Protocol Number: NIDA-CTO-0007	**Subject Identification Number:** 0103
Cabergoline for Cocaine Dependence	**Date:** (mm/dd/yyyy)
Study Day SCRNBASE	**Form Not Done** ☐

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
		◯ ◯		◯ ◯	◯ ◯
		◯ ◯		◯ ◯	◯ ◯
		◯ ◯		◯ ◯	◯ ◯
		◯ ◯		◯ ◯	◯ ◯
		◯ ◯		◯ ◯	◯ ◯
		◯ ◯		◯ ◯	◯ ◯
		◯ ◯		◯ ◯	◯ ◯
		◯ ◯		◯ ◯	◯ ◯
		◯ ◯		◯ ◯	◯ ◯
		◯ ◯		◯ ◯	◯ ◯
		◯ ◯		◯ ◯	◯ ◯
		◯ ◯		◯ ◯	◯ Yes ◯ No

9. Tend to be forgetful in daily activities	..as a child? ..currently?	Yes / No Yes / No		Yes / No 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):

Protocol Number: NIDA-CTO-0007

Cabergoline for Cocaine Dependence

Subject Identification Number: 0001

Study Day STDYWD

ADVERSE EVENTS

Has the subject had any Adverse Experiences during this study? ☐ Ye ☐ No *If yes, please list all Adverse Experiences below:*

Severity	Study Drug Relationship	Action Taken Regarding Investigational Agent	Other Action Taken	Outcome of AE	Serious
1 = Mild 2 = Moderate 3 = Severe	1 = Definitely 2 = Probably 3 = Possibly 4 = Remotely 5 = Definitely Not 6 = Unknown	1 = None 2 = Discontinued Perm. 3 = Discontinued Temp. 4 = Reduced Dose 5 = Increased Dose 6 = Delayed Dose	1 = None 2 = Remedial Therapy-pharm 3 = Remedial Therapy-nonpharm 4 = Hospitalization	1 = Resolved, No 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
1		(mm/dd/yyyy)	(mm/dd/yyyy)						☐ Ye ☐ No	
2		(mm/dd/yyyy)	(mm/dd/yyyy)						☐ Ye ☐ No	
3		(mm/dd/yyyy)	(mm/dd/yyyy)						☐ Ye ☐ No	
4		(mm/dd/yyyy)	(mm/dd/yyyy)						☐ Ye ☐ No	

Protocol Number: NIDA-CTO-0007

Cabergoline for Cocaine Dependence

Subject Identification Number: 0002

Date: (mm/dd/yyyy)

Study Day SCRNBASE

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 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):

Protocol Number: NIDA-CTO-0007

Cabergoline for Cocaine Dependence

Subject Identification Number: 0103

Date: (mm/dd/yyyy)

Study Day SCRNBASE

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-0007

Cabergoline for Cocaine Dependence

Subject Identification Number: 0001

Date: (mm/dd/yyyy)

Study Day SCRNBASE **Form Not Done** ☐

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):

Protocol Number: NIDA-CTO-0007

Cabergoline for Cocaine Dependence

Subject Identification Number: 0001

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 during the past week?

- ◎ 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):

Protocol Number: NIDA-CTO-0007

Cabergoline for Cocaine Dependence

Subject Identification Number: 0001

Date: (mm/dd/yyyy)

