

## NIDA Clinical Trials Network

### Adverse Events (AD1)

Web Version: 1.0; 4.00; 10-02-15

Adverse event onset date (AEDATE):

Event number (AESEQNUM):

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

**For the purposes of this protocol, Grade 1 (mild) unrelated adverse events should not be reported in AdvantageEDC.**

1. Adverse event name: (A1DESCPT)

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

3. Severity of event: (A1SEVRTY)

4. Is there a reasonable possibility that the study drug caused the event?  
(A1RDRUG1)

☐ No ☐ Yes

If "Yes", action taken with the study drug: (A1ADRUG1)

5. If "Unrelated" to the study drug, alternative etiology: (A1ALTESD)

If "Other," specify: (A1AEPSP)

6. Outcome of event: (A1OUTCM)

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

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

8. Was this event associated with: (A1ASSOC)

a. If "Death", date of death: (A1DTHDT)

b. If "Inpatient admission to hospital or prolongation of hospitalization":

Date of hospital admission: (A1HOSPAD)

Date of hospital discharge: (A1HOSPDG)

Comments:(AD1 COMM)



## Additional Selection Options for AD1

### Event 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

### Was this event associated with:

5- Congenital anomaly or birth defect  
6- Important medical event that required intervention to prevent any of the above  
7- Seizure  
8- Hospitalization for a medical event

Serious Adverse Event Summary (AD2)

Web Version: 1.0; 1.00; 02-25-15

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

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

1. Initial narrative description of serious adverse event:

(A2SUMM)

2. Relevant past medical history: (A2SAEMHX) ☐ No ☐ Yes ☐ Unknown  
Allergies, pregnancy, smoking and alcohol use, hypertension, diabetes, epilepsy, depression, etc.

(A2MEDHX)

3. Medications at the time of the event: (A2SAEMED) ☐ No ☐ Yes ☐ Unknown

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

4. Treatments for the event: (A2SAE TRT) ☐ No ☐ Yes ☐ Unknown

Treatment	Indication	Date Treated (mm/dd/yyyy)
(A2_1TNME) <input type="text"/>	(A2_1TIND) <input type="text"/>	(A2_1LTDT) <input type="text"/>

(A2_2TNME)		(A2_2TIND)		(A2_2LTD T)	
(A2_3TNME)		(A2_3TIND)		(A2_3LTD T)	
(A2_4TNME)		(A2_4TIND)		(A2_4LTD T)	
(A2_5TNME)		(A2_5TIND)		(A2_5LTD T)	

5. Labs/tests performed in conjunction with this event: (A2SAELAB) ☐ No ☐ Yes ☐ Unknown

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

6. Follow-up:  
Include labs/test results as they become available, clinical changes, consultant diagnosis, etc.

(A2FOLLUP)

7. Additional information requested by the Medical Monitor:

(A2ADDINF)

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

## Additional Selection Options for AD2

Event 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

### Serious Adverse Event Medical Reviewer (AD3)

Web Version: 1.0; 3.00; 08-19-14

Adverse event onset date (AEDATE):

Event number (AESEQNUM):

1. Was this determined to be a serious adverse event?(A3SAE) ☐ No ☐ Yes
2. Was this event considered associated with the study drug?(A3RELDRG) ☐ No ☐ Yes
3. Was this event expected?(A3EXPECT) ☐ No ☐ Yes
4. Is this a standard expedited/reportable event?  
(i.e., is it serious, unexpected and related to therapy)(A3EXPFDA) ☐ No ☐ Yes  
If "No", is this an expedited/reportable event for other reasons?(A3EXPOTH) ☐ No ☐ Yes
5. Does the protocol need to be modified based on this event?(A3MPROT) ☐ No ☐ Yes
6. Does the consent form need to be modified based on this event?(A3MCNST) ☐ No ☐ Yes
7. Is the review complete?(A3REVDNE) ☐ No ☐ Yes  
If "No", what additional information is required:(A3ADDINF)

Assessed by:(A3ASRID)

 (initials)

Reviewed by:(A3REVID)

 (initials)

Comments:(A3COMM)

## Additional Selection Options for AD3

Event 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

### Concise Health Risk Tracking (CHRT) - Clinician Rated Module (CHC)

Web Version: 1.0; 1.00; 01-16-14

Segment (*PROTSEG*):

Visit number (*VISNO*):

Date of assessment: (*CHCASMDT*)

(mm/dd/yyyy)

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

**This last week did you think you might be better off dead or wish you were dead?**

**Did you have any thoughts of harming or injuring yourself in any way?**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Comments: (*CHCCOMM*)

## NIDA Clinical Trials Network

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

Web Version: 1.0; 1.02; 04-09-14

Segment (*PROTSEG*):

Visit number (*VISNO*):

Date of assessment: (*CHPASMDT*)

(mm/dd/yyyy)

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

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

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

CM Summary Form (CMS)

Web Version: 1.0; 1.01; 08-05-15

Segment (PROTSEG):  
Visit number (VISNO):

Date of assessment:(CMSASMDT)

(mm/dd/yyyy)

1. Attendance reward grand total:(CMSATTEN)

\$

(xxx)

2. Abstinence reward grand total:(CMSABSTI)

\$

(xxx)

Comments:(CMSCOMM)

# NIDA Clinical Trials Network

## Cannabis Use Quantification (CUQ)

Web Version: 1.0; 1.00; 10-21-13

Date of assessment: (mm/dd/yyyy)	In the past 30 days, have you used any of these methods to administer cannabis?	If "Ingestion" or "Other", specify:	On average, how much cannabis do you use? (xx.xx grams)	What would be the estimated dollar value for this amount of cannabis? (\$xxx)
1. (CUAS01DT) <input type="text"/>	(CUMETH01) <div><div></div></div>	(CUMESP01) <input type="text"/>	(CUAMT1) <input type="text"/>	(CUSPNT01) <input type="text"/>
2. (CUAS02DT) <input type="text"/>	(CUMETH02) <div><div></div></div>	(CUMESP02) <input type="text"/>	(CUAMT2) <input type="text"/>	(CUSPNT02) <input type="text"/>
3. (CUAS03DT) <input type="text"/>	(CUMETH03) <div><div></div></div>	(CUMESP03) <input type="text"/>	(CUAMT3) <input type="text"/>	(CUSPNT03) <input type="text"/>
4. (CUAS04DT) <input type="text"/>	(CUMETH04) <div><div></div></div>	(CUMESP04) <input type="text"/>	(CUAMT4) <input type="text"/>	(CUSPNT04) <input type="text"/>
5. (CUAS05DT) <input type="text"/>	(CUMETH05) <div><div></div></div>	(CUMESP05) <input type="text"/>	(CUAMT5) <input type="text"/>	(CUSPNT05) <input type="text"/>
6. (CUAS06DT) <input type="text"/>	(CUMETH06) <div><div></div></div>	(CUMESP06) <input type="text"/>	(CUAMT6) <input type="text"/>	(CUSPNT06) <input type="text"/>
7. (CUAS07DT) <input type="text"/>	(CUMETH07) <div><div></div></div>	(CUMESP07) <input type="text"/>	(CUAMT7) <input type="text"/>	(CUSPNT07) <input type="text"/>

	<div>1-Joints 2-Blunts 3-Pipe/Bowl 4-Bong 5-Ingestion *Additional Options Listed Below</div>			
8. (CUAS08DT) <div></div>	(CUMETH08) <div></div>	(CUMESP08) <div></div>	(CUAMT8) <div></div>	(CUSPNT08) <div></div>

Comment(CUQCOMM)

**Additional Selection Options for CUQ**

- Method 1**
- 6-Vaporizers
- 98-Other 1
- 99-Other 2

# NIDA Clinical Trials Network

## Cannabis Withdrawal Scale (CWS)

Web Version: 1.0; 1.01; 03-20-14

Segment (PROTSEG):

Visit number (VISNO):

Date of assessment:(CWSA SMDT)

(mm/dd/yyyy)

The following statements describe how you have felt over the **last 24 hours**. Please check the box that most closely represents your personal experiences for each statement. For each statement, please rate its **negative** impact on normal daily activities on the same scale (0 = Not at all to 10 = Extremely), indicating the number in the right hand column.

