone 5-Prison/Jail *Additional O ptions Listed Below	(LAV1 1ASP)
	Specify Locations:(LAC11ASP)	
Week 11 Visit 2(LAVOC11B) 1-Yes 2-Missed V isit 3-Participant terminated from the study	1-O nsite at CTP/Research Office 2-O ffsite at Participants Residence 3-O ffsite - O ther Location 4-T elephone 5-Prison/J ail *Additional O ptions Listed Below (LAVIS11B)	(LAV11BSP)
	Specify Locations:(LAC11BSP)	
Week 11 Visit 3(LAVOC11C) 1-Yes 2-Missed V isit 3-Participant terminated from the study	1-Onsite at CTP/Research Office 2-Offsite at Participant's Residence 3-Offsite - Other Location 4-T elephone 5-Prison/Jail *Additional Options Listed Below	(LAV11CSP)
	Specify Locations:(LAC11CSP)	
Week 12 Visit 1(LAVOC12A) 1-Yes 2-Missed V isit 3-Participant terminated from the study	1-O nsite at CTP/Research Office 2-O ffsite at Participant's Residence 3-O ffsite - O ther Location 4-T elephone 5-Prison/J ail *Additional O ptions Listed Below (LAVIS12A)	(LAV12ASP)
	Specify Locations:(LAC12ASP)	

Week 12 Visit 2(LAVOC12B) 1-Yes 2-Missed V isit 3-Participant terminated from the study	1-O nsite at CTP/Research Office 2-O ffsite at Participants Residence 3-O ffsite - O ther Location 4-T elephone 5-Prison/J ail *Additional O ptions Listed Below (LAVIS12B)	(LAV12BSP)
	Specify Locations:(LAC12BSP)	
Week 12 Visit 3(LAVOC12C) 1-Yes 2-Missed V isit 3-Participant terminated from the study	1-Onsite at CTP/Research O ffice 2-Offsite at Participant's Residence 3-Offsite - Other Location 4-T elephone 5-Prison/Jail *Additional Options Listed Below	(LAV12CSP)
	Specify Locations:(LAC12CSP)	

Additional Selection Options for LOA

Week 1 visit 1 6-Combination

NIDA Clinical Trials Network

Continuation Phase Assessment Location Form (LOC)

(LOVIS16A)

Specify Locations: (LOC16ASP)

Segment (PROTSEG):

Did This Visit Occur?	Visit Location	Comments:
Week 13 Visit 1 (LOVOC13A) 1-Yes 2-Missed V isit 3-Participant terminated from the study	1-Onsite at CTP/Research Office 2-Offsite at Participants Residence 3-Offsite - Other Location 4-T elephone 5-Prison/Jail *Additional Options Listed Below	(LOV13ASP)
	Specify Locations: (LOC13ASP)	
Week 14 Visit 1 (LOVOC14A) 1-Yes 2-Missed V isit 3-Participant terminated from the study	1-Onsite at CTP/Research Office 2-Offsite at Participant's Residence 3-Offsite - Other Location 4-T elephone 5-Prison/Jail *Additional Options Listed Below	(LOV14ASP)
	Specify Locations: (LOC1 4ASP)	
Week 15 Visit 1 (LOVOC15A) 1-Yes 2-Missed V isit 3-Participant terminated from the study	1-Onsite at CTP/Research Office 2-Offsite at Participants Residence 3-Offsite - Other Location 4-Telephone 5-Prison/Jail *Additional Options Listed Below	(LOV15ASP)
	Specify Locations: (LO C1 5ASP)	
Week 16 Visit 1 (LOVOC16A) 1-Yes 2-Missed V isit 3-Participant terminated from the study	1-Onsite at CTP/Research Office 2-Offsite at Participants Residence 3-Offsite - Other Location 4-Telephone 5-Prison/Jail *Additional Options Listed Below	(LOV16ASP)

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Week 17 Visit 1(LOVOC17A) 1-Yes 2-Missed V isit 3-Participant terminated from the study	1-Onsite at CTP /Research Office 2-Offsite at Participants Residence 3-Offsite - Other Location 4-T elephone 5-Prison/Jail *Additional Options Listed Below (LO VIS17A)	(LOV17ASP)
	Specify Locations: (LO C1 7ASP)	
Week 18 Visit 1(LOVOC18A) 1-Yes 2-Missed V isit 3-Participant terminated from the study	1-Onsite at CTP/Research Office 2-Offsite at Participants Residence 3-Offsite - Other Location 4-T elephone 5-Prison/Jail *Additional Options Listed Below	(LOV18ASP)
	Specify Locations: (LOC18ASP)	
Week 19 Visit 1(LOVOC19A) 1-Yes 2-Missed V isit 3-Participant terminated from the study	1-Onsite at CTP /Research Office 2-Offsite at Participants Residence 3-Offsite - Other Location 4-Telephone 5-Prison/Jail *Additional Options Listed Below (LOVIS19A)	(LOV19ASP)
	Specify Locations: (LOC19ASP)	
Week 20 Visit 1(LOVOC20A) 1-Yes 2-Missed V isit 3-Participant terminated from the study	1-Onsite at CTP/Research Office 2-Offsite at Participants Residence 3-Offsite - Other Location 4-T elephone 5-Prison/J ail *Additional O ptions Listed Below	(LOV20ASP)
	Specify Locations: (LOC2 0ASP)	
Week 21 Visit 1(LOVOC21A) 1-Yes 2-Missed V isit 3-Participant terminated from the study	1-Onsite at CTP/Research Office 2-Offsite at Participants Residence 3-Offsite - Other Location 4-T elephone 5-Prison/J ail *Additional Options Listed Below	(LOV21ASP)
	Specify Locations: (LOC2 1ASP)	

Week 22 Visit 1(LOVOC22A) 1-Yes 2-Missed V isit 3-Participant terminated from the study	1-Onsite at CTP/Research Office 2-Offsite at Participants Residence 3-Offsite - Other Location 4-Telephone 5-Prison/Jail *Additional Options Listed Below (LOVIS22A)	(LOV22ASP)
	Specify Locations: (LOC22ASP)	
Week 23 Visit 1(LOVOC23A) 1-Yes 2-Missed V isit 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	(LOV23ASP)
	Specify Locations: (LOC2 3ASP)	
Week 24 Visit 1(LOVOC24A) 1-Yes 2-Missed V isit 3-Participant terminated from the study	1-Onsite at CTP /Research Office 2-Offsite at Participants Residence 3-Offsite - Other Location 4-T elephone 5-Prison/Jail *Additional Options Listed Below (LOVIS24A)	(LOV24ASP)
	Specify Locations: (LOC2 4ASP)	
Week 25 Visit 1(LOVOC25A) 1-Yes 2-Missed V isit 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	(LOV25ASP)
	Specify Locations: (LOC25ASP)	
Week 26 Visit 1(LOVOC26A) 1-Yes 2-Missed V isit 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	(LOV26ASP)
	Specify Locations: (LOC26ASP)	

Week 27 Visit 1(LOVOC27A) 1-Yes 2-Missed V isit 3-Participant terminated from the study	1-Onsite at CTP /Research Office 2-Offsite at Participant's Residence 3-Offsite - Other Location 4-T elephone 5-Prison /J ail *Additional Options Listed Below (LO VIS27A) Specify Locations: (LO C2 7ASP)	(LOV27ASP)
	Chosely Essential (Essential)	
Week 28 Visit 1(LOVOC28A) 1-Yes 2-Missed V isit 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	(LOV28ASP)
	Specify Locations: (LOC28ASP)	
Week 29 Visit 1(LOVOC29A) 1-Yes 2-Missed V isit 3-Participant terminated from the study	1-Onsite at CTP/Research Office 2-Offsite at Participant's Residence 3-Offsite - Other Location 4-T elephone 5-Prison/J ail *Additional Options Listed Below (LOVIS29A)	(LOV29ASP)
	Specify Locations: (LOC29ASP)	
Week 30 Visit 1(LOVOC30A) 1-Yes 2-Missed V isit 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 /J ail *Additional Options Listed Below	(LOV30ASP)
	Specify Locations: (LOC30ASP)	
Week 31 Visit 1(LOVOC31A) 1-Yes 2-Missed V isit 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	(LOV31ASP)
	Specify Locations: (LO C31ASP)	

Week 32 Visit 1(LOVOC32A) 1-Yes 2-Missed V isit 3-Participant terminated from the study	1-Onsite at CTP/Research Office 2-Offsite at Participant's Residence 3-Offsite - Other Location 4-T elephone 5-Prison/J ail *Additional Options Listed Below (LO VIS32A)	(LOV32ASP)
	Specify Locations: (LO C32ASP)	
Week 33 Visit 1(LOVOC33A) 1-Yes 2-Missed V isit 3-Participant terminated from the study	1-Onsite at CTP/Research Office 2-Offsite at Participant's Residence 3-Offsite - Other Location 4-T elephone 5-Prison/J ail *Additional Options Listed Below	(LOV33ASP)
	Specify Locations: (LOC33ASP)	
Week 34 Visit 1(LOVOC34A) 1-Yes 2-Missed V isit 3-Participant terminated from the study	1-Onsite at CTP/Research Office 2-Offsite at Participant's Residence 3-Offsite - Other Location 4-T elephone 5-Prison/J ail *Additional Options Listed Below (LOVIS34A)	(LOV34ASP)
	Specify Locations: (LO C3 4ASP)	
Week 35 Visit 1(LOVOC35A) 1-Yes 2-Missed V isit 3-Participant terminated from the study	1-Onsite at CTP/Research Office 2-Offsite at Participant's Residence 3-Offsite - Other Location 4-T elephone 5-Prison/J ail *Additional Options Listed Below	(LOV35ASP)
	Specify Locations: (LO C35ASP)	
Week 36 Visit 1(LOVOC36A) 1-Yes 2-Missed V isit 3-Participant terminated from the study	1-Onsite at CTP/Research Office 2-Offsite at Participant's Residence 3-Offsite - Other Location 4-T elephone 5-Prison/J ail *Additional Options Listed Below (LOV/S36A)	(LOV36ASP)
	Specify Locations: (LOC36ASP)	

Week 37 Visit 1(LOVOC37A) 1-Yes 2-Missed V isit 3-Participant terminated from the study	1-Onsite at CTP/Research Office 2-Offsite at Participant's Residence 3-Offsite - Other Location 4-T elephone 5-Prison/J ail *Additional Options Listed Below (LOVIS37A)	(LOV37ASP)
	Specify Locations: (LOC37ASP)	

Additional Selection Options for LOC

Week 13 visit 1 6-Combination

NIDA Clinical Trials Network		

Maximal Exercise Test (MET)

Web Version: 1.0; 2.05; 02-27-12

Segment (PROTSEG):			
Visit Number (VISNO):			

,	
Date of assessment: (MEASMTDT)	(mm/dd/yyyy)
1. Weight:(MEWGHTLB)	(xxx.x) lbs (MEWGHTKG) (xxx.x) kgs
2. Height:(MEHGHTIN)	(xx) in (MEHGHTM) (x.xx) m
3. BMI:(MEBMI)	(xx.x)
4. Resting heart rate: (MERSTBPM)	(xxx) beats per minute
5. Resting blood pressure: (MERSTSYS)	(xxx) / (MERSTDIA) (xxx) mmHg
6. Test duration:(MEDURMIN)	(xx) : (MEDURSEC) (xx) mm:ss
7. Max speed: (MEMAXMPH)	(x.x) mph
8. Max grade: (MEMAX GRD)	(xx.x) %
9. Maxheart rate:(MEMAXBPM)	(xxx) beats per minute
10. Max blood pressure: (MEMAXSYS)	(xxx) / (MEMAXDIA) (xxx) mmHg
11. METs calculation: (MEMETS)	(xx.x)
12. He art rate at 2 minute recovery: (ME2MNBPM)	(xxx) beats per minute
13. Blood pressure at 2 minute recovery:(ME2MNSYS)	(xxx) / (ME2MNDIA, (xxx) mmHg
14. He art rate at 6 minute recovery: (ME6MNBPM)	(xxx) beats per minute
15. Blood pressure at 6 minute recovery:(ME6MNSYS)	(xxx) / (ME6MNDIA, (xxx) mmHg
16. Signs of ischemia:(MEISCHEM)	☐ No ☐ Yes If "Yes":
a. ST depression: (MESTDEPR)	□ No □ Yes
b. ST elevation: (MESTELEV)	□ No □ Yes

17. Clinically significant symptoms: (MECLNSIG)	□ No □ Yes
If "Yes", describe:(MECLSGSP)	
18. Clinically significant arrhythmia: (MEARRHYT)	□ No □ Yes
If "Yes", describe:(MEARRHSP)	I NO I TES
Comments:(MECOMM)	
Comments (MECOMM)	

NIDA Clinical Trials Network
Missed Visit Form (MVF)
Web Version: 1.0; 3.01; 05-31-13

Segment (PROTSEG): Visit Number (VISNO):

Missed visit target date:(MVTRGTDT)

Reason for missed visit: (MVREASON)

If "Other", specify: (MVOTHRSP)

(mm/dd/yyyy) Click here to view calendar

2-Participant too ill 3-Participant missed the study visit 4-Unable to contact participant

9-Other

	Network

Prior and Concomitant Medications (PCM)

Web Version: 1.0; 2.03; 01-18-12

Is the partic ipant currently taking any prescribed medications or has the participant taken any prescribed medications within the past 7 days?(CMMEDNY) No 🗀 Yes

h addition to prescription medications, please also record over the counter Zantac, ranitione, Wal-zan, or Tritec, or anything that is intended to substitute for these. If you are unsure about a medication, please make note of it and find out if it is in fact a substitute for these;

if not, you can correct later. If you are asked why we are interested in these medications, please explain that we have found that they are

a category of medication that we are interested in tracking for the study, just as we are tracking prescription medications.

