Protocol Number: NIDA-CTO-0003

Tolcapone for Cocaine Dependence

Subject Identification Number: 0001

Date: (mm/dd/yyyy)

Study Day VISITD4

Form Not Done ☐

ADJECTIVE SCALE

Actual Time (00:00 - 23:59)

For each item presented, indicate HOW YOU FEEL RIGHT NOW.

ADJECTIVES	Not at all	A Little Bit	Moderately	Quite a bit	Extremely
1. Craving for Cocaine	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
2. Dizzy/Lightheaded	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
3. Drug Effect	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
4. Dry Mouth	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
5. Excited	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
6. Fearful	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
7. Feel a Thrill	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
8. Feeling of Power	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
9. Fidgety	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
10. Irritable	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
11. Jittery	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
12. Nervous	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
13. Numbness	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
14. Seeing/Hearing Things	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
15. Sleepy	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
16. Stimulated	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
17. Stomach Upset/ Nausea	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
18. Suspicious	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
19. Sweating	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
20. Thirsty	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
21. Tingling	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
22. Tremor	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4

Source Completed By (Initials):

Protocol Number: NIDA-CTO-0003

Subject Identification Number: 0001

Tolcapone for Cocaine Dependence

Study Day STDYWD

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 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-nonphar 4 = Hospitalization	1 = Resolved, No Sequela 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	Yes No (If yes, complete SAE form)

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

Protocol Number: NIDA-CTO-0003	**Subject Identification Number:** 0001
Tolcapone for Cocaine Dependence	**Date:** ______ (mm/dd/yyyy)
Study Day VISITD4	**Form Not Done** ☐

ARCI SHORT FORM

These 49 items may or may not describe how you feel right now. Mark T (for true) next to each item that does describe how you feel, and F (for false) for each item that does not describe how you feel.

Actual Time ______ (00:00 - 23:59)

Feelings		
	○	○
	○	○
	○	○
	○	○
	○	○
	○	○
	○	○
	○	○
	○	○
	○	○
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	○	○
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	○	○
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	○	○
	○	○
	○	○
	○	○
	○	○
	○	○
	○	○

27. Less discouraged	◯ True	◯ False
	◯	◯
	◯	◯
	◯	◯
	◯	◯
	◯	◯
	◯	◯
	◯	◯
	◯	◯
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	◯	◯
	◯	◯
	◯	◯
	◯	◯

Source Completed By (Initials)

Protocol Number: NIDA-CTO-0003

Tolcapone for Cocaine Dependence

Subject Identification Number: 0001

Date: (mm/dd/yyyy)

Study Day VISITD1

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
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	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 hospit
2) How many times have you been treated for any psychological or emotional problem(s) as an out
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):

Protocol Number: NIDA-CTO-0003

Tolcapone for Cocaine Dependence

Subject Identification Number: 0001

Date: (mm/dd/yyyy)

Study Day VISITD1

Form Not Done ☐

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

GENERAL INFORMATION

1) Date of Admission: (mm/dd/yyyy)
2) Class:
3) Contact code:
4) Gender;
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			☐	☐	☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐	☐	☐

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): [ ]

Protocol Number: NIDA-CTO-0003

Tolcapone for Cocaine Dependence

Subject Identification Number: 0001

Date: (mm/dd/yyyy)

Study Day SCRNG

Form Not Done ☐

BECK DEPRESSION INVENTORY (BDI)

Which statement best describes the way you have been feeling the PAST WEEK, (INCLUDING TODAY).

1)		8)		15)	
2)		9)		16)	
3)		10)		17)	
4)		11)		18)	
5)		12)		19)	
6)		13)		20)	
7)		14)		21)	

Source Completed By (Initials):

Protocol Number: NIDA-CTO-0003

Tolcapone for Cocaine Dependence

Subject Identification Number: 0028

Date: (mm/dd/yyyy)

Study Day VISITD4

Form Not Done ☐

BRIEF PSYCHIATRIC RATING SCALE

Actual Time: (00:00 - 23:59)

	Not Assessed	Not Present	Very Mild	Mild	Moderate	Moderately Severe	Severe	Extremely Severe
1-Somatic Concern	NA	1	2	3	4	5	6	7

Source Completed By (Initials):

Protocol Number: NIDA-CTO-0003

Tolcapone for Cocaine Dependence

Subject Identification Number: 999

Date: (mm/dd/yyyy)

Study Day VISITD1

Form Not Done ☐

BRIEF SYMPTOM INVENTORY

For the past week, how much were you distressed by:

1)	Nervousness or shakiness inside	28)	Feeling afraid to travel on buses, subways, or trains.
2)	Faintness or dizziness	29)	Trouble getting your breath
3)	The idea that someone else can control your thoughts	30)	Hot or cold spells
4)	Feeling others are to blame for most of your problems	31)	Having to avoid certain things, places or activities..
5)	Trouble remembering things	32)	Your mind going blank
6)	Feeling easily annoyed or irritated	33)	Numbness or tingling in parts of your body
7)	Pains in heart or chest	34)	The idea that you should be punished for your sins
8)	Feeling afraid in open spaces or on the streets	35)	Feeling hopeless about the future
9)	Thoughts of ending your life	36)	Trouble concentrating
10)	Feeling that most people cannot be trusted	37)	Feeling weak in parts of your body
11)	Poor Appetite	38)	Feeling tense or keyed up
12)	Suddenly scared for no reason	39)	Thoughts of death or dying
13)	Temper outbursts that you could not control	40)	Having urges to beat, injure or harm someone
14)	Feeling lonely even when you are with people	41)	Having urges to break or smash things
15)	Feeling blocked in getting things done	42)	Feeling very self-conscious with others
16)	Feeling lonely	43)	Feeling very uneasy in crowds (shopping, movie)
17)	Feeling blue	44)	Never feeling close to another person
18)	Feeling no interest in things	45)	Spells of terror or panic
19)	Feeling fearful	46)	Getting into frequent arguments
20)	Your feelings being easily hurt	47)	Feeling nervous when you are left alone
21)	Feeling that people are unfriendly and dislike you	48)	Others not giving you proper credit for achievements
22)	Feeling inferior to others	49)	Feeling so restless you couldn't sit still
23)	Nausea or upset stomach	50)	Feelings of worthlessness
24)	Feeling that you are watched or talked about by others	51)	Feeling that people will take advantage of you...
25)	Trouble falling asleep	52)	Feelings of guilt
26)	Having to check and double-check what you do	53)	The idea that something is wrong with your mind
27)	Difficulty making decisions		

Source Completed By

Protocol Number: NIDA-CTO-0003

Tolcapone for Cocaine Dependence

Study Day VISITD1

Subject Identification Number: 999

Date: ______ (mm/dd/yyyy)

Form Not Done ☐

CHEMISTRIES

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

Provide comments for any abnormal value(s) ______

Source Completed By (Initials): ______

Protocol Number: NIDA-CTO-0003

Tolcapone for Cocaine Dependence

Subject Identification Number: 0001

Date: (mm/dd/yyyy)

Study Day VISITD3

Form Not Done ☐

COGNITIVE BATTERY SUMMARY SCORE SHEET (CBS)

Am-NART SCORE

Rey O'Complex Figure

Copy Score: Percentile: Intrusions:

30 Min Delay: Percentile: Intrusions:

Wechsler Memory Scale

Faces Recognition I Score: Percentile:

Faces Recognition II Score: Percentile:

Spatial Span

Forward: Backwards:

Total Score: Percentile:

Letter Number Sequencing Total Score: Percentile:

Logical Memory I

Recall Story A: Recall Story B (1st): Recall Story B (2nd):

Total Score: Percentile:

Logical Memory II

Recall Story A: Recall Story B:

Total Score: Percentile:

Rey Auditory Verbal Learning Test

Trial I Score: Percentile:

Trial 2: Trial 3: Trial 4: Trial 5: Trial 5 Percentile:

Trials 1-5 Total: Percentile:

Short Delay Recall: Percentile:

Long Delay Recall: Percentile:

Recognition: False positives: Perseverations: Intrusions:

Trailmaking Test

Trails A: seconds Percentile: Errors:

Trails B: seconds Percentile: Errors:

Color Trails

Trails A: (seconds) Percentile: Errors:

Trails B: (seconds) Percentile: Errors:

Symbol Digit Modalities Test Score: Percentile:

Stroop Test

Word score: Color Score: Color Word Score: Interference:
Percentile: Percentile: Percentile: Percentile:

Verbal Fluency

F: A: S: Total Score: Percentile:

Figural Fluency

Trial 1: Preseverations:
Trial 2: Preseverations:
Trial 3: Preseverations:
Trial 4: Preseverations:
Trial 5: Preseverations:
Total Score: Preseverations: Percentile:

Source Completed By (Initials):

Protocol Number: NIDA-CTO-0003

Tolcapone for Cocaine Dependence

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 of Medication	CAP = capsule	PUF = puff	ONCE = single dose		PO = oral	AUR = auricular
	g = gram	SPY = spray/squirt	QD = once daily		TD = transdermal	IA = intra-articular
	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
				☐		

Protocol Number: NIDA-CTO-0003

Tolcapone for Cocaine Dependence

Subject Identification Number: 0001

Date: (mm/dd/yyyy)

Study Day UNSCHD

Form Not Done ☐

GENERAL CRAVING SCALE (GCS)

When I am experiencing a craving:

	Not at all	Rarely	Sometimes	Usually	Always
1. Sweets like gum or candy will satisfy craving	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐
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	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐

32. Other activities will satisfy my craving	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Source Completed By (Initials):

Protocol Number: NIDA-CTO-0003

Tolcapone for Cocaine Dependence

Subject Identification Number: 0002

Study Day UNSCHD

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): _____

Protocol Number: NIDA-CTO-0003

Tolcapone for Cocaine Dependence

Subject Identification Number: 0002

Date: (mm/dd/yyyy)

Study Day UNSCHD

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
- ☐ Hispanic or Latino
- ☐ African American, Black, not of Hispanic Origin
- ☐ Asian or Pacific Islander
- ☐ American Indian or Alaska native
- ☐ Other, (specify):
- ☐ 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)
- ☐ 2 - Part time (regular hours)
- ☐ 3 - Part time (irregular hours, day work)
- ☐ 4 - Student
- ☐ 5 - Military Service
- ☐ 6 - Retired/Disabled
- ☐ 7 - Homemaker
- ☐ 8 - Unemployed
- ☐ 9 - In controlled environment

3) Usual employment pattern, past 3 years:

- ☐ 1 - Full time (35+ hours/week)
- ☐ 2 - Part time (regular hours)
- ☐ 3 - Part time (irregular hours, day work)
- ☐ 4 - Student
- ☐ 5 - Military Service
- ☐ 6 - Retired/Disabled
- ☐ 7 - Homemaker
- ☐ 8 - Unemployed
- ☐ 9 - In controlled environment

4) Marital Status:

- ☐ 1 - Legally married
- ☐ 2 - Living with partner/cohabitating
- ☐ 3 - Widowed
- ☐ 4 - Separated
- ☐ 5 - Divorced
- ☐ 6 - Never Married

DRUG/ALCOHOL USE

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

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

- ☐ 0 - No problem
- ☐ 1 - Alcohol (any)
- ☐ 2 - Alcohol to intoxication
- ☐ 3 - Heroin
- ☐ 4 - Methadone/LAAM (presc.)
- ☐ 5 - Methadone/LAAM (illicit)
- ☐ 6 - Opiates/analgesics
- ☐ 7 - Barbiturates
- ☐ 8 - Sed./hyp./tranq./benzos.
- ☐ 9 - Cocaine
- ☐ 10- Amph./methamph.
- ☐ 11 - Cannabis
- ☐ 12 - Hallucinogens
- ☐ 13 - Inhalants
- ☐ 14 - Nicotine
- ☐ 15 - Alcohol and Drug addictiion
- ☐ 16 - Polydrug addiction

Source Completed By (Initials): ______

Protocol Number: NIDA-CTO-0003

Tolcapone for Cocaine Dependence

Subject Identification Number: 999

Date: (mm/dd/yyyy)

Study Day SCRNG

Form Not Done ☐

ELECTROCARDIOGRAM 5-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

Protocol Number: NIDA-CTO-0003

Tolcapone for Cocaine Dependence

Subject Identification Number: 999

Date: (mm/dd/yyyy)

Study Day VISITD1

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):

D. PR (ms):

E. QRS (ms):

F. QTc (ms):

Source Completed By

Protocol Number: NIDA-CTO-0003 **Subject Identification Number:** 0001

Tolcapone for Cocaine Dependence

Study Day UNSCHD

END OF TRIAL

1) Date of Last visit? (mm/dd/yyyy

2) Was the subject terminated early from the trial ☐ 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 signific 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):

Protocol Number: NIDA-CTO-0003

Tolcapone for Cocaine Dependence

Subject Identification Number: 0002

Study Day UNSCHD

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): _____

Protocol Number: NIDA-CTO-0003

Tolcapone for Cocaine Dependence

Subject Identification Number: 0001

Date: (mm/dd/yyyy)

Study Day UNSCHD

EXCLUSION CRITERIA

Participant must not:

1.	Have any history or evidence suggestive of seizures or brain injury.	☐ Yes ☐ No
2.	Have any previous medically adverse reaction to cocaine, including loss of consciousness, chest pain or seizure.	☐ Yes ☐ No
3.	According to DSM-IV criteria as determined by structured clinical interview (SCID), have any history of major psychiatric illness other than drug dependence or disorders secondary to drug use.	☐ Yes ☐ No
4.	Have any evidence of untreated clinically significant heart disease or hypertension.	☐ Yes ☐ No
5.	Have any evidence of untreated or unstable medical illness (including untreated thyroid disease, autoimmune disease, unstable asthma, tuberculosis, etc.).	☐ Yes ☐ No
6.	If female be pregnant or nursing. [Females must have a negative pregnancy test (blood or urine) at or before study entry. Females must either be unable to conceive (i.e. surgically sterilized, sterile or post menopausal) or be using a reliable form of contraception (e.g. abstinence, birth control pills, intrauterine device, norplant, condoms, or spermicide). A second pregnancy test will be performed one to two weeks after study participation to determine whether pregnancy occurred during study.]	☐ Yes ☐ No
7.	Have a significant family history of early cardiovascular morbidity or mortality.	☐ Yes ☐ No
8.	Have any history of asthma, coughing and wheezing, or other respiratory illnesses.	☐ Yes ☐ No
9.	Currently use albuterol or other beta agonist medications.	☐ Yes ☐ No
10.	Have any illness, condition, and use of medications, in the opinion of the principal investigator and the admitting physician, which would preclude safe safe and/or successful completion of the study.	☐ Yes ☐ No

