

Protocol Number: NIDA-CTO-0006

Metyrapone for Cocaine Dependence

Study Day UNSCHD

Subject Identification Number: 0001

ADVERSE EVENTS

Has the subject had any Adverse Experiences during this study?

Yes No

If yes, please list all Adverse Experiences below:

Severity	Study Drug Relationship	Action Taken Regarding Investigational Agent	Other Action Taken	Outcome of AE	Serious
1 = Mild 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
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="checkbox"/> <input type="checkbox"/>	<input type="text"/>

Protocol Number: NIDA-CTO-0006

Subject Identification Number: 0002

Metyrapone for Cocaine Dependence

Date: (mm/dd/yyyy)

Study Day HOSPD2

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

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:

- 9) Mother In the past 30 days Lifetime

- 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:

- | | <u>In the past 30 days</u> | <u>Lifetime</u> |
|--|----------------------------|----------------------|
| 4) Experienced serious depression? | <input type="text"/> | <input type="text"/> |
| 5) Experienced serious anxiety or tension? | <input type="text"/> | <input type="text"/> |
| 6) Experienced hallucinations? | <input type="text"/> | <input type="text"/> |
| 7) Experienced trouble understanding, concentrating, or remembering? | <input type="text"/> | <input type="text"/> |
| 8) Experienced trouble controlling violent behavior? | <input type="text"/> | <input type="text"/> |
| 9) Experienced serious thoughts of suicide? | <input type="text"/> | <input type="text"/> |
| 10) Attempted suicide? | <input type="text"/> | <input type="text"/> |
| 11) Been prescribed medication for any psychological or emotional problem? | <input type="text"/> | <input type="text"/> |
| 12) How many days in the last 30 have you experienced psychological or emotional problems? | | <input type="text"/> |

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-0006

Subject Identification Number: 0002

Metrapone for Cocaine Dependence

Date: (mm/dd/yyyy)

Study Day HOSPD2

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 lif
If yes to #2, specify:
3) Are you taking any prescribed medication on a regular basis for a physical problem?
4) Do you receive a pension for a physical disability? (Exclude psychiatric disabilities)
5) If yes to #4, specify:
6) How many days have you experienced medical problems in the past 30 days?

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

- 7) How troubled or bothered have you been by these medical problems in the past 30 days?
8) How important to you now is treatment for these medical problems?

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

- 9) Subject's misrepresentation?
10) Subject's inability to understand?
11) Comments Medical Score

EMPLOYMENT/SUPPORT STATUS

- 1) Education completed (GED = 12 years): (years) (months)
2) Training or technical education completed: (months)
3) Do you have a valid driver's license?
4) Do you have an automobile available for use? (Answer NO if no valid driver's license)
5) How long was your longest full-time job? (years) (months)
6a) Usual (or last) occupation:
6b) Hollingshead occupational category:
7) Does someone contribute to your support in any way?
8) Usual employment pattern, past 3 years.
9) How many days were you paid for working in the past 30 days?

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

- 10) Employment (net income) \$
11) Unemployment compensation \$
12) Public assistance (welfare) \$
13) Pension, benefits or social security \$
14) Mate, family or friends (money for personal expenses) \$
15) Illegal \$

- 16) How many people depend on you for the majority of their food, shelter, etc.?
- 17) How many days have you experienced employment problems in the past 30 days?
- FOR QUESTIONS 18 AND 19, PLEASE ASK THE SUBJECT TO USE THE SUBJECT RATING SCALE**
- 18) How troubled or bothered have you been by these employment problems in the past 30 days?
- 19) How important to you now is counseling for these employment problems?
- CONFIDENCE RATINGS (Is the above information significantly distorted by):**
- 20) Subject's misrepresentation?
- 21) Subject's inability to understand?
- 22) Comments **Employment Score**

DRUG/ALCOHOL USE

SUBSTANCE	Days in Past 30 Days	Lifetime Years	ROUTE OF ADMINISTRATION						
			oral	nasal	smoking	non iv inj.	iv inj.	Refused	N/A
1. Alcohol-any use at all	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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- 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-0006
 Metyrapone for Cocaine Dependence

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Date:
 (mm/dd/yyyy)

Study Day UNSCHD

Form Not Done

CHEMISTRIES

Analyte	Std. Quantity	Standard Unit	Other Unit	Normal	Abnormal	Abnormal Significant	Not Done
01. Sodium				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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Provide comments for any abnormal value(s)

