Subject Identification Number: 001

Date: _____

Study Day UNSCHD

Form Not Done ☐

(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

Question	Timeframe				
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

Protocol Number: NIDA-CTO-0005

Ondansetron for Cocaine Dependence

Study Day STDYWD

Subject Identification Number: 0001

ADVERSE EVENTS

Has the subject had any Adverse Experiences during this study?   ☑ Yes   ☐ 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	1 = Definitely	1 = None	1 = None	1 = Resolved, No Sequela	Yes
2 = Moderate	2 = Probably	2 = Discontinued Perm.	2 = Remedial	2 = AE still present - no tx	No
3 = Severe	3 = Possibly	3 = Discontinued Temp.	Therapy-pharm	3 = AE still present - being tx	(If yes,
	4 = Remotely	4 = Reduced Dose	3 = Remedial	4 = Residual effects present-no tx	complete
	5 = Definitely Not	5 = Increased Dose	Therapy-nonpharm	5 = Residual effects present-tx	SAE form)
	6 = Unknown	6 = Delayed Dose	4 = Hospitalization	6 = Death	
				7 = Unknown	

#	EVENT	Start Date	Stop Date	Sev.	Drug Rel.	Action Taken	Other Action	Out.	Serious	Initials
	d								☐ ☐	

AE v1

Subject Identification Number: 0001

Date: _____
(mm/dd/yyyy)

Study Day SCRNBASE

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 comment for any action taken:

_____

Source Completed By (Initials): _____

ALBREATH v1

Protocol Number: NIDA-CTO-0005

Ondansetron for Cocaine Dependence

Study Day   SCRNBASE

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 lif [   ]

   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	[ ]	[ ]	☐	☐	☐	☐	☐	☐	☐
	[ ]	[ ]	☐	☐	☐	☐	☐	☐	☐
	[ ]	[ ]	☐	☐	☐	☐	☐	☐	☐
	[ ]	[ ]	☐	☐	☐	☐	☐	☐	☐
	[ ]	[ ]	☐	☐	☐	☐	☐	☐	☐
	[ ]	[ ]	☐	☐	☐	☐	☐	☐	☐
	[ ]	[ ]	☐	☐	☐	☐	☐	☐	☐
	[ ]	[ ]	☐	☐	☐	☐	☐	☐	☐
	[ ]	[ ]	☐	☐	☐	☐	☐	☐	☐
	[ ]	[ ]	☐	☐	☐	☐	☐	☐	☐
	[ ]	[ ]	☐	☐	☐	☐	☐	☐	☐
	[ ]	[ ]	☐	☐	☐	☐	☐	☐	☐
	[ ]	[ ]	☐	☐	☐	☐	☐	☐	☐

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

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-0005

Ondansetron for Cocaine Dependence

Study Day | UNSCHD

Subject Identification Number: | 001

Date: _____ (mm/dd/yyyy)

Form Not Done ☐

BARETT'S IMPULSIVITY SCALE (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
	☐	☐	☐	☐
	☐	☐	☐	☐
	☐	☐	☐	☐
	☐	☐	☐	☐
	☐	☐	☐	☐
	☐	☐	☐	☐
	☐	☐	☐	☐
	☐	☐	☐	☐
	☐	☐	☐	☐
	☐	☐	☐	☐
	☐	☐	☐	☐
	☐	☐	☐	☐
	☐	☐	☐	☐
	☐	☐	☐	☐
	☐	☐	☐	☐
	☐	☐	☐	☐
	☐	☐	☐	☐
	☐	☐	☐	☐
	☐	☐	☐	☐
	☐	☐	☐	☐
	☐	☐	☐	☐
	☐	☐	☐	☐
	☐	☐	☐	☐
	☐	☐	☐	☐
	☐	☐	☐	☐
	☐	☐	☐	☐
	☐	☐	☐	☐
	☐	☐	☐	☐

Source Completed By (Initials): _____

Protocol Number: NIDA-CTO-0005	Subject Identification Number:	0001
Ondansetron for Cocaine Dependence	Date:	