Study Day SCRNBASE

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-0007	**Subject Identification Number:** 0001
Cabergoline for Cocaine Dependence	**Date:** ____ (mm/dd/yyyy)
Study Day SCRNBASE	**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
	◯	◯	◯	◯	◯	◯	◯
	◯	◯	◯	◯	◯	◯	◯
	◯	◯	◯	◯	◯	◯	◯
	◯	◯	◯	◯	◯	◯	◯
	◯	◯	◯	◯	◯	◯	◯
	◯	◯	◯	◯	◯	◯	◯
	◯	◯	◯	◯	◯	◯	◯
	◯	◯	◯	◯	◯	◯	◯
	◯	◯	◯	◯	◯	◯	◯
	◯	◯	◯	◯	◯	◯	◯
	◯	◯	◯	◯	◯	◯	◯
	◯	◯	◯	◯	◯	◯	◯
	◯	◯	◯	◯	◯	◯	◯
	◯	◯	◯	◯	◯	◯	◯
	◯	◯	◯	◯	◯	◯	◯
	◯	◯	◯	◯	◯	◯	◯
	◯	◯	◯	◯	◯	◯	◯
	◯	◯	◯	◯	◯	◯	◯
	◯	◯	◯	◯	◯	◯	◯
	◯	◯	◯	◯	◯	◯	◯
	◯	◯	◯	◯	◯	◯	◯
	◯	◯	◯	◯	◯	◯	◯
	◯	◯	◯	◯	◯	◯	◯

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

Source Completed By (Initials): _____

Protocol Number: NIDA-CTO-0007

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

Provide comments for any abnormal value(s) ______

Source Completed By (Initials): ______

Protocol Number: NIDA-CTO-0007

Cabergoline for Cocaine Dependence

Subject Identification Number: 0001

Date: (mm/dd/yyyy)

Study Day SCRNBASE

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):

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Cabergoline for Cocaine Dependence

Subject Identification Number: 0001

Study Day STDYWD

CONCOMITANT MEDICATIONS

Has the subject taken any Concomitant Medications during this study? ☐ Ye ☐ 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
				☐		

No.	Medication	Dose	Unit	Other (specify)	Frequency	Other (specify)
2						

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

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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

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DEATH REPORT

Subject Date of Death (mm/dd/yyyy)

Was autopsy performed? ☐ Ye ☐ No ☐ Unknown

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

Is cause of death known? ☐ Ye ☐ 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):

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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
  - ☐ Puerto Rican
  - ☐ Cuban
  - ☐ Other (specify)
- ☐ Yes ☐ No Asian (mark all that apply)
  - ☐ Asian Indian
  - ☐ Chinese
  - ☐ Filipino
  - ☐ Japanese
  - ☐ Korean
  - ☐ Vietnamese
  - ☐ Other (specify)
- ☐ Yes ☐ No Native Hawaiian or Pacific Islander (mark all that apply)
  - ☐ Native Hawaiian
  - ☐ Guamanian or Chamorro
  - ☐ Samoan
  - ☐ 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

SUBSTANCE	Days in Past 30 Days	Lifetime Years	ROUTE OF ADMINISTRATION oral	nasal	smoking	injection	N/A
Alcohol (any use at all)			☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐

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 - Cannibis
- ☐ 12 - Hallucinogens
- ☐ 13 - Inhalants
- ☐ 14 - Nicotine
- ☐ 15 - Alcohol and Drug addictiion
- ☐ 16 - Polydrug addiction

Source Completed By (Initials): ____

Protocol Number: NIDA-CTO-0007

Cabergoline for Cocaine Dependence

Subject Identification Number: 0001

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
1) Increased QRS Voltage	☐	☐
2) QTc Prolongation	☐	☐
3) Left Atrial Hypertrophy	☐	☐
4) Right Atrial Hypertrophy	☐	☐
5) Left Ventricular Hypertrophy	☐	☐
6) Right Ventricular Hypertrophy	☐	☐
7) Acute Infarction	☐	☐
8) Subacute Infarction	☐	☐
9) Old Infarction	☐	☐
10) Myocardial Ischemia	☐	☐
11) Digitalis Effect	☐	☐
12) Symmetrical T-Wave Inversions	☐	☐
13) Poor R-Wave Progression	☐	☐
14) Other Nonspecific ST/T	☐	☐
15) Sinus Tachycardia	☐	☐
16) Sinus Bradycardia	☐	☐