Note: All answers to EXCLUSION CRITERIA must be NO.

Source Completed By (Initials): _____

Protocol Number: NIDA-CTO-0003

Tolcapone for Cocaine Dependence

Subject Identification Number: 0028

Date: (mm/dd/yyyy)

Study Day VISITD19

Form Not Done ☐

FOLLOW-UP COGNITIVE BATTERY SCORE SHEET

srt1:

mean reaction time

median reaction time

crt:

mean reaction time

median reaction time

1-back:

median reaction time

% accuracy

2-back:

median reaction time

% accuracy

srt2:

mean reaction time

median reaction time

Source Completed By (Initials):

Protocol Number: NIDA-CTO-0003

Tolcapone for Cocaine Dependence

Subject Identification Number: 0001

Date: (mm/dd/yyyy)

Study Day UNSCHD

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):

Protocol Number: NIDA-CTO-0003

Tolcapone for Cocaine Dependence

Subject Identification Number: 999

Date: (mm/dd/yyyy)

Study Day VISITD1

Form Not Done ☐

HEMATOLOGY

_____ _____	Std. Quantity	Standard Unit	Other Unit	Normal	Abnormal	Abnormal Significant	Not Done
Hemaglobin				☐	☐	☐	☐
				☐	☐	☐	☐
				☐	☐	☐	☐
				☐	☐	☐	☐
				☐	☐	☐	☐
				☐	☐	☐	☐
				☐	☐	☐	☐
				☐	☐	☐	☐
				☐	☐	☐	☐
				☐	☐	☐	☐
				☐	☐	☐	☐
				☐	☐	☐	☐

Provide comments for any abnormal value(s)

Source Completed By (Initials):

Protocol Number: NIDA-CTO-0003

Tolcapone for Cocaine Dependence

Subject Identification Number: 0001

Date: (mm/dd/yyyy)

Study Day UNSCHD

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

Protocol Number: NIDA-CTO-0003

Tolcapone for Cocaine Dependence

Subject Identification Number: 0001

Date: (mm/dd/yyyy)

Study Day UNSCHD

INCLUSION CRITERIA

Participant must:

1.	Be volunteers who are dependent on cocaine and are non-treatment seeking at time of study.	☐ Yes ☐ No
2.	Be between 18 - 45 years of age.	☐ Yes ☐ No
3.	Meet DSM-IV criteria for cocaine abuse or dependence.	☐ Yes ☐ No
4.	Use cocaine by the smoked or I.V. route on average at least twice per week for at least 4 of the past 6 weeks, as assessed by self report and a positive benzoylecognine (BE) urine test within 2 weeks of entering the study.	☐ Yes ☐ No
5.	Have a history and brief physical examination that demonstrates no clinically significant contraindication for participating in the study, in the judgement of the admitting physician and the principal investigator.	☐ Yes ☐ No
6.	Have vital signs as follows: resting pulse between 50 and 90 bpm, BP below 150 mm/Hg systolic and 90 mm/Hg diastolic.	☐ Yes ☐ No
7.	Have electrolytes (Na, K, Cl, HCO3) and hematocrit that is clinically normal (+/-10% of laboratory limits).	☐ Yes ☐ No
8.	Have liver function tests (total bilirubin, ALT, AST, and alkaline phosphatase) within normal limits.	☐ Yes ☐ No
9.	Have kidney function tests (creatinine and BUN) less than twice the upper limit of normal.	☐ Yes ☐ No
10.	Have an EKG performed that demonstrates normal sinus rhythm, normal conduction, and no clinically significant arrhythmias.	☐ Yes ☐ No

Note: All answers to INCLUSION CRITERIA must be YES.

