Protocol Number: NIDA-CTO-0011

Ondansetron for Methamphetamine Dependence

Site Identification Number: 980203

Subject Identification Number: 0001

Study Day UNSCHD

Form Not Done ☐

Date: _____
(mm/dd/yyyy)

ATTENTION-DEFICIT DISORDER (ADD) ASSESSMENT

Did you or do you:			If so, how old were you when this problem started?	Did/does this cause you trouble at home?	Did/does this cause you trouble at school/work?
1. Fail to give close attention to details	..as a child?	◯ Yes ◯ No		◯ Yes ◯ No	◯ Yes ◯ No
	..currently?	◯ Yes ◯ No		◯ Yes ◯ No	◯ Yes ◯ No
2. Have difficulty sustaining attention in tasks	..as a child?	◯ Yes ◯ No		◯ Yes ◯ No	◯ Yes ◯ No
	..currently?	◯ Yes ◯ No		◯ Yes ◯ No	◯ Yes ◯ No
3. Not listen when you were spoken to directly	..as a child?	◯ Yes ◯ No		◯ Yes ◯ No	◯ Yes ◯ No
	..currently?	◯ Yes ◯ No		◯ Yes ◯ No	◯ Yes ◯ No
4. Not follow through and fail to finish chores	..as a child?	◯ Yes ◯ No		◯ Yes ◯ No	◯ Yes ◯ No
	..currently?	◯ Yes ◯ No		◯ Yes ◯ No	◯ Yes ◯ No
5. Have difficulty organizing tasks and activities	..as a child?	◯ Yes ◯ No		◯ Yes ◯ No	◯ Yes ◯ No
	..currently?	◯ Yes ◯ No		◯ Yes ◯ No	◯ Yes ◯ No
6. Avoid engaging in tasks with mental effort	..as a child?	◯ Yes ◯ No		◯ Yes ◯ No	◯ Yes ◯ No
	..currently?	◯ Yes ◯ No		◯ Yes ◯ No	◯ Yes ◯ No
7. Lose things necessary for tasks or activities	..as a child?	◯ Yes ◯ No		◯ Yes ◯ No	◯ Yes ◯ No
	..currently?	◯ Yes ◯ No		◯ Yes ◯ No	◯ Yes ◯ No
8. Become easily distracted by irrelevant movement	..as a child?	◯ Yes ◯ No		◯ Yes ◯ No	◯ Yes ◯ No
	..currently?	◯ Yes ◯ No		◯ Yes ◯ No	◯ Yes ◯ No

9. Tend to be forgetful in daily activities	..as a child?	◯ Yes ◯ No		◯ Yes ◯ No	◯ Yes ◯ No
	..currently?	◯ Yes ◯ No		◯ Yes ◯ No	◯ Yes ◯ No
10. Fidget with your hands, feet or squirm in seat	..as a child?	◯ Yes ◯ No		◯ Yes ◯ No	◯ Yes ◯ No
	..currently?	◯ Yes ◯ No		◯ Yes ◯ No	◯ Yes ◯ No
11. Leave your seat where being seated is expected	..as a child?	◯ Yes ◯ No		◯ Yes ◯ No	◯ Yes ◯ No
	..currently?	◯ Yes ◯ No		◯ Yes ◯ No	◯ Yes ◯ No
12. Run/climb excessively where it's inappropriate	..as a child?	◯ Yes ◯ No		◯ Yes ◯ No	◯ Yes ◯ No
	..currently?	◯ Yes ◯ No		◯ Yes ◯ No	◯ Yes ◯ No
13. Difficulty engaging in activities quietly	..as a child?	◯ Yes ◯ No		◯ Yes ◯ No	◯ Yes ◯ No
	..currently?	◯ Yes ◯ No		◯ Yes ◯ No	◯ Yes ◯ No
14. Tend to be 'on the go' or 'driven by motor'	..as a child?	◯ Yes ◯ No		◯ Yes ◯ No	◯ Yes ◯ No
	..currently?	◯ Yes ◯ No		◯ Yes ◯ No	◯ Yes ◯ No
15. Talk excessively	..as a child?	◯ Yes ◯ No		◯ Yes ◯ No	◯ Yes ◯ No
	..currently?	◯ Yes ◯ No		◯ Yes ◯ No	◯ Yes ◯ No
16. Blurt out answers before questions completed	..as a child?	◯ Yes ◯ No		◯ Yes ◯ No	◯ Yes ◯ No
	..currently?	◯ Yes ◯ No		◯ Yes ◯ No	◯ Yes ◯ No
17. Have difficulty awaiting your turn	..as a child?	◯ Yes ◯ No		◯ Yes ◯ No	◯ Yes ◯ No
	..currently?	◯ Yes ◯ No		◯ Yes ◯ No	◯ Yes ◯ No
18. Interrupt or intrude on others	..as a child?	◯ Yes ◯ No		◯ Yes ◯ No	◯ Yes ◯ No
	..currently?	◯ Yes ◯ No		◯ Yes ◯ No	◯ Yes ◯ No

19) Does the subject have a diagnosis of childhood ADHD? ◯ Yes ◯ No

20) Does the subject have a diagnosis of adult ADD? ◯ Yes ◯ No

Source Completed By (Initials): _____

ADD v1

Study Day UNSCHD

ADVERSE EVENTS

Has the subject had any Adverse Experiences during this study? ☐ Ye ☐ No

If yes, please list all Adverse Experiences below:

Severity	Study Drug Relationship	Action Taken Regarding Investigational Agent	Other Action Taken	Outcome of AE	Serious
1 = Mild 2 = Moderate 3 = Severe	1 = Definitely 2 = Probably 3 = Possibly 4 = Remotely 5 = Definitely Not 6 = Unknown	1 = None 2 = Discontinued Perm. 3 = Discontinued Temp. 4 = Reduced Dose 5 = Increased Dose 6 = Delayed Dose	1 = None 2 = Remedial Therapy-pharm 3 = Remedial Therapy-nonpharm 4 = Hospitalization	1 = Resolved, No Sequelae 2 = AE still present - no tx 3 = AE still present - being tx 4 = Residual effects present-no tx 5 = Residual effects present-tx 6 = Death 7 = Unknown	1 = Yes 2 = No (If yes, complete SAE form)

#	EVENT	Start Date	Stop Date	Sev.	Drug Rel.	Action Taken	Other Action	Out.	Serious	Initials
1		(mm/dd/yyyy)	(mm/dd/yyyy)						☐ Ye ☐ No	

AE v1

Protocol Number: NIDA-CTO-0011

Ondansetron for Methamphetamine Dependence

Study Day   UNSCHD

Site Identification Number: 980203
Subject Identification Number: 0001
Date:
(mm/dd/yyyy)

Form Not Done ☐

ALCOHOL BREATHALYZER TEST

1) Was alcohol breathalyzer test performed?   ☐ Yes   ☐ No   ☐ Unknown

2) Date alcohol breathalyzer test performed   [ ] (mm/dd/yyyy)

3) Blood Alcohol Content (BAC):   [ ] (mg/ml)

4) Provide comments for any action taken:

[ ]

Source Completed By (Initials): [ ]

ALBREATH v1

Protocol Number: NIDA-CTO-0011

Ondansetron for Methamphetamine Dependence

Study Day WEEK1V2

Site Identification Number: 980203

Subject Identification Number: 0001

Form Not Done ☐

Date: _____
(mm/dd/yyyy)

ADDICTION SEVERITY INDEX: LITE CF VERSION (ASI) - Part 2 (Follow-Up)

LEGAL STATUS

2) Are you on probation or parole?

How many times in your life have you been arrested and charged with the following:

3) Shoplifting/vandalism

4) Parole/probation violation(s)

5) Drug charge(s)

6) Forgery

7) Weapons offense

8) Burglary, larceny, B and E

9) Robbery

10) Assault

11) Arson

12) Rape

13) Homicide, manslaughter

14) Prostitution

15) Contempt of Court

16) Other, specify:

17) How many of these charges resulted in conviction?

How many times in your life have you been charged with the following:

18) Disorderly conduct, vagrancy, public intoxication?

19) Driving while intoxicated?

20) Major driving violations (reckless driving, speeding, no license, etc.)?

21) How many months were you incarcerated in your life? (months)

22) Are you presently awaiting charges, trial or sentence?

23) What for? (if multiple charges use most severe from codes for #03 through 16 above, or use the following codes: 18=disorderly conduct, 19=driving while intoxicated, 20=major driving violation)

24) How many days in the past 30 days were you detained or incarcerated? (days)

25) How many days in the past 30 days have you engaged in illegal activities for profit? (days)

FOR QUESTIONS 26 - 27, PLEASE ASK THE SUBJECT TO USE THE SUBJECT RATING SCALE

26) How serious do you feel your present legal problems are?

27) How important to you now is counseling or referral for these legal problems?

CONFIDENCE RATINGS *(Is the above information significantly distorted by):*

28) Subject's misrepresentation?

29) Subject's inability to understand?

30) Comments

Legal Score

FAMILY/SOCIAL RELATIONSHIPS

1) Marital status

2) Are you satisfied with this situation?

3) Usual living arrangements (past three years)

4) Are you satisfied with these living arrangements?

5) Do you live with anyone who has a current alcohol problem?

6) Do you live with anyone who uses non-prescribed drugs?

7) With whom do you spend most of your free time?

8) Are you satisfied with spending your free time this way?

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

	In the past 30 days		In the past 30 days
9) Mother		14) Other significant family	

10) Father [   ] 15) If 14 is yes, specify: [   ]
11) Siblings [   ] 16) Close friends [   ]
12) Sexual partner/spouse [   ] 17) Neighbors [   ]
13) Children [   ] 18) Co-workers [   ]

Did any of these people (#'s 9-18 above) abuse you?

19) Physically [   ] (caused you physical harm)
20) Sexually [   ] (forced sexual advances or sexual acts)
21) How many days in the past 30 days have you had serious conflicts with your family? [   ]
22) How many days in the past 30 days have you had serious conflicts with other people excluding family? [   ]

FOR QUESTIONS 23 - 26, PLEASE ASK THE SUBJECT TO USE THE SUBJECT RATING SCALE

23) How troubled or bothered have you been in the past 30 days by family problems? [   ]
24) How troubled or bothered have you been in the past 30 days by social problems? [   ]
25) How important to you now is treatment or counseling for family problems? [   ]
26) How important to you now is treatment or counseling for social problems? [   ]

CONFIDENCE RATINGS   (Is the above information significantly distorted by):

27) Subject's misrepresentation? [   ]
28) Subject's inability to understand? [   ]
29) Comments [   ]   **Family Score** [   ]

PSYCHIATRIC STATUS

1) How many times have you been treated for any psychological or emotional problem(s) in a hospital? [   ]
2) How many times have you been treated for any psychological or emotional problem(s) as an outpatient? [   ]
3) Do you receive a pension for a psychiatric disability? [   ]

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

In the past 30 days

4) Experienced serious depression? [   ]
5) Experienced serious anxiety or tension? [   ]
6) Experienced hallucinations? [   ]
7) Experienced trouble understanding, concentrating, or remembering? [   ]
8) Experienced trouble controlling violent behavior? [   ]
9) Experienced serious thoughts of suicide? [   ]
10) Attempted suicide? [   ]
11) Been prescribed medication for any psychological or emotional problem? [   ]
12) How many days in the last 30 have you experienced psychological or emotional problems? [   ]

FOR QUESTIONS 13 - 14, PLEASE ASK THE SUBJECT TO USE THE SUBJECT RATING SCALE

13) How much have you been troubled or bothered by these psychological or emotional problems in the past 30 days? [   ]
14) How important to you now is treatment for these psychological problems? [   ]