	Medication Name	Indication	Medication Start Date	Ongoing?	Medication Stop Date	Used to Treat an AE
1.	(CM_01 DNM)	(CM_01DIN) 1-Analgesic/NSAD/Antipyretic 2-Anesthetic 3-Antacid 4-Ant-as hma/Bronchodilator 4-Ant-as hma/Bronchodilator 5-Antbiotic/Anti-infective/Anti-parasite/Anti-fungal/Anti-inflammatory/Anti-microbial *Additional Options Listed Below	(CM_0 ISDT) (m m/ddJyy yy)	(CM_010NG) O-No 1-Yes 2-Yes (continuing at protocol completion or study terminator).	(CM_01PDT) (mm/dd/yyyy)	(CM_01TAE) O-No 1-Yes
2.	(CM @ DNM)	CM_02DIN 1-Analgesic:NSAD:Antipyretic 2-Anesthetic 3-Aneticid 4-Anti-as hma/Bronchodilator 5-Antibiotic/Anti-infedtive/Anti-parasite:Anti-fungal/Anti-inflammatory:Anti-microbial *Additional Optons Listed Below	(CM_02SDT) [mm/dd/yyyy)	(CM 020/NS) O-No 1-Yes 2-Yes (continuing at protocol completion or study terminator)	(CM_ cz PDT) (mm/d dłyyyy)	ONO 1-Yes
3.	(CM_03DNM)	(CM_03DIN) 1-Analgesic:\(\text{NSAD:Antipyretic}\) 2-Anesthetic 3-Aneticid 4-Anti-as hma/Bronchodilator 5-Antibiotic/Anti-infective/Anti-parasite:\(\text{Anti-fungal/Anti-inflammatory:}\(\text{Ant-microbial}\) *Additional Optons Listed Below	(CM_03SDT) (m m/dd/yy yy)	(CM 0:30NG) O-No 1-Yes 2-Yes (continuing at protocol completion or study terminator)	(CM_ 03PDT) (mm/d d'yyyy)	(CM @TAE) ONO 1-Yes
4.	(CM_04DNM)	(CM_04DIN) 1-Analgesic/NSAD/Antipyretic 2-Anesthetic 3-Antecid 4-Anti-as hma/Bronchodilator 5-Antbiotic/Anti-infective/Anti-parasite/Anti-fungal/Anti-inflammatory/Anti-microbial *Additional Optons Listed Below	(CM_04SDT) (m m/ddlyyyy)	(CM_040NG) O-No 1-Yes 2-Yes (continuing at protocol completion or study terminator)	(CM_ O4PDT) (mm/dd/yyyy)	(CM_04TAE) O-No 1-Yes
5.	(CM_06DNM)	(CM_05DIN) 1-Analgesic/NS A D /Antipyretic 2-Anesthetic 3-Antacid 4-Ant-as hma/Bronchodilator 5-Antbiotic/Anti-infective/Anti-parasite/Anti-fungal/Anti-inflammatory/Anti-microbial *Additional Optons Listed Below	(CM_OSSDT) (m m/ddl/yyyy)	(CM_050N6) O-No 1-Yes 2-Yes (continuing at protocol completion or study terminator)	(CM_ 05PDT) (mm/d d/yyyy)	(CM_05TAE) O-No 1-Yes
6.	(CM_OGDNM)	(CM_06DIN) 1-Analgesic/NSAD/Antipyretic 2-Anesthetic 3-Antecid 4-Ant-as hma/Bronchodilator 4-Ant-as hma/Bronchodilator 5-Antbiotic/Anti-infective/Anti-parasite/Anti-fungal/Anti-inflammatory/Anti-microbial *Additional Optons Listed Below	(CM_06SDT) (m m/dd/yyyy)	(CM_060NG) O-No 1-Yes 2-Yes (continuing at protocol completion or study terminator)	(CM_O6PDT) (mm/dd ⁱ yyyy)	(CM 06TAE) O-No 1-Yes
7.	(CM. 07 DNM)	(CM_07DIN) 1-Analgesic:NSAD:Antipyretic 2-Anesthetic 3-Antecid 4-Ant-as hma/Bronchodilator 5-Antbiotic/Anti-infedtive/Anti-parasite:Anti-fungal/Anti-inflammatory:Anti-microbial *Additional Optons Listed Below	(CM_07SDT) [(m m/dd/yy yy)	(CM_070NS) O-No 1-Yes 2-Yes (contnuing at protocol completion or study terminator)	(CM_07PDT) (mm/dd/yyyy)	(CM 07 TA E) O-No 1-Yes

8. (CM_OBDNM)	(CM - 08D IN) 1-A nalgesic: NS A D: Antipyretic 2-A nesthetic 3-A nescid 4-A nt-as hma/Bronchodilator 5-A ntbiotic/Anti-nifective/Anti-parasite./A nti-fungal/Anti-inflammatory/A nt-microbial *Additional O ptons Listed Below	(CM_08SDT) (m m/ddlyyyy)	(CM 080NG) O-No 1-Yes 2-Yes (continuing at protocol completion or study termination)	(CM_08PDT) (mm/dd/yyyy)	(CM_08TAE) O-No 1-Y es
9. (CM_09DNM)	(CM_09DIM) 1-Analgesic:NIS AID:Antipyretic 2-Anesthetic 3-Antecid 4-Ant-ashma/Bronchodilator 5-Antbiotic/Anti-infective/Anti-parasite/Anti-fungal/Anti-inflammatory/Anti-microbial 'Additional Optons Listed Below	(CM_09SDT) (m m/dd/yy yy)	(CM_990NG) Q-No 1-Yes 2-Yes (continuing at protocol completion or study termination).	(CM_09PDT) (mm/dd/yyyy)	(CM_09TAE) O-No 1-Y es
10. (CM_10DNM)	(CM_10D1N) 1-Analgesic./NSAID./Antipyretic 2-Anesthetic 3-Antecid 4-Ant-ashma/Bronchodilator 5-Antibiotic/Anti-infective/Anti-parasite./Anti-fungal/Anti-inflammatory/Ant-microbial *Additional Options Listed Below	(CM_10SDT) (m m/dd fyy yy)	(CM_100NG) O-No 1-Yes 2-Yes (continuing at protocol completion or study termination)	(CM_10PDT) (mm/dd/yyyy)	(CM_10TAE) O-No 1-Y es
11. (CM_11DNM)	(CM_11DIN) 1-Analgesic./NSAID:/Antipyretic 2-Anesthetic 3-Antecid 4-Ant-as hma/Bronchodilator 5-Antibiotic/Anti-infective/Anti-parasite/Anti-fungal/Anti-inflammatory/Ant-microbial "Additional Optons Listed Below	(CM_11SDT) (m m/dd/yyyy)	(CM_110NG) O-No 1-Yes 2-Yes (continuing at protocol completion or study termination)	(CM_11PDT) (mm/dd/yyyy)	(CM_11TAE) O-No 1-Y es
12. (CM. 12 DNM)	(CM 12DIN) 1-Analgesic./NSAID./Antipyretic 2-Anesthetic 3-Antacid 4-Ant-astma/Bronchodilator 5-Antbiotic/Anti-infective/Anti-parasite/Anti-furgal/Anti-inflammatory/Ant-microbial *Additional Optons Listed Below	(CM_12SDT) (m m/dd lyy yy)	(CM_120NG) O-No 1-Yes 2-Yes (continuing at protocol completion or study termination)	(CM_12PDT) (mm/dd/yyyy)	(CM 12 TAE) ONO 1-Y es
13. (CM_13DNM)	(CM 1:3DIN) 1-Analgesic:NSAID:Antipyretic 2-Anesthetic 3-Antacid 4-Ant-astma/Bronchodilator 5-Antibiotic/Anti-inflective/Anti-parasite:Anti-fungal/Anti-inflammatory:Ant-microbial *Additional Optons Listed Below	(CM_13SDT) (m m/dd/yyyy)	(CM 130NG) O-No 1-Yes 2-Yes (continuing at protocol completion or study termination)	(CM_13PDT) (mm/dd/yyyy)	(CM 13TAE) O-No 1-Y es
14. (CM_14DNM)	(CM 14DIN) 1-Analgesic:NSAID:Antipyretic 2-Anesthetic 3-Antacid 4-Ant-as thra/Bronchodilator 5-Antibiotic/Anti-inflective/Anti-parasite:Anti-fungal/Anti-inflammatory:Anti-microbial *Additional Options Listed Below	(CM_14SDT) (m m/dd/yy yy)	(CM 140NG) O-No 1-Yes 2-Yes (continuing at protocol completion or study termination)	(CM_14PDT) (mm/dd/yyyy)	(CM_14TAE) ONO 1-Y es
15. (CM_15DNM)	(CM_15DIN) 1-Analgesic.NSAID:Antipyretic 2-Anesthetic 3-Antacid 4-Ant-astma/Bronchodilator 5-Antbiotic/Anti-infective/Anti-parasite/Anti-fungal/Anti-inflammatory/Ant-microbial *Additional Optons Listed Below	(CM_15SDT) (m m/dd/yy yy)	(CM_150NG) O-No 1-Yes 2-Yes (continuing at protocol completion or study termination)	(CM_15PDT) (mm/dd/yyyy)	(CM_ 15TAE) ONO 1-Y es
16. (CM_16DNM)	(CM_16DIN) 1-Analgesic.NSAID:Antipyretic 2-Anesthetic 3-Antacid 4-Ant-as thra/Bronchodilator 5-Antibiotic/Anti-inflective/Anti-parasite./Anti-fungal/Anti-inflammatory/Ant-microbial *Additional Optons Listed Below	(CM_16SDT) (m m/dd/yyyy)	(CM_160NG) O-No 1-Yes 2-Yes (continuing at protocol completion or study termination)	(CM_16PDT) (mm/dd/yyyy)	(CM_ 16TAE) ONO 1.Y es
17. (CM_17DNM)	(CM_17DIN)	(CM_17SDT) (m m/dd/yy yy)	(CM_170NG) O-No 1-Yes 2-Yes (confinuing at protocol completion or study termination)	(CM_17PDT) (mm/dd/yyyy)	(CM 17TAE) O-No 1-Y es