Source Completed By (Initials): _____

Protocol Number: NIDA-CTO-0003

Tolcapone for Cocaine Dependence

Subject Identification Number: 0001

Date: (mm/dd/yyyy)

Study Day UNSCHD

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)

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):

Protocol Number: NIDA-CTO-0003

Tolcapone for Cocaine Dependence

Study Day UNSCHD

Form Not Done ☐

Subject Identification Number: 0002

Date: (mm/dd/yyyy)

INFUSION MONITORING 20mg. Cocaine/Placebo: Infusion #1

Infusion Start Time: (00:00 - 23:59)

Infusion Stop Time: (00:00 - 23:59)

Infusion Administered By: (Initials)

Time Interval	Actual Time	Blood Pressure (sys)	(dias)	Heart Rate (beats/min)	Comments	Init.
-15 min						

Protocol Number: NIDA-CTO-0003

Tolcapone for Cocaine Dependence

Study Day UNSCHD

Form Not Done ☐

Subject Identification Number: 0002

Date: (mm/dd/yyyy)

INFUSION MONITORING 20mg. Cocaine/Placebo: Infusion #2

Infusion Start Time: (00:00 - 23:59)

Infusion Stop Time: (00:00 - 23:59)

Infusion Administered By: (Initials)

Time Interval	Actual Time	Blood Pressure (sys)	(dias)	Heart Rate (beats/min)	Comments	Init.
62 min						

Protocol Number: NIDA-CTO-0003

Tolcapone for Cocaine Dependence

Study Day UNSCHD

Subject Identification Number: 0001

Date: ______ (mm/dd/yyyy)

Form Not Done ☐

INFUSION MONITORING 40mg. Cocaine/Placebo: Infusion #1

Infusion Start Time: ______ (00:00 - 23:59)

Infusion Stop Time: ______ (00:00 - 23:59)

Infusion Administered By: ______ (Initials)

Time Interval	Actual Time	Blood Pressure (sys)	(dias)	Heart Rate (beats/min)	Comments	Init.
-15 min						

Protocol Number: NIDA-CTO-0003

Tolcapone for Cocaine Dependence

Study Day UNSCHD

Form Not Done ☐

Subject Identification Number: 0002

Date: ____ (mm/dd/yyyy)

INFUSION MONITORING 40mg. Cocaine/Placebo: Infusion #2

Infusion Start Time: ____ (00:00 - 23:59)

Infusion Stop Time: ____ (00:00 - 23:59)

Infusion Administered By: ____ (Initials)

Time Interval	Actual Time	Blood Pressure (sys)	(dias)	Heart Rate (beats/min)	Comments	Init.
62 min						

Protocol Number: NIDA-CTO-0003

Tolcapone for Cocaine Dependence

Subject Identification Number: 0001

Study Day VISITD6

Form Not Done ☐

INVESTIGATIONAL AGENT ADMINISTRATION

Line No.	Day of Week	Date	No. of Tablets Administered	Time Administered	Administered By

Source Completed By (Initials):

Protocol Number: NIDA-CTO-0003

Tolcapone for Cocaine Dependence

Subject Identification Number: 0001

Date: (mm/dd/yyyy)

Study Day VISITD8

Form Not Done ☐

LAB TEST TRACKING FORM (DAY 8)

	☐		
	☐		
	☐		
	☐		
	☐		
	☐		
	☐		
	☐		
	☐		

Source Completed By (Initials):

Protocol Number: NIDA-CTO-0003

Tolcapone for Cocaine Dependence

Subject Identification Number: 0001

Date: (mm/dd/yyyy)

Study Day VISITD13

Form Not Done ☐

LAB TEST TRACKING FORM (DAY 13)

	Tolcapone Assay	Tolcapone Time	COMT Assay	COMT Time
	☐		☐	
	☐		☐	
	☐		☐	

Source Completed By (Initials):

Protocol Number: NIDA-CTO-0003

Tolcapone for Cocaine Dependence

Subject Identification Number: 0001

Date: (mm/dd/yyyy)

Study Day VISITD14

Form Not Done ☐

LAB TEST TRACKING FORM (DAY 14)

Time of Infusion	Cocaine Assay	Cocaine Time	Tolcapone Assay	Tolcapone Time	COMT Assay	COMT Time
	☐		☐		☐	
	☐		☐		☐	
	☐		☐		☐	
	☐		☐		☐	
	☐		☐		☐	
	☐		☐		☐	
	☐		☐		☐	
	☐		☐		☐	
	☐		☐		☐	
	☐		☐		☐	

Source Completed By (Initials):

Protocol Number: NIDA-CTO-0003

Tolcapone for Cocaine Dependence

Subject Identification Number: 0001

Date: (mm/dd/yyyy)

Study Day VISITD20

Form Not Done ☐

LAB TEST TRACKING FORM (DAY 20)

Time of Infusion	Tolcapone Assay	Tolcapone Time	COMT Assay	COMT Time
	☐		☐	
	☐		☐	
	☐		☐	

Source Completed By (Initials):

Protocol Number: NIDA-CTO-0003

Tolcapone for Cocaine Dependence

Subject Identification Number: 0001

Date: (mm/dd/yyyy)

Study Day VISITD21

Form Not Done ☐

LAB TEST TRACKING FORM (DAY 21)