Source Completed By (Initials):

Protocol Number: NIDA-CTO-0006

Subject Identification Number: 0001

Metyrapone for Cocaine Dependence

Study Day UNSCHD

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	Frequency	Other	
1							
				(specify)		(specify)	
	Route	Other	Date Started	Date Stopped	Cont.?	Indication	Initials
			(mm / dd / yyyy)	(mm / dd / yyyy)	<input type="checkbox"/>		
		(specify)					

Protocol Number: NIDA-CTO-0006

Metyrapone for Cocaine Dependence

Study Day UNSCHD

Subject Identification Number: 0001

Date: (mm/dd/yyyy)

EXCLUSION CRITERIA

Participants must not:

- 1. Require detoxification from alcohol, opiates, or sedative-hypnotics. Yes No
- 2. Have a history of significant hepatic, renal, endocrine, cardiac, (i.e., arrhythmia requiring medication, angina pectoris, myocardial infarction), stroke, seizure, neurological, non-drug-related psychiatric, gastrointestinal, pulmonary, hematological, or metabolic disorders. Yes No
- 3. Have a history of adverse reaction to cocaine including loss of consciousness, chest pain, psychosis, or seizure. Yes No
- 4. Have a history of adverse reaction/hypersensitivity to MRP. Yes No
- 5. Test positive upon urine toxicology screen for opiates, benzodiazepines, barbiturates or related CNS depressants, amphetamines or related stimulants. Yes No
- 6. Have a clinically significant laboratory abnormality in hematology, serum chemistries or ECG. Yes No
- 7. Have any significant active medical, or psychiatric illness which might inhibit their ability to complete the study or might be complicated by administration of the test drug. Yes No
- 8. Have active hypertension as defined by the American Heart Association criteria. Yes No
- 9. Currently receive any medications for the treatment of any significant medical conditions. Yes No
- 10. Have a history of seizures or seizure disorder. Yes No
- 11. Have any medical history or condition considered by the investigator(s) to place the subject at increased risk. Yes No
- 12. Receiving therapy with any of the opiate-substitutes (methadone, LAAM, buprenorphine) within 60 days of enrollment in this study. Yes No
- 13. Have a diagnosis of adult asthma, including those with a history of acute asthma within the past two years, and those with current or recent (past 2 years) treatment with inhaled or oral beta-agonist or steroid therapy (due to potential serious adverse interactions with cocaine). Yes No
- 14. Actively using albuterol or other beta agonist medications, regardless of whether they are diagnosed with asthma. (Inhalers are sometimes used by cocaine addicts to enhance cocaine delivery to the lungs.) If respiratory disease is excluded and the subject will consent to discontinue agonist use, he/she may be considered for inclusion. Yes No
- 15. May be suspect to have asthma but carry no diagnosis, that is 1) history of coughing and wheezing, 2) history of asthma and/or asthma treatment two or more years ago, 3) have a history of other respiratory illness, e.g., COPD (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 tests should be performed prior to including or excluding from the study. Patients with FEV1 <70% of predicted should be excluded. Yes No
- 16. Have a hematocrit value below 40 for men and 36 for women. Yes No

All Exclusion Criteria must be answered NO to be eligible for the study.

Source Completed By (Initials):

(EXCLUS v1)

Protocol Number: NIDA-CTO-0006

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Metyrapone for Cocaine Dependence

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):

DEATH v1

Protocol Number: NIDA-CTO-0006

Subject Identification Number: 0001

Metyrapone for Cocaine Dependence

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
Samoa
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

<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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 addiction
- 16 - Polydrug addiction

Source Completed By (Initials):

DEMOG v1

Protocol Number: NIDA-CTO-0006

Subject Identification Number: 0001

Metyrapone for Cocaine Dependence

Date: (mm/dd/yyyy)

Study Day: HOSPD10

Form Not Done

ELECTROCARDIOGRAM 12-LEAD

A. ECG overall results were: Normal Abnormal

Time: (00:00 - 23:59)

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.

Table with 32 rows of ECG findings and checkboxes for Abnormal and Abnormal Significant.