	Not at All										Extremely	Negative Impact on
	0	1	2	3	4	5	6	7	8	9	10	Daily Activity (0-10)
1. The only thing I could think about was smoking some cannabis:	(CWSMOKE) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	(CWSMOKEN) <input type="text"/> (xx)
2. I had a headache:	(CWHEAD) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	(CWHEADN) <input type="text"/> (xx)
3. I had no appetite:	(CWAPPET) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	(CWAPPETN) <input type="text"/> (xx)
4. I felt nauseous (like vomiting):	(CWVOMIT) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	(CWVOMITN) <input type="text"/> (xx)
5. I felt nervous:	(CWNERVE) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	(CWNERVEN) <input type="text"/> (xx)
6. I had some angry outbursts:	(CWANGRY) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	(CWANGRYN) <input type="text"/> (xx)
7. I had mood swings:	(CWMOOD) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	(CWMOODN) <input type="text"/> (xx)
8. I felt depressed:	(CWDEPRES) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	(CWDEPREN) <input type="text"/> (xx)
9. I was easily irritated:	(CWIRRITA) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	(CWIRRITN) <input type="text"/> (xx)
10. I had been imagining being stoned:	(CWSTONE) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	(CWSTONEN) <input type="text"/> (xx)
11. I felt restless:	(CWREST) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	(CWRESTN) <input type="text"/> (xx)
12. I woke up early:	(CWWOKEUP) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	(CWWOKEN) <input type="text"/> (xx)
13. I had a stomach ache:	(CWACHE) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	(CWACHEN) <input type="text"/> (xx)
14. I had nightmares and/or strange dreams:	(CWDREAM) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	(CWDREAMN) <input type="text"/> (xx)
15. Life seemed like an uphill struggle:	(CWUPHILL) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	(CWUPHLLN) <input type="text"/> (xx)
16. I woke up sweating at night:	(CWSWEAT) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	(CWSWEATN) <input type="text"/> (xx)
17. I had trouble getting to sleep at night:	(CWINSOMN) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	(CWINSOMNN) <input type="text"/> (xx)
18. I felt physically tense:	(CWTENSE) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	(CWTENSEN) <input type="text"/> (xx)
19. I had hot flashes:	(CWFLASH) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	(CWFLASHN) <input type="text"/> (xx)

## NIDA Clinical Trials Network

### Demographics (DEM)

Web Version: 1.0; 2.02; 07-11-14

1. Date of birth: *(DEBRTHDT)*

(mm/dd/yyyy)

3. Gender: *(DEGENDER)*

☐ Male ☐ Female ☐ Don't know ☐ Refused

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

☐ No ☐ Yes ☐ Don't know ☐ Refused

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

5. What race does the participant consider him or herself to represent:

*(Check all that apply)*

White: *(DEWHITE)* ☐

Black/ African American: *(DEBLACK)* ☐

Indian (American): *(DEAMEIND)* ☐

Alaska native: *(DEALASKA)* ☐

Native Hawaiian: *(DEHAWAII)* ☐

Guamanian: *(DEGUAM)* ☐

Samoa: *(DESAMOAN)* ☐

Other Pacific Islander: *(DEPACISL)* ☐ Specify: *(DEPACISO)*

Asian Indian: *(DEASAIND)* ☐

Chinese: *(DECHINA)* ☐

Filipino: *(DEFILIPN)* ☐

Japanese: *(DEJAPAN)* ☐

Korean: *(DEKOREA)* ☐

Vietnamese: *(DEVIETNM)* ☐

Other Asian: *(DEASIAN)* ☐ Specify: *(DEASIAOT)*

Some other race: *(DERACEOT)* ☐ Specify: *(DERACESP)*

**-OR-**

Don't know: *(DERACEDK)* ☐

Refused: *(DERACERF)* ☐

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



7. We would like to know about what the participant does -- is he/she working now, looking for work, retired, keeping house, a student, or what?(DEJOB)

If "Other", specify:(DEJOBSP)

8. Is the participant married, widowed, divorced, separated, never married, or living with a partner?(DEMARL)

Comments:(DEM COMM)

## Additional Selection Options for DEM

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

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

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

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

We would like to know about what the participant does -- is he/she working now, looking for work, retired, keeping house, a student, or what?

- 06-Keeping house
- 07-Student
- 99-Other

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

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

End of Medication (EOM)

Web Version: 1.0; 4.00; 08-05-15

Segment (PROTSEG):

1. Did study medication end early?(EOEARLY)

Primary reason for not completing study medication:(EOSTOP53)

☐ No ☐ Yes

If "Other", specify:(EOSTOPSP)

Comments:(EOMCOMM)

## **Additional Selection Options for EOM**

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

6-Participant left study and never returned

7-Clinical deterioration: new onset of psychiatric or medical condition

8-Physical illness or condition that precludes taking study medication

9-Participant feels study treatment no longer necessary, cured

10-Participant feels study treatment no longer necessary, not working

11-Participant terminated early from study

99-Other

## NIDA Clinical Trials Network

0053B (ENR)

Web Version: 1.0; 1.01; 09-10-15

Date of assessment: (R2ASMDT)

(mm/dd/yyyy)

### Inclusion Criteria

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

1. Participant is between the ages of 18 and 50: (R2PTAGE) ☐ No ☐ Yes ☐ Unknown
2. Participant is able to understand the study and provide written informed consent: (R2INFORM) ☐ No ☐ Yes ☐ Unknown
3. Participant meets DSM-IV criteria for cannabis dependence in the last 30 days: (R2CANDEP) ☐ No ☐ Yes ☐ Unknown
4. Participant has expressed interest in treatment for cannabis dependence: (R2SEEKTX) ☐ No ☐ Yes ☐ Unknown
5. Participant had a positive urine cannabinoid test at screening: (R2URINE) ☐ No ☐ Yes ☐ Unknown
6. If female, participant agrees to use appropriate birth control methods during study participation: (R2BCUSE) ☐ No ☐ Yes ☐ Unknown ☐ Not applicable

### Exclusion Criteria

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

1. Participant has a known allergy or intolerance to NAC: (R2ALLERGY) ☐ No ☐ Yes ☐ Unknown
2. If female, participant is currently pregnant or breastfeeding: (R2PREGNT) ☐ No ☐ Yes ☐ Unknown ☐ Not applicable
3. Participant is on NAC or a supplement containing NAC and will not agree to stop taking any such supplement throughout study participation: (R2USENAC) ☐ No ☐ Yes ☐ Unknown
4. Participant used carbamazepine or nitroglycerin within 14 days of randomization: (R2NITRO) ☐ No ☐ Yes ☐ Unknown
5. Participant is enrolled in a treatment program for cannabis dependence: (R2TXPRGM) ☐ No ☐ Yes ☐ Unknown
6. Participant used synthetic cannabinoids (such as K2/Spice) in the 30 days prior to screening or during the period between screening and randomization: (R2SYNCAN) ☐ No ☐ Yes ☐ Unknown
7. Participant is dependent on substances other than cannabis or nicotine: (R2DRGDEP) ☐ No ☐ Yes ☐ Unknown
8. Participant had a positive urine drug screen for substances other than cannabis or amphetamines at the randomization visit: (R2DRGUDS) ☐ No ☐ Yes ☐ Unknown
9. Participant had a positive urine drug screen for amphetamines at the randomization visit without having a valid prescription for it: (R2AMPHET) ☐ No ☐ Yes ☐ Unknown
10. Participant is on maintenance treatment with buprenorphine or methadone: (R2MTDMNT) ☐ No ☐ Yes ☐ Unknown
11. Participant has a recent history of asthma (within the last 3 years): (R2ASTHMA) ☐ No ☐ Yes ☐ Unknown
12. Participant has a history of seizure disorder, bipolar disorder, schizophrenia, or other significant or unstable medical or psychiatric illness that may place the participant at increased risk in the judgment of the medical clinician: (R2PSYCH) ☐ No ☐ Yes ☐ Unknown
13. Participant shows a significant risk of homicide or suicide: (R2SUICDE) ☐ No ☐ Yes ☐ Unknown

### Stratification

Participant self-reports smoking tobacco: (R2SMOKE)

☐ No ☐ Yes

### Eligibility for Randomization

1. Is the participant eligible for the study? (R2ELGSTY) ☐ No ☐ Yes
  2. Will the participant be randomized? (R2ELGRDM) ☐ No ☐ Yes
- If "No", specify: (R2NORSP)

If "Judgment of research staff", specify: (R2JGTSP)

If "Other", specify: (R2OTHRSP)

Comments:(R2COMM)

## NIDA Clinical Trials Network

### Fagerstrom Test for Nicotine Dependence (FND)

Web Version: 1.0; 1.01; 10-21-13

Segment (*PROTSEG*):

Visit number (*VISNO*):

Date of assessment: (*FNDASMDT*)

(mm/dd/yyyy)

Do you currently smoke cigarettes? (*FNSMOKE*)

☐ No ☐ Yes

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

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

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

☐ No ☐ Yes

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

☐ The first one in the morning ☐ All others

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

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

☐ No ☐ Yes

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

☐ No ☐ Yes

Heatherton TF; Kozlowski LT; Frecker RC; The Fagerström Test for Nicotine Dependence: a revision of the Fagerström Tolerance Questionnaire. *Br J Addict* (1991), 86, 119-1127.