Study Day SCRNBASE   **Form Not Done** ☐   (mm/dd/yyyy)

BRIEF SUBSTANCE CRAVING SCALE (BSCS)

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

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

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

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

5) Write in the total TIME spent craving cocaine 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 cocaine 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

Protocol Number: NIDA-CTO-0005	Subject Identification Number:	0021
Ondansetron for Cocaine Dependence	Date:	
		(mm/dd/yyyy)

Study Day SCRNBASE

Form Not Done ☐

COCAINE CLINICAL GLOBAL IMPRESSION - OBSERVER (CCGI-O)

1) Global Severity of Cocaine Dependence

Considering your total clinical experience with the cocaine dependent population, how severe are his/her cocaine 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 Cocaine Dependence

Rate the total improvement in the participant's cocaine 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 cocaine use	◯ 1	◯ 2	◯ 3	◯ 4	◯ 5	◯ 6	◯ 7
	◯	◯	◯	◯	◯	◯	◯
	◯	◯	◯	◯	◯	◯	◯
	◯	◯	◯	◯	◯	◯	◯
	◯	◯	◯	◯	◯	◯	◯
	◯	◯	◯	◯	◯	◯	◯
	◯	◯	◯	◯	◯	◯	◯
	◯	◯	◯	◯	◯	◯	◯

Source Completed By (Initials):

CCGIOBSV v1

Subject Identification Number: 001

Date:
(mm/dd/yyyy)

Study Day UNSCHD

Form Not Done ☐

COCAINE CLINICAL GLOBAL IMPRESSION - SELF (CCGI-S)

1) Cocaine Global Severity

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

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

2) Cocaine Global Improvement

How would you rate yourself for changes in Cocaine use and Cocaine 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):

CCGISELF v1

Protocol Number: NIDA-CTO-0005

Ondansetron for Cocaine Dependence

Subject Identification Number: 001

Date: _____ (mm/dd/yyyy)

Study Day UNSCHD   **Form Not Done** ☐

COCAINE CRAVING QUESTIONNAIRE

CRAVINGS	Strongly disagree					Strongly agree	
1. If I were using cocaine, I could think clearly	○ 1	○ 2	○ 3	○ 4	○ 5	○ 6	○ 7
	○	○	○	○	○	○	○
	○	○	○	○	○	○	○
	○	○	○	○	○	○	○
	○	○	○	○	○	○	○
	○	○	○	○	○	○	○
	○	○	○	○	○	○	○
	○	○	○	○	○	○	○
	○	○	○	○	○	○	○
	○	○	○	○	○	○	○
	○	○	○	○	○	○	○
	○	○	○	○	○	○	○
	○	○	○	○	○	○	○
	○	○	○	○	○	○	○
	○	○	○	○	○	○	○
	○	○	○	○	○	○	○
	○	○	○	○	○	○	○
	○	○	○	○	○	○	○
	○	○	○	○	○	○	○
	○	○	○	○	○	○	○
	○	○	○	○	○	○	○
	○	○	○	○	○	○	○
	○	○	○	○	○	○	○
	○	○	○	○	○	○	○

	1	2	3	4	5	6	7
25. I would feel energetic if I used cocaine	○	○	○	○	○	○	○
	○	○	○	○	○	○	○
	○	○	○	○	○	○	○
	○	○	○	○	○	○	○
	○	○	○	○	○	○	○
	○	○	○	○	○	○	○
	○	○	○	○	○	○	○
	○	○	○	○	○	○	○
	○	○	○	○	○	○	○
	○	○	○	○	○	○	○
	○	○	○	○	○	○	○
	○	○	○	○	○	○	○
	○	○	○	○	○	○	○
	○	○	○	○	○	○	○
	○	○	○	○	○	○	○
	○	○	○	○	○	○	○
	○	○	○	○	○	○	○
	○	○	○	○	○	○	○
	○	○	○	○	○	○	○
	○	○	○	○	○	○	○
	○	○	○	○	○	○	○

Source Completed By (Initials):