CONFIDENCE RATINGS   (Is the above information significantly distorted by):

15) Subject's misrepresentation? [   ]
16) Subject's inability to understand? [   ]
17) Comments [   ]   **Psychiatric Score** [   ]

Source Completed By (Initials): [   ]

Protocol Number: NIDA-CTO-0011

Ondansetron for Methamphetamine Dependence

Study Day WEEK1V2

Site Identification Number: 980203

Subject Identification Number: 0001

Form Not Done ☐

Date: _____
(mm/dd/yyyy)

ADDICTION SEVERITY INDEX: LITE CF VERSION (ASI) - Part 1 (Follow-Up)

GENERAL INFORMATION

2) Class: _____

3) Contact code: _____

5) Special: _____

10) Have you been in a controlled environment in the last 30 days? _____

11) How many days? _____

MEDICAL STATUS

1) How many times in your life have you been hospitalized for medical problems? _____

3) Are you taking any prescribed medication on a regular basis for a physical problem? _____

4) Do you receive a pension for a physical disability? _____ (Exclude psychiatric disabilities)

5) If yes to #4, specify: _____

6) How many days have you experienced medical problems in the past 30 days? _____

FOR QUESTIONS 7 AND 8, PLEASE ASK THE SUBJECT TO USE THE SUBJECT RATING SCALE

7) How troubled or bothered have you been by these medical problems in the past 30 days? _____

8) How important to you now is treatment for these medical problems? _____

CONFIDENCE RATINGS   (Is the above information significantly distorted by):

9) Subject's misrepresentation? _____

10) Subject's inability to understand? _____

11) Comments _____   **Medical Score** _____

EMPLOYMENT/SUPPORT STATUS

1) Education completed (GED = 12 years): _____ (years) _____ (months)

2) Training or technical education completed: _____ (months)

3) Do you have a valid driver's license? _____

4) Do you have an automobile available for use? _____ (Answer NO if no valid driver's license)

6a) Usual (or last) occupation: _____

6b) Hollingshead occupational category: _____

7) Does someone contribute to your support in any way? _____

9) How many days were you paid for working in the past 30 days? _____

How much money did you receive from the following sources in the past 30 days?

10) Employment (net income) $ _____

11) Unemployment compensation $ _____

12) Public assistance (welfare) $ _____

13) Pension, benefits or social security $ _____

14) Mate, family or friends (money for personal expenses) $ _____

15) Illegal $ _____

16) How many people depend on you for the majority of their food, shelter, etc.? _____

17) How many days have you experienced employment problems in the past 30 days? _____

FOR QUESTIONS 18 AND 19, PLEASE ASK THE SUBJECT TO USE THE SUBJECT RATING SCALE

18) How troubled or bothered have you been by these employment problems in the past 30 days? _____

19) How important to you now is counseling for these employment problems? _____

CONFIDENCE RATINGS   (Is the above information significantly distorted by):

20) Subject's misrepresentation? [____]
21) Subject's inability to understand? [____]
22) Comments [_____]   **Employment Score** [____]

DRUG/ALCOHOL USE

SUBSTANCE	Days in Past 30 Days	ROUTE OF ADMINISTRATION						
		oral	nasal	smoking	non iv inj.	iv inj.	Refused	N/A
1. Alcohol-any use at all	[____]	☐	☐	☐	☐	☐	☐	☐
2. Alcohol to Intoxication	[____]	☐	☐	☐	☐	☐	☐	☐
3. Heroin	[____]	☐	☐	☐	☐	☐	☐	☐
4. Methadone	[____]	☐	☐	☐	☐	☐	☐	☐
5. Other opiates/analgesics	[____]	☐	☐	☐	☐	☐	☐	☐
6. Barbiturates	[____]	☐	☐	☐	☐	☐	☐	☐
7. Other sedatives/hypnotics/tranquilizers	[____]	☐	☐	☐	☐	☐	☐	☐
8. Cocaine	[____]	☐	☐	☐	☐	☐	☐	☐
9. Amphetamines	[____]	☐	☐	☐	☐	☐	☐	☐
10. Cannabis	[____]	☐	☐	☐	☐	☐	☐	☐
11. Hallucinogens	[____]	☐	☐	☐	☐	☐	☐	☐
12. Inhalants	[____]	☐	☐	☐	☐	☐	☐	☐
13. More than 1 substance	[____]	☐	☐	☐	☐	☐	☐	☐

15) How many times in your life have you been treated for Alcohol abuse? [_____]
16) How many times in your life have you been treated for Drug abuse? [_____]
17) How many of these were detox only (Alcohol)? [_____]
18) How many of these were detox only (Drugs)? [_____]
19) How much money have you spent during the past 30 days on Alcohol? $ [_____]
20) How much money have you spent during the past 30 days on Drugs? $ [_____]
21) How many days have you been treated in an outpatient setting for alcohol [_____] or drugs in the past 30 days? (Include NA, AA)
22) How many days in the past 30 days have you experienced Alcohol problems? [_____]
23) How many days in the past 30 days have you experienced Drug problems? [_____]

FOR QUESTIONS 24 - 27, PLEASE ASK THE SUBJECT TO USE THE SUBJECT RATING SCALE

24) How troubled or bothered have you been in the past 30 days by these Alcohol problems? [_____]
25) How troubled or bothered have you been in the past 30 days by these Drug problems? [_____]
26) How important to you now is treatment for these Alcohol problems? [_____]
27) How important to you now is treatment for these Drug problems? [_____]

CONFIDENCE RATINGS   (Is the above information significantly distorted by):

28) Subject's misrepresentation? [_____]
29) Subject's inability to understand? [_____]   **Alcohol Score** [_____]
30) Comments [_____]   **Drug Score** [_____]

Source Completed By (Initials): [_____]

ASIFU v1

Study Day UNSCHD

Date: _____
(mm/dd/yyyy)

Form Not Done ☐

ADDICTION SEVERITY INDEX: LITE CF VERSION (ASI) - Part 2

LEGAL STATUS

1) Was this admission prompted or suggested by the criminal justice system (judge, probation/parole officer, etc.)? _____

2) Are you on probation or parole? _____

How many times in your life have you been arrested and charged with the following:

3) Shoplifting/vandalism		10) Assault	
4) Parole/probation violation(s)		11) Arson	
5) Drug charge(s)		12) Rape	
6) Forgery		13) Homicide, manslaughter	
7) Weapons offense		14) Prostitution	
8) Burglary, larceny, B and E		15) Contempt of Court	
9) Robbery		16) Other, specify:	

17) How many of these charges resulted in conviction? _____

How many times in your life have you been charged with the following:

18) Disorderly conduct, vagrancy, public intoxication? _____

19) Driving while intoxicated? _____

20) Major driving violations (reckless driving, speeding, no license, etc.)? _____

21) How many months were you incarcerated in your life? _____ (months)

22) Are you presently awaiting charges, trial or sentence? _____

23) What for? (if multiple charges use most severe from codes for #03 through 16 above, or use the following codes: 18=disorderly conduct, 19=driving while intoxicated, 20=major driving violation) _____

24) How many days in the past 30 days were you detained or incarcerated? _____ (days)

25) How many days in the past 30 days have you engaged in illegal activities for profit? _____ (days)

FOR QUESTIONS 26 - 27, PLEASE ASK THE SUBJECT TO USE THE SUBJECT RATING SCALE

26) How serious do you feel your present legal problems are? _____

27) How important to you now is counseling or referral for these legal problems? _____

CONFIDENCE RATINGS *(Is the above information significantly distorted by):*

28) Subject's misrepresentation? _____

29) Subject's inability to understand? _____

30) Comments _____   **Legal Score** _____

FAMILY/SOCIAL RELATIONSHIPS

1) Marital status _____

2) Are you satisfied with this situation? _____

3) Usual living arrangements (past three years) _____

4) Are you satisfied with these living arrangements? _____

5) Do you live with anyone who has a current alcohol problem? _____

6) Do you live with anyone who uses non-prescribed drugs? _____

7) With whom do you spend most of your free time? _____

8) Are you satisfied with spending your free time this way? _____

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

	In the past 30 days	Lifetime
9) Mother		

10) Father   [ ] [ ]

11) Siblings   [ ] [ ]

12) Sexual partner/spouse   [ ] [ ]

13) Children   [ ] [ ]

14) Other significant family   [ ] [ ]

15) If 14 is yes, specify: [ ]

16) Close friends   [ ] [ ]

17) Neighbors   [ ] [ ]

18) Co-workers   [ ] [ ]

Did any of these people (#'s 9-18 above) abuse you?

19) Physically   [ ] [ ]   (caused you physical harm)

20) Sexually   [ ] [ ]   (forced sexual advances or sexual acts)

21) How many days in the past 30 days have you had serious conflicts with your family?   [ ]

22) How many days in the past 30 days have you had serious conflicts with other people excluding family?   [ ]

FOR QUESTIONS 23 - 26, PLEASE ASK THE SUBJECT TO USE THE SUBJECT RATING SCALE

23) How troubled or bothered have you been in the past 30 days by family problems?   [ ]

24) How troubled or bothered have you been in the past 30 days by social problems?   [ ]

25) How important to you now is treatment or counseling for family problems?   [ ]

26) How important to you now is treatment or counseling for social problems?   [ ]

CONFIDENCE RATINGS   *(Is the above information significantly distorted by):*

27) Subject's misrepresentation?   [ ]

28) Subject's inability to understand?   [ ]

29) Comments   [ ]   **Family Score** [ ]

PSYCHIATRIC STATUS

1) How many times have you been treated for any psychological or emotional problem(s) in a hospital?   [ ]

2) How many times have you been treated for any psychological or emotional problem(s) as an outpatient?   [ ]

3) Do you receive a pension for a psychiatric disability?   [ ]

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

	In the past 30 days	Lifetime
4) Experienced serious depression?	[ ]	[ ]
5) Experienced serious anxiety or tension?	[ ]	[ ]
6) Experienced hallucinations?	[ ]	[ ]
7) Experienced trouble understanding, concentrating, or remembering?	[ ]	[ ]
8) Experienced trouble controlling violent behavior?	[ ]	[ ]
9) Experienced serious thoughts of suicide?	[ ]	[ ]
10) Attempted suicide?	[ ]	[ ]
11) Been prescribed medication for any psychological or emotional problem?	[ ]	[ ]

12) How many days in the last 30 have you experienced psychological or emotional problems?   [ ]

FOR QUESTIONS 13 - 14, PLEASE ASK THE SUBJECT TO USE THE SUBJECT RATING SCALE

13) How much have you been troubled or bothered by these psychological or emotional problems in the past 30 days?   [ ]

14) How important to you now is treatment for these psychological problems?   [ ]

CONFIDENCE RATINGS   *(Is the above information significantly distorted by):*

15) Subject's misrepresentation?   [ ]

16) Subject's inability to understand?   [ ]

17) Comments   [ ]   **Psychiatric Score** [ ]

Source Completed By (Initials): [ ]   ASILITE2 v1

Protocol Number: NIDA-CTO-0011

Ondansetron for Methamphetamine Dependence

Study Day   UNSCHD

Site Identification Number: 980203

Subject Identification Number: 0001

Date: _____
(mm/dd/yyyy)

Form Not Done ☐

ADDICTION SEVERITY INDEX: LITE CF VERSION (ASI) - Part 1

GENERAL INFORMATION

1) Date of Admission: _____ (mm/dd/yyyy)

2) Class: _____   4) Gender: _____

3) Contact code: _____   5) Special: _____

6) How long have you lived at your current address? _____ (years) _____ (months)

7) Date of Birth: _____

8) Of what race do you consider yourself? _____

9) Do you have a religious preference? _____

10) Have you been in a controlled environment in the last 30 days? _____

11) How many days? _____

MEDICAL STATUS

1) How many times in your life have you been hospitalized for medical problems? _____

2) Do you have any chronic medical problem(s) which continue to interfere with your life? _____

   If yes to #2, specify: _____

3) Are you taking any prescribed medication on a regular basis for a physical problem? _____

4) Do you receive a pension for a physical disability? _____ (Exclude psychiatric disabilities)

5) If yes to #4, specify: _____

6) How many days have you experienced medical problems in the past 30 days? _____

FOR QUESTIONS 7 AND 8, PLEASE ASK THE SUBJECT TO USE THE SUBJECT RATING SCALE

7) How troubled or bothered have you been by these medical problems in the past 30 days? _____

8) How important to you now is treatment for these medical problems? _____

CONFIDENCE RATINGS   *(Is the above information significantly distorted by):*

9) Subject's misrepresentation? _____

10) Subject's inability to understand? _____

11) Comments _____   **Medical Score** _____

EMPLOYMENT/SUPPORT STATUS

1) Education completed (GED = 12 years): _____ (years) _____ (months)

2) Training or technical education completed: _____ (months)

3) Do you have a valid driver's license? _____

4) Do you have an automobile available for use? _____ (Answer NO if no valid driver's license)

5) How long was your longest full-time job? _____ (years) _____ (months)

6a) Usual (or last) occupation: _____

6b) Hollingshead occupational category: _____

7) Does someone contribute to your support in any way? _____

8) Usual employment pattern, past 3 years. _____

9) How many days were you paid for working in the past 30 days? _____

How much money did you receive from the following sources in the past 30 days?