## NIDA Clinical Trials Network

### Hospital Anxiety and Depression Scale (HAD)

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

Segment (*PROTSEG*):

Visit number (*VISNO*):

Date of assessment:(*HADASMDT*)

(mm/dd/yyyy)

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

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

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

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

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

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

6. I feel cheerful:(*HACHERFL*)

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

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

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



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

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

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

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

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

**NIDA Clinical Trials Network**

### Marijuana Craving Questionnaire (MCQ)

Web Version: 1.0: 1.01: 03-20-14

**Segment (*PROTSEG*):**

Visit number (*VISNO*):

Date of assessment:(MCQASMDT)

(mm/dd/yyyy)

*Indicate how strongly you agree or disagree with each of the following statements by checking one of the spaces between STRONGLY DISAGREE and STRONGLY AGREE. The closer you place your check mark to one end or the other indicates the strength of your agreement or disagreement. If you don't agree or disagree with a statement, place your check mark in the middle space. Please complete every item. We are interested in how you are thinking or feeling right now as you are filling out the questionnaire.*

[illegible]

# NIDA Clinical Trials Network

## Medication Compliance - Pill Count (MPC)

Web Version: 1.0; 4.00; 01-13-15

Segment (PROTSEG):

Blister Card for Study Week	Date Dispensed (mm/dd/yyyy)	# Pills Taken		# Pills Reported Lost (xx)	Card Not Returned	Are Expected and Actual Consistent?	Check If Not Dispensed	
		EXPECTED (xx)	ACTUAL (xx)				(Enter Comment)	
(MPWEEK01)	(MPDSDT01)	(MPPDSP01)	(MPRACT01)	(MPLOST01)	(MPCARD01)	(MPCSNT01)	(MPNODS01)	(MPCOM01)
					<input type="checkbox"/>		<input type="checkbox"/>	
(MPWEEK02)	(MPDSDT02)	(MPPDSP02)	(MPRACT02)	(MPLOST02)	(MPCARD02)	(MPCSNT02)	(MPNODS02)	(MPCOM02)
					<input type="checkbox"/>		<input type="checkbox"/>	
(MPWEEK03)	(MPDSDT03)	(MPPDSP03)	(MPRACT03)	(MPLOST03)	(MPCARD03)	(MPCSNT03)	(MPNODS03)	(MPCOM03)
					<input type="checkbox"/>		<input type="checkbox"/>	
(MPWEEK04)	(MPDSDT04)	(MPPDSP04)	(MPRACT04)	(MPLOST04)	(MPCARD04)	(MPCSNT04)	(MPNODS04)	(MPCOM04)
					<input type="checkbox"/>		<input type="checkbox"/>	
(MPWEEK05)	(MPDSDT05)	(MPPDSP05)	(MPRACT05)	(MPLOST05)	(MPCARD05)	(MPCSNT05)	(MPNODS05)	(MPCOM05)
					<input type="checkbox"/>		<input type="checkbox"/>	
(MPWEEK06)	(MPDSDT06)	(MPPDSP06)	(MPRACT06)	(MPLOST06)	(MPCARD06)	(MPCSNT06)	(MPNODS06)	(MPCOM06)
					<input type="checkbox"/>		<input type="checkbox"/>	
(MPWEEK07)	(MPDSDT07)	(MPPDSP07)	(MPRACT07)	(MPLOST07)	(MPCARD07)	(MPCSNT07)	(MPNODS07)	(MPCOM07)
					<input type="checkbox"/>		<input type="checkbox"/>	

1-1 2-2 3-3 4-4 5-5 *Additional Options Listed Below								
(MPWEEK08)	(MPDSDT08)	(MPPDSP08)	(MPRACT08)	(MPLOST08)	(MPCARD08)	(MPCSNT08)	(MPNODS08)	(MPRCOM08)
					<input type="checkbox"/>		<input type="checkbox"/>	
Blister Card for Study Week	Date Dispensed (mm/dd/yyyy)	# Pills Taken		# Pills Reported Lost (xx)	Card Not Returned	Are Expected and Actual Consistent?	Check If Not Dispensed  (Enter Comment)	
		EXPECTED (xx)	ACTUAL (xx)					
(MPWEEK09)	(MPDSDT09)	(MPPDSP09)	(MPRACT09)	(MPLOST09)	(MPCARD09)	(MPCSNT09)	(MPNODS09)	(MPRCOM09)
					<input type="checkbox"/>		<input type="checkbox"/>	
(MPWEEK10)	(MPDSDT10)	(MPPDSP10)	(MPRACT10)	(MPLOST10)	(MPCARD10)	(MPCSNT10)	(MPNODS10)	(MPRCOM10)
					<input type="checkbox"/>		<input type="checkbox"/>	
(MPWEEK11)	(MPDSDT11)	(MPPDSP11)	(MPRACT11)	(MPLOST11)	(MPCARD11)	(MPCSNT11)	(MPNODS11)	(MPRCOM11)
					<input type="checkbox"/>		<input type="checkbox"/>	
(MPWEEK12)	(MPDSDT12)	(MPPDSP12)	(MPRACT12)	(MPLOST12)	(MPCARD12)	(MPCSNT12)	(MPNODS12)	(MPRCOM12)
					<input type="checkbox"/>		<input type="checkbox"/>	
(MPWEEK13)	(MPDSDT13)	(MPPDSP13)	(MPRACT13)	(MPLOST13)	(MPCARD13)	(MPCSNT13)	(MPNODS13)	(MPRCOM13)
					<input type="checkbox"/>		<input type="checkbox"/>	
(MPWEEK14)	(MPDSDT14)	(MPPDSP14)	(MPRACT14)	(MPLOST14)	(MPCARD14)	(MPCSNT14)	(MPNODS14)	(MPRCOM14)
					<input type="checkbox"/>		<input type="checkbox"/>	

(MPWEEK15)	(MPDSDT15)	(MPPDSP15)	(MPRACT15)	(MPLOST15)	(MPCARD15) <input type="checkbox"/>	(MPCSNT15)	(MPNODS15) <input type="checkbox"/>	(MPRCOM15)
(MPWEEK16)	(MPDSDT16)	(MPPDSP16)	(MPRACT16)	(MPLOST16)	(MPCARD16) <input type="checkbox"/>	(MPCSNT16)	(MPNODS16) <input type="checkbox"/>	(MPRCOM16)
Blister Card for Study Week	Date Dispensed (mm/dd/yyyy)	# Pills Taken		# Pills Reported Lost (xx)	Card Not Returned	Are Expected and Actual Consistent?	Check If Not Dispensed  (Enter Comment)	
		EXPECTED (xx)	ACTUAL (xx)					
(MPWEEK17)	(MPDSDT17)	(MPPDSP17)	(MPRACT17)	(MPLOST17)	(MPCARD17) <input type="checkbox"/>	(MPCSNT17)	(MPNODS17) <input type="checkbox"/>	(MPRCOM17)
(MPWEEK18)	(MPDSDT18)	(MPPDSP18)	(MPRACT18)	(MPLOST18)	(MPCARD18) <input type="checkbox"/>	(MPCSNT18)	(MPNODS18) <input type="checkbox"/>	(MPRCOM18)
(MPWEEK19)	(MPDSDT19)	(MPPDSP19)	(MPRACT19)	(MPLOST19)	(MPCARD19) <input type="checkbox"/>	(MPCSNT19)	(MPNODS19) <input type="checkbox"/>	(MPRCOM19)

Comments:(MPCCOMM)

## Additional Selection Options for MPC

Study week number row 01

6-6

7-7

8-8

9-9

10-10

11-11

12-12

13-EOT

14-Replacement

## NIDA Clinical Trials Network

### Medication Compliance - Daily Dosage (MPR)

Web Version: 1.0; 3.00; 08-07-14

Segment (PROTSEG):  
Study weeks (WKNM53):