			T			I
	1-Analgesic/NSAID/Antipyretic 2-Anesthetic 3-Antacid 4-Ant-as-hma/Bronchodilator 5-Antibiotic/Anti-infective/Anti-parasite/Anti-fungal/Antibiotic/Anti-infective/Anti-parasite/Anti-fungal/Antibiotic/Anti-infective/Anti-parasite/Anti-fungal/Antibiotic/Anti-infective/Anti-parasite/Anti-fungal/Antibiotic/Anti-infective/Anti-parasite/Anti-fungal/Antibiotic/Anti-infective/Anti-parasite/Anti-fungal/Antibiotic/Anti-infective/Anti-parasite/Anti-fungal/Antibiotic/Anti-infective/Anti-parasite/Anti-fungal/Antibiotic/Anti-infective/Anti-parasite/Anti-fungal/Antibiotic/Anti-infective/Anti-parasite/Anti-fungal/Antibiotic/Anti-infective/Anti-parasite/Anti-fungal/Anti-infective/Anti-parasite/Anti-fungal/Anti-fungal/Anti-infective/Anti-parasite/Anti-fungal/	inti-inflammatory.A.nti-microbial				
18. (CM_18DNM)	(CM_18DIN) 1-Analgesic.NSAID./Antipyretic 2-Anesthetic 3-Antecid 4-Ant-as-hma/Bronchodilator 5-Antibiotic/Anti-infective/Anti-parasite./Anti-fungal/Antibiotic/Anti-infective/Anti-parasite./Anti-fungal/Antibiotic/Antibio	(CM_18S) (mm/dd/) inti-inflammatory.Anti-microbial	O-N 1-Y		(CM_18PDT) (mm/dd/yyyy)	(CM_ 18TA E) O-No 1-Y es
19. (CM_19DNM)	(CM. 19D/N) 1-Analgesic/NSAID/Antipyretic 2-Anesthetic 3-Antecid 4-Ant-as-hma/Bronchodilator 5-Antibiotic/Anti-infective/Anti-parasite/Anti-fungal/Antibiotic/Anti-infective/Anti-parasite/Anti-fungal/Antibiotic/Antibioti	(CM_19S (mm/dd/g	O-N 1-Y		(CM_19PDT) (mm/dd'yyyy)	(CM 19TAE) O-No 1-Yes
20. (CM_20DNM)	(CM_20DIN) 1-Analgesic.NSAID./Antipyretic 2-Anesthetic 3-Antecid 4-Ant-as-hma/Bronchodilator 5-Antibiotic/Anti-infective/Anti-parasite./Anti-fungal/i	(CM, 205 (m m/dd/)	O-N 1-Y		(CM_20PDT) (mm/dd/yyyy)	(CM_20TAE) O-No 1-Yes
21. (CM_21DNM)	(CM. 2 1DIN) 1-Analgesic ANS AID /Antipyretic 2-Anesthetic 3-Antecid 4-Ant-ashma/Bronchodilator 5-Antibiotic /Anti-infective /Anti-parasite /Anti-fungal /Anti-sted Below	(CM, 2 15) (m m/dd/) (m filammatory / Ant-microbial	O-N 1-Yo		(CM_21PDT) (mm/dd/yyyy)	(CM 21TAE) O-No 1-Y es
22. (CM_22DNM)	(CM_22DIN) 1-Analgesic.NSAID./Antipyretic 2-Anesthetic 3-Antecid 4-Ant-ashma/Bronchodilator 5-Antibiotic/Anti-infective/Anti-parasite./Anti-fungal/Anti-bashma/Bronchodilator	(CM_228 (m m/dd)	O-N 1-Yo		(CM_22PDT) (mm/dd/yyyy)	(CM_22 TA E) O-No 1-Y es
23. (CM_23DNM)	(CM 230 IN) 1-Analgesic /NSAID /Antipyretic 2-Anesthetic 3-Antecid 4-Ant-as hma/Bronchodilator 5-Ant biotic/Anti-infective/Anti-parasite/Anti-fungal/in/Additional Optons Listed Below	(CM_23S) (im m/dd/) Inti-inflammatory/Anti-microbial	O-N 1-Y		(CM_23PDT) (mm/dd/yyyy)	(CM 23TAE) O-No 1-Y cs
24. (CM_24DNM)	(CM 24DIN) 1Analgesic:AISAID:Antipyretic 2Anesthetic 3Antacid 4Antas. hma/Bronchodilator 5Antibiotic/Anti-infective/Anti-parasite:Anti-fungal/Antibiotic/Anti-infective/Anti-parasite.Anti-fungal/Antibiotic/Anti-infective/Anti-parasite.Anti-fungal/Antibiotic/Anti-infective/Anti-parasite.Anti-fungal/Antibiotic/Anti-infective/Anti-parasite.Anti-fungal/Antibiotic/Anti-infective/Anti-parasite.Anti-fungal/Antibiotic/Anti-infective/Anti-parasite.Anti-fungal/Antibiotic/Anti-infective/Anti-parasite.Anti-fungal/Antibiotic/Anti-infective/Anti-parasite.Anti-fungal/Antibiotic/Anti-infective/Anti-parasite.Anti-fungal/Antibiotic/Anti-infective/Anti-parasite.Anti-fungal/Antibiotic/Anti-infective/Anti-parasite.Anti-fungal/Antibiotic/Anti-infective/Anti-parasite.Anti-fungal/Antibiotic/Anti-infective/Anti-parasite.Anti-fungal/Anti-infective/Anti-parasite.Anti-fungal/Anti-infective/Anti-parasite.Anti-fungal/Anti-infective/Anti-parasite.Anti-fungal/Anti-infective/Anti-parasite.Anti-fungal/Anti-infective/Anti-parasite.Anti-fungal/Anti-infective/Anti-parasite.Anti-fungal/Anti-infective/Anti-parasite.Anti-fungal/Anti-infective/Anti-parasite.Anti-fungal/Anti-infective/Anti-parasite.Anti-fungal/Anti-infective/Anti-parasite.Anti-fungal/Anti-infective/Anti-parasite.Anti-fungal/Anti-infective/Anti-parasite.Anti-fungal/Anti-infective/Anti-parasite.Anti-fungal/Anti-infective/Anti-parasite.Anti-fungal/Anti-parasite.Anti-fungal/Anti-parasite.Anti-fungal/Anti-parasite.Anti-fungal/Anti-parasite.Anti-fungal/Anti-parasite.Anti-fungal/Anti-parasite.Anti-fungal/Anti-parasite.Anti-fungal/Anti-parasite.Anti-fungal/Anti-parasite.Anti-fungal/Anti-parasite.Anti-fungal/Anti-parasite.Anti-fungal/Anti-parasite.Anti-fungal/Anti-	(CM_24S) (m m/dd/) Inti-inflammatory/Ant-microbial	O-N 1-Y		(CM_24PDT) (mm/dd/yyyy)	(CM 24TAE) O-No 1-Y cs
25. (CM_25DNM)	(CM 250 IN) 1-Analgesic AIS AID /A ntipyre tic 2-A nesthetic 3-Antacid 4-Ant as hma/Bronchodilator 5-Antibiotic/Anti-infective/Anti-parasite./Anti-fungal// *Additional Optons Listed Below	(CM_25S (m m/dd)	O-N 1-Y	_250NG) lo les les (contnuing at protocol completion or study terminator)	(CM_25PDT) (mm/dd/yyyy)	(CM_25TAE) O-No 1-Yes
26. (CM_26DNM)	(CM_26DIN)	(CM_26S) (m m/dd/)	O-N 1-Yo		(CM_26PDT) [mm/dd/yyyy)	(CM_26TAE) O-No 1-Y cs

	1-Analgesic /NSA D /A ntipyre tic 2-Ane sthetic 3-Antacid 4-Ant-as thma/Bronchodil ator 5-Antbiotic /Anti-infective /Anti-parasite /Anti-fungal / Anti-inflammatory /Anti-microbial *Additional Options Listed Below				
27. (CM_27 DNM)	(CM_27D/N) 1-Analgesic:\text{\text{NSAID}Antipyre-tic} 2-Anesthetic 3-Antacid 4-Ant-as-thma/Bronchodilator 5-Antbiotic/Anti-infective/Anti-parasite/Anti-fungal/Anti-inflammatory/Anti-microtial *Additional Options Listed Below	(CM_27SDT) (m m/dd/yyyy)	(CM_270NG) O-No 1-Yes 2-Yes (continuing at protocol completion or study terminaton)	(CM_27PDT) (mm/dd/yyyy)	(CM_27TAE) ONO 1-Yes
28. (CM_28DNM)	(CM 28DIN) 1-Analgesic:NSAID:Antipyretic 2-Anesthetic 3-Antacid 4-Ant-as-hma/Bronchodilator 5-Antbiotic/Anti-infective/Anti-parasite/Anti-fungal/Anti-inflammatory/Anti-microbial *Additional Options Listed Below	(CM_28SDT) (m m/dd/yyyy)	(CM_280NG) O-No 1-Yes 2-Yes (continuing at protocol completion or study termination)	(CM_28PDT) (mm/dd/yyyy)	(CM 28TAE) O-No 1-Y es
29. (CM_29 DNM)	(CM_29D/N) 1-Analgesic:NSAID:Antipyretic 2-Anesthetic 3-Antacid 4-Ant-as-thma/Bronchodilator 5-Antbiotic:/Anti-infective/Anti-parasite:/Anti-fungal/Anti-inflammatory:/Ant-microbial *Additional Options Listed Below	(CM_29SDT) (m m/dd/yyyy)	(CM_290NG) O-No 1-Yes 2-Yes (continuing at protocol completion or study terminaton)	(CM_29PDT) (mm/dd/yyyy)	(CM_29TAE) ONO 1-Y es
30. (CM_30DNM)	(CM 30DIN) 1-Analgesic AISA D./A ntipyre tic 2-Anesthetic 3-Antacid 4-Ant-as-hma/Bronchodilator 5-Antbiotic/Anti-infective/Anti-parasite/Anti-fungal/Anti-inflammatory/Anti-microbial *Additional Options Listed Below	(CM_30SDT) [(m m/dd/yy yy)	(CM 300NG) O-No 1-Yes 2-Yes (continuing at protocol completion or study terminator)	(CM_30PDT) (mm/dd/yyyy)	(CM 30TAE) O-No 1-Yes
31. (CM_31DNM)	(CM_31DIN) 1-Analgesic.NSAD/Antipyretic 2-Anesihetic 3-Anticid 4-Ant-as hma/Bronchodilator 5-Antibiotic/Anti-infective/Anti-parasite/Anti-fungal/Anti-inflammatory/Anti-microtial *Additional Options Listed Below	(CM_31SDT) (m m/dd/yy yy)	(CM_310NG) O-No 1-Yes 2-Yes (continuing at protocol completion or study termination)	(CM_3! PDT) (mm/dd/yyyy)	(CM_31 TA E) O-No 1-Y es
32. (CM_32DNM)	(CM 32DIN) 1-Analgesic AISAID /Antipyretic 2-Anesthetic 3-Antacid 4-Ant-as thma/Bronchodil ator 5-Antbiotic /Anti-infective /Anti-parasite /Anti-fungal /Anti-inflammatory /Anti-microbial 'Additional Optons Listed Below	(CM_32SDT) (m m/dd/yy yy)	(CM 320NG) O-No 1-Yes 2-Yes (confinuing at protocol completion or study terminaton)	(CM_XPDT) (mm/dd/yyyy)	(CM X TAE) ONo 1-Y cs
33. (CM_33DNM)	(CM. 3301/N) 1-Analgesic-NSAID/Antippretic 2-Anesthetic 3-Anteid 4-Ant-as thma/Bronchodilator 5-Antbiotic/Anti-infective/Anti-parasite/Anti-fungal/Anti-inflammatory/Anti-microbial *Additional Optons Listed Below	(CM_33SDT) (m m/dd/yy yy)	(CM_330NG) O-No 1-Yes 2-Yes (confinuing at protocol completion or study terminaton)	(CM_33PDT) (mm/dd/yyyy)	(CM 33TAE) ONo 1-Yes
34. (CM_34DNM)	(CM. 34DIN) 1-Analgesic-NS A D./A ntipyre tic 2-Ane-sthetic 3-Antacid 4-Ant-as-thma/Bronchodilator 5-Antbiotic/Anti-infective/Anti-parasite/Anti-fungal/Anti-inflammatory/Anti-microbial *Additional Options Listed Below	(CM_34SDT) (m m/dd/yy yy)	(CM_340NG) O-No 1-Yes 2-Yes (contnuing at protocol completion or study terminator)	(CM_34PDT) (mm/dd/yyyy)	(CM_34TAE) O-No 1-Yes
35. (<i>CM_35DNM</i>)	(CM_35D1N)	(CM_35SDT) (m m/dd/yy yy)	(CM_350NG) O-No 1-Yes 2-Yes (continuing at protocol completion or study terminaton)	(CM_35PDT) (mm\/ddyyyy)	(CM_35TAE) O-No 1-Yes

	I-Analgesic A\S A\D\Antipyretic 2-Anesthetic 3-Antecid 4-Ant-ashma/Bronchodilator 5-Antbiotic/Anti-infective/Anti-parasite/Anti-fungal/Anti-inflammatory/Anti-microbial *Additional Optons Listed Below		
Comments: (CM C OM M)			

Additional Selection Options for PCM

Medication purpose/ind 01
6-Antico agulant/Haemo static/Anti-hemo rrha gic
7-Anti-co mulsa nt
8-Antide pressant
9-Anti-da betic
33-Antitungal
10-Antihis ta mine

11-Antihyp ertensive 32-Antiretroviral 12-Cardiovascular Agent, Other Than Hyperlipidemic/HTN