10) Employment (net income) $ _____

11) Unemployment compensation $ _____

12) Public assistance (welfare) $ _____

13) Pension, benefits or social security $ _____

14) Mate, family or friends (money for personal expenses) $ _____

15) Illegal $ _____

16) How many people depend on you for the majority of their food, shelter, etc.? `[____]`

17) How many days have you experienced employment problems in the past 30 days? `[____]`

FOR QUESTIONS 18 AND 19, PLEASE ASK THE SUBJECT TO USE THE SUBJECT RATING SCALE

18) How troubled or bothered have you been by these employment problems in the past 30 days? `[____]`

19) How important to you now is counseling for these employment problems? `[____]`

CONFIDENCE RATINGS   *(Is the above information significantly distorted by):*

20) Subject's misrepresentation? `[____]`

21) Subject's inability to understand? `[____]`

22) Comments `[_____]`   **Employment Score** `[____]`

DRUG/ALCOHOL USE

SUBSTANCE	Days in Past 30 Days	Lifetime Years	ROUTE OF ADMINISTRATION						
			oral	nasal	smoking	non iv inj.	iv inj.	Refused	N/A
1. Alcohol-any use at all			☐	☐	☐	☐	☐	☐	☐
2. Alcohol to Intoxication			☐	☐	☐	☐	☐	☐	☐
3. Heroin			☐	☐	☐	☐	☐	☐	☐
4. Methadone			☐	☐	☐	☐	☐	☐	☐
5. Other opiates/analgesics			☐	☐	☐	☐	☐	☐	☐
6. Barbiturates			☐	☐	☐	☐	☐	☐	☐
7. Other sedatives/hypnotics/tranquilizers			☐	☐	☐	☐	☐	☐	☐
8. Cocaine			☐	☐	☐	☐	☐	☐	☐
9. Amphetamines			☐	☐	☐	☐	☐	☐	☐
10. Cannabis			☐	☐	☐	☐	☐	☐	☐
11. Hallucinogens			☐	☐	☐	☐	☐	☐	☐
12. Inhalants			☐	☐	☐	☐	☐	☐	☐
13. More than 1 substance			☐	☐	☐	☐	☐	☐	☐

14) How many times have you had alcohol DTs? `[____]`

15) How many times in your life have you been treated for Alcohol abuse? `[____]`

16) How many times in your life have you been treated for Drug abuse? `[____]`

17) How many of these were detox only (Alcohol)? `[____]`

18) How many of these were detox only (Drugs)? `[____]`

19) How much money have you spent during the past 30 days on Alcohol? $ `[____]`

20) How much money have you spent during the past 30 days on Drugs? $ `[____]`

21) How many days have you been treated in an outpatient setting for alcohol or drugs in the past 30 days? (Include NA, AA) `[____]`

22) How many days in the past 30 days have you experienced Alcohol problems? `[____]`

23) How many days in the past 30 days have you experienced Drug problems? `[____]`

FOR QUESTIONS 24 - 27, PLEASE ASK THE SUBJECT TO USE THE SUBJECT RATING SCALE

24) How troubled or bothered have you been in the past 30 days by these Alcohol problems? `[____]`

25) How troubled or bothered have you been in the past 30 days by these Drug problems? `[____]`

26) How important to you now is treatment for these Alcohol problems? `[____]`

27) How important to you now is treatment for these Drug problems? `[____]`

CONFIDENCE RATINGS   *(Is the above information significantly distorted by):*

28) Subject's misrepresentation? `[____]`

29) Subject's inability to understand? `[____]`   **Alcohol Score** `[____]`

30) Comments `[_____]`   **Drug Score** `[____]`

Source Completed By (Initials): `[____]`

ASILITE v1

Protocol Number: NIDA-CTO-0011

Ondansetron for Methamphetamine Dependence

Study Day   UNSCHD

Site Identification Number: 980203

Subject Identification Number: 0001

Date:

(mm/dd/yyyy)

Form Not Done ☐

PERSONAL EVALUATION: BIS-II

Read each statement carefully and choose to the right of the statement.

ACTIONS	Rarely Never	Occasionally	Often	Almost Always
1. I plan tasks carefully	☐ 0	☐ 1	☐ 2	☐ 3
2. I do things w/o thinking	☐ 0	☐ 1	☐ 2	☐ 3
3. I make up my mind quickly	☐ 0	☐ 1	☐ 2	☐ 3
4. I am happy-go-lucky	☐ 0	☐ 1	☐ 2	☐ 3
5. I don't "pay attention"	☐ 0	☐ 1	☐ 2	☐ 3
6. I have "racing" thoughts	☐ 0	☐ 1	☐ 2	☐ 3
7. I plan trips well ahead of time	☐ 0	☐ 1	☐ 2	☐ 3
8. I am self-controlled	☐ 0	☐ 1	☐ 2	☐ 3
9. I concentrate easily	☐ 0	☐ 1	☐ 2	☐ 3
10. I save regularly	☐ 0	☐ 1	☐ 2	☐ 3
11. I "squirm" at plays or lectures	☐ 0	☐ 1	☐ 2	☐ 3
12. I am a careful thinker	☐ 0	☐ 1	☐ 2	☐ 3
13. I plan for job security	☐ 0	☐ 1	☐ 2	☐ 3
14. I say things without thinking	☐ 0	☐ 1	☐ 2	☐ 3
15. I like to think about complex problems	☐ 0	☐ 1	☐ 2	☐ 3
16. I change jobs	☐ 0	☐ 1	☐ 2	☐ 3
17. I act "on impulse"	☐ 0	☐ 1	☐ 2	☐ 3
18. I get easily bored solving thought problems	☐ 0	☐ 1	☐ 2	☐ 3
19. I act on the spur of the moment	☐ 0	☐ 1	☐ 2	☐ 3
20. I am a steady thinker	☐ 0	☐ 1	☐ 2	☐ 3
21. I change where I live	☐ 0	☐ 1	☐ 2	☐ 3
22. I buy things on impulse	☐ 0	☐ 1	☐ 2	☐ 3
23. I can only think about one problem at a time	☐ 0	☐ 1	☐ 2	☐ 3
24. I change hobbies	☐ 0	☐ 1	☐ 2	☐ 3
25. I spend or charge more than I earn	☐ 0	☐ 1	☐ 2	☐ 3
26. I have outside thoughts when thinking	☐ 0	☐ 1	☐ 2	☐ 3
27. I am more interested in present than future	☐ 0	☐ 1	☐ 2	☐ 3
28. I am restless at lectures or talks	☐ 0	☐ 1	☐ 2	☐ 3
29. I like puzzles	☐ 0	☐ 1	☐ 2	☐ 3
30. I plan for the future	☐ 0	☐ 1	☐ 2	☐ 3

Source Completed By (Initials):

Protocol Number: NIDA-CTO-0011

Ondansetron for Methamphetamine Dependence

Study Day UNSCHD

Site Identification Number: 980203

Subject Identification Number: 0001

Date: _____
(mm/dd/yyyy)

Form Not Done ☐

BRIEF SUBSTANCE CRAVING SCALE (BSCS)

1) The INTENSITY of my craving, that is, how much I desired methamphetamine in the past 24 hrs was: _____

2) The FREQUENCY of my craving, that is, how often I desired methamphetamine in the past 24 hrs was: _____

3) The LENGTH of time I spent in craving for methamphetamine during the past 24 hrs was: _____

4) Write in the NUMBER of times you think you had craving for methamphetamine during the past 24 hours: _____

5) Write in the total TIME spent craving methamphetamine during the past 24 hours: _____ HOURS _____ MINUTES

6) WORST day: During the past week my most intense craving occurred on the following day: _____

7) The date for that day was: _____ (mm/dd/yyyy) *(If "All days the same, then skip to Question #8)*

8) The INTENSITY of my craving, that is, how much I desired methamphetamine on that WORST day was: _____

9) A 2nd craved drug during the past 24 hours was: _____

_____ Other (specify)

10) The INTENSITY of my craving, that is, how much I desired this second drug in the past 24 hrs was: _____

11) The FREQUENCY of my craving, that is, how often I desired this second drug in the past 24 hrs was: _____

12) The LENGTH of time I spent in craving for this second drug during the past 24 hrs was: _____

13) A 3rd craved drug during the past 24 hours was: _____

_____ Other (specify)

14) The INTENSITY of my craving, that is, how much I desired this third drug in the past 24 hrs was: _____

15) The FREQUENCY of my craving, that is, how often I desired this third drug in the past 24 hrs was: _____

16) The LENGTH of time I spent in craving for this third drug during the past 24 hrs was: _____

Source Completed By (Initials): _____

BSCS v1

Study Day   UNSCHD

Date: _____
(mm/dd/yyyy)

Form Not Done ☐

COGNITIVE FUNCTION TEST (Part 1)

1. Symbol-digit score: ☐

2. Trail making - Part A: ☐ (seconds)

3. Trail making - Part B: ☐ (seconds)

4. Stroop

    a. Word score (W) ☐

    b. Color score (C) ☐

    c. Color-word score ☐

5. D2 Test of Attention

	Raw Score	Percentage
1. TN (total number)		
2. Omissions: E1		
3. Commissions: E2		
4. E (errors)		
5. TN-E (total-errors)		
6. CP (concentration performance)		
7. FR (fluctuation rate)		

Source Completed By (Initials): _____

CFT1 v1

Protocol Number: NIDA-CTO-0011

Ondansetron for Methamphetamine Dependence

Study Day   UNSCHD

Site Identification Number: 980203

Subject Identification Number: 0001

Date:
(mm/dd/yyyy)

Form Not Done ☐

COGNITIVE FUNCTION TEST (Part 2)