CCQ v1

Protocol Number: NIDA-CTO-0005

Ondansetron for Cocaine Dependence

Subject Identification Number: 0001

Date: _____ (mm/dd/yyyy)

Study Day SCRNBASE

Form Not Done ☐

CHEMISTRIES

Analyte	Std. Quantity	Standard Unit	Other Unit	Normal	Abnormal	Abnormal Significant	Not Done
01. Sodium				☐	☐	☐	☐
				☐	☐	☐	☐
				☐	☐	☐	☐
				☐	☐	☐	☐
				☐	☐	☐	☐
				☐	☐	☐	☐
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				☐	☐	☐	☐
				☐	☐	☐	☐
				☐	☐	☐	☐
				☐	☐	☐	☐
				☐	☐	☐	☐
				☐	☐	☐	☐
				☐	☐	☐	☐

Provide comments for any abnormal value(s) _____

Source Completed By (Initials): _____

CHEM v1

Subject Identification Number: 001

Form Not Done ☐

COCAINE TIMELINE FOLLOW BACK

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

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

Day	Cocaine Use	
Day 1	○ Yes	○ No
	○	○
	○	○
	○	○
	○	○
	○	○
	○	○
	○	○
	○	○
	○	○
	○	○
	○	○
	○	○
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	○	○
	○	○
	○	○
	○	○
	○	○
	○	○
	○	○

Source Completed By (Initials): _____

Protocol Number: NIDA-CTO-0005	Subject Identification Number:	001
Ondansetron for Cocaine Dependence	Date:	

Study Day | UNSCHD | **Form Not Done** ☐   (mm/dd/yyyy)

TREATMENT COMPLIANCE - INVESTIGATIONAL AGENTS

1) **Date tablets dispensed**

2) **Number of tablets dispensed**

3) **Date unused tablets returned**

4) **Number of tablets returned**

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

6) **Comments**

Source Completed By (Initials):

| Protocol Number: NIDA-CTO-0005 | Subject Identification Number: | 001 |

Protocol Number: NIDA-CTO-0005

Ondansetron for Cocaine Dependence

Study Day UNSCHD

Subject Identification Number: 001

Date:

(mm/dd/yyyy)

Form Not Done ☐

TREATMENT COMPLIANCE - PSYCHOSOCIAL THERAPY

1) **Did subject receive standardized, manual-guided individual psychotherapy?**

◯ Yes   ◯ No   ◯ Unknown

2) **If yes, length of psychotherapy session** _____ (minutes)

3) **Was psychotherapy session audiotaped?**

◯ Yes   ◯ No   ◯ Unknown

Comments

Source Completed By (Initials):

COMPTHER v1

Subject Identification Number: | 0001

Study Day | STDYWD

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	C A P = capsule	PUF = puff	O N C E = single dose	PO = oral	A U R = auricular
of	g = gram	SPY = spray/squirt	Q D = once daily	TD = transdermal	IA = intra-articular
Medication	GR = grain	SUP = suppository	BID = twice daily	INH = inhaled	N A S = 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	T A B = tablet	Q O D = every other day	REC = rectal	OTH = other, specify
	mg = milligram	UNK = unknown	PRN = as needed	V A G = vaginal	
	mL = milliliter	OTH = other, specify	OTH = other, specify	SQ = subcutaneous	
	O Z = ounce			SL = sublingual	

CONMEDS v1

Protocol Number: NIDA-CTO-0005

Ondansetron for Cocaine Dependence

Subject Identification Number: 0021

Date: _____
(mm/dd/yyyy)

Study Day   SCRNBASE

Form Not Done ☐

COCAINE SELECTIVE SEVERITY ASSESSMENT

Date of last cocaine use: _____ (mm/dd/yyyy)

1)	Hyperphagia:		10)	Energy Level:	
2)	Hypophagia:		11)	Activity Level:	
3)	Carbohydrate craving:		12)	Tension:	
4)	Cocaine craving:		13)	Attention:	
5)	Craving frequency:		14)	Paranoid ideation:	
6)	Bradycardia:		15)	Anhedonia:	
7)	Insomnia:		16)	Depression:	
8)	Hypersomnia:		17)	Suicidality:	
9)	Anxiety:		18)	Irritability:	