12C dardiovascular Agent, Other Than Hyperlipidemic/HTN
13C ontraceptive
14D erma bilogic Agent
15E mergency/Support Agent
15E mergency/Support Agent
17-G1 Agent/Antidiar rheal/An 1 ements/Antispasmodic/Laxative
18-Growth Factor
19-Herbal/Homeopathic Product
20-Hormone/Site roid/Anti-inflammatory Steroid/Corticos teroid
21-Immunomod ulatory Agent
22-OTC C old and Flu/Sleep Aid
23-Sed attive

22-OTC Cold and Flu/Sleep Aid
23-Sedative
24-Skeletal Muscle Relaxant
25-Therapeutic Agent/Remedy for Eyes
26-Therapeutic Agent/Remedy for Mouth/Teeth
27-Vaccine/Prophylaxis
28-Vitamin/Mineral/Food Supplemen/Electrolyte Replacement
29-Antipsychotic
30-Mood Sabilizar
31-Other CMS-acting Agent
99-Other, Specify

NIDA Clinical Trials Network

Web Version: 1.0; 1.00; 05-06-10

I			Pain Fre	quency, Intensity	and Bur	den Scale (P-F	BS) (PFI)	
Segment <i>(PROTSI</i> Visit Number <i>(VISI</i>	,							
Date of assess	sment: (PFASSMDT)				(m	nm/dd/yyyy) (PFTODAY)	Click here f	or today's date
Indicate how	you feel by choos	ing one number on th	he scale for e	each question (items	1-4).			
1. How frequently	/ have you experier	nced pain in the past we	eek?					
Neve	er	Some of the Days		About Half of the Days		Most of the Days		Everyday
(PFFRPAIN)								
0	1	2	3	4	5	6	7	8
^{2.} How would you	u rate the intensity of	of your pain in the past	week?					
No Pain	1	Mild Pain		Moderate Pain		Severe Pain		Unbearable Pain
(PFINPAIN)								
0	1	2	3	4	5	6	7	8
3. How much did	pain interfere with	your daily life in the pas	st week?					
Neve	er	Some of the Days		About Half of the Days		Most of the Days		Everyday
(PFDYPAIN)								
0	1	2	3	4	5	6	7	8
4. How often did	you use medicatio	n or other treament to r	manage your	pain in the past week?				
Neve	er	Some of the Days		About Half of the Days		Most of the Days		Everyday
(PFMDPAIN)								
0		2	3					

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NIDA Clinical Trials Network
Physiological Measures (PME)

Segment (PROTSEG): Visit Number (VISNO):

Date of assessment: (PM DATE)

- 1. Height: (PMHGHTIN)
- 2. Height (PM HG HTIN)
- 3. Weight: (PMWGHTLB)
- 4. BMI: (PMBMI)
- 5. Waist circumference: (PM WS TCIN)

Comments: (PMCOMM)

(xx) in (PMHGHTCM) (xxx) cn (xx) in (PMHGHTCM) (xxx) ci	
(xx) in (PMHGHTCM) (xxx) ci	1
	m
(xxx.x) lbs (PMWGHTKG)	(xxx.x) kg
(xx. x)	
(xxx) in (PMWSTCCM) (xxx) cr	

Web Version: 1.0; 1.03; 10-11-12

NIDA Clinical Trials Network				
	Pregnancy Outcome 1 (PO1) Web Version: 1.0; 1.01; 01-29-13			
Pregnancy Number (PREGNO):				
Newborn Information				
1. Gender: (PO1GENDR)	☐ Male ☐ Female ☐ Unknown			
2. Gestational age at delivery:(P01GESWK)	(xx) Weeks (PO1GESDY) (x) Days (PO1GESUN) CR Unknown			
3. Weight at delivery: (PO1WTLBS)	(xx) Lbs (PO1WTOZ) (xx) Oz (PO1WTUNK) OR Unknown			
4. Apgar score at 1 minute: (PO 1APG 1M)	(xx) (PO11APUK) OR Unknown			
5. Apgar score at 5 minutes: (PO1APG5M)	(xx) (PO15APUK) OR Unknown			
6. Normal infant? (PO1NORML)	□ No □ Yes			
If "No", is there a congenital anomaly? (PO1CONAN)	□ No □ Yes □ Unknown			
If "Yes", specify abnormality and contributing factors: (PO1ABNSP)				

Comments: (PO1 COMM)

Additional Selection Options for PO1

Pregnancy Number (PREGNO) (key field): 1-1 2-2 3-3

NIDA Clinical Trials Network					
	Pregnancy Outcome 2 (PO2)				
Pregnancy Number (PREGNO):	Web Version: 1.0; 2.01; 01-29-13				
Newborn Information					
1. Gender: (PO2 GENDR)	☐ Male ☐ Female ☐ Unknown				
2. Gestational age at delivery:(PO2GESWK)	(xx) Weeks (PO2GESDY, (x) Days (PO2GESUN)OR Unknown				
3. Weight at delivery: (PO2WTLBS)	(xx) Lbs (PO2WTOZ) (xx) Oz (PO2WTUNK) OR Unknown				
4. Apgar score at 1 minute: (PO2APG 1M)	(xx) (PO21APUK) OR Unknown				
5. Apgar score at 5 minutes: (PO2APG5M)	(xx) (PO25APUK) OR Unknown				
6. Normal infant?(PO2NORML) If "No", is there a congenital anomaly?(PO2CONAN) If "Yes", specify abnormality and contributing factors:(PO2ABNSP)	No Yes No Yes Unknown				

Comments: (PO2 COMM)

	(xx) Lbs (PO2WTOZ)	(xx) Oz (PO2WTUNK) OR	Unkno
	(xx) (P021APUK) 0R	Unknown	
	(xx) (P025APUK) 0R	Unknown	
□ No □ No	Yes Unknown		٦
			_

Additional Selection Options for PO2

Pregnancy Number (PREGNO) (key field): 1-1 2-2 3-3

NIDA Clinical Trials Network						
Pregnancy Outcome 3 (PO3)						
Pregnancy Number (PREGNO):	Web Version: 1.0; 2.01; 01-29-13					
Newborn Information						
1. Gender: (PO3GENDR)	☐ Male ☐ Female ☐ Unknown					
2. Gestational age at delivery:(PO3GESWK)	(xx) Weeks (PO3GESDY) (x) Days (PO3GESUN)OR Unknown					
3. Weight at delivery: (PO 3WTLBS)	(xx) Lbs (PO3WTOZ) (xx) Oz (PO3WTUNK) OR Unknown					
4. Apgar score at 1 minute: (PO 3APG 1M)	(xx) (PO31APUK) OR Unknown					
5. Apgar score at 5 minutes: (PO3APG5M)	(xx) (PO35APUK) OR Unknown					
6. Normal infant?(PO3NORML) If "No", is there a congenital anomaly?(PO3CONAN) If "Yes", specify abnormality and contributing factors:(PO3ABNSP)	□ No □ Yes □ No □ Yes □ Unknown					

Comments: (PO3COMM)

	(xx) Weeks (PO3GES)	DY,	(x) Day	s (PO3GESUN)	OR 🗆 U	Jn
	(xx) Lbs (PO3WTOZ)		- (xx) Oz (F	O3WTUNK) OR	Unkn	ov
	(xx) (P031APUK) 0R	□ Un	known			
	(xx) (P035APUK) 0R	□ Un	known			
□ No	Yes Unknown					
					」 ¬	

Additional Selection Options for PO3

Pregnancy Number (PREGNO) (key field): 1-1 2-2 3-3

	NIDA Clinical Trials Network			
Pregnancy Outcome 4 (PO4) Web Version: 1.0; 2.01; 01-29-13 Pregnancy Number (PREGNO):				
Newborn Information				
1. Gender: (PO4GENDR)	☐ Male ☐ Female ☐ Unknown			
2. Gestational age at delivery:(PO4GESWK)	(xx) Weeks (PO4GESDY, (x) Days (PO4GESUN)OR Unknown			
3. Weight at delivery: (PO4WTLBS)	(xx) Lbs (PO4WTOZ) (xx) Oz (PO4WTUNK) OR Unknown			
4. Apgar score at 1 minute: (PO4APG1M)	(xx) (PO41APUK) OR Unknown			
5. Apgar score at 5 minutes: (PO4APG5M)	(xx) (PO45APUK) OR Unknown			
6. Normal infant?(PO4NORML) If "No", is there a congenital anomaly?(PO4CONAN) If "Yes", specify abnormality and contributing factors:(PO4ABNSP)	No Yes No Yes Unknown			

Comments: (PO4COMM)

Additional Selection Options for PO4

Pregnancy Number (PREGNO) (key field): 1-1 2-2 3-3

NIDA Clinical Trials Network

Confirmed Pregnancy and Outcome (PRG)

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

Pregnancy Number (PREGNO):

Information About Pregnancy	
Date of assessment (PRASMTDT)	(mm/dd/yyyy) Click here for calendar
Date on which study staff became aware of pregnancy: (PRAWARDT)	(mm/dd/yyyy) Click here for calendar
How was the pregnancy confirmed (select all that apply)? a. Urine pregnancy test result:(PRURICNF) b. Serum pregnancy test result:(PRSERCNF) c. Ultrasound result:(PRULTCNF) d. Other:(PROTHCNF) If "Other", specify:(PROTCNSP) Date on which the pregnancy was confirmed:(PRCNFMDT)	No Yes No Yes No Yes No Yes No Yes (mm/dd/yyyy) Click here for calendar
Action taken with study intervention: (PRACTIND)	1-None 2-Temporarily stopped intervention 3-Permanently stopped intervention 4-Participant terminated from study
Approximate due date: (PRADUEDT)	(mm/dd/yyyy) (PRDDTUNK) OR Unknow
Outcome of pregnancy: (PROUTCME)	1-Vaginal delivery 2-Cesarean delivery 3-Mscarriage 4-Termination 98-0 ther *A dditional Options Listed Below
If "Other", specify:(PROTCMSP)	
Date of pregnancy outcome: (PROTCMDT)	(mm/dd/yyyy) (PRODTUNK) OR Unknow
Number of live birth s: (PRNMLIVB)	0-0 1-1 2-2 3-3 4-4 *A dditional Options Listed Below

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

Additional Selection Options for PRG

Pregnancy Number (PREGNO) (key field): 1-1 2-2 3-3

Outcome of pregnancy:

99-Unknown

Number of live births:

99-Other

98-Unknown

NIDA Clinical Trials Network	
Participant Calf Depart Massures (DCD)	
Participant Self-Report Measures (PSR)	
Segment (PROTSEG): Visit Number (VISNO):	Web Version: 1.0; 1.00; 03-25-11
Welcome!	
You are about to answer some questions using this computer by clicking on checkboxes like this: (PSBOX1)	
When you're done, click on the "Save" button at the top or bottom of the screen.	
Try it out!	
Click this checkbox and then click on the "Save" button: (PSBOX2)	

NIDA Clinical Trials Network			
	Protocol Violation Log (PVL)		
Date of Violation (PVDATE): Protocol Violation Number (PVSEQNUM):	Web Version: 1.0; 3.04; 10-04-12		
To be filled in by person(s) reporting this protocol violation:			
1. Violation type:(PVTYPE37)	Z01-INFORMED CONSENT PROCEDURES 01A- No consent/assentobtained 01C- Invalid/incomplete informed consent 01D- Unauthorized assessments and/or procedures conducted prior to obtaining informed consent 01Z- Other (specify) *A dditional Options Listed Below		
If "Other" is indicated, provide the specification: (PVTPSP37)			
2. Description of violation: (PVDESC)			
3. Has this protocol violation been resolved? (PVRESOL)	□ No □ Yes		

Protocol violation resolution and corrective action: (PVRSCASP)	
4. Does this protocol violation require IRB reporting?(PVIRB)	□ No □ Yes
If "Yes", provide date reported:(PVIRBDT)	(mm/dd/yyyy) Click here for calendar
Comments:(PVLCOMM)	
Comments: (PVL COMM)	

Additional Selection Options for PVL

Protocol Violation Number (PVSEQNUM) (key field):

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

Violation type:

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

NIDA Clinical Trials No	twork	

Quick Inventory of Depressive Symptomatology (Clinician Rated) (QDS)

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

Segment (PROTSEG): Visit Number (VISNO):

Date of assessment: (QDDATE)

(mm/dd/yyyy)

I would like to ask you some questions about how you have been feeling over the past 7 days. When answering these questions, I would like you to compare the last week to a time when you were feeling okay, more like your normal self.