Word	A. Recall	B. Recognition
1. Airplane	◉	◉
2. Anchor	◉	◉
3. Bicycle	◉	◉
4. Cannon	◉	◉
5. Cap	◉	◉
6. Chair	◉	◉
7. Cigar	◉	◉
8. Cigarette	◉	◉
9. Deer	◉	◉
10. Garbage can	◉	◉
11. Glove	◉	◉
12. Kite	◉	◉
13. Monkey	◉	◉
14. Nail	◉	◉
15. Ostrich	◉	◉
16. Owl	◉	◉
17. Plug	◉	◉
18. Saltshaker	◉	◉
19. Saw	◉	◉
20. Stove	◉	◉
21. Sweater	◉	◉
22. Thimble	◉	◉
23. Tie	◉	◉
24. Train	◉	◉
25. Watermelom	◉	◉

Intrusions:

26. Recall

27. Recognition

Source confusion:

28. Recall

Source Completed By (Initials):

CFT2 v1

Study Day   UNSCHD

Date: _____
(mm/dd/yyyy)

Form Not Done ☐

COGNITIVE FUNCTION TEST (Part 3)

Pictures	A. Recall	B. Recognition
1. Boot	○	○
2. Box	○	○
3. Cloud	○	○
4. Door	○	○
5. Elephant	○	○
6. Flute	○	○
7. Frog	○	○
8. Glasses	○	○
9. Mountain	○	○
10. Nail file	○	○
11. Needle	○	○
12. Nose	○	○
13. Pear	○	○
14. Pen	○	○
15. Rocking chair	○	○
16. Seal	○	○
17. Skunk	○	○
18. Snake	○	○
19. Squirrel	○	○
20. Strawberry	○	○
21. Traffic light	○	○
22. Truck	○	○
23. Turtle	○	○
24. Vase	○	○
25. Vest	○	○

Intrusions:

26. Recall _____

27. Recognition _____

Source confusion:

28. Recall _____

Source Completed By (Initials): _____

CFT3 v1

Protocol Number: NIDA-CTO-0011

Ondansetron for Methamphetamine Dependence

Study Day UNSCHD

Site Identification Number: 980203

Subject Identification Number: 0001

Date:

(mm/dd/yyyy)

Form Not Done ☐

COGNITIVE FUNCTION TEST (Part 4)

Word	A. Recall	B. Recognition
1. Accordian	◉	◉
2. Ant	◉	◉
3. Bear	◉	◉
4. Beetle	◉	◉
5. Blouse	◉	◉
6. Carrot	◉	◉
7. Cat	◉	◉
8. Chain	◉	◉
9. Church	◉	◉
10. Clothespin	◉	◉
11. Corn	◉	◉
12. Couch	◉	◉
13. Gorilla	◉	◉
14. Lamp	◉	◉
15. Lion	◉	◉
16. Peach	◉	◉
17. Peacock	◉	◉
18. Pepper	◉	◉
19. Pot	◉	◉
20. Ring	◉	◉
21. Star	◉	◉
22. Suitcase	◉	◉
23. Tennis racket	◉	◉
24. Umbrella	◉	◉
25. Wrench	◉	◉

Intrusions:

26.   Recall

27.   Recognition

Source confusion:

28.   Recall

Source Completed By (Initials):

CFT4 v1

Site Identification Number: 980203

Subject Identification Number: 0001

Date:

(mm/dd/yyyy)

Form Not Done ☐

COGNITIVE FUNCTION TEST (Part 5)

Pictures	A. Recall	B. Recognition
1. Apple	◉	◉
2. Ashtray	◉	◉
3. Axe	◉	◉
4. Banana	◉	◉
5. Bird	◉	◉
6. Bow	◉	◉
7. Bowl	◉	◉
8. Cake	◉	◉
9. Candle	◉	◉
10. Hair	◉	◉
11. Hammer	◉	◉
12. Heart	◉	◉
13. Ironing board	◉	◉
14. Knife	◉	◉
15. Ladder	◉	◉
16. Lightbulb	◉	◉
17. Pumpkin	◉	◉
18. Screwdriver	◉	◉
19. Shirt	◉	◉
20. Skate	◉	◉
21. Spoon	◉	◉
22. Sun	◉	◉
23. Tiger	◉	◉
24. Violin	◉	◉
25. Zebra	◉	◉

Intrusions:

26. Recall

27. Recognition

Source confusion:

28. Recall

Source Completed By (Initials):

CFT5 v1

Protocol Number: NIDA-CTO-0011	Site Identification Number: 980203
Ondansetron for Methamphetamine Dependence	Subject Identification Number: 0001

Study Day UNSCHD

Form Not Done ☐

Date: _____
(mm/dd/yyyy)

CHEMISTRIES

Analyte	Std. Quantity	Standard Unit	Other Unit	Normal	Abnormal	Abnormal Significant	Not Done
01. Sodium				☐	☐	☐	☐
02. Potassium				☐	☐	☐	☐
03. Chloride				☐	☐	☐	☐
04. CO2				☐	☐	☐	☐
05. Glucose				☐	☐	☐	☐
06. Creatinine				☐	☐	☐	☐
07. Albumin				☐	☐	☐	☐
08. Total Protein				☐	☐	☐	☐
09. Calcium				☐	☐	☐	☐
10. Cholesterol				☐	☐	☐	☐
11. Triglycerides				☐	☐	☐	☐
12. Phosphorus				☐	☐	☐	☐
13. SGOT/AST				☐	☐	☐	☐
14. SGPT/ALT				☐	☐	☐	☐
15. GGT				☐	☐	☐	☐
16. Total Bilirubin				☐	☐	☐	☐
17. LDH				☐	☐	☐	☐
18. CPK				☐	☐	☐	☐
19. AlkPhos				☐	☐	☐	☐
20. BUN				☐	☐	☐	☐
21. Uric Acid				☐	☐	☐	☐
22. Iron				☐	☐	☐	☐
23. IgG				☐	☐	☐	☐
24. IgM				☐	☐	☐	☐
25. IgA				☐	☐	☐	☐

Provide comments for any abnormal value(s) _____

Source Completed By (Initials): _____

CHEM v1

Protocol Number: NIDA-CTO-0011

Ondansetron for Methamphetamine Dependence

Site Identification Number: 980203

Subject Identification Number: 0001

Study Day UNSCHD

Date: _____ (mm/dd/yyyy)

Form Not Done ☐

TREATMENT COMPLIANCE - STUDY DRUG

1) **Date tablets dispensed** _____ (mm/dd/yyyy)

2) **Number of tablets dispensed** _____

3) **Date unused tablets returned** _____ (mm/dd/yyyy)

4) **Number of tablets returned** _____

5) **Number of tablets reported lost by subject** _____

6) **Comments**

_____

Source Completed By (Initials): _____

COMPAGNT v1

Study Day UNSCHD

Date:

(mm/dd/yyyy)

Form Not Done ☐

TREATMENT COMPLIANCE - THERAPY

1) **Did subject receive standardized, manual-guided group CBT?**

○ Yes   ○ No   ○ Unknown

2) **If yes, length of CBT session attended**   (minutes)

3) **Was CBT session audiotaped?**

○ Yes   ○ No   ○ Unknown

Additional Comments

Source Completed By (Initials):

COMPTHER v1

CONCOMITANT MEDICATIONS

Has the subject taken any Concomitant Medications during this study?   ☐ Yes   ☐ No   *If yes, please list all below:*

Dose	Unit of Medication				Frequency		Route of Administration			
Strength	CAP	= capsule	PUF	= puff	ONCE	= single dose	PO	= oral	AUR	= auricular
of	g	= gram	SPY	= spray/squirt	QD	= once daily	TD	= transdermal	IA	= intra-articular
Medication	GR	= grain	SUP	= suppository	BID	= twice daily	INH	= inhaled	NAS	= nasal
	GTT	= drop	TSP	= teaspoon	TID	= three times a day	IM	= intramuscular	IO	= intraocular
	ug	= microgram	TBS	= tablespoon	QID	= four times a day	IV	= intravenous	UNK	= unknown
	uL	= microliter	TAB	= tablet	QOD	= every other day	REC	= rectal	OTH	= other, specify
	mg	= milligram	UNK	= unknown	PRN	= as needed	VAG	= vaginal		
	mL	= milliliter	OTH	= other, specify	OTH	= other, specify	SQ	= subcutaneous		
	OZ	= ounce					SL	= sublingual		

No.	Medication	Dose	Unit	Other (specify)	Frequency	Other (specify)
1						

Route	Other (specify)	Date Started (mm / dd / yyyy)	Date Stopped (mm / dd / yyyy)	Cont.?	Indication	Initials
				☐		

CONMEDS v1

DEATH REPORT

Subject Date of Death ☐ (mm/dd/yyyy)

Was autopsy performed? ☐ Yes ☐ No ☐ Unknown

   If yes, is autopsy report available? ☐ Yes ☐ No

Is cause of death known? ☐ Yes ☐ No

If yes, in the investigator's clinical judgement, what was the primary cause of death?

Narrative description of death (include information about why cause of death is unknown, if applicable.)

Source Completed By (Initials):

DEATH v1

Protocol Number: NIDA-CTO-0011

Ondansetron for Methamphetamine Dependence

Study Day ☐ UNSCHD

Site Identification Number: ☐ 980203

Subject Identification Number: ☐ 0006

Date: ☐

(mm/dd/yyyy)

Form Not Done ☐

DEMOGRAPHICS

DEMOGRAPHIC DATA

1) Gender   ☐ Male   ☐ Female

2) Date of Birth   ☐   (mm/dd/yyyy)

3) Indicate which single major race/ethnicity applies:

☐ White, not of Hispanic Origin   ☐ American Indian or Alaska native

☐ Hispanic or Latino   ☐ Other, (specify):

☐ African American, Black, not of Hispanic Origin   ☐

☐ Asian or Pacific Islander   ☐ Unknown

4) Ethnicity/Race all that apply:

For each of the following, answer Yes to all that apply and No to those that do not.

☐ Yes   ☐ No   White

☐ Yes   ☐ No   Black or African American

☐ Yes   ☐ No   American Indian or Alaskan Native

☐ Yes   ☐ No   Spanish, Hispanic, or Latino (mark all that apply)

　　☐ Mexican, Mexican-American, or Chicano   ☐ Cuban

　　☐ Puerto Rican   ☐ Other (specify) ☐

☐ Yes   ☐ No   Asian (mark all that apply)

　　☐ Asian Indian   ☐ Korean

　　☐ Chinese   ☐ Vietnamese

　　☐ Filipino   ☐ Other (specify) ☐

　　☐ Japanese

☐ Yes   ☐ No   Native Hawaiian or Pacific Islander (mark all that apply)

　　☐ Native Hawaiian   ☐ Samoan

　　☐ Guamanian or Chamorro   ☐ Other (specify) ☐

☐ Yes   ☐ No   Other (specify) ☐

　　☐ **Participant chooses not to answer**

EMPLOYMENT/SUPPORT STATUS

1) Education completed (GED = 12 years):   ☐ (years)   ☐ (months)

2) Usual employment pattern, past 30 days:

☐ Full time (35+ hours/week)   ☐ Part time (regular hours)   ☐ Part time (irregular hours, day work)

☐ Student   ☐ Military Service   ☐ Retired/Disabled

☐ Homemaker   ☐ Unemployed   ☐ In controlled environment

3) Usual employment pattern, past 3 years:

| ☐ Full time (35+ hours/week) | ☐ Part time (regular hours) | ☐ Part time (irregular hours, day work) |

☐ Student   ☐ Military Service   ☐ Retired/Disabled

☐ Homemaker   ☐ Unemployed   ☐ In controlled environment

4) **Marital Status:**

☐ Legally married   ☐ Living with partner/cohabitating   ☐ Widowed

☐ Separated   ☐ Divorced   ☐ Never Married

DRUG/ALCOHOL USE

SUBSTANCE	Days in Past 30 Days	Lifetime Years	ROUTE OF ADMINISTRATION				
			oral	nasal	smoking	injection	N/A
Alcohol (any use at all)			☐	☐	☐	☐	☐
Alcohol (to intoxication)			☐	☐	☐	☐	☐
Heroin			☐	☐	☐	☐	☐
Methadone (prescribed)			☐	☐	☐	☐	☐
Methadone (illicit)			☐	☐	☐	☐	☐
Other opiates/analgesics			☐	☐	☐	☐	☐
Barbiturates			☐	☐	☐	☐	☐
Sedatives/Hypnotics/Tranquilizers			☐	☐	☐	☐	☐
Cocaine			☐	☐	☐	☐	☐
Amphetamines			☐	☐	☐	☐	☐
Methamphetamine			☐	☐	☐	☐	☐
Cannabis			☐	☐	☐	☐	☐
Hallucinogens			☐	☐	☐	☐	☐
Inhalants			☐	☐	☐	☐	☐
Nicotine			☐	☐	☐	☐	☐
More than one Substance per day			☐	☐	☐	☐	☐

According to the interviewer, which substance is the major problem? (Select only one item.)