#### Study Week 1

#### Study Week 7

	Study Day	Study Day	Date	Mgs. Prescribed (xxxx)	Mgs. Taken (xxx)	Comments
1	43		(MPDTD01) <input type="text"/>	(MPRXD01) <input type="text"/>	(MPTKND01) <input type="text"/>	(MPCOMD01) <input type="text"/>
2	44		(MPDTD02) <input type="text"/>	(MPRXD02) <input type="text"/>	(MPTKND02) <input type="text"/>	(MPCOMD02) <input type="text"/>
3	45		(MPDTD03) <input type="text"/>	(MPRXD03) <input type="text"/>	(MPTKND03) <input type="text"/>	(MPCOMD03) <input type="text"/>
4	46		(MPDTD04) <input type="text"/>	(MPRXD04) <input type="text"/>	(MPTKND04) <input type="text"/>	(MPCOMD04) <input type="text"/>
5	47		(MPDTD05) <input type="text"/>	(MPRXD05) <input type="text"/>	(MPTKND05) <input type="text"/>	(MPCOMD05) <input type="text"/>
6	48		(MPDTD06) <input type="text"/>	(MPRXD06) <input type="text"/>	(MPTKND06) <input type="text"/>	(MPCOMD06) <input type="text"/>
7	49		(MPDTD07) <input type="text"/>	(MPRXD07) <input type="text"/>	(MPTKND07) <input type="text"/>	(MPCOMD07) <input type="text"/>

#### Study Week 2

#### Study Week 8

	Study Day	Study Day	Date	Mgs. Prescribed (xxxx)	Mgs. Taken (xxx)	Comments
8	50		(MPDTD08) <input type="text"/>	(MPRXD08) <input type="text"/>	(MPTKND08) <input type="text"/>	(MPCOMD08) <input type="text"/>
9	51		(MPDTD09) <input type="text"/>	(MPRXD09) <input type="text"/>	(MPTKND09) <input type="text"/>	(MPCOMD09) <input type="text"/>
10	52		(MPDTD10) <input type="text"/>	(MPRXD10) <input type="text"/>	(MPTKND10) <input type="text"/>	(MPCOMD10) <input type="text"/>
11	53		(MPDTD11) <input type="text"/>	(MPRXD11) <input type="text"/>	(MPTKND11) <input type="text"/>	(MPCOMD11) <input type="text"/>
12	54		(MPDTD12) <input type="text"/>	(MPRXD12) <input type="text"/>	(MPTKND12) <input type="text"/>	(MPCOMD12) <input type="text"/>
13	55		(MPDTD13) <input type="text"/>	(MPRXD13) <input type="text"/>	(MPTKND13) <input type="text"/>	(MPCOMD13) <input type="text"/>
14	56		(MPDTD14) <input type="text"/>	(MPRXD14) <input type="text"/>	(MPTKND14) <input type="text"/>	(MPCOMD14) <input type="text"/>

#### Study Week 3

#### Study Week 9

	Study Day	Study Day	Date	Mgs. Prescribed (xxxx)	Mgs. Taken (xxx)	Comments
15	57		(MPDTD15) <input type="text"/>	(MPRXD15) <input type="text"/>	(MPTKND15) <input type="text"/>	(MPCOMD15) <input type="text"/>

16	58	(MPDTD16) <input type="text"/>	(MPRXD16) <input type="text"/>	(MPTKND16) <input type="text"/>	(MPCOMD16) <input type="text"/>
17	59	(MPDTD17) <input type="text"/>	(MPRXD17) <input type="text"/>	(MPTKND17) <input type="text"/>	(MPCOMD17) <input type="text"/>
18	60	(MPDTD18) <input type="text"/>	(MPRXD18) <input type="text"/>	(MPTKND18) <input type="text"/>	(MPCOMD18) <input type="text"/>
19	61	(MPDTD19) <input type="text"/>	(MPRXD19) <input type="text"/>	(MPTKND19) <input type="text"/>	(MPCOMD19) <input type="text"/>
20	62	(MPDTD20) <input type="text"/>	(MPRXD20) <input type="text"/>	(MPTKND20) <input type="text"/>	(MPCOMD20) <input type="text"/>
21	63	(MPDTD21) <input type="text"/>	(MPRXD21) <input type="text"/>	(MPTKND21) <input type="text"/>	(MPCOMD21) <input type="text"/>

Study Week 4

Study Week 10

Study Day	Study Day	Date	Mgs. Prescribed (xxx)	Mgs. Taken (xxx)	Comments
22	64	(MPDTD22) <input type="text"/>	(MPRXD22) <input type="text"/>	(MPTKND22) <input type="text"/>	(MPCOMD22) <input type="text"/>
23	65	(MPDTD23) <input type="text"/>	(MPRXD23) <input type="text"/>	(MPTKND23) <input type="text"/>	(MPCOMD23) <input type="text"/>
24	66	(MPDTD24) <input type="text"/>	(MPRXD24) <input type="text"/>	(MPTKND24) <input type="text"/>	(MPCOMD24) <input type="text"/>
25	67	(MPDTD25) <input type="text"/>	(MPRXD25) <input type="text"/>	(MPTKND25) <input type="text"/>	(MPCOMD25) <input type="text"/>
26	68	(MPDTD26) <input type="text"/>	(MPRXD26) <input type="text"/>	(MPTKND26) <input type="text"/>	(MPCOMD26) <input type="text"/>
27	69	(MPDTD27) <input type="text"/>	(MPRXD27) <input type="text"/>	(MPTKND27) <input type="text"/>	(MPCOMD27) <input type="text"/>
28	70	(MPDTD28) <input type="text"/>	(MPRXD28) <input type="text"/>	(MPTKND28) <input type="text"/>	(MPCOMD28) <input type="text"/>

Study Week 5

Study Week 11

Study Day	Study Day	Date	Mgs. Prescribed (xxx)	Mgs. Taken (xxx)	Comments
29	71	(MPDTD29) <input type="text"/>	(MPRXD29) <input type="text"/>	(MPTKND29) <input type="text"/>	(MPCOMD29) <input type="text"/>
30	72	(MPDTD30) <input type="text"/>	(MPRXD30) <input type="text"/>	(MPTKND30) <input type="text"/>	(MPCOMD30) <input type="text"/>
31	73	(MPDTD31) <input type="text"/>	(MPRXD31) <input type="text"/>	(MPTKND31) <input type="text"/>	(MPCOMD31) <input type="text"/>
32	74	(MPDTD32) <input type="text"/>	(MPRXD32) <input type="text"/>	(MPTKND32) <input type="text"/>	(MPCOMD32) <input type="text"/>
33	75	(MPDTD33) <input type="text"/>	(MPRXD33) <input type="text"/>	(MPTKND33) <input type="text"/>	(MPCOMD33) <input type="text"/>
34	76	(MPDTD34) <input type="text"/>	(MPRXD34) <input type="text"/>	(MPTKND34) <input type="text"/>	(MPCOMD34) <input type="text"/>
35	77	(MPDTD35) <input type="text"/>	(MPRXD35) <input type="text"/>	(MPTKND35) <input type="text"/>	(MPCOMD35) <input type="text"/>

Study Week 6

Study Week 12



	Study Day	Study Day	Date	Mgs. Prescribed (xxxx)	Mgs. Taken (xxxx)	Comments
	36	78	(MPDTD36) <input type="text"/>	(MPRXD36) <input type="text"/>	(MPTKND36) <input type="text"/>	(MPCOMD36) <input type="text"/>
	37	79	(MPDTD37) <input type="text"/>	(MPRXD37) <input type="text"/>	(MPTKND37) <input type="text"/>	(MPCOMD37) <input type="text"/>
	38	80	(MPDTD38) <input type="text"/>	(MPRXD38) <input type="text"/>	(MPTKND38) <input type="text"/>	(MPCOMD38) <input type="text"/>
	39	81	(MPDTD39) <input type="text"/>	(MPRXD39) <input type="text"/>	(MPTKND39) <input type="text"/>	(MPCOMD39) <input type="text"/>
	40	82	(MPDTD40) <input type="text"/>	(MPRXD40) <input type="text"/>	(MPTKND40) <input type="text"/>	(MPCOMD40) <input type="text"/>
	41	83	(MPDTD41) <input type="text"/>	(MPRXD41) <input type="text"/>	(MPTKND41) <input type="text"/>	(MPCOMD41) <input type="text"/>
	42	84	(MPDTD42) <input type="text"/>	(MPRXD42) <input type="text"/>	(MPTKND42) <input type="text"/>	(MPCOMD42) <input type="text"/>

Study Week 13

	Study Day	Date	Mgs. Prescribed (xxxx)	Mgs. Taken (xxxx)	Comments
	85	(MPDTD85) <input type="text"/>	(MPRXD85) <input type="text"/>	(MPTKND85) <input type="text"/>	(MPCOMD85) <input type="text"/>
	86	(MPDTD86) <input type="text"/>	(MPRXD86) <input type="text"/>	(MPTKND86) <input type="text"/>	(MPCOMD86) <input type="text"/>
	87	(MPDTD87) <input type="text"/>	(MPRXD87) <input type="text"/>	(MPTKND87) <input type="text"/>	(MPCOMD87) <input type="text"/>

Comments: (MPRCOMM)

## Additional Selection Options for MPR

Study weeks (*WKNM53*) (key field):

1-1, 2, 3, 4, 5, 6

2-7, 8, 9, 10, 11, 12

3-13

## NIDA Clinical Trials Network

### Marijuana Problem Scale (MPS)

Web Version: 1.0; 1.01; 03-21-14

Segment (*PROTSEG*):

Visit number (*VISNO*):

Date of assessment: (*MPSASMDT*)

(mm/dd/yyyy)

Following are different types of problems you may have experienced as a result of smoking marijuana. Please select the box that indicates whether this has been a problem for you in the **past 30 days**.