Time of Infusion	Cocaine Assay	Cocaine Time	Tolcapone Assay	Tolcapone Time	COMT Assay	COMT Time
	☐		☐		☐	
	☐		☐		☐	
	☐		☐		☐	
	☐		☐		☐	
	☐		☐		☐	
	☐		☐		☐	
	☐		☐		☐	
	☐		☐		☐	
	☐		☐		☐	
	☐		☐		☐	

Source Completed By (Initials):

Protocol Number: NIDA-CTO-0003

Tolcapone for Cocaine Dependence

Subject Identification Number: 0001

Date: (mm/dd/yyyy)

Study Day VISITD14

Form Not Done ☐

LIVER FUNCTION TESTS

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

Provide comments for any abnormal value(s)

Source Completed By (Initials):

Protocol Number: NIDA-CTO-0003

Tolcapone for Cocaine Dependence

Subject Identification Number: 0001

Date: (mm/dd/yyyy)

Study Day VISITD11

Form Not Done ☐

MULTIPLE CHOICE QUESTIONNAIRE

Time Administered (00:00-23:59)

Number at which subject switched

Monetary value of number switched at

What did subject switch to? ◉ Money ◉ Drug

Source Completed By (Initials):

Protocol Number: NIDA-CTO-0003

Tolcapone for Cocaine Dependence

Subject Identification Number: 0001

Date: (mm/dd/yyyy)

Study Day UNSCHD

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):

Protocol Number: NIDA-CTO-0003

Tolcapone for Cocaine Dependence

Subject Identification Number: 0001

Date: (mm/dd/yyyy)

Study Day VISITD11

Form Not Done ☐

MODIFIED WITHIN SESSION RATING SCALE (MWSRS)

Time (24 hr)

(00:00-23:59)

(1) How much do you desire or feel like using methamphetamine/cocaine right now?

0 10 20 30 40 50 60 70 80 90 100

Not at all **Extremely**

(2) If you had access to methamphetamine/cocaine right now, how likely would you be to use it?

0 10 20 30 40 50 60 70 80 90 100

Not at all **Extremely**

(3) I feel disgusted by the video and paraphernalia.

0 10 20 30 40 50 60 70 80 90 100

Not at all **Extremely**

(4) Please rate the effect of the medication you have taken today

In the past ten minutes, have you felt:

	Not at all 0 10 20 30 40 50 60 70 80 90 100 Extremely
Any drug effect?	
A rush?	
Good effects?	
Bad effects?	
Did you like the drugs?	

Source Completed By (Initials):

Protocol Number: NIDA-CTO-0003

Tolcapone for Cocaine Dependence

Subject Identification Number: 999

Date: (mm/dd/yyyy)

Study Day VISITD1 **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-0003	Subject Identification Number: 999
Tolcapone for Cocaine Dependence	Date: ________ (mm/dd/yyyy)
Study Day VISITD1	Form Not Done ☐

PROFILE OF MOOD STATUS (POMS)

How have you been feeling during the past week including today?

FEELINGS	Not at all	A Little Bit	Moderately	Quite a bit	Extremely
1. Friendly	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐
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	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐

31. Annoyed	0	1	2	3	4

Source Completed By (Initials):

Protocol Number: NIDA-CTO-0003

Tolcapone for Cocaine Dependence

Subject Identification Number: 999

Date: (mm/dd/yyyy)

Study Day SCRNG

Form Not Done ☐

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):

Protocol Number: NIDA-CTO-0003

Tolcapone for Cocaine Dependence

Subject Identification Number: 0001

Study Day SCRNG

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 of Medication	CAP	= capsule	PUF	= puff	ONCE	= single dose	PO	= oral	AUR	= auricular
	g	= gram	SPY	= spray/squirt	QD	= once daily	TD	= transdermal	IA	= intra-articular
	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
				☐		

Protocol Number: NIDA-CTO-0003

Tolcapone for Cocaine Dependence

Subject Identification Number: 0001

Study Day STDYWD

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
☐ Hispanic or Latino
☐ African American, Black, not of Hispanic Origin
☐ Asian or Pacific Islander
☐ American Indian or Alaska native
☐ Other, (specify):
☐ 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

☐ none
☐ discontinued permanently
☐ discontinued temporarily
☐ reduced dose
☐ increased dose
☐ delayed dose

Other action(s) taken

☐ none
☐ remedial therapy - pharmacologic
☐ remedial therapy - nonpharmacologic
☐ hospitalization (new or prolonged)

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

☐ death
☐ life-threatening event
☐ hospitalization
☐ disability
☐ congenital anomaly
☐ 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 (mm/dd/yyyy) **Stop date** (mm/dd/yyyy) or ☐ continuing