	Abnormal	Abnormal Significant
17) Supraventricular Premature Beat	☐	☐
18) Ventricular Premature Beat	☐	☐
19) Supraventricular Tachycardia	☐	☐
20) Ventricular Tachycardia	☐	☐
21) Atrial Fibrillation	☐	☐
22) Atrial Flutter	☐	☐
23) Other Rhythm Abnormalities	☐	☐
24) Implanted Pacemaker	☐	☐
25) 1st Degree A-V Block	☐	☐
26) 2nd Degree A-V Block	☐	☐
27) 3rd Degree A-V Block	☐	☐
28) LBB Block	☐	☐
29) RBB Block	☐	☐
30) Pre-excitation Syndrome	☐	☐
31) Other Intraventricular Condition Block	☐	☐
32) Other (specify	☐	☐

C. Ventricular rate (bpm):

D. PR (ms):

E. QRS (ms):

F. QTc (ms):

Source Completed By (Initials)

ECG v1

Protocol Number: NIDA-CTO-0007 **Subject Identification Number:** 0001

Cabergoline for Cocaine Dependence

Study Day SCRNBASE

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 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):

Protocol Number: NIDA-CTO-0007

Cabergoline for Cocaine Dependence

Subject Identification Number: 0100

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-0007	**Subject Identification Number:** 0103
Cabergoline for Cocaine Dependence	**Date:** (mm/dd/yyyy)
Study Day SCRNBASE	

EXCLUSION CRITERIA

Potential subjects must not:

1.	Have current dependence, defined by DSM-IV criteria, on any psychoactive substance other than cocaine, alcohol, nicotine, or marijuana or physiological dependence on alcohol requiring medical detoxification.	☐ Yes ☐ No
2.	Have neurological or psychiatric disorders such as: psychosis; bipolar illness; major depression as assessed by SCID; organic brain disease; dementia; 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.	☐ 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); 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 because probable incarceration or relocation from the clinic area.	☐ Yes ☐ No
6.	Have AIDS (see note in protocol).	☐ Yes ☐ No
7.	Have active syphilis that has not been treated or refuse 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 Cabergoline.	☐ Yes ☐ No
10.	Be taking Cabergoline 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 received medications that could interact adversely with Cabergoline, with the time of administration of study agent and other medications based on the longest time interval or A, B, C below: 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 that fall into this category include D2-aonists, such as: phenothiazines; butyrophenones; thioxanthines; and metoclopramide.	☐ Yes ☐ No
13.	Have participated in any experimental study within 4 weeks, or must not have ever participated on a clinical trial utilizing Cabergoline.	☐ Yes ☐ No
14.	Be pregnant or lactating.	☐ Yes ☐ No
15.	Have any clinically significant abnormal laboratory value. (See Protocol Appendix II)	☐ Yes ☐ No
16.	Have had electroconvulsive therapy within the 3 months preceding screening.	☐ Yes ☐ No
17.	Have had any opiate-substitutes (methadone, LAAM, buprenorphine) within two months preceding screening.	☐ Yes ☐ No

18.	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
19.	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
20.	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 (an FEV1 <70% will exclude a subject from participation).	☐ Yes ☐ No
21.	Female using Norplant for birth control with date of Norplant insertion after October 20, 1999 and unable to provide information to document that the Norplant product was not drawn from the lot numbers of failed products.	☐ Yes ☐ No

All answers to Exclusion Criteria must be answered NO.

Source Completed By (Initials): _____

Protocol Number: NIDA-CTO-0007

Cabergoline for Cocaine Dependence

Subject Identification Number: 0001

Date: (mm/dd/yyyy)

Study Day SCRNBASE

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? ◯ Ye ◯ 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-0007

Cabergoline for Cocaine Dependence

Subject Identification Number: 0001

Date: (mm/dd/yyyy)

Study Day SCRNBASE

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

Protocol Number: NIDA-CTO-0007

Cabergoline for Cocaine Dependence

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-0007

Cabergoline for Cocaine Dependence

Subject Identification Number: 0001

Date: (mm/dd/yyyy)

Study Day SCRNBASE

Form Not Done ☐

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? ◯ Ye ◯ No ◯ Unknow

Sex Score

Source Completed By (Initials):