Has marijuana caused you...

	No Problem	Minor Problem	Serious Problem
1. Problems between you and your partner: ( <i>MPPARTNR</i> )	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Problems in your family: ( <i>MPFAMILY</i> )	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. To neglect your family: ( <i>MPNEGLCT</i> )	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Problems between you and your friends: ( <i>MPFRIEND</i> )	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. To miss days at work or miss classes: ( <i>MPMISSWK</i> )	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. To lose a job: ( <i>MPJOB</i> )	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. To have lower productivity: ( <i>MPPROD</i> )	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. Medical problems: ( <i>MPMED</i> )	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. Withdrawal symptoms: ( <i>MPWITH</i> )	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. Blackouts or flashbacks: ( <i>MPBLACK</i> )	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11. Memory loss: ( <i>MPMEMORY</i> )	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12. Difficulty sleeping: ( <i>MPSLEEP</i> )	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13. Financial difficulties: ( <i>MPMONEY</i> )	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14. Legal problems: ( <i>MPLEGAL</i> )	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15. To have lower energy level: ( <i>MPENERGY</i> )	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16. To feel bad about your use: ( <i>MPBADUSE</i> )	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17. Lowered self-esteem: ( <i>MPESTEEM</i> )	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18. To procrastinate: ( <i>MPPROCR</i> )	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19. To lack self-confidence: ( <i>MPCONFID</i> )	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Missed Visit Form (MVF)

Web Version: 1.0; 1.00; 12-06-13

Segment (PROTSEG):  
Visit number (VISNO):

Reason for missed visit:(M VREASON)

If "Other", specify:(MVO THRSP)

Comments:(M VF COMM)

## Additional Selection Options for MVF

### Reason for missed visit:

6-Participant moved from area

7-Participant incarcerated

8-CT P/Site closed

9-Participant withdrew consent

10-Participant deceased

99-Other

## NIDA Clinical Trials Network

### Obsessive Compulsive Drug Use - Marijuana (OCM)

Web Version: 1.0; 1.01; 03-24-14

Segment (*PROTSEG*):

Visit number (*VISNO*):

Date of assessment: (*OCMASMDT*)

(mm/dd/yyyy)

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

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

2. How frequently do these thoughts related to marijuana occur? (*OCTKFREQ*)

3. How much do these thoughts related to marijuana interfere with your social or work functioning? (*OCTKSOCL*)

4. How much distress or disturbances do these ideas, thoughts, impulses, or images related to marijuana cause you when you are not taking marijuana? (*OCDISTR*)

5. How much of an effort do you make to resist these thoughts related to marijuana or try to disregard or turn your attention away from these thoughts? (*Rate your efforts to resist these thoughts, not your success in controlling them*) (*OCRESIST*)

6. How successful are you in stopping or diverting these thoughts related to marijuana? (*OCDIVERT*)

7. If you do not use, how often do you feel the urge or drive to use marijuana? (*OCURGEOF*)

8. If you do not use, how much time of the day do you feel the urge or drive to use marijuana? (*OCURGETM*)

9. How much does the urge to use marijuana interfere with your social life or your occupational activities?  
(OCURGES)

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

11. How much of an effort do you make to resist the use of marijuana?(OCEFFORT)

12. How strong was the drive to use marijuana in the past week?(OCSTRONG)

13. How much control do you have over your marijuana use?(OCCONTRL)

## NIDA Clinical Trials Network

### Penetration of Blind Assessment (PBA)

Web Version: 1.0; 1.00; 10-24-13

Segment (*PROTSEG*):

Visit number (*VISNO*):

Date of assessment: (*PBAASMDT*)

(mm/dd/yyyy)

1. Has the blind been broken due to a medical necessity? (*PBBROKEN*)

☐ No ☐ Yes

*RA form:*

2. Based on the participant's study performance, do you think s/he has been receiving N-Acetylcysteine (NAC) or a placebo during the course of the study? (*PBRADRUG*)

☐ N-Acetylcysteine ☐ Placebo

*Medical Clinician form:*

3. Based on the participant's study performance, do you think s/he has been receiving N-Acetylcysteine (NAC) or a placebo during the course of the study? (*PBMCDRUG*)

☐ N-Acetylcysteine ☐ Placebo

Comments: (*PBACOMM*)



## NIDA Clinical Trials Network

### Pregnancy and Birth Control Assessment (PBC)

Web Version: 1.0; 3.02; 12-09-14

Segment (PROTSEG):

Visit number (VISNO):

Complete this form only for females.

Date of assessment:(PBCASMDT)

(mm/dd/yyyy)

1. Is the participant breastfeeding?(PBBSTFED)

☐ No ☐ Yes

2. Does the participant agree to use an acceptable method of birth control?  
(PBUSEBC)

☐ No ☐ Yes

If "Yes", select all that apply:

a. Oral contraceptives:(PBORALCN)

☐ No ☐ Yes

b. Contraceptive patch:(PBPATCH)

☐ No ☐ Yes

c. Barrier (diaphragm or condom):(PBBARRIR)

☐ No ☐ Yes

d. Levonorgestrel implant:(PBLEVIMP)

☐ No ☐ Yes

e. Medroxyprogesterone acetate injection:(PBMEDINJ)

☐ No ☐ Yes

f. Complete abstinence from sexual intercourse:(PBABSTIN)

☐ No ☐ Yes

g. Hormonal vaginal contraceptive ring:(PBRING)

☐ No ☐ Yes

h. Surgical sterilization:(PBSURGSZ)

☐ No ☐ Yes

i. Other:(PBBCOTH)

☐ No ☐ Yes

If "Other", specify:(PBBCOSP)

3. Was a pregnancy test performed?(PBPRGTST)

☐ No ☐ Yes

a. Date of pregnancy test:(PBPTSTDY)

(mm/dd/yyyy)

b. Result of pregnancy test:(PBRESULT)

☐ Negative ☐ Positive

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

Comments:(PBCCOMM)

## NIDA Clinical Trials Network

### Penetration of Blind Assessment - Participant (PBP)

Web Version: 1.0; 1.01; 03-20-14

Segment (*PROTSEG*):

Visit number (*VISNO*):

Date of assessment: (*PBPASMDT*)

(mm/dd/yyyy)

1. Do you think you have been receiving N-Acetylcysteine (NAC) or a placebo during the course of the study? (*PBPTDRUG*)

☐

N-Acetylcysteine

☐

Placebo

**NIDA Clinical Trials Network**

### Prior and Concomitant Medications (PCM)

Web Version: 1.0; 1.00; 10-04-13

Medication name (*PCMEDNME*):  
Medication start date (*PCSTRTDT*):

1. Indication for use: (PCINDICT)


If "Other," specify: (PCINDOTH)

2. Was this medication used to treat an adverse event?(PCMEDAE)

☐ No    ☐ Yes

3. Is medication ongoing? (PCONGOIN)

☐ No    ☐ Yes    ☐ Yes (continuing at protocol completion or study termination)

If "No", specify date medication was discontinued or changed:(*PCTERM DT*)

(mm/dd/yyyy)

Comments:(PCM COMM)

[illegible]

## Additional Selection Options for PCM

### Indication for use:

05 A--Diabetes  
06 A--Vitamins  
07 A--Mineral  
99 B-BLOOD AND BLOOD FORMING ORGANS  
01 B---Aspirin/coumadin/heparin  
02 B---Antianemic  
03 B---Blood products/IV fluids  
99 C- CARDIOVASCULAR SYSTEM  
01 C--Antihypertensives  
02 C--Diuretics  
03 C--Beta blocking  
04 C--Calcium Channel  
05 C--Lipid modifying agents  
01 D-ALL SKIN CREAMS  
01 G-CONTRACEPTIVES/ED/SEX HORMONES  
01 H-STERIODS/THYROID HORMONES  
01 J-ANTIBACTERIAL/ANTIVIRAL/ANTIFUNGAL/TB/VACCINES  
99 M-MUSCULOSKELETAL SYSTEM  
01 M--Antiinflammatory and antirheumatic  
02 M--Muscle relaxants  
03 M--Antigout  
99 N-NERVOUS SYSTEM  
01 N--Analgesics including antipyretics  
02 N--Antiepileptics  
03 N--Anxiety/Depression/Sleep  
99 R-RESPIRATORY SYSTEM  
01 R--Nasal  
02 R--Throat  
03 R--Obstructive airway  
04 R--Cough and cold  
05 R--Antihistamines  
01 S-EYE AND EAR DROPS  
Z01-VARIOUS  
01 V--Allergens  
02 V--All other therapeutic products  
03 V--Diagnostic agents  
04 V--General nutrients  
05 V--All other non-therapeutic products  
06 V--Contrast media  
07 V--Diagnostic radiopharmaceuticals  
08 V--Therapeutic radiopharmaceuticals  
99 -OTHER