Route of administration

- ☐ auricular
- ☐ inhaled
- ☐ intra-articular
- ☐ intramuscular
- ☐ intraocular
- ☐ intravenous
- ☐ nasal
- ☐ oral
- ☐ rectal
- ☐ subcutaneous
- ☐ sublingual
- ☐ transdermal
- ☐ vaginal
- ☐ unknown
- ☐ other (specify)

Frequency

- ☐ single dose
- ☐ once daily
- ☐ every other day
- ☐ twice daily
- ☐ three times a day
- ☐ four times a day
- ☐ as needed
- ☐ other (specify)

Comments

Source Completed by:

Protocol Number: NIDA-CTO-0003

Tolcapone for Cocaine Dependence

Subject Identification Number: 0001

Date: (mm/dd/yyyy)

Study Day VISITD1

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):

Protocol Number: NIDA-CTO-0003

Tolcapone for Cocaine Dependence

Subject Identification Number: 0009

Date: (mm/dd/yyyy)

Study Day VISITD19

Form Not Done ☐

COGNITIVE BATTERY SUBSET SCORE SHEET

Spatial Span

Forward: Backwards:

Total Score: Percentile:

Letter Number Sequencing Total Score: Percentile:

Rey Auditory Verbal Learning Test

Trial I Score: Percentile:

Trial 2: Trial 3: Trial 4: Trial 5: Trial 5 Percentile:

Trials 1-5 Total: Percentile:

Short Delay Recall: Percentile:

Long Delay Recall: Percentile:

Recognition: False positives: Perseverations: Intrusions:

Trailmaking Test

Trails A: seconds Percentile: Errors:

Trails B: seconds Percentile: Errors:

Symbol Digit Modalities Test Score: Percentile:

Stroop Test

Word score: Color Score: Color Word Score: Interference:

Percentile: Percentile: Percentile: Percentile:

Verbal Fluency

F: A: S: Total Score: Percentile:

Figural Fluency

Trial 1: Preseverations:

Trial 2: Preseverations:

Trial 3: Preseverations:

Trial 4: Preseverations:

Trial 5: Preseverations:

Total Score: Preseverations: Percentile:

Source Completed By (Initials):

Protocol Number: NIDA-CTO-0003

Tolcapone for Cocaine Dependence

Subject Identification Number: 0001

Date: (mm/dd/yyyy)

Study Day UNSCHD **Form Not Done** ☐

SUBSTANCE USE INVENTORY ADDENDUM (SUI)

Indicate how much of each drug you have used IN THE PAST (DAYS) and how often that use occurred. If you did not use the drug, check "Did not use" and proceed to the next drug.

1) How often have you used methamphetamine in the past ____ days? ____
   Indicate the DAILY average amount used IN THE PAST DAYS. $ ____ (Dollar amount that the drug was WORTH)
   If known, what was the total weight (GRAMS) of that quantity? ____

2) How often have you used alcohol in the past ____ days? ____
   Indicate the DAILY average amount used IN THE PAST DAYS. ____ (Number of drinks)

3) How often have you used marijuana in the past ____ days? ____
   Indicate the DAILY average amount used IN THE PAST DAYS. ____ (Number of joints)

4) How often have you used cocaine in the past ____ days? ____
   Indicate the DAILY average amount used IN THE PAST DAYS. $ ____ (Dollar amount that the drug was WORTH)
   If known, what was the total weight (GRAMS) of that quantity? ____

5) How often have you used heroin in the past ____ days? ____
   Indicate the DAILY average amount used IN THE PAST DAYS. $ ____ (Dollar amount that the drug was WORTH)
   If known, what was the total weight (GRAMS) of that quantity? ____

6) How often have you used tran/sed/hyp/barbiturates in the past ____ days? ____
   Indicate the DAILY average amount used IN THE PAST DAYS. ____ (Number of pills)
   If known, what was the total weight (GRAMS) of that quantity? ____

7) How often have you PCP or other hallucinogens in the past ____ days? ____
   Indicate the DAILY average amount used IN THE PAST DAYS. $ ____ (Dollar amount that the drug was WORTH)
   If known, what was the total weight (GRAMS) of that quantity? ____

8) How often have you used other drugs in the past ____ days? ____
   Indicate the DAILY average amount used IN THE PAST DAYS. $ ____ (Dollar amount that the drug was WORTH)
   If known, what was the total weight (GRAMS) of that quantity? ____

Source Completed By (Initials): ____

Protocol Number: NIDA-CTO-0003

Tolcapone for Cocaine Dependence

Study Day SCRNG

Subject Identification Number: 0001

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)

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

Source Completed By (Initials):

Protocol Number: NIDA-CTO-0003

Tolcapone for Cocaine Dependence

Study Day VISITD12

Subject Identification Number: 0001

Date: (mm/dd/yyyy)

Form Not Done ☐

VISUAL ANALOG SCALE

20mg. Cocaine/Placebo **Infusion #** 1

Time Interval	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?