NOTE. Patients with chronic symptoms may not be able to identify a period of normalcy or may report that "depressed" is their usual state. However, depression should not be rated as "normal" (i.e., a rating of "0") in these cases. In making each rating, consider the frequency, duration, and intensity/severity of the symptom. The degree of functional impairment caused by the symptom may be important in the ratings of some, but not all symptoms.

1. Sleep Onset Insomnia

How have you been sleeping in the past week? Have you had any trouble falling asleep when you go to bed? Right after you go to bed, how long does it take you to fall asleep? How many days in the past week have you had trouble falling a sleep?

0-0 Never takes longer than 30 minutes to fall asleep.

- 1-1 Takes at least 30 minutes to fall asleep, less than half the time.
- 2-2 Takes at least 30 minutes to fall asleep, more than half the time.
- 3-3 Takes more than 60 minutes to fall asleep, more than half the time.

(QDSLEEP)

2. Mid-Nocturnal Insomnia

During the past week, have you been waking in the middle of the night? How long do you stay awake?

Do you get out of bed?

Has your sleep been restless or disturbed some nights?

0-0 Does notwake up atnight.

- 1-1 Restless, light sleep with fewawakenings.
- 2-2 Wakes up at least once a night, but goes back to sleep.
- 3-3 A wakens more than once a night and stays awake for 20 minutes or more, more than half the time.

(QDNOCT)

3. Early Morning Insomnia

What time have you been waking up in the past week? With or without an alarm? Is this earlier than is normal for you? How many days in the past week? Are you able to go back to sleep?

0-0 Less than half the time, awakens no more than 30 minutes before necessary.

- 1-1 More than half the time, awakens more than 30 minutes before need be.
- 2-2 A wakens at least one hour before need be, more than half the time.
- 3-3 A wakens at least two hours before need be, more than half the time.

(QDEARLY

4. Hypersomnia

How many hours on average have you been sleeping in a 24-hour period in the past week, including naps?

What is the longest you've slept in a 24-hour period last week?

- 0-0 Sleeps no longer than 7-8 hours/hight, without naps.
- 1-1 Sleeps no longer than 10 hours in a 24 hour period (including naps).
- 2-2 Sleeps no longer than 12 hours in a 24 hour period (including naps).
- 3-3 Sleeps longer than 12 hours in a 24 hour period (including naps).

(QDHYPER

5. Mood (Sad)

How would you describe your mood in the past week?
Have you been feeling down, blue, sad, or depressed?
In the past week, how much of the time have you felt_____?
All day? Everyday?

0-0 Does not feel sad.

- 1-1 Feels sad less than half the time.
- 2-2 Feels sad more than half the time.
- 3-3 Feels intensely sad virtually all the time.

(QDMOOD,

COMPLETE EITHER 6 OR 7 (NOT BOTH)

6. Appetite (Decreased)

How has your appetite been this past week? Have you had to force yourself to eat? Have others urged or reminded you to eat?

0-0 No change from usual appetite.

- 1-1 Eats somewhat less often and for lesser amounts than usual.
- 2-2 Eats much less than usual and only with personal effort
- 3-3 E ats rarely within a 24-hour period, and only with extreme personal effort or with persuasion.

(QDDNAPP

7. Appetite (Increased)

Have you found yourself eating more than usual? Have you felt driven to eat? Have you had eating binges?

0-0 No change from usual appetite.

- 1-1 More frequently feels a need to eat than usual.
- 2-2 Regularly eats more often and/orgreater amounts than usual.
- 3-3 Feels driven to overeat at and between meals.

(QDUPAPP)

COMPLETE EITHER 8 OR 9 (NOT BOTH)

8. Weight (Decreased) Within The Last Two Weeks

Have you noticed any change in your weight? Are your clothes fitting differently than usual? How much has your weight changed in the past 2 weeks? 0-0 Has experienced no weight change.

- 1-1 Feels as if some slight weight loss has occurred.
- 2-2 Has lost 2 pounds or more.
- 3-3 Has lost 5 pounds or more.

(QDDNWEIG

9. Weight (Increased) Within The Last Two Weeks

0-0 Has experienced no weight change.

- 1-1 Feels as if some slight weight gain has occurred.
- 2-2 Has gained 2 pounds or more.
- 3-3 Has gained 5 pounds or more.

(QDUPWEIG)

10. Concentration/Decision Making

How has your concentration been in the past week?

Were you able to focus on what you were doing (like reading or watching TV)?

Did you notice that minor decisions were more difficult to make than usual (what to wear, eat, what to watch on TV)?

0-0 No change in usual capacity to concentrate and decide.

- 1-1 Occasionally feels indecisive or notes that attention often wanders.
- 2-2 Most of the time struggles to focus attention or make decisions
- 3-3 Cannot concentrate well enough to read or cannot make even minor decisions.

(QDDECISN)

11. Outlook (Self)

In the past week, how have you felt about yourself?

Have you been down on yourself in the past week?

More than is normal for you?

Have you been feeling guilty?

Do you feel like you're being punished?

Have you noticed your self-esteem has been down in the past week?

How would you rate your worth as a person compared to others?

0-0 Sees self as equally worthwhile and deserving as others.

- 1-1 Is more self-blaming than usual.
- 2-2 Largely believes that he/she causes problems for others.
- 3-3 Ruminates over major and minor defects in self.

(QDSELF)

12. Suicidal Ideation

In the past week, have you felt that life was not worth living?

Do you have thoughts of death or suicide?

How often do these thoughts come?

How long do they stay?

What have you thought about?

Have you thought of a plan in the last week?

Have you done anything to hurt yourself?

- 0-0 Does not think of suicide or death.
- 1-1 Feels life is empty or is not worth living.
- 2-2 Thinks of suicide /death several times a week for several minutes.
- 3-3 Thinks of suicide /death several times a day in depth, or has made specific plans, or attempted.

(QDIDEA)

13. Involvement

How have you been spending your time this last week (when not at home)? Is that normal for you?

Have you stopped doing anything you used to do?

How would you describe your level of interest and motivation to complete daily activities? Do you feel you have to push yourself?

Is there anything you look forward to or still enjoy?

- 0-0 No change from usual level of interest in other people and activities.
- 1-1 Notices a reduction in former interests/activities.
- 2-2 Finds only one or two former interests remain.
- 3-3 Has virtually no interest in formerly pursued activites.

(QDINVOLV)

14. Energy/Fatiguability

How has your energy been this past week? Have you noticed that you tire more easily than you used to? Have you been tired all the time?

0-0 No change in usual level of energy.

- 1-1 Tires more easily than usual.
- 2-2 Makes significant personal effort to initiate or maintain usual daily activities.
- 3-3 Unable to carry outmost of usual daily activities due to lack of energy.

(QDENERGY

15. Psychomotor Slowing

Have you felt slowed down in your thinking, speaking, or movement in the past week? Have others commented on this?

(RATING BASED ON OBSERVATION DURING INTERVIEW AND PATIENT SELF-REPORT.)

- 0-0 Normal speed of thinking, gesturing, and speaking.
- 1-1 Patient notes slowed thinking, and voice modulation is reduced.
- 2-2 Takes several seconds to respond to most questions; reports slowed thinking.
- 3-3 Is largely unresponsive to most questions without strong encouragement

(QDSLOW,

16. Psychomotor Agitation

Have you noticed feeling restless or fidgety in the past week?

Have you found yourself unable to stay seated or needing to move around?

(RATING BASED ON OBSERVATION DURING INTERVIEW AND PATIENT SELF-REPORT.)

DAGED ON OBSERVATION DOKING INTERVIEW AND LATIENT SEET-RELIGION

- 0-0 No increased speed or disorganization in thinking or gesturing.
- 1-1 Fidgets, wrings hands and shifts positions often.
- 2-2 Describes impulse to move about and displays motor restlessness.
- 3-3 Unable to stay seated. Paces about with or without permission.

(QDAGIT)

Total score: (QDTOTAL)

(xx)

NIDA Clinical Trials Network		

Quality of Life Enjoyment and Satisfaction Questionnaire (Q-LES-Q) (QLS)

Web Version: 1.0: 1.00: 05-06-10

Segment (PROTSEG): Visit Number (VISNO): Date of assessment: (QLASSDT) (mm/dd/yyyy) (QLTODAY) \(\subseteq \text{Click here for today's date} \) **GENERAL ACTIVITIES OVERALL LEVEL OF SATISFACTION** Very Good Taking everything into consideration, during the Very Poor Poor Fair Good past week how satisfied have you been with your... ...physical health? □ 3 (QLPHYSIC) \square 1 \square 2 □ 5 □ 3 ...mood? (QLMOOD) 🗌 1 □ 5 ...work? \square 3 \Box 4 (QLWORK) 🗆 1 \Box 5 ...household activities? \square 3 □ 4 □ 5 (QLHOUSE) \square 1 \square 2 ...social relationships? (QLSOCIAL) \Box 1 \Box 2 \square 3 \Box 5 ...family relationships? $(QLFAMILY) \Box 1 \Box 2$ \square 3 □ 4 □ 5 ...leisure time activities? (QLLEISUR) \Box 1 \Box 2 \square 3 □ 4 □ 5 ...ability to function in daily life? □ 3 □ 4 □ 5 (QLFXN) \[\Backsquare 1 □ 5 ...sexual drive, interest, and/or performance? (QLSEXDRV) \Bigcap 1 \Bigcap 2 \square 3 □ 4 ...economic status? \square 3 □ 4 \Box 5 (QLECON) 1 ...living/housing situation? □ 3 □ 5 □ 2 ...ability to get around physically without feeling (QLFALL) 🗌 1 \Box 2 □ 3 □ 5 dizzy or unsteady or falling? ...your vision in terms of ability to do work or hobbies? □ 3 □ 5 (QLVISION) 1 ...overall sense of well-being? □ 3 □ 5 (QLBEING) 🗆 1 ...medication? (If not taking any, check here(QLNOMED) (QLMED) 1 □ 3 □ 5 and leave item blank) How would you rate your overall life satisfaction and □ 3 □ 4 □ 5 (QLSATISF) \square 1 \square 2

Endicott J, Nee J, Harrison W, Blumenthal R. Quality of Life Enjoyment and Satisfaction Questionnaire: A New Measure. Psychopharmacology Bulletin 1993;29:321-326.

contentment during the past week?

NIDA Clinical Trials Network
W 11 04 0 4 1 (0.01)

Weekly Step Counter Log (SCL)

Web Version: 1.0; 2.00; 09-13-10

Segment (PROTSEG): Visit Number (VISNO):

Date

Instructions: Enter the start date in the upper left hand box. Enter the number of steps for each day in the boxes. You should NOT include the steps that are taken during your daily exercise session; therefore you should take your step counter off during your exercise sessions at home. Include any notes about your activity in the space provided.