## NIDA Clinical Trials Network

### Protocol Deviation Review (PDR)

Web Version: 1.0; 2.00; 03-24-14

Date of deviation (*PDDATE*):

Protocol deviation number (*PDSEQNUM*):

#### Completed by Protocol Specialist:

1. What section of the protocol does this deviation refer to? (*PDSECTN*)

2. Does the report of this deviation require site staff retraining? (*PDTRAIN*)

If "Yes", specify plan for retraining: (*PDPLATRA*)

☐ No ☐ Yes

3. Deviation was discussed with Lead Investigative Team on: (*PDDISCDT*)

4. Deviation is categorized as: (*PDCA TGRY*)

5. Deviation assessment by Protocol Specialist complete: (*PDPSCMP*)

Protocol Specialist reviewer: (*PDPSRVID*)

(mm/dd/yyyy)

☐ Major ☐ Minor

☐ No ☐ Yes

(initials)

#### Completed by Protocol Monitor:

6. Corrective action for this deviation was completed and documented on-site as described: (*PDACTDOC*)

If "No", specify reason: (*PDSITE SP*)

☐ No ☐ Yes

7. Deviation was reported to the IRB as required: (*PDIRBRPT*)

☐ No ☐ Yes

If "No", specify reason:(PDIRBSP)

8. Preventive action plan related to this event was completed and documented on-site as described:(PDPREVNT)

☐ No ☐ Yes

9. Review by Protocol Monitor is complete:(PDPMCMP)

☐ No ☐ Yes

Protocol Monitor reviewer:(PDPMRVID)

(initials)

Comments:(PVCOMM)

**Additional Selection Options for PDR**

**Protocol deviation number (*PDSEQNUM*) (key field):**

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

Protocol Deviation (PDV)

Web Version: 1.0; 1.00; 03-21-14

Date of deviation (PDDATE):  
Protocol deviation number (PDSEQNUM):

1. Date deviation identified: (PDVDATE)

(mm/d d/yyyy)

2. Deviation type: (PDTYPE)

If "Other", specify: (PDTYPSP)

3. Brief description of what occurred: (PDDESCPT)

4. Brief description of the actual or expected corrective action for this event: (PDACTION)

5. Brief description of the plan to prevent recurrence: (PDPREVRE)

6. Is this deviation reportable to your IRB? (PDIRBREP)

☐ No ☐ Yes



If "Yes" , will the IRB be notified at the time of continuing review?:(*PDIRBCON*)

☐ No ☐ Yes

If "Yes", date of planned submission::(*PDIRBPD**T*)

(mm/d d/yyyy)

If "No", date of actual submission::(*PDIRBAD**T*)

(mm/d d/yyyy)

Comments::(*PDVCOMM*)

## Additional Selection Options for PDV

### Protocol deviation number (*PDSEQNUM*) (key field):

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

### Deviation type:

01 E--- Informed consent process not properly conducted and/or documented  
01 Z--- Other (specify)  
Z02-INCLUSION/EXCLUSION CRITERIA  
02 A-- Ineligible participant randomized/inclusion/exclusion criteria not met  
02 Z--- Other (specify)  
Z04-LABORATORY ASSESSMENTS  
04 A-- Biologic specimen not collected/processed as per protocol  
04 Z--- Other (specify)  
Z05-STUDY PROCEDURES/ASSESSMENTS  
05 A-- Protocol required visit/assessment not scheduled or conducted  
05 B--- Study assessments not completed/followed as per protocol  
05 C--- Inappropriate unblinding  
05 Z--- Other (specify)  
Z06-ADVERSE EVENT  
06 A-- AE not reported  
06 B--- SAE not reported  
06 C--- AE/SAE reported out of protocol specified reporting time frame  
06 D--- AE/SAE not elicited, observed and/or documented as per protocol  
06 E--- Safety assessment (e.g. labs, ECG, clinical referral to care) not conducted per protocol  
06 Z--- Other (specify)  
Z07-RANDOMIZATION PROCEDURES  
07 A-- Stratification error  
07 Z--- Other (specify)  
Z08-STUDY MEDICATION MANAGEMENT  
08 A-- Medication dispensed to ineligible participant  
08 B--- Medication dispensed to incorrect participant  
08 C--- Medication dosing errors (protocol specified dose not dispensed)  
08 D--- Participant use of protocol prohibited medication  
08 Z--- Other (specify)  
Z09-STUDY BEHAVIORAL INTERVENTION  
09 A-- Study behavioral intervention was not provided/performed as per protocol  
09 Z--- Other (specify)  
Z99-OTHER SIGNIFICANT DEVIATIONS  
99 A-- Destruction of study materials without prior authorization from sponsor  
99 B--- Breach of Confidentiality  
99 Z--- Other (specify)

Pregnancy Outcome 1 (PO1)

Web Version: 1.0; 1.00; 07-26-13

Pregnancy number (PGSEQNUM):

Newborn Information

1. Gender:(PO1GENDR)

☐ Male ☐ Female ☐ Unknown

2. Gestational age at delivery:(PO1GESWK)

(xx) Weeks (PO1GESDY)

(x) Days (PO1GESUN)

OR ☐ Unknown

3. Weight at delivery:(PO1WTLBS)

(xx) Lbs (PO1WTOZ)

(xx) Oz (PO1WTUNK)

OR ☐ Unknown

4. Apgar score at 1 minute:(PO1APG1M)

(xx) (PO11APUK)

OR ☐ Unknown

5. Apgar score at 5 minutes:(PO1APG5M)

(xx) (PO15APUK)

OR ☐ Unknown

6. Normal infant?(PO1NORML)

☐ No ☐ Yes

☐ No ☐ Yes ☐ Unknown

If "No", is there a congenital anomaly?(PO1CONAN)

If "Yes", specify abnormality and contributing factors:(PO1ABNSP)

Comments:(PO1COMM)

## Additional Selection Options for PO1

**Pregnancy number (*PGSEQNUM*) (key field):**

- 01 -1st Pregnancy
- 02 -2nd Pregnancy
- 03 -3rd Pregnancy
- 04 -4th Pregnancy

## NIDA Clinical Trials Network

### Confirmed Pregnancy and Outcome (PRG)

Web Version: 1.0; 1.00; 07-26-13

Pregnancy number (PGSEQNUM):

#### Information About Pregnancy

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

(mm/dd/yyyy)

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

a. Urine pregnancy test result: (PRURICNF)

☐ No ☐ Yes

b. Serum pregnancy test result: (PRSERCNF)

☐ No ☐ Yes

c. Ultrasound result: (PRULTCNF)

☐ No ☐ Yes

d. Other: (PROTHCNF)

☐ No ☐ Yes

If "Other", specify: (PROTCNSP)

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

(mm/dd/yyyy)

4. Action taken with study drug: (PRACTIND)

5. Approximate due date: (PRAPXDDT)

(mm/dd/yyyy) (PRDDTUNK)OR ☐ Unknown

6. Outcome of pregnancy: (PROUTCME)

If "Other", specify: (PROTCMSP)

7. Date of pregnancy outcome: (PROTCMDT)

(mm/dd/yyyy)

8. Number of live births: (PRNMLIVB)

If "0" live births, indicate reason: (PRRSOBSP)

Comments: (PRGCOMM)

**Additional Selection Options for PRG**

**Pregnancy number (*PGSEQNUM*) (key field):**

- 01 -1st Pregnancy
- 02 -2nd Pregnancy
- 03 -3rd Pregnancy
- 04 -4th Pregnancy

**Outcome of pregnancy:**

- 97 -Unknown

**Number of live births:**

- 99 -Other
- 97 -Unknown

Pittsburgh Sleep Quality Index (PSQ)

Web Version: 1.0; 1.02; 03-17-15

Segment (PROTSEG):  
Visit number (VISNO):

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

Instructions: The following questions relate to your usual sleep habits during the past week (7 days). Your answers should indicate the most accurate reply for the majority of days and nights in the past month. Please answer all questions.