Time Interval	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?

Time Interval	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?

Time Interval	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?

Time Interval	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?

Time Interval	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?
Time Interval	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?
Time Interval	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?
Time Interval	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?
Time Interval	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?

Source Completed By (Initials):

Protocol Number: NIDA-CTO-0003

Tolcapone for Cocaine Dependence

Study Day VISITD12

Form Not Done ☐

Subject Identification Number: 0001

Date: ______ (mm/dd/yyyy)

VISUAL ANALOG SCALE

20mg. Cocaine/Placebo **Infusion #** **2**

Time Interval						
	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?

Time Interval						
	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?

Time Interval						
	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?

Time Interval						
	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?

Time Interval						
	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?

Time Interval	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?
Time Interval	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?
Time Interval	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?

Source Completed By (Initials):

Protocol Number: NIDA-CTO-0003

Tolcapone for Cocaine Dependence

Study Day VISITD5

Subject Identification Number: 0001

Date: (mm/dd/yyyy)

Form Not Done ☐

VISUAL ANALOG SCALE

40mg. Cocaine/Placebo **Infusion #** **1**

Time Interval	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?
Time Interval	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?
Time Interval	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?
Time Interval	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?
Time Interval	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?

Time Interval	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?
Time Interval	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?
Time Interval	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?
Time Interval	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?
Time Interval	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?

Source Completed By (Initials):

Protocol Number: NIDA-CTO-0003

Tolcapone for Cocaine Dependence

Subject Identification Number: 0001

Date: ________ (mm/dd/yyyy)

Study Day VISITD5

Form Not Done ☐

VISUAL ANALOG SCALE

40mg. Cocaine/Placebo **Infusion #** **2**

Time Interval						
Time Interval	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?
Time Interval	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?
Time Interval	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?
Time Interval	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?
Time Interval	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?

Time Interval	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?

Time Interval	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?

Time Interval	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?

Source Completed By (Initials):

Protocol Number: NIDA-CTO-0003

Tolcapone for Cocaine Dependence

Subject Identification Number: 0004

Date: (mm/dd/yyyy)

Study Day UNSCHD

Form Not Done ☐

VITAL SIGNS (Screening)

Time: (00:00-23:59)

Pulse Rate: beats/min

Blood Pressure: /
(sys) (dias)

Source Completed By (Initials):

(VITALSCR v1)

Protocol Number: NIDA-CTO-0003

Tolcapone for Cocaine Dependence

Subject Identification Number: 999

Date: (mm/dd/yyyy)

Study Day VISITD4

Form Not Done ☐

VITAL SIGNS POST INFUSION

Post Infusion	Actual Time	Temp F or C	Resp. Rate	Pulse Rate	Blood Pressure (systolic) / (diastolic)	Comp.By: (Initials)
		☐ ☐			/	
		☐ ☐			/	

Protocol Number: NIDA-CTO-0003

Tolcapone for Cocaine Dependence

Subject Identification Number: 999

Date: (mm/dd/yyyy)

Study Day SCRNG

Form Not Done ☐

VITAL SIGNS

Time: (00:00-23:59)

Weight: ☐ pounds ☐ kilograms

Temp: ☐ F ☐ C

POSITION	Resp. Rate	Pulse Rate	Blood Pressure (systolic) / (diastolic)
			/
			/
			/

Source Completed By (Initials):

Protocol Number: NIDA-CTO-0003

Tolcapone for Cocaine Dependence

Study Day SCRNG

Subject Identification Number: 0001

Date: ____ (mm/dd/yyyy)

Form Not Done ☐

WENDER UTAH RATING SCALE (WURS)

Please check the square that best describes your answer.

As a child I:	Not at all	Mildly	Moderately	Quite a bit	Very Much
1. Was active, restless, always on the go	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐
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	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐

24. Acted without thinking, was impulsive	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐
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	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐

55. In school I had problems with spelling	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐

Repeated Grades (Question #60 specify)

Was suspended or expelled/which grades (Question #61 specify)

Source Completed By (Initials):

Protocol Number: NIDA-CTO-0003

Tolcapone for Cocaine Dependence

Subject Identification Number: 0001

Date: (mm/dd/yyyy)

Study Day VISITD11

Form Not Done ☐

WITHIN SESSION RATING SCALE (WSRS)

Time (24 hr)

(00:00-23:59)

(1) How much do you desire or feel like using methamphetamine/cocaine right now?

0 10 20 30 40 50 60 70 80 90 100

Not at all **Extremely**

(2) If you had access to methamphetamine/cocaine right now, how likely would you be to use it?

0 10 20 30 40 50 60 70 80 90 100

Not at all **Extremely**

Source Completed By (Initials):