CSSA Total Score: _____

Source Completed By (Initials): _____

CSSA 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

Study Day SCRNBASE

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, African American, or Negro

☐ 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:

☐ 1 - Full time (35+ hours/week) ☐ 6 - Retired/Disabled

☐ 2 - Part time (regular hours) ☐ 7 - Homemaker

☐ 3 - Part time (irregular hours, day work) ☐ 8 - Unemployed

☐ 4 - Student ☐ 9 - In controlled environment

☐ 5 - Military Service

3) Usual employment pattern, past 3 years:

☐ 1 - Full time (35+ hours/week)　　　　☐ 6 - Retired/Disabled

☐ 2 - Part time (regular hours)　　　　　☐ 7 - Homemaker

☐ 3 - Part time (irregular hours, day work)　☐ 8 - Unemployed

☐ 4 - Student　　　　　　　　　　　　☐ 9 - In controlled environment

☐ 5 - Military Service

4) Marital Status:

☐ 1 - Legally married　　　　　　　　　☐ 4 - Separated

☐ 2 - Living with partner/cohabitating　　☐ 5 - Divorced

☐ 3 - Widowed　　　　　　　　　　　　☐ 6 - Never Married

DRUG/ALCOHOL USE

			☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐
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			☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐

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

☐ 0 - No problem　　　　☐ 6 - Opiates/analgesics　　☐ 12 - Hallucinogens

☐ 1 - Alcohol (any)　　　☐ 7 - Barbiturates　　　　　☐ 13 - Inhalants

☐ 2 - Alcohol to intoxication　☐ 8 - Sed./hyp./tranq./benzos.　☐ 14 - Nicotine

☐ 3 - Heroin　　　　　　☐ 9 - Cocaine　　　　　　　☐ 15 - Alcohol and Drug addictiion

☐ 4 - Methadone/LAAM (presc.)　☐ 10- Amph./methamph.　☐ 16 - Polydrug addiction

☐ 5 - Methadone/LAAM (illicit)　☐ 11 - Cannibis

Source Completed By (Initials): _____

Protocol Number: NIDA-CTO-0005	Subject Identification Number:	0001

Ondansetron for Cocaine Dependence

Date: _____
(mm/dd/yyyy)

Study Day   SCRNBASE   **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

Subject Identification Number: 0001

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   ☐ Drug Free   ☐ Inpatient Detox or Treatment

    ☐ LAAM   ☐ 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

Subject Identification Number: 0001

ENROLLMENT

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

If yes, was subject enrolled into the study? ☐ Yes ☐ No

If subject was enrolled in the study, 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

Subject Identification Number: | -

Date: |

(mm/dd/yyyy)

EXCLUSION CRITERIA

Participant must not:

		Yes	No
1.	Have current dependence, defined by DSM-IV criteria, on any psychoactive substance other than cocaine, alcohol, nicotine, caffeine, or marijuana or physiological dependence on alcohol requiring medical detoxification. (Although heavy alcohol use and "behavioral" dependence may be included, physiological dependence on alcohol showing signs of withdrawal at zero breath alcohol levels and requiring medical detoxification will cause exclusion.)	☐ Yes	☐ No
2.	Have neurological or psychiatric disorders such as: psychosis; bipolar illness; major depression as assessed by SCID; organic brain disease; dementia; seizure disorders; any disorder which would require ongoing treatment or which would make study agent compliance difficult; history of suicide attempts assessed by SCID and/or current suicidal ideation/plan as assessed by SCID or HAM-D question #3. (See note in protocol).	☐ Yes	☐ No
3.	Have serious medical illnesses including, but not limited to: uncontrolled hypertension; significant heart disease, including myocardial infarction within one year of enrollment; angina; active hepatitis or tuberculosis (see note in protocol); clinically significant cardiovascular abnormality (ECG); disease of the gastrointestinal system, liver, or kidneys that could result in altered metabolism or excretion of the study agent; history of major gastrointestinal tract surgery (e.g., gastrectoy, gastrostomy, bowel resections); current or historical diagnosis of chronic disease of the gastrointestinal tract (e.g., ulcerative colitis, regional enteritis, or gastrointestinal bleeding); serious, potentially life-threatening or progressive medical illness other than addiction that may compromise subject safety or study conduct.	☐ Yes	☐ No
4.	Be mandated by the court to obtain treatment for cocaine-dependence.	☐ Yes	☐ No
5.	Be anyone who in the opinion of the investigator would not be expected to complete the study protocol due to probable incarceration or relocation from the clinic area.	☐ Yes	☐ No
6.	Have AIDS or CD4 positive T cell counts less 500 mm3 (see note in protocol).	☐ Yes	☐ No
7.	Have active syphilis that has not been treated or refused treatment for syphilis (see note in protocol).	☐ Yes	☐ No
8.	Have a history of neuroleptic malignant syndrome.	☐ Yes	☐ No
9.	Have known or suspected hypersensitivity to Ondansetron.	☐ Yes	☐ No
10.	Be taking Ondansetron for any reason.	☐ Yes	☐ No
11.	Have received a drug with known potential for toxicity to a major organ system within 30 days prior to study entry (e.g., isoniazid, methotrexate).	☐ Yes	☐ No
12.	Have concurrent (within two weeks of study participation) pharmacotherapy with psychotropics including, but not limited to antidepressants, anxiolytics, antipsychotics, anticonvulsants, and psychomotor stimulant-type medications.	☐ Yes	☐ No
13.	Have within two weeks used St. John's Wort, yohimbine, ginko biloba, horehound, or any other central nervous system active herbal preparations.	☐ Yes	☐ No

14. Have received medications or herbal supplements that could interact adversely with Ondansetron, with the time of administration of study agent and other medication/herbal supplement based on the longest time interval or A, B, C: 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 in this category include any seretonin-active substances and drugs specifically metabolized by the P-450, such as: serotonin-active substances, i.e., sumitriptan (Imitrex), zolmitriptan (Zomig), cyproheptadine, ketanserin, ritanserin, fluoxetine, paroxetine, setraline, methysergide, ergotamine, ergonovine; drugs significantly metabolized by the P-450, i.e., cimetidine and phenobarbital; herbals that enhance serotonergic effects, i.e., horehound. ☐ Yes ☐ No

15. Have participated in any experimental study within 4 weeks, or must not have ever participated on a clinical trial utilizing Ondansetron. ☐ Yes ☐ No

16. Be pregnant or lactating. ☐ Yes ☐ No

17. Have any clinically significant abnormal laboratory value. (See protocol Appendix I) ☐ Yes ☐ No

18. Have had electroconvulsive therapy within the 3 months preceding screening. ☐ Yes ☐ No

19. Have had any opiate-substitutes (methadone, LAAM, buprenorphine) within two months preceding screening. ☐ 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 (because of potential serious adverse interactions with cocaine). ☐ Yes ☐ No

21. Be actively using albuterol or other beta agonist medications, regardless of formal diagnosis of asthma. (Inhalers are sometimes used by cocaine addicts to enhance cocaine delivery to the lungs.) A subject without respiratory disease who will consent to discontinue agonist use, may be considered for inclusion. ☐ Yes ☐ No

22. For subjects suspect to have asthma but without a formal diagnosis, 1) have 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), or 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 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-0005		Subject Identification Number:	0001
Ondansetron for Cocaine Dependence		Date:	

Study Day WEEK12   **Form Not Done** ☐   (mm/dd/yyyy)

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-0005		Subject Identification Number:	001

Ondansetron for Cocaine Dependence

Date: _____
(mm/dd/yyyy)

Study Day [UNSCHD]   **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

Subject Identification Number: 0001

Date: _____ (mm/dd/yyyy)