1. During the past week, what time (in 24-hour format) have you usually gone to bed at night?(PSBEDHR)

(hh:mm)
2. During the past week, how long (in minutes) has it usually taken you to fall asleep each night?(PSBEDMIN)

(xxx)
3. During the past week, what time (in 24-hour format) have you usually gotten up in the morning?(PSAWAKE)

(hh:mm)
4. During the past week, how many hours of actual sleep did you get at night? (This may be different than the number of hours you spent in bed.)(PSHRSSLP)

(xx.xx)

For each of the remaining questions, check the one best response. Please answer all questions.

5. During the past week, how often have you had trouble sleeping because you...

- a. Cannot get to sleep within 30 minutes:

(PSNOSLP) ☐
- b. Wake up in the middle of the night or early morning:

(PSWAKEUP) ☐
- c. Have to get up to use the bathroom:

(PSBATHRM) ☐
- d. Cannot breathe comfortably:

(PSBREATH) ☐
- e. Cough or snore loudly:

(PSSNORE) ☐
- f. Feel too cold:

(PSCOLD) ☐
- g. Feel too hot:

(PSHOT) ☐
- h. Had bad dreams:

(PSDREAMS) ☐
- i. Have pain:

(PSPAIN) ☐
- j. Are there other reasons why during the past week you have had trouble sleeping?(PSSLPOTR) ☐ No ☐ Yes

i. If "Yes", specify:(PSSLPSP)

Not During the Past Week	Once in the Past Week	Twice in the Past Week	Three or More Times in the Past Week
(PSNOSLP) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(PSWAKEUP) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(PSBATHRM) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(PSBREATH) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(PSSNORE) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(PSCOLD) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(PSHOT) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(PSDREAMS) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(PSPAIN) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
(PSOTRFRQ) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

6. During the past week, how would you rate your sleep quality overall?(PSSLPQLT)
7. During the past week, how often have you taken medicine to help you sleep (prescribed or "over the counter")?(PSSMEDWK)

8. During the past week, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?  
(PSALRTWK)


9. During the past week, how much of a problem has it been for you to keep up enough enthusiasm to get things done?(PSENTHUS)




Quality of Life - PhenX (QLP)

Web Version: 1.0; 1.02; 01-03-14

Segment (PROTSEG):  
Visit number (VISNO):

Date of assessment:(QLPASMDT)

(mm/dd/yyyy)

1. Would you say that in general your health is:(QLHEALTH)

2. Now thinking about your physical health, which includes physical illness and injury, for how many days during the past 30 days was your physical health not good?(QLHLTNGD)

(xx) Number of days

3. Now thinking about your mental health, which includes stress, depression, and problems with emotions, for how many days during the past 30 days was your mental health not good?(QLMTLNG)

(xx) Number of days

4. During the past 30 days, for about how many days did poor physical or mental health keep you from doing your usual activities, such as self-care, work, or recreation?(QLACT)

(xx) Number of days

## NIDA Clinical Trials Network

### Study Termination (STT)

Web Version: 1.0; 2.03; 09-16-14

Segment (*PROTSEG*):

1. Date of study completion or last attended study visit: (*STTRMDT*)

(mm/dd/yyyy)

2. Did the participant complete the study? (*STCOMPLT*)

☐ No ☐ Yes

If "No", select the primary reason for not completing the study: (*STTRMRES*)

If "Participant terminated for other clinical reasons", "Participant discharged for administrative issues", or "Participant terminated for other reason", specify: (*STTRMOSP*)

Comments: (*STTCOMM*)

### Investigator's Signature

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

Principal Investigator: (*STPISIGN*)

Date: (*STPISGDT*)

(mm/dd/yyyy)

## Additional Selection Options for STT

If "No", select the primary reason for not completing the study:

- 6-Participant terminated for other clinical reasons
- 7-Participant had a significant psychiatric risk (suicidal, homicidal, psychotic)
- 8-Participant withdrew consent
- 9-Participant deceased
- 10-Participant discharged for administrative issues
- 11-Participant terminated due to pressure or advice from outsiders
- 12-Participant feels treatment no longer necessary, cured
- 13-Participant feels treatment no longer necessary, not working
- 99-Participant terminated for other reason

## NIDA Clinical Trials Network

### TLFB Assessment Period (TAP)

Web Version: 1.0; 3.02; 07-11-14

Segment (*PROTSEG*):

Visit number (*VISNO*):

Date of assessment: (*TAPASMDT*)

1. Assessment period: (*TATFSTDT*)

(*TATFENDT*)

(mm/dd/yyyy)

From:  (mm/dd/yyyy)

To:  (mm/dd/yyyy)

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

☐ No ☐ Yes

Comments: (*TAPCOMM*)

# NIDA Clinical Trials Network

## Timeline Followback (T53)

Web Version: 1.0; 2.00; 07-24-14

TFB week start date (TFWKSTDY):

Day	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Date	(TLDATE1) <input type="text"/>	(TLDATE2) <input type="text"/>	(TLDATE3) <input type="text"/>	(TLDATE4) <input type="text"/>	(TLDATE5) <input type="text"/>	(TLDATE6) <input type="text"/>	(TLDATE7) <input type="text"/>
1. Have any illicit substances, alcohol, or cigarettes been used on this day?	(TLSUBAL1) <input type="checkbox"/> No <input type="checkbox"/> Yes	(TLSUBAL2) <input type="checkbox"/> No <input type="checkbox"/> Yes	(TLSUBAL3) <input type="checkbox"/> No <input type="checkbox"/> Yes	(TLSUBAL4) <input type="checkbox"/> No <input type="checkbox"/> Yes	(TLSUBAL5) <input type="checkbox"/> No <input type="checkbox"/> Yes	(TLSUBAL6) <input type="checkbox"/> No <input type="checkbox"/> Yes	(TLSUBAL7) <input type="checkbox"/> No <input type="checkbox"/> Yes
2. Number of cigarettes (xx):	(TLNMCIG1) <input type="text"/>	(TLNMCIG2) <input type="text"/>	(TLNMCIG3) <input type="text"/>	(TLNMCIG4) <input type="text"/>	(TLNMCIG5) <input type="text"/>	(TLNMCIG6) <input type="text"/>	(TLNMCIG7) <input type="text"/>
3. Alcohol number of standard drinks (xx):	(TLALCHL1) <input type="text"/>	(TLALCHL2) <input type="text"/>	(TLALCHL3) <input type="text"/>	(TLALCHL4) <input type="text"/>	(TLALCHL5) <input type="text"/>	(TLALCHL6) <input type="text"/>	(TLALCHL7) <input type="text"/>
4. Cannabinoids/Marijuana method A:	(TLTHCR11) <div><div></div></div>	(TLTHCR12) <div><div></div></div>	(TLTHCR13) <div><div></div></div>	(TLTHCR14) <div><div></div></div>	(TLTHCR15) <div><div></div></div>	(TLTHCR16) <div><div></div></div>	(TLTHCR17) <div><div></div></div> <span>w</span>
Quantity (xxx):	(TLTHCN11) <input type="text"/>	(TLTHCN12) <input type="text"/>	(TLTHCN13) <input type="text"/>	(TLTHCN14) <input type="text"/>	(TLTHCN15) <input type="text"/>	(TLTHCN16) <input type="text"/>	(TLTHCN17) <input type="text"/>
5. Cannabinoids/Marijuana method B:	(TLTHCR21) <div><div></div></div>	(TLTHCR22) <div><div></div></div>	(TLTHCR23) <div><div></div></div>	(TLTHCR24) <div><div></div></div>	(TLTHCR25) <div><div></div></div>	(TLTHCR26) <div><div></div></div>	(TLTHCR27) <div><div></div></div> <span>w</span>
Quantity (xxx):	(TLTHCN21) <input type="text"/>	(TLTHCN22) <input type="text"/>	(TLTHCN23) <input type="text"/>	(TLTHCN24) <input type="text"/>	(TLTHCN25) <input type="text"/>	(TLTHCN26) <input type="text"/>	(TLTHCN27) <input type="text"/>
6. Cannabinoids/Marijuana method C:	(TLTHCR31) <div><div></div></div>	(TLTHCR32) <div><div></div></div>	(TLTHCR33) <div><div></div></div>	(TLTHCR34) <div><div></div></div>	(TLTHCR35) <div><div></div></div>	(TLTHCR36) <div><div></div></div>	(TLTHCR37) <div><div></div></div> <span>w</span>
Quantity (xxx):	(TLTHCN31) <input type="text"/>	(TLTHCN32) <input type="text"/>	(TLTHCN33) <input type="text"/>	(TLTHCN34) <input type="text"/>	(TLTHCN35) <input type="text"/>	(TLTHCN36) <input type="text"/>	(TLTHCN37) <input type="text"/>
7. K2/Spice:	(TLK2D1) <div><div></div></div>	(TLK2D2) <div><div></div></div>	(TLK2D3) <div><div></div></div>	(TLK2D4) <div><div></div></div>	(TLK2D5) <div><div></div></div>	(TLK2D6) <div><div></div></div>	(TLK2D7) <div><div></div></div>
8. Cocaine:	(TLCOCR1) <div><div></div></div>	(TLCOCR2) <div><div></div></div>	(TLCOCR3) <div><div></div></div>	(TLCOCR4) <div><div></div></div>	(TLCOCR5) <div><div></div></div>	(TLCOCR6) <div><div></div></div>	(TLCOCR7) <div><div></div></div> <span>w</span>