☐ No problem	☐ Alcohol (any)	☐ Alcohol to intoxication
☐ Heroin	☐ Methadone/LAAM (presc.)	☐ Methadone/LAAM (illicit)
☐ Opiates/analgesics	☐ Barbiturates	☐ Sed./Hyp./Tranq./Benzos.
☐ Cocaine	☐ Amphetamines	☐ Methamphetamine
☐ Cannibis	☐ Hallucinogens	☐ Inhalants
☐ Nicotine	☐ Alcohol and Drug Addiction	☐ Polydrug addiction

Source Completed By (Initials): _____

DEMOG v1

Study Day UNSCHD

Date: _____ (mm/dd/yyyy)

Form Not Done ☐

ELECTROCARDIOGRAM 12-LEAD

A. ECG overall results were: ☐ Normal   ☐ Abnormal

If ECG was normal, skip to question C; otherwise indicate if any result was ABNORMAL but does not exclude the subject from participation in the study, or ABNORMAL SIGNIFICANT and does preclude (continued) participation in the study.

	Abnormal	Abnormal Significant			Abnormal	Abnormal Significant
1) Increased QRS Voltage	☐	☐	17) Supraventricular Premature Beat		☐	☐
2) QTc Prolongation	☐	☐	18) Ventricular Premature Beat		☐	☐
3) Left Atrial Hypertrophy	☐	☐	19) Supraventricular Tachycardia		☐	☐
4) Right Atrial Hypertrophy	☐	☐	20) Ventricular Tachycardia		☐	☐
5) Left Ventricular Hypertrophy	☐	☐	21) Atrial Fibrillation		☐	☐
6) Right Ventricular Hypertrophy	☐	☐	22) Atrial Flutter		☐	☐
7) Acute Infarction	☐	☐	23) Other Rhythm Abnormalities		☐	☐
8) Subacute Infarction	☐	☐	24) Implanted Pacemaker		☐	☐
9) Old Infarction	☐	☐	25) 1st Degree A-V Block		☐	☐
10) Myocardial Ischemia	☐	☐	26) 2nd Degree A-V Block		☐	☐
11) Digitalis Effect	☐	☐	27) 3rd Degree A-V Block		☐	☐
12) Symmetrical T-Wave Inversions	☐	☐	28) LBB Block		☐	☐
13) Poor R-Wave Progression	☐	☐	29) RBB Block		☐	☐
14) Other Nonspecific ST/T	☐	☐	30) Pre-excitation Syndrome		☐	☐
15) Sinus Tachycardia	☐	☐	31) Other Intraventricular Condition Block		☐	☐
16) Sinus Bradycardia	☐	☐	32) Other (specify) _____		☐	☐

C. Ventricular rate (bpm): _____   E. QRS (ms): _____

D. PR (ms): _____   F. QTc (ms): _____

Source Completed By (Initials) _____

ECG v1

Protocol Number: NIDA-CTO-0011	Site Identification Number:	980203
Ondansetron for Methamphetamine Dependence	Subject Identification Number:	0001

Study Day [UNSCHD]

END OF TRIAL

1) <u>Date of Last visit?</u> [ ] (mm/dd/yyyy)

2) <u>Was the subject terminated early from the trial?</u> ☐ Yes   ☐ No

Reason subject's participation has ended (Mark all that apply):

☐ Subject completed study.

☐ Subject was determined after enrollment to be ineligible. (Provide comments)

☐ Subject requested to withdraw. (Provide comments)

☐ Subject experienced an intercurrent illness, unrelated medical condition, or clinically significant
adverse events which prompted early termination. (Complete AE form, provide comments)

☐ Subject terminated for administrative reasons. (Include protocol non-compliance
in this category. Provide comments)

☐ Subject transferred to another treatment program (check all that apply)

☐ Methadone   ☐ LAAM   ☐ Drug Free   ☐ Inpatient Detox or Treatment

☐ Therapeutic Community   ☐ Other (specify) [ ]

☐ Subject was incarcerated.

☐ Subject became pregnant.

☐ Subject developed sensitivity to study agent.

☐ Subject was lost to follow-up.

☐ Subject moved from area.

☐ Subject died. (If subject died, a Death Report Case Report Form must be completed)

☐ Subject can no longer attend clinic.

☐ Subject no longer attends clinic.

☐ Subject is in a controlled environment.

☐ Subject is a screen failure

☐ Other (Provide comments)

Comments:

[ ]

Source Completed By (Initials): [ ]   ENDTRIAL v1

| Protocol Number: NIDA-CTO-0011 | Site Identification Number: | 980203 |
| Ondansetron for Methamphetamine Dependence | Subject Identification Number: | 0001 |

Study Day UNSCHD

ENROLLMENT

Is subject eligible for study enrollment based on the Eligibility Criteria?   ☐ Yes   ☐ No

If yes, was subject enrolled?   ☐ Yes   ☐ No

Date enrolled: _____ (mm/dd/yyyy)

If not enrolled, indicate reason

☐ failed to return to clinic

☐ declined study participation

☐ other, specify: _____

Source Completed By (Initials): _____

ENROLL v1

Protocol Number: NIDA-CTO-0011

Ondansetron for Methamphetamine Dependence

Study Day UNSCHD

Site Identification Number: 980203

Subject Identification Number: 0001

Date: _____
(mm/dd/yyyy)

EXCLUSION CRITERIA

Participant must not:

1. Have current dependence, defined by DSM-IV criteria, on any psychoactive substance other than Methamphetamine, nicotine, or marijuana or physiological dependence on alcohol or a sedative-hypnotic, e.g. a benzodiazepine that requires medical detoxification. ☐ Yes ☐ No

2. Meet the current diagnostic criteria for the following Axis I disorders as assessed by SCID: psychosis, bipolar I disorder, organic brain disease, dementia, major depression, schizoaffective disorder, or schizophrenia. ☐ Yes ☐ No

3. Have a current suicidal ideation/plan as assessed by SCID interview and/or HAM-D question #3. ☐ Yes ☐ No

4. Have serious medical illnesses including, but not limited to: uncontrolled hypertension; significant heart disease (including myocardial infarction within one year of enrollment); angina; hepatic or renal disorders; or any serious, potentially life-threatening or progressive medical illness other than addiction that may compromise subject safety or study conduct; or any ECG/cardiovascular abnormality (e.g., QTC interval prolongation > 450 milliseconds in men or 480 milliseconds in women), which in the judgment of the investigator is clinically significant. ☐ Yes ☐ No

5. Have had a head trauma that resulted in neurological sequelae (e.g., loss of memory for greater than 5 minutes or that required hospitalization). ☐ Yes ☐ No

6. Have renal insufficiency (plasma creatinine > 1.7 mg/dL). ☐ Yes ☐ No

7. Have diabetes with unstable control of blood glucose and have any incidence of hypoglycemia in the past year before screening. ☐ Yes ☐ No

8. Be mandated by the court to obtain treatment for methamphetamine-dependence, where such mandate required the results of urine toxicology tests to be reported to the court. ☐ Yes ☐ No

9. In the opinion of the investigator, be expected to fail to complete the study protocol due to the probable incarceration or relocation from the clinic area. ☐ Yes ☐ No

10. Be undergoing HIV treatment with antiviral and non-antiviral therapy. ☐ Yes ☐ No

11. Have AIDS - according to the current CDC criteria for AIDS-MMWR 1998;48 (no. RR-13:29-31). ☐ Yes ☐ No

12. Have active syphilis that has not been treated or refuse treatment for syphilis (see note). ☐ Yes ☐ No

13. Have known or suspected hypersensitivity to ondansetron. ☐ Yes ☐ No

14. Be using ondansetron or any medication that could interact adversely with ondansetron, within the following times of beginning of administration of ondansetron based on the longest time interval of A, B, and C, below or as otherwise specified: A) Five half lives of other medication or active metabolite(s), whichever is longer; B) Two weeks; C) Interval recommended by other medication's product labeling. Medications/herbal supplements that fall into this category include any serotonin-active substances and drugs significantly metabolized by the P-450, such as: serotonin-active substances, i.e., sumitriptan (Imitrex), zolmitriptan (Zomig), cyproheptadine, citalopram, ketanserin, ritanserin, fluoxetine, paroxetine, sertraline, methysergide, ergotamine, ergonovine; psychoactive medications such as Neuroleptics; drugs significantly metabolized by the P-450, i.e., cimetidine and phenobarbital, St. John's Wort; herbals that enhance serotonergic effects, i.e., horehound. ☐ Yes ☐ No

15. Have participated in any experimental study within 8 weeks (the nature of excluded studies may be discussed with NIDA investigators). ☐ Yes ☐ No

16. Be pregnant or lactating. ☐ Yes ☐ No

17.	Have clinically significant laboratory values (outside of normal limits), in the judgment of the investigator (Appendix I).	☐ Yes	☐ No
18.	Have had electroconvulsive therapy within the past 90 days before screening.	☐ Yes	☐ No
19.	Have had opiate-substitution therapy (methadone, LAAM, buprenorphine) within 2 months of enrollment.	☐ Yes	☐ No
20.	Have a diagnosis of adult asthma, including those with a history of acute asthma within the past two years, and those with current or recent (past 2 years) treatment with inhaled or oral beta-agonist or steroid therapy (due to potential serious adverse interactions with methamphetamine).	☐ Yes	☐ No
21.	Be actively using albuterol or other beta agonist medications, regardless of formal diagnosis of asthma. (Inhalers are sometimes used by methamphetamine users to enhance methamphetamine delivery to the lungs.) If respiratory disease is excluded and the subject will consent to discontinue agonist use, s/he may be considered for inclusion.	☐ Yes	☐ No
22.	For subjects suspect for asthma but without a formal diagnosis, 1) have a history of coughing and/or wheezing, 2) have history of asthma and/or asthma treatment two or more years before, 3) have history of other respiratory illness, e.g., complications of pulmonary disease (exclude if on beta agonists), 4) use of over-the-counter agonist or allergy medication for respiratory problems (e.g., Primatene Mist): a detailed history and physical exam, pulmonary consult, and pulmonary function tests should be performed prior to including or excluding from the study or 5) have an FEV1 < 70%.	☐ Yes	☐ No

All answers to Exclusion Criteria must be NO.