Study Day SCRNBASE

Form Not Done ☐

HEMATOLOGY

Complete Blood Count	Std. Quantity	Standard Unit	Other Unit	Normal	Abnormal	Abnormal Significant	Not Done
Hemaglobin				☐	☐	☐	☐
				☐	☐	☐	☐
				☐	☐	☐	☐
				☐	☐	☐	☐
				☐	☐	☐	☐
				☐	☐	☐	☐
				☐	☐	☐	☐
				☐	☐	☐	☐
				☐	☐	☐	☐
				☐	☐	☐	☐
				☐	☐	☐	☐

Provide comments for any abnormal value(s) _____

Source Completed By (Initials): _____

HEMAT v1

Protocol Number: NIDA-CTO-0005	Subject Identification Number:	0001
Ondansetron for Cocaine Dependence	Date:	

Study Day SCRNBASE   **Form Not Done** ☐   (mm/dd/yyyy)

HIGH 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

Subject Identification Number: [-]

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 cocaine dependence as determined by SCID.	☐ Yes	☐ No
3.	Be seeking treatment for cocaine dependence.	☐ Yes	☐ No
4.	Have at least 1 positive Urine BE specimen (>300 ng/mL) within the two-week baseline period prior to randomization with a minimum of 4 samples tested.	☐ Yes	☐ No
5.	Have the ability to understand, and having understood, provide written informed consent.	☐ Yes	☐ No
6.	If female, use one of the following methods of birth control: oral contraceptives; barrier (diaphragm or condom) with spermicide; intrauterine progesterone contraceptive system; levonorgestrel implant; medroxyprogesterone acetate contraceptive injection; surgical sterilization; complete abstinence from sexual intercourse. (NOTE: Women who are post-menopausal, have had hysterectomies, or have been sterilized may be included without these methods of birth control.)	☐ Yes	☐ No

All answers to Inclusion Criteria must be YES

Source Completed By (Initials): [ ]

(INCLUS V1)

Protocol Number: NIDA-CTO-0005		Subject Identification Number:	0021

Ondansetron for Cocaine Dependence

Date: _____ (mm/dd/yyyy)

Study Day | SCRNBASE | **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.

Provide comments for any abnormal value

Infectious Disease	Result	
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)

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

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

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-0005

Ondansetron for Cocaine Dependence

Study Day SCRNBASE

Subject Identification Number: 0001

Form Not Done ☐

LAB TEST TRACKING FORM

Date: _____
(mm/dd/yyyy)

Tests:
- ☐ Urine Toxicology Screen
- ☐ Serum Prolactin
- ☐ ERG
- ☐ Platelet Serotonin Function
- ☐ Serotonin Receptor Genotype
- ☐ Plasma Ondansetron Levels

Source Completed By (Initials): _____

LABTRACK v1

Subject Identification Number: 0001

Date:

(mm/dd/yyyy)

Study Day   SCRNBASE   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

Protocol Number: NIDA-CTO-0005

Ondansetron for Cocaine Dependence

Study Day   SCRNBASE

Subject Identification Number: 0001

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)	☐	☐	☐	☐	

_____ (%)

	Normal	Abnormal	Abnormal Significant	Not Done	If Abnormal, explain below
Other (specify)	☐	☐	☐	☐	
Other (specify)	☐	☐	☐	☐	

Source Completed By (Initials): _____

PHYSEXAM v1

Protocol Number: NIDA-CTO-0005	Subject Identification Number:	0001

Ondansetron for Cocaine Dependence

Study Day   SCRNBASE   **Form Not Done** ☐

Date: ⬚
(mm/dd/yyyy)

PREGNANCY

Was a pregnancy test performed?
(If no, skip to birth control method)

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

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

Source Completed By (Initials):

PREGNANT v1

Subject Identification Number: 0001

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	

PRIORMED v1

Study Day UNSCHD

Form Not Done ☐

QUANTITY AND FREQUENCY DRUG HISTORY (QFI)

#	Drug Class	Ever Used	Types Used	When Last Used	Life Use Total	Main Type	Usual Route	# Days use Past 7	# Days use Past 30	Estimate Quantity Freq.	Duration of Pattern	Typical Freq.	Age First Began	Age Last Used	Patient Problem Y or N?	Heaviest Lifetime Pattern Usual route	Heaviest Lifetime Pattern Estimate Quan./Freq.	Heaviest Lifetime Pattern Duration of pattern
		○ ○				○ ○												