9. Crack:	(TLCRAKR1)	(TLCRAKR2)	(TLCRAKR3)	(TLCRAKR4)	(TLCRAKR5)	(TLCRAKR6)	(TLCRAKR7)
10. Amphetamine-type stimulants:	(TLAMPR1)	(TLAMPR2)	(TLAMPR3)	(TLAMPR4)	(TLAMPR5)	(TLAMPR6)	(TLAMPR7)
11. Opioid analgesics, including methadone:	(TLMTDR1)	(TLMTDR2)	(TLMTDR3)	(TLMTDR4)	(TLMTDR5)	(TLMTDR6)	(TLMTDR7)
12. Heroin:	(TLHERR1)	(TLHERR2)	(TLHERR3)	(TLHERR4)	(TLHERR5)	(TLHERR6)	(TLHERR7)
13. Hallucinogens, including MDMA/ecstasy:	(TLM DAR1)	(TLM DAR2)	(TLM DAR3)	(TLM DAR4)	(TLM DAR5)	(TLM DAR6)	(TLM DAR7)
14. Sedatives and hypnotics, excluding Benzodiazepines:	(TLBARR1)	(TLBARR2)	(TLBARR3)	(TLBARR4)	(TLBARR5)	(TLBARR6)	(TLBARR7)
15. Benzodiazepines:	(TLBZOR1)	(TLBZOR2)	(TLBZOR3)	(TLBZOR4)	(TLBZOR5)	(TLBZOR6)	(TLBZOR7)
16. Inhalants:	(TLINHR1)	(TLINHR2)	(TLINHR3)	(TLINHR4)	(TLINHR5)	(TLINHR6)	(TLINHR7)
Other Drugs							

17. Other drug 1 use:	(TLOT1R1) <div></div>	(TLOT1R2) <div></div>	(TLOT1R3) <div></div>	(TLOT1R4) <div></div>	(TLOT1R5) <div></div>	(TLOT1R6) <div></div>	(TLOT1R7) <div></div>
Specify other drug 1:	(TLOTSP11) <input type="text"/>	(TLOTSP12) <input type="text"/>	(TLOTSP13) <input type="text"/>	(TLOTSP14) <input type="text"/>	(TLOTSP15) <input type="text"/>	(TLOTSP16) <input type="text"/>	(TLOTSP17) <input type="text"/>
18. Other drug 2 use:	(TLOT2R1) <div></div>	(TLOT2R2) <div></div>	(TLOT2R3) <div></div>	(TLOT2R4) <div></div>	(TLOT2R5) <div></div>	(TLOT2R6) <div></div>	(TLOT2R7) <div></div>
Specify other drug 2:	(TLOTSP21) <input type="text"/>	(TLOTSP22) <input type="text"/>	(TLOTSP23) <input type="text"/>	(TLOTSP24) <input type="text"/>	(TLOTSP25) <input type="text"/>	(TLOTSP26) <input type="text"/>	(TLOTSP27) <input type="text"/>

Comments:(T53COMM)

**Additional Selection Options for T53**

**D1 cannabinoids r1**  
5-05-Ingestion  
6-06-Vaporizers  
7-07-Spliff  
98-98-Other 1  
99-99-Other 2

**D1 cocaine**  
5-05-IV injection  
99-99-Other



## NIDA Clinical Trials Network

### Urine Drug Screen (UDS)

Web Version: 1.0; 4.00; 03-06-14

Segment (*PROTSEG*):

Visit number (*VISNO*):

1. Was a urine drug screen performed? (*UDTEST1*)

If "No", reason: (*UDNORSN*)

☐ No ☐ Yes

If "Other", specify: (*UDNOSP1*)

#### 1st Urine Drug Screen

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

3. Was the 1st urine temperature within range? (90 - 100 °F) (*UDTEMP1*)

4. Was the 1st urine specimen determined to be adulterated? (*UDADULT1*)

5. 1st Urine Drug Screen Result(s):

Drug Name (Abbreviation)	Negative	Positive	Invalid
Benzodiazepines (BZO):	( <i>UDBZO1</i> ) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Amphetamine (AMP):	( <i>UDAMP1</i> ) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Marijuana (THC):	( <i>UDTHC1</i> ) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Methamphetamine (MET):	( <i>UDMET1</i> ) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Opiates (2000 ng) (OPI):	( <i>UDOPI1</i> ) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cocaine (COC):	( <i>UDCOC1</i> ) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ecstasy (MDMA):	( <i>UDMDA1</i> ) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Oxycodone (OXY):	( <i>UDOXY1</i> ) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Methadone (MTD):	( <i>UDMTD1</i> ) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Barbiturate (BAR):	( <i>UDBAR1</i> ) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Buprenorphine (BUP): (*UDBUP1*)

☐ Negative ☐ Positive ☐ Invalid

#### 2nd Urine Drug Screen

6. If the 1st urine specimen was determined to be adulterated, was a second specimen collected? (*UDTEST2*)

If "No", reason: (*UDNORSN2*)

☐ No ☐ Yes

If "Other", specify: (*UDNOSP2*)

7. Was the 2nd urine temperature within range? (90 - 100 °F) (*UDTEMP2*)

8. Was the 2nd urine specimen determined to be adulterated? (*UDADULT2*)

9. 2nd Urine Drug Screen Result(s):

Drug Name (Abbreviation)	Negative	Positive	Invalid
Benzodiazepines (BZO):	( <i>UDBZO2</i> ) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Amphetamine (AMP):	( <i>UDAMP2</i> ) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Marijuana (THC):	( <i>UDTHC2</i> ) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Methamphetamine (MET):	( <i>UDMET2</i> ) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

☐ No ☐ Yes

☐ No ☐ Yes

Opiates (2000 ng) (OPI):	(UDOPI2) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cocaine (COC):	(UDCOC2) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ecstasy (MDMA):	(UDMDA2) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Oxycodone (OXY):	(UDOXY2) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Methadone (MTD):	(UDMTD2) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Barbiturate (BAR):	(UDBAR2) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Buprenorphine (BUP):(UDBUP2)

☐ Negative ☐ Positive ☐ Invalid

Urine Sample Processing and Shipping

10. If the unadulterated sample was negative for Marijuana (THC), was it the 1<sup>st</sup> time during the course of the trial?(UDTHCNEG)

If "Yes", was the sample processed and shipped to Soft Landing laboratory for synthetic cannabinoid testing?(UDTHC3)

If "No", provide reason:(UDTHCRSN)

If "Other", specify:(UDTHCSP)

11. Was the unadulterated sample processed for shipping to the MUSC central laboratory for riboflavin testing?(UDRIBOFL)

If "No", provide reason:(UDRIBRSN)

If "Other", specify:(UDRIBSP)

12. Was the unadulterated sample processed for shipping to the MUSC central laboratory for cannabinoids and creatinine testing?(UDCANNAB)

If "No", provide reason:(UDCABRSN)

If "Other", specify:(UDCABSP)

Comments:(UDSCOMM)

☐ No ☐ Yes

☐ No ☐ Yes

☐ Study staff error ☐ Other

☐ No ☐ Yes

☐ Study staff error ☐ Other

☐ No ☐ Yes

☐ Study staff error ☐ Other

Vital Signs (VIS)

Web Version: 1.0; 3.02; 01-09-15

Segment (PROTSEG):  
Visit number (VISNO):

Date of assessment:(VISASMDT)

(mm/dd/yyyy)

Body Mass Index

1. Standing height:(VIHGTIN)
2. Measured weight:(VIWTLBS)
- BMI:(VIBM I)

(xx.x) inches (VIHGTCM)

(xxx) cm

(xxx.x) lbs (VIWTKGS)

(xxx.x) kgs

Vital Signs

3. Heart rate:(VIPULSE)
4. Blood pressure:(VIBPSYS1)

(xxx) BPM

/ (VIBPDIS1)

Systolic/Diastolic (mmHg)

Comments:(VISCOMM)