Source Completed By (Initials): _____

(EXCLUS v1)

Protocol Number: NIDA-CTO-0011	Site Identification Number:	980203

Ondansetron for Methamphetamine Dependence

Subject Identification Number: 0001

Study Day: UNSCHD

Date: _____ (mm/dd/yyyy)

Form Not Done ☐

FOLLOW-UP

1) Has contact been made with the subject? ○ Yes ○ No

If so, date: _____ (mm/dd/yyyy)

2) If unable to reach subject, has contact been made with someone who can verify his/her status? ○ Yes ○ No

If yes, has the subject died? ○ Yes ○ No *(If the subject died, a Death Report CRF must be completed)*

3) If contact has not been made with the subject, explain: _____

4) Does subject report use of any of the following and if so, for how many days in the last week? *(Check all that apply).*

DRUG	Days Used	DRUG	Days Used	
☐ Cocaine		☐ Sedatives		
☐ Methamphetamines		☐ Nicotine		
☐ Amphetamines		☐ Opiates		
☐ Benzodiazepines		☐ Barbiturates		
☐ Alcohol		☐ None		
☐ Marijuana		☐ Other		*(specify)*

5) Does the subject report currently receiving treatment for drug or alcohol abuse/dependence? ○ Yes ○ No

6) Does the subject report that he/she would take the study drug again if it were generally available for substance abuse treatment? ○ Yes ○ No ○ Unknown

7) Have any adverse events occurred? ○ Yes ○ No

8) Have any serious adverse events occurred? ○ Yes ○ No *(If yes, a Serious Adverse Event CRF must be completed)*

9) Additional comments: _____

Source Completed By (Initials): _____

FOLLOWUP v1

Protocol Number: NIDA-CTO-0011

Ondansetron for Methamphetamine Dependence

Study Day UNSCHD

Site Identification Number: 980203

Subject Identification Number: 0001

Date: _____
(mm/dd/yyyy)

Form Not Done ☐

HAMILTON DEPRESSION RATING SCALE

1) Depressed Mood	
2) Feelings of Guilt	
3) Suicide	
4) Insomnia Early	
5) Insomnia Middle	
6) Insomnia Late	
7) Work and Activities	
8) Retardation	
9) Agitation	
10) Anxiety Psychic	
11) Anxiety Somatic	
12) Somatic Symptoms Gastrointestinal	
13) Somatic Symptoms General	

14) Genital Symptoms	
15) Hypochondriasis	
16) Loss of Weight	
17) Insight	
18) Diurnal Variation	

If answer is 1 or 2, note whether the symptoms are worse in:

○ a.m.   ○ p.m.

19) Depersonalization	
20) Paranoid Symptoms	
21) Obsessive and Compulsive Symptoms	
22) Helplessness	
23) Hopelessness	
24) Worthlessness	

Hamilton Depression Score: _____

Source Completed By (Initials): _____

HAMD v1

Site Identification Number: 980203

Subject Identification Number: 0001

Study Day UNSCHD

Date: _____ (mm/dd/yyyy)

Form Not Done ☐

HEMATOLOGY

Complete Blood Count	Std. Quantity	Standard Unit	Other Unit	Normal	Abnormal	Abnormal Significant	Not Done
Hemaglobin				☐	☐	☐	☐
Hematocrit				☐	☐	☐	☐
RBC				☐	☐	☐	☐
Platelet Count				☐	☐	☐	☐
WBC				☐	☐	☐	☐
Neutrophils				☐	☐	☐	☐
Lymphocytes				☐	☐	☐	☐
Monocytes				☐	☐	☐	☐
Eosinophils				☐	☐	☐	☐
Basophils				☐	☐	☐	☐
CD4 Positive				☐	☐	☐	☐

Provide comments for any abnormal value(s) _____

Source Completed By (Initials): _____

HEMAT v1

Protocol Number: NIDA-CTO-0011

Ondansetron for Methamphetamine Dependence

Study Day | UNSCHD

Site Identification Number: 980203

Subject Identification Number: 0001

Date:
(mm/dd/yyyy)

Form Not Done ☐

HIV RISK-TAKING BEHAVIOR SCALE (HRBS)

DRUG USE

1) How many times have you hit up (i.e. injected any drugs) in the last month?

If you have not injected drugs in the last month, go to Question 7.

2) How many times in the last month have you used a needle after someone else had already used it?

3) How many different people have used a needle before you in the past month?

4) How many times in the last month has someone used a needle after you?

5) How often, in the last month, have you cleaned needles before re-using them?

6) Before using needles again, how often in the past month did you use bleach to clean them?

Drug Score

SEXUAL BEHAVIOR

7) How many people, including clients, have you had sex with in the last month?

If no sex in the last month, skip to question #12

8) How often have you used condoms when having sex with your regular partner(s) in the last month?

9) How often have you used condoms when you had sex with casual partners?

10) How often have you used condoms when you have been paid for sex in the last month?

11) How many times have you had anal sex in the last month?

12) Have you had an HIV test come back positive?   ○ Yes   ○ No   ○ Unknown

Sex Score

Source Completed By (Initials):

HRBS Score

HRBS v1

Protocol Number: NIDA-CTO-0011	Site Identification Number:	980203
Ondansetron for Methamphetamine Dependence	Subject Identification Number:	0001

Study Day | UNSCHD

Date: _____
(mm/dd/yyyy)

INCLUSION CRITERIA

Participant must:

1. Be at least 18 years of age. ☐ Yes ☐ No

2. Have a DSM-IV diagnosis of methamphetamine dependence as determined by SCID. ☐ Yes ☐ No

3. Be seeking treatment for methamphetamine dependence. ☐ Yes ☐ No

4. Have at least 1 methamphetamine or amphetamine positive urine specimen (>1000 ng/mL) within the two-week baseline period prior to randomization with a minimum of 4 samples tested. ☐ Yes ☐ No

5. Be able to verbalize understanding of consent form, able to provide written informed consent, and verbalize willingness to complete study procedures. ☐ Yes ☐ No

6. Be female and have a negative pregnancy test and agree to use one of the following methods of birth control, or be postmenopausal, have had a hysterectomy or have been sterilized, or be male:

   a) oral contraceptives; b) barrier (diaphragm or condom) with spermicide; c) intrauterine progesterone contraceptive system; d) levonorgestrel implant; e) medroxyprogesterone acetate contraceptive injection; f) complete abstinence from sexual intercourse.

   ☐ Yes ☐ No

All answers to Inclusion Criteria must be YES

Source Completed By (Initials): _____

(INCLUS V1)

Protocol Number: NIDA-CTO-0011		Site Identification Number:	980203

Ondansetron for Methamphetamine Dependence

Subject Identification Number: 0001

Study Day | UNSCHD

Date: _____ (mm/dd/yyyy)

Form Not Done ☐

INFECTIOUS DISEASE ASSESSMENT

Indicate whether the laboratory value is NEGATIVE: negative test result, POSITIVE: but DOES NOT EXCLUDE subject from participation or continued study participation, POSITIVE SIGNIFICANT: significant during screening means subject is ineligible for study; significant while on study means consider reporting result as adverse event if unexpected and at least possibly related to investigational agent or early termination of the subject from study, INDETERMINANT: result was not interpretable.

Infectious Disease	**Result**	**Provide comments for any abnormal value**
Hepatitis B surface antigen result		
Hepatitis B surface antibody result		
Hepatitis B core antibody result		
Hepatitis C virus antibody result		

Date PPD test administered _____ (mm/dd/yyyy)

Time PPD test administered _____ (00:00 - 23:59)

Date PPD test read _____ (mm/dd/yyyy)

☐ **PPD Previously Positive**
  *(Test not done, chest X-ray required)

Time PPD test read _____ (00:00 - 23:59)

PPD test result _____ *If positive, chest X-ray required.

If test not done, state reason. _____

Provide comments for any positive value. _____

Date chest X-ray performed _____ (mm/dd/yyyy)

Results of chest X-ray _____

If chest X-ray not done, state reason. _____

Provide comments for any abnormal finding. _____

Source Completed By (Initials): _____

INFECDIS v1

Protocol Number: NIDA-CTO-0011		Site Identification Number: 980203
Ondansetron for Methamphetamine Dependence		Subject Identification Number: 0001

Study Day UNSCHD

Form Not Done ☐

LAB TEST TRACKING FORM

Date:	Tests:		Completed By
01/01/2002 (mm/dd/yyyy)	☐ Urine Toxicology Screen Onsite Test Device	☐ Urine Toxicology Screen at NWT	 (Initials)
	☐ UrineMeth/Creatinine	☐ Medical Urinalysis	
	☐ Blood Sample for Genotyping	☑ Urine Riboflavin	

LABTRACK v1

Protocol Number: NIDA-CTO-0011

Ondansetron for Methamphetamine Dependence

Study Day | SCRNBASE

Site Identification Number: 980203

Subject Identification Number: 0001

Date: _____
(mm/dd/yyyy)

Form Not Done ☐

MCTG METHAMPHETAMINE WITHDRAWAL QUESTIONNAIRE
(MAWQ) - Part 2

Please tell me if you agree with each statement below on how you have felt in the LAST 24 HOURS

STATEMENT	Don't Agree or Agree?	If you agree, please choose one
1. I am not feeling well	◉ Don't Agree ◉ Agree	◉ Mildly ◉ Moderately ◉ Strongly
2. Sometimes it feels like people are watching me	◉ Don't Agree ◉ Agree	◉ Mildly ◉ Moderately ◉ Strongly
3. Sometimes it feels like someone is touching me	◉ Don't Agree ◉ Agree	◉ Mildly ◉ Moderately ◉ Strongly
4. I often think about taking methamphetamine	◉ Don't Agree ◉ Agree	◉ Mildly ◉ Moderately ◉ Strongly
5. My sexual pleasure is less than usual	◉ Don't Agree ◉ Agree	◉ Mildly ◉ Moderately ◉ Strongly
6. Recently my interest in sex is less than usual	◉ Don't Agree ◉ Agree	◉ Mildly ◉ Moderately ◉ Strongly
7. I am not able to deal w/stress as well as usual	◉ Don't Agree ◉ Agree	◉ Mildly ◉ Moderately ◉ Strongly
8. Sometimes hear voices no one else can hear	◉ Don't Agree ◉ Agree	◉ Mildly ◉ Moderately ◉ Strongly

VITAL SIGNS/PATELLAR REFLEX *(to be assessed after participant has been seated for five minutes)*

VITAL SIGNS

Temperature (F) _____

Blood Pressure (mm Hg) _____ / _____
                        (sys)   (dias)

Pulse (BPM) _____

Respirations (1 MIN) _____

Weight (LB) _____

PATELLAR REFLEX   (choose one)

◉ No Response

◉ Hyperreflexia

◉ Hyporeflexia

◉ Marked Hyperreflexia

◉ Normal

Source Completed By (Initials): _____

MAWQPT2 v1

Study Day UNSCHD

Date: _____ (mm/dd/yyyy)

Form Not Done ☐

## MCTG METHAMPHETAMINE WITHDRAWAL QUESTIONNAIRE
(MAWQ) - Part I

Date of Participant's Last Methamphetamine Use: _____ (mm/dd/yyyy)