Notes

(SLSTP1DT) (mm/dd/yyyy) (SLNOSTP1) (xxxxx) (SLNOTE1)	
(SLSTP2DT) (mm/dd/yyyy) (SLNOSTP2) (xxxxx) (SLNOTE2)	
(SLSTP3DT) (mm/dd/yyyy) (SLNOSTP3) (xxxxx) (SLNOTE3)	
(SLSTP4DT) (mm/dd/yyyy) (SLNOSTP4) (xxxxx) (SLNOTE4)	
$(SLSTP5DT) \hspace{3.1cm} (mm/dd/yyyy) \hspace{3.1cm} (SLNOSTP5) \hspace{3.1cm} (xxxxx) \hspace{3.1cm} (SLNOTE5)$	
$(SLSTP6DT) \hspace{3.1cm} (mm/dd/yyyy) \hspace{3.1cm} (SLNOSTP6) \hspace{3.1cm} (xxxxx) \hspace{3.1cm} (SLNOTE6)$	
$(SLSTP7DT) \hspace{3.1cm} (mm/dd/yyyy) \hspace{3.1cm} (SLNOSTP7) \hspace{3.1cm} (xxxxx) \hspace{3.1cm} (SLNOTE7)$	
Comments: (SLCOMM)	\neg

Daily Steps

		NIDA Clinical Tria	ls Network		
		NIDA CIIIICAI IIIA	is itelwork		
		SF-36 (SF	FF)		
		•	,		
ment (<i>PROTSEG</i>): Number (<i>VISNO</i>):					
Date of assessment:(SFDATE)			(mm/dd/yyyy) (SFTODAY	Click here for t	oday's date
This survey asks for your views abou activities. Thank you for completing a	-	will help keep track of how you fe	eel and how well you are	e able to do youi	usual
For each of the following questions, p	please check the box that best o	describes your answer.			
n general, would you say your health	is:				
Excellent	Very good	Good	Fair		Poor
(SFHEALTH)					
(SFREALIR)					
Compared to one year ago, how wou	ıld you rate your health in genera	al now?			
Much better now than one	Somew hat better now	About the same as one	Somewhat worse now		Much worse now than one
year ago	than one year	year ago	than one year		year a go
	ago		ago		
(SFHLT1YR)					
he following questions are about ac	tivities you might do during a typ	pical day. Does <u>your health now</u>	limit you in these activiti	es? If so, how m	uch?
			Yes,	Yes,	No, not
			limited a lot	limited a little	limited at all
a. <u>Vigorous activities,</u> such as runni	ng, lifting heavy objects, particip	pating in strenuous sports:	(SFVIGACT)		
b. Moderate activities, such as mov	ring a table, pushing a vacuum c	leaner, bowling, or playing golf:	(SFMODACT)		
c. Lifting or carrying groceries:			(SFGROCER)		
d. Climbing several flights of stairs:			(SFSEVFLS)		
- Climbing one flight of stairs:			(27.7.2)		
e. Climbing one flight of stairs:			(SF1FLS)		

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

g. Walking more than a mile:						(SFW	MILE)			
h. Walking <u>several hundred yards</u> :						(SFSE	VHYD) 🗆			
i. Walking <u>one hundred yards</u> :						(SF1	HYD) 🗆			
j. Bathing or dress	sing yourself:					(SFB	ватн) 🗆			
During the past 4 we	<u>eeks,</u> how muc	h of the time ha	ve you had any	of the fol	owing problems	with your work or o	other regular da	aily activities <u>as</u>	a result of you	<u>rphysical heal</u>
						All of the time	Most of the time	Some of the time	A little of the time	None of the time
a. Cut down on the	e amount of tim	ne vou spent on	work or other a	activities:		(SFPTMWRK)				
b. Accomplished le			Work of Other C	2011 111100.		(SFPACCMP)				
c. Were limited in			ties:			(SFPKDWRK)				
d. Had <u>difficulty</u> pe				mple, it too	ok extra effort):	(SFPDFWRK)				
						Most of	Some of	A little	None of	
					the time	the time	the time	of the time	the time	
a. Cut down on the	e <u>amount of tim</u>	ne you spent on	work or other a	activities:	the time	the time		of the		
a. Cut down on the b. Accomplished le			work or other a	activities:		the time	the time	of the time	the time	
	ess than you w	ould like:		activities:	(SFETMWRK)	the time	the time	of the time	the time	
b. Accomplished le	ess than you were activities les	ould like: s carefully than	usual:		(SFETMWRK) (SFEACCMP) (SFECARE)	the time	the time	of the time	the time	hbors, or grou
b. Accomplished le	ess than you were activities les	ould like: s carefully than	usual:		(SFEACCMP) (SFECARE)	the time	the time	of the time	the time	hbors, or grou
b. Accomplished le c. Did work or othe	ess than you we er activities lesseeks, to what e	ould like: s carefully than xtent has your g	usual: Dhysical health o	or emotior	(SFEACCMP) (SFECARE)	the time	the time	of the time	the time	hbors, or grou
b. Accomplished le c. Did work or othe During the past 4 we Not at all	ess than you wer activities lesseeks, to what estightly	ould like: s carefully than xtent has your p Moderately	usual: hysical health o Quite a bit	or emotion Extrem	(SFEACCMP) (SFECARE)	the time	the time	of the time	the time	hbors, or grou
b. Accomplished le c. Did work or othe During the past 4 we Not at all (SFNRMSOC)	ess than you wer activities lesseeks, to what estightly	ould like: s carefully than xtent has your p Moderately ad during the pa	usual: physical health of Quite a bit st 4 weeks?	or emotion Extrem	(SFEACCMP) (SFECARE)	the time	the time	of the time	the time	hbors, or grou
b. Accomplished in c. Did work or other control of the past 4 w. Not at all (SFNRMSOC)	ess than you we er activities less eeks, to what e Slightly	ould like: s carefully than xtent has your p Moderately ad during the pa ild M	usual: physical health of Quite a bit st 4 weeks?	Extrem	(SFEACCMP) (SFEACCMP) (SFECARE) all problems interely	the time	the time	of the time	the time	hbors, or grou

Not at all

A little bit

Moderately

Quite a bit

Extremely

(SFNRMWRK)										
				en with y	ou <u>during the p</u>	o <u>ast 4 weeks</u> . Fo	r each questioı	n, please give the	e one answer that	comes closest to t
eeling. How much	of the time duri	ing the <u>past 4 we</u>	<u>eeks</u>		All of the tim					
a. Did you feel ful	l of life?				(SFFLLIFE)					_
. Have you been)			(SFVNERVS)					
. Have you felt s	-		na could cheer	vou up?	(SFNCHEER)					-
. Have you felt c		·		<u> </u>	(SFCALM)					-
. Did you have a	· · · · · · · · · · · · · · · · · · ·				(SFENERGY)					-
Have you felt do					(SFDEPRES)					-
. Did you feel wo		·			(SFWORN)					-
. Have you been					(SFHAPPY)					-
Did you feel tire					(SFTIRED)					-
					!					
uring the <u>past 4 w</u> All of the time	eeks, how muc Most of the time	Some of the time	s your <u>physica</u> A little of the time	None	e of	<u>oblems</u> interfere	d with your soc	ial activities (like	e visiting friends, re	elatives, etc.)?
(SFVISSOC)										
	05:	the Caller See S								
low TRUE or FAL	SE IS <u>each</u> of t	the following sta	De	efinitely true	Mostly true	Don't know	Mostly false	Definitely false		
a. I seem to get si	ick a little cosic	or than other acc	plo: (a====	🗆						
b. I am as healthy		·	((() () ()	(LY) [-	
<u> </u>	· ·		,	LTY)						
c. I expect my hea		e: 		HLT)				_		
d. My health is ex	cellent:		(SFEXC	HLT)						

THANK YOU FOR COMPLETING THESE QUESTIONS!

	NIDA Clinical Trials Network				
	Snaith-Hamilton Pleasure Scale (SPS)				
Segment (<i>PROTSEG</i>): /isit Number (<i>VISNO</i>):	Web Version: 1.0 ; 1.00; 05-06-10				
Date of assessment:(SPASMTDT)	(mm/dd/yyyy) (SPTODAY) Click here for today's date				
This questionnaire is designed to measure your ability to experience much you agree or disagree with each statement.	e pleasure <u>in the last few days</u> . It is important to read each statement very <u>carefully</u> . Choose one of the answers to indicate hov				
1. I would enjoy my favorite television or radio program: (SPTELEV) □ Strongly disagree □ Disagree □ Agree □ Strongly agree					
2. I would enjoy being with my family or close friends: (SPFAMILY) □ Definitely agree □ Agree □ Disagree □ Strongly disagree					
3. I would find pleasure in my hobbies and pastimes: (SPHOBBY) ☐ Strongly disagree ☐ Disagree ☐ Agree ☐ Strongly agree					
4. I would be able to enjoy my favorite meal: (SPMEAL) Definitely agree Agree Disagree Strongly disagree					
5. I would enjoy a warm bath or refreshing shower: (SPSHOWER) □ Definitely agree □ Agree □ Disagree □ Strongly disagree					

6. I would find pleasure in the scent of flowers or the smell of fresh sea breeze or freshly baked bread:

(SPSCENT) ☐ Strongly disagree ☐ Disagree
☐ Agree
☐ Strongly agree
7. I would enjoy seeing other people's smiling faces: (SPFACE) □ Definitely agree □ Agree □ Disagree □ Strongly disagree
8. I would enjoy looking smart when I have made an effort with my appearance: (SPSMART) Strongly disagree Disagree Agree Strongly agree
9. I would enjoy reading a book, magazine, or newspaper: (SPREAD) □ Definitely agree □ Agree □ Disagree □ Strongly disagree
10. I would enjoy a cup of tea or coffee or my favorite drink: (SPTEA) ☐ Strongly disagree ☐ Disagree ☐ Agree ☐ Strongly agree
11. I would find pleasure in small things, e.g., bright sunny day, a telephone call from a friend: (SPCALL) ☐ Strongly disagree ☐ Disagree ☐ Agree ☐ Strongly agree
12. I would be able to enjoy the beautiful landscape or view: (SPVIEW) □ Definitely agree □ Agree □ Disagree □ Strongly disagree
13. I would get pleasure from helping others: (SPHELP) ☐ Strongly disagree ☐ Disagree ☐ Agree ☐ Strongly agree

14. I would feel pleasure when I receive praise from other people:

(SPPRAISE) ☐ Definitely agree
Agree
Disagree
☐ Strongly disagree

Snaith RP; Hamilton M; Morley S; Humayan A; Hargreaves D and Trigwell P. British Journal of Psychiatry (1995), 167, 199-103.

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Stimulant Selective Severity Assessment (SSA)

Web Version: 1.0; 1.02; 10-18-11

3	- y		(JLG	η.
۷i	s it	Num	ber	(VI	SNC):

segment (PROTSEG): isit Number (VISNO):			
Date of assessment: (SSASDT) Date of last use: (SSLUSEDT)	(mm/dd/yyyy) (mm/dd/yyyy)		
1. Hyperphagia:		(SSHYPRPH)	(x)
0= normal appetite 3-4 = eats a lot more than usual 7 = eats more than twice usual amount of food			
2. Hypophagia:		(SSHYPOPH)	(x)
0 = normal appetite 3-4 = eats less than half of normal amount of food 7 = no appetite at all			
3. Carbohydrate craving:		(SSCARBCR)	(x)
0 = no craving 3-4 = strong craving for sweets half the time 7 = strong craving for sweets all the time			
Please have the participant rate the intensity and frequency of cravings on paper and record	the results in Questions 4-9 below.		
4. Cocaine craving:		(SSCOKECR)	(x)
5. Cocaine craving frequency:		(SSCOKEFR)	(x)
6. Methamphetamine craving:		(SSMETHCR)	(x)
7. Methamphetamine craving frequency:		(SSMETHFR)	(x)
8. Other stimulant craving:		(SSOTSTCR)	(x)
9. Other stimulant craving frequency:		(SSOTSTFR)	(x)
10. Bradycardia:		(SSBRADYC)	(x)
0 = >64 1 = 64-63 2 = 62-61 3 = 60-59 4 = 58-57 5 = 56-55 6 = 54-53 7 = <53			
11. Sleep I:		(SSSLEEP1) ((x)

0 = normal amount of sleep 3-4 = half of normal amount of sleep 7 = no sleep at all	
12. Sleep II:	(SSSLEEP2) (x)
0 = normal amount of sleep 3-4 = could sleep or do sleep half the day 7 = sleep or could sleep all the time	
13. Anxiety:	(SSANXIET) (x)
0 = usually does not feel anxious 3-4 = feels anxious half the time 7 = feels anxious all the time	
14. Energy level:	(SSENERGY) (x)
0 = feels alert and has usual amount of energy 3-4 = feels tired half the time 7 = feels tired all the time	
15. Activity level:	(SSACTVTY) (x)
0 = no change in usual activities 3-4 = participa tes in half of usual activities 7 = no participation in usual activities	
16. Tension:	(SSTENSN) (x)
0 = rarely feels tense 3-4 = feels tense half the time 7 = feels tense most or all of the time	
17. Attention:	(SSATTN) (x)
0 = able to concentrate on reading, conversation, tasks, and make plans without difficulty 3-4 = has difficulty with the above half the time 7 = has difficulty with the above all of the time	
18. Paranoid ideation:	(SSPARAND) (x)
0 = no evidence of paranoid thoughts 3-4 = unable to trust anyone 7 = feels people are out to get him/her 8 = feels a specific person/group is plotting against him/her	
19. Anhedonia:	(SSANHEDN) (x)
0 = ability to enjoy themselves remains unchanged 3-4 = able to enjoy themselves half the time 7 = unable to enjoy themselves at all	
20. Depression:	(SSDEPRES) (x)
0 = no feelings related to sadness or depression 3-4 = feels sad or depressed half the time 7 = feels depressed all the time	
21. Suicidality:	(SSSUICID) (x)
0 = does not think about being dead 3-4 = feels like life is not worth living 7 = feels like actually ending life	

	22. Irritability:	(SSIRRTBL)	(x)
ı	0 = feels that most things are not irritating		
ı	3-4 = feels that many things are irritating		
ı	7 = feels that mostly everything is irritating and upsetting		

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	Stimulant Craving Questionnaire (STC)	
Segment (PROTSEG): Visit Number (VISNO):		Web Version: 1.0; 1.00; 05-06-10
Date of assessment:(STASDT)	(mm/dd/yyyy) (STTODAY) Click here fortoday's date	

Indicate how much you agree or disagree with each of the following statements by checking a box between "Strongly Agree" and "Strongly Disagree." The closer you check a box to one end or the other indicates the strength of your disagreement or agreement. Please complete every item. We are interested in how you are thinking or feeling **right now** as you are filling out the questionnaire.