Source Completed By (Initials):

QFI v1

Subject Identification Number: | 0001 |

<div align="center">

SERIOUS ADVERSE EVENT

</div>

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 Sponsor by: | |　**Date reported to sponsor:** | | (mm/dd/yyyy)

Reported to FDA by: | |　**Initial Date reported to FDA:** | | (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 Case 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) ☐ 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

Protocol Number: NIDA-CTO-0005

Ondansetron for Cocaine Dependence

Subject Identification Number: 0001

Date: _____

(mm/dd/yyyy)

Study Day UNSCHD

Form Not Done ☐

SCID WORKSHEET

AXIS I - Diagnosis

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

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

Source Completed By (Initials): _____

SCID v1

Subject Identification Number: 001

Date: _____
(mm/dd/yyyy)

Study Day UNSCHD

Form Not Done ☐

SENSATION SEEKING SCALE (SSS)

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

Protocol Number: NIDA-CTO-0005

Ondansetron for Cocaine Dependence

Subject Identification Number: 0001

Study Day UNSCHD

Form Not Done ☐

SUBSTANCE USE INVENTORY

Indicate whether the subject has used any amount of the listed substance on the given day since the last visit

and the most common route of administration

Route of Administration (ROA) codes:

1 = Oral   2 = Nasal   3 = Smoking   4 = non-intravenous injection   5 = intravenous injection

Line No.	Week No.	Day of Week	Date (mm/dd/yyyy)	Cocaine	ROA	Alcohol	Marijuana	ROA	Ampheta-mines	ROA
1				☐ Yes ☐ No		☐ Yes ☐ No	☐ Yes ☐ No		☐ Yes ☐ No	

Opiates	ROA	Barbitu-rates	ROA	Metham-phetamine	ROA	Benzo-diazepines	ROA	Nicotine	ROA	PCP	ROA	Propoxy-phene	ROA
☐ Yes ☐ No		☐ Yes ☐ No		☐ Yes ☐ No		☐ Yes ☐ No		☐ Yes ☐ No		☐ Yes ☐ No		☐ Yes ☐ No	

Source Completed By (Initials):

SUI v1

Protocol Number: NIDA-CTO-0005	**Subject Identification Number:** 0021
Ondansetron for Cocaine Dependence	**Date:**
Study Day SCRNBASE	**Form Not Done** ☐ (mm/dd/yyyy)

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

Study Day SCRNBASE

Subject Identification Number: 0001

Form Not Done ☐

URINE BE and TOXICOLOGY SPECIMEN COLLECTION Form

Date Urine Collected	Urine temperature within expected range? (96.4 < or = T < or = 100.4 F)		
	☐	☐	☐

Source Completed By (Initials):

URINEBE v1

Subject Identification Number: 0001

Date:
(mm/dd/yyyy)

Study Day SCRNBASE

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

Source Completed By (Initials):

URINE v1

Subject Identification Number: 0021

Date:

(mm/dd/yyyy)

Form Not Done ☐

URINE TOXICOLOGY

Urine temperature within expected range?   ☑ Yes   ☐ No   ☐ Unknown   (96.4 < or = T < or = 100.4 F)

Drug/Test	Positive	Negative	Not Done
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐

Source Completed By (Initials):

URINETOX v1

Protocol Number: NIDA-CTO-0005

Ondansetron for Cocaine Dependence

Study Day   UNSCHD

Subject Identification Number: 001

Date: _____
(mm/dd/yyyy)

Form Not Done ☐

VITAL SIGNS RECORD

Line No.	Time (00:00 - 23:59)	Temp (oral) Fahrenheit or Celcius			Sitting Resp. Rate (Breaths/Min)	Sitting Blood Pressure (systolic) / (diastolic)		Sitting Pulse Rate (Beats/Min)	Comp.By: (Initials)
			☐	☐					

VITALS v1