List of Symptoms	Absent	Severity			Relapse	Description of Action Taken
1. Headaches	☐	○ Mild	○ Moderate	○ Severe	☐	
2. Constipation	☐	○ Mild	○ Moderate	○ Severe	☐	
3. Diarrhea	☐	○ Mild	○ Moderate	○ Severe	☐	
4. Irregular or Pounding heartbeat	☐	○ Mild	○ Moderate	○ Severe	☐	
5. Muscle or joint pain	☐	○ Mild	○ Moderate	○ Severe	☐	
6. Red eyes	☐	○ Mild	○ Moderate	○ Severe	☐	
7. Sweaty or Clammy	☐	○ Mild	○ Moderate	○ Severe	☐	
8. Angry	☐	○ Mild	○ Moderate	○ Severe	☐	
9. Anxious/Nervous	☐	○ Mild	○ Moderate	○ Severe	☐	
10. Craving	☐	○ Mild	○ Moderate	○ Severe	☐	
11. Depressed	☐	○ Mild	○ Moderate	○ Severe	☐	
12. Irritable	☐	○ Mild	○ Moderate	○ Severe	☐	
13. No motivation	☐	○ Mild	○ Moderate	○ Severe	☐	
14. Loss of interest or pleasure	☐	○ Mild	○ Moderate	○ Severe	☐	
15. Restless	☐	○ Mild	○ Moderate	○ Severe	☐	
16. Suicidal thoughts	☐	○ Mild	○ Moderate	○ Severe	☐	
17. Increased Appetite	☐	○ Mild	○ Moderate	○ Severe	☐	
18. Decreased Appetite	☐	○ Mild	○ Moderate	○ Severe	☐	
19. Poor Concentration	☐	○ Mild	○ Moderate	○ Severe	☐	
20. Poor Memory	☐	○ Mild	○ Moderate	○ Severe	☐	
21. Sleep Difficulties	☐	○ Mild	○ Moderate	○ Severe	☐	
22. Tired or Low Energy	☐	○ Mild	○ Moderate	○ Severe	☐	

Source Completed By (Initials): _____

MAWQPT1 v1
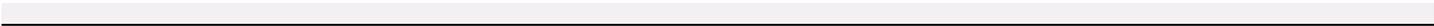
Protocol Number: NIDA-CTO-0011

Ondansetron for Methamphetamine Dependence

Site Identification Number: 980203

Subject Identification Number: 0001

Study Day UNSCHD

Date: _____ (mm/dd/yyyy)

Form Not Done ☐

METHAMPHETAMINE CLINICAL GLOBAL
IMPRESSION - OBSERVER (MCGI-O)

1) Global Severity of

Methamphetamine Dependence

Considering your total clinical experience with the methamphetamine dependent population, how severe are his/her methamphetamine dependence symptoms at this time?

- ○ Normal, no symptoms
- ○ Borderline symptoms
- ○ Mild symptoms
- ○ Moderate symptoms
- ○ Marked symptoms
- ○ Severe symptoms
- ○ Among the most extreme symptoms

2) Global Improvement of

Methamphetamine Dependence

Rate the total improvement in the participant's methamphetamine dependence symptoms whether or not in your judgement, it is due entirely to drug treatment. Compared to his/her admission to the project how much has she/he changed?

- ○ Not assessed, first rating
- ○ Very much improved
- ○ Much improved
- ○ Minimally improved
- ○ Unchanged
- ○ Minimally worse
- ○ Much worse
- ○ Very much worse

3) Please rate the subject's current severity in the eight specific problem areas below:

Specific Problem Area	None least severe					Most severe	
1. Reported methamphetamine use	○ 1	○ 2	○ 3	○ 4	○ 5	○ 6	○ 7
2. Methamphetamine seeking	○ 1	○ 2	○ 3	○ 4	○ 5	○ 6	○ 7
3. Reported use of other drugs	○ 1	○ 2	○ 3	○ 4	○ 5	○ 6	○ 7
4. Observable psychiatric symptoms	○ 1	○ 2	○ 3	○ 4	○ 5	○ 6	○ 7
5. Reported psychiatric symptoms	○ 1	○ 2	○ 3	○ 4	○ 5	○ 6	○ 7
6. Physical/medical problems	○ 1	○ 2	○ 3	○ 4	○ 5	○ 6	○ 7
7. Maladaptive coping in the family/social area	○ 1	○ 2	○ 3	○ 4	○ 5	○ 6	○ 7
8. Maladaptive coping in other areas	○ 1	○ 2	○ 3	○ 4	○ 5	○ 6	○ 7

Source Completed By (Initials): _____

MCGIOBS v1

Study Day UNSCHD

Date: _____
(mm/dd/yyyy)

Form Not Done ☐

METHAMPHETAMINE CLINICAL GLOBAL
IMPRESSION - SELF (MCGI-S)

1) Methamphetamine Global Severity

At this time, how would you have rate yourself for Methamphetamine use and Methamphetamine related problems?

- ◯ No problems
- ◯ Borderline problems
- ◯ Mild problems
- ◯ Moderate problems
- ◯ Marked problems
- ◯ Severe problems
- ◯ Most extreme problems possible

2) Methamphetamine Global Improvement

How would you rate yourself for changes in Methamphetamine use and Methamphetamine related problems since the beginning of this study?

- ◯ Not assessed, first rating
- ◯ Very much improved
- ◯ Much improved
- ◯ Minimally improved
- ◯ Unchanged
- ◯ Minimally worse
- ◯ Much worse
- ◯ Very much worse

Source Completed By (Initials): _____

MCGISELF v1

Protocol Number: NIDA-CTO-0011

Site Identification Number: 980203

Ondansetron for Methamphetamine Dependence

Subject Identification Number: 0001

Study Day UNSCHD

Date: _____

(mm/dd/yyyy)

Form Not Done ☐

MEDICAL HISTORY ADDENDUM FOR FEMALES

1) **Date of last menstrual cycle:** _____ (mm/dd/yyyy)

2) **History of irregular cycle:** ☐ Yes ☐ No

3) **Please specify form of birth control used:**

☐ Oral Contraceptives

☐ Barrier (diaphragm or condom) plus spermicide or condom only

☐ Levonorgestrel implant (Norplant)

☐ Intrauterine progesterone contraceptive system (IUD)

☐ Medroxyprogesterone acetate contraceptive injection (Depo-provera)

☐ Tubal ligation   Date of Tubal Ligation: _____ (mm/dd/yyyy)

☐ Complete abstinence

☐ None (specify reason): _____

☐ Other (specify): _____

Source Completed By (Initials): _____

MEDHISAD v1

Study Day   UNSCHD

Date: _____
(mm/dd/yyyy)

Form Not Done ☐

MEDICAL HISTORY

Disorder	Yes excludes	Yes doesn't exclude	No history of disorder	Not evaluated	If yes, specify or describe
1. Allergies: drug	☐	☐	☐	☐	
2. Allergies: other, specify	☐	☐	☐	☐	
3. Sensitivity to Agent/Compounds	☐	☐	☐	☐	
4. History of Asthma	☐	☐	☐	☐	
5. HEENT	☐	☐	☐	☐	
6. Cardiovascular	☐	☐	☐	☐	
7. Renal	☐	☐	☐	☐	
8. Hepatic	☐	☐	☐	☐	
9. Pulmonary	☐	☐	☐	☐	
10. Gastrointestinal	☐	☐	☐	☐	
11. Musculoskeletal	☐	☐	☐	☐	
12. Neurologic	☐	☐	☐	☐	
13. Psychiatric	☐	☐	☐	☐	
14. Dermatologic	☐	☐	☐	☐	
15. Metabolic	☐	☐	☐	☐	
16. Hematologic	☐	☐	☐	☐	
17. Endocrine	☐	☐	☐	☐	
18. Genitourinary	☐	☐	☐	☐	
19. Reproductive System	☐	☐	☐	☐	
20. Seizure	☐	☐	☐	☐	
21. Infectious Disease	☐	☐	☐	☐	
22. Other 1, specify:	☐	☐	☐	☐	
23. Other 2, specify:	☐	☐	☐	☐	

24. **Was major surgery ever performed?** ☐ Yes ☐ No *(If Yes, list surgeries:)*

Type of Surgery	**Date of Surgery** (mm/dd/yyyy)	**Yes** excludes	**Yes** doesn't exclude	**No**
25.		☐	☐	☐
26.		☐	☐	☐
27.		☐	☐	☐
28.		☐	☐	☐
29.		☐	☐	☐
30.		☐	☐	☐
31.		☐	☐	☐

TOBACCO HISTORY

32. Has subject used any tobacco product (e.g. cigarettes, cigars, pipe, chewing tobacco) in the past week? ☐ Yes ☐ No

33. Has subject ever used any tobacco product for at least one year? ☐ Yes ☐ No

34. If yes, number of years tobacco used? _____

COMMENTS

_____

Source Completed By (Initials): _____

MEDHIST v1

Study Day UNSCHD

Form Not Done ☐

METHAMPHETAMINE TIMELINE FOLLOW BACK

Today's Date: _____ (mm/dd/yyyy)

Date 30 Days Prior to today's date: _____ (mm/dd/yyyy)

Day	Methamphetamine Use		Alcohol Use	
	Yes	No	Yes	No
Day 1	○	○	○	○
Day 2	○	○	○	○
Day 3	○	○	○	○
Day 4	○	○	○	○
Day 5	○	○	○	○
Day 6	○	○	○	○
Day 7	○	○	○	○
Day 8	○	○	○	○
Day 9	○	○	○	○
Day 10	○	○	○	○
Day 11	○	○	○	○
Day 12	○	○	○	○
Day 13	○	○	○	○
Day 14	○	○	○	○
Day 15	○	○	○	○
Day 16	○	○	○	○
Day 17	○	○	○	○
Day 18	○	○	○	○
Day 19	○	○	○	○
Day 20	○	○	○	○
Day 21	○	○	○	○
Day 22	○	○	○	○
Day 23	○	○	○	○
Day 24	○	○	○	○
Day 25	○	○	○	○
Day 26	○	○	○	○
Day 27	○	○	○	○
Day 28	○	○	○	○
Day 29	○	○	○	○
Day 30	○	○	○	○

Source Completed By (Initials): _____

METHTIME v1

Study Day UNSCHD

Date: _____ (mm/dd/yyyy)

Form Not Done ☐

PHYSICAL EXAMINATION

Height: _____ ☐ inches ☐ centimeters

Weight: _____ ☐ pounds ☐ kilograms

General Exam	Normal	Abnormal	Abnormal Significant	Not Done	If Abnormal, explain below
Oral (mouth)	☐	☐	☐	☐	
Head and Neck	☐	☐	☐	☐	
EENT	☐	☐	☐	☐	
Cardiovascular	☐	☐	☐	☐	
Chest	☐	☐	☐	☐	
Lungs	☐	☐	☐	☐	
Abdomen (include liver/spleen)	☐	☐	☐	☐	
Extremities	☐	☐	☐	☐	
Skin, Hair, Nails	☐	☐	☐	☐	
Neuropsychiatric mental status	☐	☐	☐	☐	
Neuropsychiatric sensory/motor	☐	☐	☐	☐	
Musculoskeletal	☐	☐	☐	☐	
General Appearance	☐	☐	☐	☐	
Rectal	☐	☐	☐	☐	
Prostate	☐	☐	☐	☐	
Breast	☐	☐	☐	☐	
Lymph	☐	☐	☐	☐	
Genital	☐	☐	☐	☐	
Pelvic	☐	☐	☐	☐	
Forced Expiratory Volume (FEV1)	☐	☐	☐	☐	
_____ (%)					
Other (specify)	☐	☐	☐	☐	
_____					
Other (specify)	☐	☐	☐	☐	
_____					

Source Completed By (Initials): _____

Protocol Number: NIDA-CTO-0011	Site Identification Number:	980203
Ondansetron for Methamphetamine Dependence	Subject Identification Number:	0001

Study Day UNSCHD

Date: _____
(mm/dd/yyyy)

Form Not Done ☐

PREGNANCY

Was a pregnancy test performed?

○ Yes   ○ No   IF Yes, type: ○ Urine   ○ Serum

(If no, skip to birth control method)

Pregnancy test result:

○ Positive

○ Negative

○ Unknown

○ Not applicable, subject is male

Pregnancy test comments:

Is the subject lactating?   ○ Yes   ○ No   ○ Not Applicable

Is the subject using an acceptable method of birth control?   ○ Yes   ○ No

What method of birth control is the subject using?