1. I want cocaine, methamphetamine, or other stime STRONGLY AGREE (STTASTE)	
2. I have an urge for cocaine, methamphetamine, of STRONGLY AGREE (STURGE) .	r other stimulants. STRONGLY DISAGREE
3. I am going to use cocaine, methamphetamine, or STRONGLY AGREE (STUSE)	other stimulants as soon as possible. STRONGLY DISAGREE
4. I think that I could resist using cocaine, methamped STRONGLY AGREE (STRESIST)	netamine, or other stimulants now. STRONGLY DISAGREE
5. I crave cocaine, methamphetamine, or other stime. STRONGLY AGREE (STCRAVE)	ulants right now. STRONGLY DISAGREE
6. All I want to use now are cocaine, methamphetan STRONGLY AGREE (STUSENOW)	nine, or other stimulants. STRONGLY DISAGREE
7. I have no desire for cocaine, methamphetamine, STRONGLY AGREE (STNODESI)	or other stimulants right now.
8. Using cocaine, methamphetamine, or other stimu STRONGLY AGREE (STPRFECT)	alants now would make things seem just perfect. STRONGLY DISAGREE
9. I will use cocaine, methamphetamines, or other s	timulants as soon as I get the chance. STRONGLY DISAGREE

^{10.} Nothing would be better than using cocaine, methamphetamines, or other stimulants right now.

STRONGLY AGREE	(STNOBETR)								STRONGLY DISAGREE
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**from: Sussner et al. Drug and Alcohol Dependence 83 (2006) 233-237

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Stroop Color and Word Test - Adult Version (STR)

Web Version: 1.0; 1.00; 03-23-10

Segment (PROTSEG):

Visit Number (VISNO):				
Date of assessment (SRDATE)	(mm/dd/yyyy			
1. Is the participant color-blind?(SRCLRBLD) If "Yes", leave the rest of this form blank.	□ No □ Yes			
2. Please record the time of day at which the administration of the Stroop Color Word Task beclock): (SRTOD)	gan (24 hour (hh:mm)			

3. Please complete the following fields based on the results of the Stroop Task:

	Raw Score	
Word Score (W)	(SRWRAW)	(xxx)
Color Score (C)	(SRCRAW)	(xxx)
Color-Word Score (CW)	(SRCWRAW)	(xxx)

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NIDA Clinical Trials Network
Study Termination (STZ)

Web Version: 1.0: 2.00: 01-29-13 1. Date of study completion or last assessment:(TZTRMDT) (mm/dd/yyyy) Click here for calendar 2. Did the participant complete Week 37 or have the opportunity to complete Week 37?(TZCOMPLT) ☐ No ☐ Yes a. If "No", select the primary reason for study termination: (TZP RM RES) 1-Death due to suicide 2-Death not due to suicide 3-Participant with drew consent 4-Participant adminis tratively withdrawn (e.g., behavioral issues, drugs on unit, danger to others) 3. Did the participant complete the Week 13 assessment? (TZW13VIS) □ No □ Yes a. If "No", select the primary reason for non-completion: (TZW13NO) 1-Incarcerated and unavailable for phone or off-site assessments 2-Lost to follow-up 3-Transferred to another 24-hour treatment setting and unavailable for phone or off-site assessments 4-Transferred to another treatment program (not 24-hour) and unavailable for phone or off-site assessm 5-Developed medical/surgical condition disallowing continuation (includes AEs/SAEs) related to study i *Additional Options Listed Below If "Other", specify:(TZ130THR) □ No □ Yes 4. Did the participant attend more than 80% of **acute** intervention visits? (TZ80A CUT) a. If "No", select the primary reason for non-completion: (TZACUTNO) 1-Incarcerated 2-Lost to follow-up 3-Transferred to another 24-hour treatment setting 4-Transferred to another treatment program (not 24-hour) 5-Began an excluded medication or treatment *Additional Options Listed Below If "Burden" or "Other", specify: (TZACUTSP) 5. Did the participant complete the Week 37 assessment? (TZW37VIS) □ No □ Yes a. If "No", select the primary reason for non-completion:(TZW37NO) 1-Incarcerated and unavailable for phone or off-site assessments 2-Lost to follow-up 3-Transferred to another 24-hour treatment setting and unavailable for phone or off-site assessments 4-Transferred to another treatment program (not 24-hour) and unavailable for phone or off-site assessm 5-Developed medical/surgical condition disallowing continuation (includes AEs/SAEs) related to study i *Additional Options Listed Below If "Other", specify: (TZ370THR)

a. If "No", select the primary reason for non-completion:(TZCONTNO)	1-Incarcerated 2-Lost to follow-up 3-Transferred to another 24-hour treatment setting 4-Transferred to another treatment program (not 24-hour) 5-Began an excluded medication or treatment *Additional Options Listed Below	
If "Burden" or "Other", specify:(TZCONTSP)		
Comments: (TZTCOMM)		
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: (TZPISIGN) Date: (TZPISGDT)	(mm/dd/yyyy) Click here for calendar	

Additional Selection Options for STZ

If "No", select the primary reason for non-completion:

- 6-Developed medical/surgical condition disallowing continuation (includes AEs/SAEs) not related to stu
- 7-Became pregnant and unavailable for phone or off-site assessments
- 8-Moved from the area and unavailable for phone or off-site assessments
- 9-Found research assessments too burdensome
- 10-Protocol violation (e.g., staff error)
- 11-Death due to suicide
- 12-Death not due to suicide
- 13-Participant withdrew consent
- 14-Participant administratively withdrawn (e.g., behavioral issues, drugs on unit, danger to others) 99-Other

If "No", select the primary reason for non-completion:

- 6-Developed medical/surgical condition disallowing continuation (includes AEs/SAEs) related to study i
- 7-Developed medical/surgical condition disallowing continuation (includes AEs/SAEs) not related to stu
- 8-Staff judgment or evidence from protocol-defined safety assessment that warranted restriction of int 9-Became pregnant
- 10-Moved from the area
- 11-Protocol violation (e.g., staff error)
- 12-No primary reason identified

Z13-DID NOT WANT TO CONTINUE WITH EXERCISE INTERVENTION

- 13 A- Beli eves substance use is sufficiently improved
- 13B- Believes intervention not effective
- 13C- Burden
- 13D- Other

Z14-DID NOT WANT TO CONTINUE WITH HEALTH EDUCATION INTERVENTION

- 14 A- Beli eves substance use is sufficiently improved
- 14B- Believes intervention not effective
- 14C- Burden
- 14D- Other
- 15-Death due to suicide
- 16-Death not due to suicide
- 17-Participant withdrew consent
- 18-Participant administratively withdrawn (e.g., behavioral issues, drugs on unit, danger to others) 99-Other

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Supe	ervised Setting (SVS)
Start Date of Superv Set (SVSTDT):	
1. What is the type of supervised setting that the participant was admitted to or entered? (SVTYPE)	1-Residential/rehab treatment for alcohol/drug 2-Hospital detoxification/detoxification unit for alcohol/drug 3-Hospital for other medical disorder 4-Hospital/residential for psychiatric disorder 5-Jail/prison *A dditional Options Listed Below
If "Other", specify: (SVTYPESP)	
2. End date of stay in supervised setting (the date the participant left the setting):(SVSPDT)	(mm/dd/yyyy) Click here for calendar
3. Both start and end dates confirmed by RA?(SVCONFRM)	□ No □ Yes
Comme nts: (SVCOMM)	

Web Version: 1.0; 1.00; 04-29-11

Additional Selection Options for SVS

What is the type of supervised setting that the participant was admitted to or entered? 6-Other $\,$

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TLFB Assessment Period (TAP)

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

Segment (PROTSEG): Visit Number (VISNO):

- 1. Date of assessment: (TAASMTDT)
- 2. Was the Substance Use Diary used during the interview?(TASUDINT)
- 3. Assessment period:(TATFSTDT)

(TATFENDT)

- 4. Was this assessment period reconstructed due to a missed visit?(TARECON)
- 5. Have any illicit substances or alcohol been taken during this assessment period?(TASUBALC)
- 6. Have any nicotine products been used during this assessment period? (TANICOTN)

	(mm/	dd/yyyy) Click here to view calendar
□ No	Yes	
From:		(mm/dd/yyyy) Click here to view calenda
To:		(mm/dd/yyyy) Click here to view calenda
□ No	Yes	
☐ No	Yes	
☐ No	Yes	

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Treatment as Usual Tracking Form (TAU)

Web Version: 1.0; 3.00; 12-12-11

Segr	nent <i>(PR</i>	OTSEG):
V is it	Number	(VISNO):

Please record the type and quantity of treatment that the participant completed (in the past week).		
Week Start Date:(TUWKSTDT)	(mr	m/dd/yyyy) Click here to view calendar
Week Stop Date (i.e., the day before the completion of this form):(TUWKSPDT)	(mr	m/dd/yyyy) Click here to view calendar

1. In the past week, what was the main type of treatment you were supposed to be receiving (select one)? (Note: If participant transitioned from 1 treatment to another, choose the treatment where the majority of the days being assessed were spent, e.g. 4 out of 7.)

- 1-Residential (24 hr) drug treatment (not including group homes, halfway or three quarter way houses)
- 2-Intensive outpatient drug treatment or day treatment (several days a week for several hours a day)
- 3-Weekly outpatient group or individual drug treatment (one time a week)
- 4-Less than weekly outpatient group or individual drug treatment
- 5-12-step/self-help groups only
- 6-Inpatient/residential detoxification
- 7-No treatment

(TUWHERE)

For questions 2-7: check yes or no. If yes is checked, enter number of hours. Round to the nearest half hour.

	Any Treatment?	# of Hours (Round to Nearest Half-Hour)
2. In the past week, were you <u>supposed</u> to receive any substance use treatment sessions of 30 minutes or longer (This includes group, individual, couples/family therapy/counseling or any other therapy/counseling. It does not include educational sessions or 12-step/self-help group meetings like AA, NA, CA)?	(TUSUBTRT) □ No □ Yes	(TUSTSHR) (xx.x)
3. In the past week, did you <u>attend</u> any group the rapy/counseling sessions for substance use of 30 minutes or longer (not including 12-step/self-help group meetings like AA, NA, CA)?	(TUGRPTRP) No Yes	(TUGTSHR) (xx.x)
4. In the past week, did you <u>attend</u> any individual therapy/counseling sessions for substance use of 30 minutes or longer?	(TUINDTRP) \(\sum \) No \(\sum \) Yes	(TUITSHR) (xx.x)
5. In the past week, did you <u>attend</u> any couples/family therapy/counseling sessions for substance use of 30 minutes or longer?	(TUFAMTRP) No Yes	(TUFTSHR) (xx.x)
6. In the past week, did you <u>attend</u> any other therapy sessions for substance use not listed above?	(TUOTHTRP) ☐ No ☐ Yes	-
a. If "Yes", specify:(TUOTP1SP)	-	(TUO TP 1HR) (xx.x)
b. If "Y es", specify:(TUOTP2SP)	-	(TUO TP2HR) (xx.x)
c. If "Yes", specify:(TUOTP3SP)	-	(TUO TP3HR) (xx.x)
7. In the past week did you <u>attend</u> any instructor led educational sessions that were part of your substance abuse treatment program (e.g. parenting classes)?	(TUDIDACT) No Yes	(TUDDCTHR) (xx.x)
8. In the past week, did you attend any 12-step/self-help group meetings for substance use (AA, NA, CA)?	(TU12STEP) ☐ No ☐ Yes	(TU12STHR) (xx.x)

9. In the past week, were you discharged from or did you leave residential treatment? (Note: only choose (TUTRANSN) \sum No \sum Yes	"yes" if the participant's discharge/leave is from the residential treatment being received at study entry.)
If "Yes", record the date the participant left the facility: (*date must be verified with the facility)(TUTRNSDT)	(mm/dd/yyyy) Click here to view calendar
10. In the past week, did you change from receiving outpatient treatment or no treatment to a 24-hour substa	nce abuse treatment setting (e.g. group home to residential, outpatient treatment to inpatient detoxification)?
11. Since you were last here were you <u>admitted</u> to a 24-hour hospital or residential treatment/rehabilitation c (TUSVSADM) \Bigcap No \Bigcap Yes	enter for <u>any reason</u> or have you been in jai <i>l/</i> prison?
If "Yes", complete the Supervised Setting (SVS) Form.	
12. Were any prior or concomitant medications updated?(TUCMUPDT)	□ No □ Yes
Comments:(TUCOMM)	