HRBS Score

Protocol Number: NIDA-CTO-0007

Cabergoline for Cocaine Dependence

Subject Identification Number: 0103

Date: (mm/dd/yyyy)

Study Day SCRNBASE

INCLUSION CRITERIA

Potential subjects must:

1.	Be at least 18 years of age.	☐ Yes ☐ No
2.	Have a DSM-IV diagnosis of cocaine dependence as determined by the 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.	☐ Yes ☐ No

All answers to Inclusion Criteria must be answered YES

Source Completed By (Initials):

Protocol Number: NIDA-CTO-0007

Cabergoline for Cocaine Dependence

Subject Identification Number: 0001

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.

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-0007

Cabergoline for Cocaine Dependence

Subject Identification Number: 0103

Study Day SCRNBASE

Form Not Done ☐

LAB TEST TRACKING FORM

Date: _____
(mm/dd/yyyy)

Tests:

☐ Urine Toxicology Screen

☐ Serum Prolactin

Source Completed By (Initials): _____

Protocol Number: NIDA-CTO-0007

Cabergoline for Cocaine Dependence

Subject Identification Number: 0103

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-0007

Cabergoline for Cocaine Dependence

Subject Identification Number: 0001

Date: (mm/dd/yyyy)

Study Day SCRNBASE

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-0007

Cabergoline for Cocaine Dependence

Subject Identification Number: 0001

Date: (mm/dd/yyyy)

Study Day SCRNBASE

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-0007

Cabergoline for Cocaine Dependence

Subject Identification Number: 0100

Study Day UNSCHD

PRIOR MEDICATIONS

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

Dose	Unit of Medication				Frequency		Route of Administration			
Strength 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
				☐		

PRIORMED v1

Protocol Number: NIDA-CTO-0007

Cabergoline for Cocaine Dependence

Subject Identification Number: 0001

Study Day SCRNBASE

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-0007

Cabergoline for Cocaine Dependence

Subject Identification Number: 0103

Date: (mm/dd/yyyy)

Study Day SCRNBASE

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-0007

Cabergoline for Cocaine Dependence

Site Identification Number: 980208

Subject Identification Number: 0101

Study Day SCRNBASE

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)	Result: Positive	Result: Negative	Result: Not Reported	This Specimen is the first urine of this week and has been flagged for urine toxicology testing in addition to BE. Please check if applicable
01/08/2003	☐ Yes ☐ No ☐ Unknown	☐	☐	☐	☐
01/09/2003	☐ Yes ☐ No ☐ Unknown	☐	☐	☐	☐
01/10/2003	☐ Yes ☐ No ☐ Unknown	☐	☐	☐	☐

Source Completed By (Initials): _____

URINEBE v1

Protocol Number: NIDA-CTO-0007

Cabergoline for Cocaine Dependence

Study Day STDYWD

Site Identification Number: 980208

Subject Identification Number: 0101

TREATMENT COMPLIANCE

#	Date Drug Dispensed (mm/dd/yyyy)	Comments	Completed by: (Initals)
1			
2			
3			

Protocol Number: NIDA-CTO-0007	**Site Identification Number:** 980208
Cabergoline for Cocaine Dependence	**Subject Identification Number:** 0101

Study Day SCRNBASE

Form Not Done ☐

SERUM PROLACTIN

Date Serum Prolactin Drawn: _____ (mm/dd/yyyy)

Prolactin Sample:
- ◉ Baseline
- ◉ Week 3 - 6
- ◉ Week 12/Termination

Time Since Last Cocaine Use _____ (hours) **or** _____ (days)

Time Since Last Cigarette Use, For Smokers _____ (hours) _____ (minutes)

Time of Going to Bed _____ (00:00 - 23:59)

Time of Awakening _____ (00:00 - 23:59)

Any New Medications Taken Since Midnight? ◉ No ◉ Yes *(if yes, please fill out Concomitant Medications Form).*

Procedural Deviations:

☐ None

☐ Drank caffeinated beverage (e.g. Coke, Coffee, Tea) after midnight

If yes, time since last occurence: _____ (Hours) _____ (Minutes)

☐ Ate food after midnight

If yes, time since last occurence: _____ (Hours) _____ (Minutes)

☐ Other *Specify:* _____

If yes, time since last occurence: _____ (Hours) _____ (Minutes)

Time Seated, Relaxed (in minutes) _____

Time of Prolactin Blood Drawing _____ (00:00 - 23:59)

Comments: _____

Source Completed By (Initials): _____

Protocol Number: NIDA-CTO-0007

Cabergoline for Cocaine Dependence

Subject Identification Number: 0001

Study Day SCRNBASE

Form Not Done ☐

SUBSTANCE USE INVENTORY (SUI) BASELINE

Use this form to account for the last 30 days. Record the number of days of drug use over this period.
Today's information will be included in the next collection period.

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

30 Days Prior: (mm/dd/yyyy)

Days Accounted For: (# of Days)

For each substance listed below, fill in a response corresponding to the subject's use of the substance since the last reported period and the mode(s) in which it was used. If no use occurred, fill in "0" for DAYS USED and leave MODE OF USE blank.

Drugs Used In Last 30 Days	Days Used	MODE OF USE				
		Smoke	I.V.	Oral	I.M.	Snort
1. Cocaine		Ye No	Ye No	Ye No	Ye No	Ye No

Source Completed By (Initials):

SUIBASE v1

Protocol Number: NIDA-CTO-0007

Cabergoline for Cocaine Dependence

Subject Identification Number: 0500

Study Day SCRNBASE

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):

Protocol Number: NIDA-CTO-0007

Cabergoline for Cocaine Dependence

Subject Identification Number: 0500

Date: (mm/dd/yyyy)

Study Day SCRNBASE

Form Not Done ☐

SYPHILIS TEST

Indicate whether the laboratory value is NEGATIVE: negative test result, POSITIVE: positive test result, INDETERMINANT: result is not interpretable or NOT DONE.

Rapid plasma reagin (RPR) test result

If RPR test is not done, state reason.

***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):

Protocol Number: NIDA-CTO-0007

Cabergoline for Cocaine Dependence

Study Day STDYWD

Site Identification Number: 980208

Subject Identification Number: 0101

TREATMENT COMPLIANCE

#	Date Drug Dispensed (mm/dd/yyyy)	Comments	Completed by: (Initals)
1			
2			
3			

Protocol Number: NIDA-CTO-0007

Cabergoline for Cocaine Dependence

Site Identification Number: 980208

Subject Identification Number: 0101

Study Day SCRNBASE

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)	Result: Positive	Result: Negative	Result: Not Reported	This Specimen is the first urine of this week and has been flagged for urine toxicology testing in addition to BE. Please check if applicable
01/08/2003	☐ Yes ☐ No ☐ Unknown	☐	☐	☐	☐
01/09/2003	☐ Yes ☐ No ☐ Unknown	☐	☐	☐	☐
01/10/2003	☐ Yes ☐ No ☐ Unknown	☐	☐	☐	☐

Source Completed By (Initials): _____

URINEBE v1

Protocol Number: NIDA-CTO-0007

Cabergoline for Cocaine Dependence

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

___	_____	_____	
Blood			

Source Completed By (Initials):

URINE v1

Protocol Number: NIDA-CTO-0007

Cabergoline for Cocaine Dependence

Subject Identification Number: 0103

Date: (mm/dd/yyyy)

Study Day SCRNBASE

Form Not Done ☐

URINE TOXICOLOGY

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

Amphetamines	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐

Source Completed By (Initials):

Protocol Number: NIDA-CTO-0007

Cabergoline for Cocaine Dependence

Subject Identification Number: 0001

Date: (mm/dd/yyyy)

Study Day SCRNBASE

Form Not Done ☐

VITAL SIGNS RECORD

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

VITALS v1