○ oral contraceptives ("The Pill")

○ barrier (diaphragm or condom) with spermicide

○ intrauterine progesterone contraceptive (IUD)

○ lovenorgestrel implant (Norplant)

○ medroxyprogesterone acetate injection

○ surgical sterilization

○ complete abstinence from sexual intercourse

○ same sex partner

Source Completed By (Initials): _____

PREGNANT v1

Study Day UNSCHD

PRIOR MEDICATIONS

Has the subject taken any medications in the PAST 30 DAYS? ☐ Yes ☐ No *If yes, please list all below:*

Dose	Unit of Medication				Frequency		Route of Administration			
Strength	CAP	= capsule	PUF	= puff	ONCE	= single dose	PO	= oral	AUR	= auricular
of	g	= gram	SPY	= spray/squirt	QD	= once daily	TD	= transdermal	IA	= intra-articular
Medication	GR	= grain	SUP	= suppository	BID	= twice daily	INH	= inhaled	NAS	= nasal
	GTT	= drop	TSP	= teaspoon	TID	= three times a day	IM	= intramuscular	IO	= intraocular
	ug	= microgram	TBS	= tablespoon	QID	= four times a day	IV	= intravenous	UNK	= unknown
	uL	= microliter	TAB	= tablet	QOD	= every other day	REC	= rectal	OTH	= other, specify
	mg	= milligram	UNK	= unknown	PRN	= as needed	VAG	= vaginal		
	mL	= milliliter	OTH	= other, specify	OTH	= other, specify	SQ	= subcutaneous		
	OZ	= ounce					SL	= sublingual		

No.	Medication	Dose	Unit	Other	Frequency	Other
1				(specify)		(specify)

Route	Other	Date Started	Date Stopped	Cont.?	Indication	Initials
	(specify)	(mm / dd / yyyy)	(mm / dd / yyyy)	☐		

PRIORMED v1

Protocol Number: NIDA-CTO-0011		Site Identification Number:	980203
Ondansetron for Methamphetamine Dependence		Subject Identification Number:	0006

Study Day UNSCHD **Form Not Done** ☐ **Date:** _____

(mm/dd/yyyy)

QUANTITY AND FREQUENCY DRUG HISTORY (QFI)

Source Completed By (Initials): _____

QFI v1

SERIOUS ADVERSE EVENT

DEMOGRAPHIC INFORMATION

Enrollment Date [_____] (mm/dd/yyyy)   **Gender** ☐ Male   ☐ Female

Date of Birth [_____] (mm/dd/yyyy)

Race

☐ White, not of Hispanic Origin   ☐ American Indian or Alaska native

☐ Hispanic or Latino   ☐ Other, (specify):

☐ African American, Black, not of Hispanic Origin   [_____]

☐ Asian or Pacific Islander   ☐ Unknown

Height [_____] ☐ inches ☐ centimeters   **Weight** [_____] ☐ pounds ☐ kilograms

AE/Diagnosis: [_____] [_____] [_____] [_____]

SERIOUS ADVERSE EVENT

SAE Description

[_____]
[_____]
[_____]
[_____]

Onset Date [_____] (mm/dd/yyyy)

Reported to FDA by: [_____]   **Initial Date reported to FDA:** [_____] (mm/dd/yyyy)

Reported to Sponsor by: [_____]   **Date reported to sponsor:** [_____] (mm/dd/yyyy)

Reported to NIDA by: [_____]   **Initial Date reported to NIDA:** [_____] (mm/dd/yyyy)

Severity grade ☐ mild   ☐ moderate   ☐ severe

Was SAE related to investigational agent?

☐ definitely   ☐ probably   ☐ possibly   ☐ remotely   ☐ definitely not   ☐ unknown

Action taken regarding investigational agent		**Other action(s) taken**
☐ none	☐ reduced dose	☐ none
☐ discontinued permanently	☐ increased dose	☐ remedial therapy - pharmacologic
☐ discontinued temporarily	☐ delayed dose	☐ remedial therapy - nonpharmacologic
		☐ hospitalization (new or prolonged)

Outcome   If outcome was death, a Death Report Form must be completed.

☐ death   ☐ disability

☐ life-threatening event   ☐ congenital anomaly

☐ hospitalization   ☐ other (specify) [_____]

Concomitant Medications

Relevant tests/laboratory data, including dates

Relevant history including pre-existing medical conditions (e.g., allergies, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

SAE resolution date [_____] (mm/dd/yyyy)   **OR**   ☐ continuing

INVESTIGATIONAL AGENT ADMINISTRATION

Is investigational agent information known?   ☐ Yes   ☐ No

If yes, investigational agent name [_____]

Lot number [_____]

Expiration date [_____] (mm/dd/yyyy)

Quantity [_____]

Unit Code [_____]   **Other unit** [_____]

Start date [_____]   **Stop date** [_____]   or   ☐ continuing
(mm/dd/yyyy)   (mm/dd/yyyy)

Route of administration   **Frequency**

☐ auricular   ☐ rectal   ☐ single dose
☐ inhaled   ☐ subcutaneous   ☐ once daily
☐ intra-articular ☐ sublingual   ☐ every other day
☐ intramuscular   ☐ transdermal   ☐ twice daily
☐ intraocular   ☐ vaginal   ☐ three times a day
☐ intravenous   ☐ unknown   ☐ four times a day
☐ nasal   ☐ other (specify)   ☐ as needed
☐ oral   ☐ other (specify)
                   [_____]
                                         [_____]

Comments

Source Completed by: [_____]

SAE v1

Site Identification Number: 980203

Subject Identification Number: 0001

Study Day   UNSCHD

Date:

(mm/dd/yyyy)

Form Not Done ☐

SCID WORKSHEET

AXIS I - Diagnosis

**<u>Please list all CURRENT and PAST Substance Abuse or Dependence Diagnoses,
OTHER CURRENT, AND OTHER PAST Diagnoses (Include DSM-IV code).</u>**

Line No.	Axis I Diagnoses Type	DSM-IV Code	Diagnosis
1			

Source Completed By (Initials):

SCID v1

Study Day UNSCHD

Date: _____

(mm/dd/yyyy)

Form Not Done ☐

INTEREST AND PREFERENCE TEST
Sensation Seeking Scale (SSS Form V)

Indicate which choice most describes your likes or the way you feel. Choose only one.

1) ___	11) ___	21) ___	31) ___
2) ___	12) ___	22) ___	32) ___
3) ___	13) ___	23) ___	33) ___
4) ___	14) ___	24) ___	34) ___
5) ___	15) ___	25) ___	35) ___
6) ___	16) ___	26) ___	36) ___
7) ___	17) ___	27) ___	37) ___
8) ___	18) ___	28) ___	38) ___
9) ___	19) ___	29) ___	39) ___
10) ___	20) ___	30) ___	40) ___

Source Completed By (Initials): _____

SSS v1

Site Identification Number: 980203

Subject Identification Number: 0001

Study Day UNSCHD

Date: _____ (mm/dd/yyyy)

Form Not Done ☐

SUBSTANCE USE REPORT

Date of substance use or no use reported for: _____ (mm/dd/yyyy)

Day of substance use or no use reported for:

○ Monday ○ Tuesday ○ Wednesday ○ Thursday ○ Friday ○ Saturday ○ Sunday

			A. Total amount	B. Unit	C. Unit code	D. Route	E. Route code
1.	Cocaine	☐ No use	i)				
			ii)				
2.	Alcohol	☐ No use	i)				
			ii)				
3.	Marijuana	☐ No use	i)				
			ii)				
4.	Opioids Specify:	☐ No use					
i)							
ii)							
5.	Nicotine	☐ No use	i)				
			ii)				
6.	Metham- phetamine	☐ No use	i)				
			ii)				

7. Other, Specify: Code

i) _____ ____ ____ _____ ____ _____ ____

ii) _____ ____ ____ _____ ____ _____ ____

iii) _____ ____ ____ _____ ____ _____ ____

Source Completed By (Initials): _____

SUR v1

Protocol Number: NIDA-CTO-0011	Site Identification Number:	980203

Ondansetron for Methamphetamine Dependence

Subject Identification Number: 0001

Study Day | UNSCHD

Date: _____
(mm/dd/yyyy)

Form Not Done ☐

SYPHILIS TEST

Indicate whether the laboratory value is NEGATIVE: negative test result, POSITIVE: positive test result,

INDETERMINANT: result is not interpretable or NOT DONE.

If RPR test is not done, state reason.

Rapid plasma reagin (RPR) test result

*If positive, fluorescent treponemal antibody absorbent (FTA-abs) confirmatory test is required.

**If RPR test is indeterminant, it must be repeated.

Date FTA-abs test administered _____ (mm/dd/yyyy)   If test not done, state reason.

FTA-abs test result

+If FTA-abs result is positive, is subject willing to undergo treatment for syphilis?

☐ Yes   ☐ No   If treated, date of written proof of treatment: _____ (mm/dd/yyyy)

If subject is unwilling to undergo treatment for active syphilis, s/he is ineligible to participate in research study.

Comments:

Source Completed By (Initials): _____

SYPHILIS v1

Site Identification Number: 980203

Subject Identification Number: 0001

Study Day UNSCHD

Date: _____
(mm/dd/yyyy)

Form Not Done ☐

URINALYSIS

Indicate whether the laboratory value is NORMAL: within normal limits, ABNORMAL: outside of normal limits but not clinically significant, ABNORMAL SIGNIFICANT: significant during screening means subject is ineligible for study; significant while on study means consider reporting result as adverse event if unexpected and at least possibly related to investigational agent, or requires early termination from study.

Dipstick Urinalysis:

Specific gravity _____

pH _____

Lab	Levels	Result	Comments for Abnormal Values
Blood			
Protein			
Glucose			
Ketones			
Leukocytes			
Nitrite			

Source Completed By (Initials): _____

URINE v1

Study Day   UNSCHD

Form Not Done ☐

Date: _____
(mm/dd/yyyy)

URINE TOXICOLOGY

Urine temperature within expected range?

☐ Yes   ☐ No   ☐ Unknown   (96.4 < or = T < or = 100.4 F)

Drug/Test	Positive	Negative	Not Done
Amphetamines	☐	☐	☐
Barbiturates	☐	☐	☐
Benzodiazepines	☐	☐	☐
Cannabinoids (THC)	☐	☐	☐
Cocaine metabolites	☐	☐	☐
Methadone	☐	☐	☐
Methamphetamine	☐	☐	☐
Methaqualone	☐	☐	☐
Opiates	☐	☐	☐
Phencyclidine (PCP)	☐	☐	☐
Propoxyphene	☐	☐	☐

Source Completed By (Initials): _____

URINETOX v1

Site Identification Numl | 980203

Ondansetron for Methamphetamine Dependence

Subject Identification Num | 0001

Study Day | UNSCHD

Date

(mm/dd/yyyy)

Form Not Do ☐

VITAL SIGNS

Time: [   ] (00:00-23:59)

Temp: [   ] ☐ F ☐ C   **Sitting Resp. Rate:** [   ] (breaths/min)

POSITION	Pulse Rate	Blood Pressure (systolic)	/	(diastolic)
Sitting			/	
	(beats/min)	(mmHg)		(mmHg)
Standing 1 Minute			/	
	(beats/min)	(mmHg)		(mmHg)
Standing 3 Minutes			/	
	(beats/min)	(mmHg)		(mmHg)

Source Completed By (Initials): [   ]

VITALS v1