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

Time Line Follow Back (TFB) Segment (PROTSEG): TLFB Date (TFASMTDT): 1. Have any nicotine products been used on this day?(TFNICOTN) □ No □ Yes 2. Cigarettes: (TFCIGRTS) □ No □ Yes a. Number of cigar ettes per day:(TFNMCIGS) (xx) 3. Other Tobacco: (TFO THTOB) □ No □ Yes a. Other tobacco type:(TFOTBTYP) 1-1 - Cigar 2-2 - Pipe 3-3 - Water pipe (e.g., hookah) 4-4 - Smokeless tobacco (e.g., dip, snuff, snuss) 5-5 - Smokeless cigarette (e.g., e-cigarette) *Additional Options Listed Below b. If "Other", specify:(TFOTOBSP) 4. Have any illicit substances or alcohol been taken on this day? (TFS UBALC) □ No □ Yes Route Codes: 01=oral 02=nasal 03=smoking 04=non IV injection 05=IV injection 09=Other 5. Alcohol:(TFALCOHL) □ No □ Yes a. Number of standard drinks: (TFNM DRNK) (xx) 6. Cannabi noids/Marijuana:(TFCANNAB) ☐ No ☐ Yes a. Number of joints or joint equivalents smoked:(TFNMJNTS) b. Rx: (TFCANRX) No, taken illicitly Yes, but more taken than prescribed 7. Cocaine: (TFCOCAIN) ☐ No ☐ Yes a. Quantity: (TFCOCQTY)

b. Route: (TFCOCROU)	1-01-0 ral 2-02-Nasal 3-03-S moking 4-04-Non-IV Injection 5-05-IV Injection *Additional Options Listed Below
8. Amphetamin es:(<i>TFAMPHET</i>) a. Quantity: (<i>TFAMPQTY</i>) b. Route: (<i>TFAMPROU</i>)	No Yes (xxx) pills 1-01-0 ral 2-02-N asal 3-03-S moking 4-04-N on-IV Injection 5-05-IV Injection *Additional Options Listed Below
c. Rx: (TFAMPRX) 9. Me tha mphe tamine: (TFMETAMP) a. Quantity: (TFMETQTY) b. Route: (TFMETROU)	No, taken illicitly Yes, but more taken than prescribed No Yes (xxx) 1-01-0 ral 2-02-N asal 3-03-S moking 4-04-N on-IV Injection 5-05-IV Injection *Additional Options Listed Below
10. Other Stimulants:(TFSTIMUL) a. Specify Other Stimulants:(TFSTMSP) b. Quantity:(TFSTMQTY) c. Route:(TFSTMROU)	(xxx) pills 1-01-0 ral 2-02-Nasal 3-03-S moking 4-04-Non-IV Injection 5-05-IV Injection *Additional Options Listed Below
d. Rx: (TFSTMRX) 11. Oxycodone/Oxycontin: (TFOXYCOD) a. Route: (TFOXYROU)	No, taken illicitly Yes, but more taken than prescribed No Yes 1-01-0 ral 2-02-Nasal 3-03-S moking 4-04-Non-IV Injection 5-05-IV Injection
b. Rx: (TFOXYRX)	*Additional Options Listed Below No, taken illicitly Yes, but more taken than prescribed
12. Methadone: (TFMETHAD)	□ No □ Yes

```
a. Route: (TFMTHROU)
   b. Rx: (TFMTHRX)
13. Opiates: (TFOPIATE)
    a. Specify Opiates: (TFOPISP)
   b. Route: (TFOPIROU)
    c. Rx: (TFOPIRX)
14. Ecstasy (MDMA): (TFECSTAS)
   a. Quantity: (TFECSQTY)
   b. Route: (TFECSROU)
15. Barbiturates: (TFBARBIT)
    a. Rx: (TFBARRX)
16. Benzo diaze pines: (TFBENZOD)
    a. Rx: (TFBENRX)
17. Sedatives:(TFSEDATV)
    a. Rx: (TFSEDRX)
18. Prescription Drugs (not captured above):(TFPRESCR)
    a. Specify Prescription Drugs:(TFPRESSP)
   b. Rx: (TFPRESRX)
19. Other drugs: (TFO THDRG)
    a. Number of other drugs (up to 9): (TFNMOTH)
   Other Drug 1
    b. Specify Other Drug 1:(TFOTH1SP)
```

1-01-0 ral 2-02-Nasal 3-03-S moking 4-04-Non-IV Injecto 5-05-IV Injection *Additional Options	
No, taken illicitly	Yes, but more taken than prescribed
No Yes	
1-01-0 ral 2-02-Nasal 3-03-S moking 4-04-Non-IV Injecto 5-05-IV Injection *Additional Options	
No, taken illicitly	Yes, but more taken than prescribed
No Yes (xx) pills	
1-01-0 ral 2-02-Nasal 3-03-S moking 4-04-Non-IV Injectio 5-05-IV Injection *Additional Options	
☐ No ☐ Yes ☐ No, taken illicitly	Yes, but more taken than prescribed
No Yes No, taken illicitly	Yes, but more taken than prescribed
No Yes No, taken illicitly	Yes, but more taken than prescribed
□ No □ Yes	
No, taken illicitly	Yes, but more taken than prescribed
No Yes	

c. Route Other Drug 1: (TFO TH1RT)

Other Drug 2

d. Specify Other Drug 2: (TFOTH2SP)

e. Route Other Drug 2: (TFO TH2RT)

Other Drug 3

f. Specify Other Drug 3: (TFOTH3SP)

g. Route Other Drug 3: (TFO TH3RT)

Other Drug 4

h. Specify Other Drug 4: (TFOTH4SP)

i. Route Other Drug 4: (TFO TH4RT)

Other Drug 5

j. Specify Other Drug 5: (TFOTH5SP)

k. Route Other Drug 5: (TFO TH5RT)

Other Drug 6

I. Specify Other Drug 6: (TFOTH6SP)

m. Route Other Drug 6: (TFO TH6RT)

1-01-0 ral 2-02-Nasal 3-03-S moking 4-04-Non-IV Injection 5-05-IV Injection *Additional Options Listed Below

1-01-0 ral

2-02-Nasal

3-03-S moking

4-04-Non-IV Injection

5-05-IV Injection

*Additional Options Listed Below

1-01-0 ral

2-02-Nasal

2-02-Nasa

3-03-S moking

4-04-Non-IV Injection

5-05-IV Injection

*Additional Options Listed Below

1-01-0 ral

2-02-Nasal

3-03-S moking

4-04-Non-IV Injection

5-05-IV Injection

*Additional Options Listed Below

1-01-0 ral

2-02-Nasal

3-03-S moking

4-04-Non-IV Injection

5-05-IV Injection

*Additional Options Listed Below

1-01-0 ral

2-02-Nasal

3-03-S moking

4-04-Non-IV Injection

5-05-IV Injection

*Additional Options Listed Below

- n. Specify Other Drug 7: (TFOTH7SP)
- o. Route Other Drug 7: (TFO TH7RT)

Other Drug 8

- p. Specify Other Drug 8: (TFOTH8SP)
- q. Route Other Drug 8: (TFO TH8RT)

Other Drug 9

- r. Specify Other Drug 9: (TFOTH9SP)
- s. Route Other Drug 9: (TFO TH9RT)

Comments:(TFBCOMM)

1-01-0 ral 2-02-Nasal 3-03-S moking 4-04-Non-IV Injection 5-05-IV Injection *Additional Options Listed Below

1-01-0 ral 2-02-N asal 3-03-S moking 4-04-N on-IV Injection 5-05-IV Injection *Additional Options Listed Below

1-01-0 ral 2-02-N asal 3-03-S moking 4-04-N on-IV Injection 5-05-IV Injection *Additional Options Listed Below

Additional Selection Options for TFB

Other tobacco type: 9-9 - Other

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	Treatment Participation Questionnaire (TPQ)			
Segment <i>(PROTSEG)</i> : Visit Number <i>(VISNO</i>):				
Date of assessment: (TPASMTDT)		Γ	(mm/dd/yyyy) (Ti	PTODAY) Click here for today's date
How much do you agree or disagree w	ith these statements?			
 Even if I relapse, I am likely to keep par outpatient treatment, counseling and/or 		n of treatment for substance	abuse, such as residential	treatment,
(TPRELAPA)	☐ Disagree	☐ Unsure	☐ Agree	☐ Strongly Agree
2. Even if I relapse, I am likely to continue (TPRELAPB) Strongly Disagree	coming to study exerc	sise or health education visits	s.	☐ Strongly Agree
3. Even if I am having cravings or urges to such as residential treatment, outpatien			n of treatment for substance	abuse,
(TPCRA VEA) Strongly Disagree	☐ Disagree	☐ Unsure	☐ Agree	☐ Strongly Agree
4. Even if I am having cravings or urges to	ouse, I am likely to co	ntinue coming to study exerc	ise or health education visit	s.
(TPCRAVEB) Strongly Disagree	☐ Disagree	Unsure	☐ Agree	☐ Strongly Agree
5. Even if I find participating in this study b	ourdensome, I am likel	y to continue coming to stud	y exercise or health educati	on visits.
(TPBURDEN) Strongly Disagree	☐ Disagree	☐ Unsure	☐ Agree	☐ Strongly Agree
e constitution Market Control D	.lla a			

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				NIDA Clinical Trials Network
				Urine Drug Screen (UDS)
Segment (<i>PROTSEG</i>): Visit Number (<i>VISNO</i>):				
Was a urine drug screen performa. If "No", provide reason: (UD1)				□ No □ Yes
a. II No , provide reason. (OD)	NOENO)			1-Participant reported being unable to provide sample 2-Participant refused to provide sample 3-S tudy stafferror 9-O ther
b. If "Other", specify:(UD1NC	OCSP)			
1st Urine Drug Scr	een			
2. Date 1st urine specimen collected:(UDCOLDT)			(mm/dd/yyyy) Click here for calendar	
3. Time 1st urine specimen collected (24 hour format): (UD1 COLTM)		ГМ)	(hh:mm)	
4. Was the 1st urine temperature within range? (90 - 100 °F)(UD1TMP)		1TMP)	□ No □ Yes	
5. Was the 1st urine specimen de	etermined to be adult	erated?(UL	1 ADULT)	□ No □ Yes
1st Urine Drug Screen Resul	lts			
6. Drug Name (Abbreviation)	Ne gative	Positive	Invalid	
Benzodiazepines (BZO):	(UD1BZO)			
Amp hetamine (AMP):	(UD1AMP)			

Marijuana (THC):

Cocaine (COC):

Ecstasy (MDMA):

Oxycodone (OXY):

Methadone (MTD):

Barbiturate (BAR):

Methamphetamine (MET):

Opiates (2000 ng) (OPI):

(UD1THC)

(UD1MET) □

(UD10PI)

(UD1COC)

(UD1MDMA) □

(UD10XY)

(UD1MTD) □

(UD1BAR)

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2nd Urine Drug Screen

Zild Offile Diag Scieen
If the 1st urine specimen was determined to be adulterated, was a second specimen collected? (UD2COLNY)
a. If "No", provide reason: (UD2 NCLRS)
b. If "Other", spe cify:(UD2NOCSP)
8. Time 2nd urine specimen collected (24 hour format): (UD2 COLTM)
9. Was the 2nd urine temperature within range? (90 - 100 °F)(UD2TMP)

2nd Urine Drug Screen Results

11. Drug Name	(Abbreviation)	Ne gative	Positive	Invalid
Benzodiazep	ines (BZO):	(UD2BZO)		
Amp hetamine	e (AMP):	(UD2AMP)		
Marijuana (T	HC):	(UD2THC)		
Methamphet	amin e (MET):	(UD2MET)		
Opiates (200	00 ng) (OPI):	(UD2OPI)		
Cocaine (CC	OC):	(UD2COC)		
Ecstasy (MD	MA):	(UD2MDMA)		
Oxycodone (OXY):	(UD2OXY)		
Methadone (MTD):	(UD2MTD)		
Barbiturate (BAR):	(UD2BAR)		

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

Comments:(UDSCOMM)

3-S tudy stafferror 9-O ther	sed to provide	oap.o	
9-0 (lei			_
(hh:n	nm)		
□ No □ Yes			
□ No □ Yes			