C. Ventricular rate (bpm):

E. QRS (ms):

D. PR (ms):

F. QTc (ms):

Source Completed By (Initials)

ECG v1

Protocol Number: NIDA-CTO-0006

Subject Identification Number: 0001

Metyrapone 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 significant adverse events which prompted early termination. (Complete AE form, provide comments)
- Subject terminated for administrative reasons. (Include protocol non-compliance in this category. Provide comments)
- Subject transferred to another treatment program (check all that apply)
 - Methadone
 - Drug Free
 - Inpatient Detox or Treatment
 - LAAM
 - Therapeutic Community
 - Other (specify)
- Subject was incarcerated.
- Subject became pregnant.
- Subject developed sensitivity to study agent.
- Subject was lost to follow-up.
- Subject moved from area.
- Subject died. (If subject died, a Death Report Case Report Form must be completed)
- Subject can no longer attend clinic.
- Subject no longer attends clinic.
- Subject is in a controlled environment.
- Subject is a screen failure
- Other (Provide comments)

Comments:

Source Completed By (Initials):

ENDTRIAL v1

Protocol Number: NIDA-CTO-0006

Subject Identification Number: 0001

Metyrapone for Cocaine Dependence

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):

ENROLL v1

Protocol Number: NIDA-CTO-0006
Metyrapone 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
<input type="checkbox"/> Cocaine		<input type="checkbox"/> Sedatives	
<input type="checkbox"/> Methamphetamines		<input type="checkbox"/> Nicotine	
<input type="checkbox"/> Amphetamines		<input type="checkbox"/> Opiates	
<input type="checkbox"/> Benzodiazepines		<input type="checkbox"/> Barbiturates	
<input type="checkbox"/> Alcohol		<input type="checkbox"/> None	
<input type="checkbox"/> Marijuana		<input type="checkbox"/> Other	

(specify)

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

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

7) Have any adverse events occurred? Yes No

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

9) Additional comments:

Source Completed By (Initials):

FOLLOWUP v1

Protocol Number: NIDA-CTO-0006

Metyrapone for Cocaine Dependence

Subject Identification Number: 0001

Date: (mm/dd/yyyy)

Study Day UNSCHD

Form Not Done

HEMATOLOGY

Complete Blood Count	Std. Quantity	Standard Unit	Other Unit	Normal	Abnormal	Abnormal Significant	Not Done
Hemaglobin				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Provide comments for any abnormal value(s)

Source Completed By (Initials):

HEMAT v1

Protocol Number: NIDA-CTO-0006

Metyrapone for Cocaine Dependence

Study Day UNSCHD

Subject Identification Number: 0001

Date: (mm/dd/yyyy)

Form Not Done

HIV RISK-TAKING BEHAVIOR SCALE (HRBS)

DRUG USE

- 1) How many times have you hit up (i.e. injected any drugs) in the last month?
If you have not injected drugs in the last month, go to Question 7.
2) How many times in the last month have you used a needle after someone else had already used it?
3) How many different people have used a needle before you in the past month?
4) How many times in the last month has someone used a needle after you?
5) How often, in the last month, have you cleaned needles before re-using them?
6) Before using needles again, how often in the past month did you use bleach to clean them?

Drug Score

SEXUAL BEHAVIOR

- 7) How many people, including clients, have you had sex with in the last month?
If no sex in the last month, skip to question #12
8) How often have you used condoms when having sex with your regular partner(s) in the last month?
9) How often have you used condoms when you had sex with casual partners?
10) How often have you used condoms when you have been paid for sex in the last month?
11) How many times have you had anal sex in the last month?
12) Have you had an HIV test come back positive? Yes No Unknown

Sex Score

Source Completed By (Initials):

HRBS Score

HRBS v1

Protocol Number: NIDA-CTO-0006

Metyrapone for Cocaine Dependence

Study Day UNSCHD

Subject Identification Number: 0001

Date: (mm/dd/yyyy)

INCLUSION CRITERIA

Participants must:

- 1. Be male or female of any race, between 18 and 45 years of age. Yes No
- 2. Be cocaine dependent according to DSM-IV criteria. Yes No
- 3. Be currently using cocaine by the smoked or intravenous route of administration and confirmed by positive urine screen for benzoylecgonine within 2 weeks prior to study enrollment. The subjects who currently use cocaine by smoked route must have a history of intravenous exposure to drugs of abuse. Yes No
- 4. Be in stable physical and mental health as judged by interview and physical examinations. Yes No
- 5. For female subjects, test non-pregnant and use adequate birth control. All female subjects will have a serum pregnancy test performed prior to the first dose of study medication. Yes No
- 6. Be capable of providing written informed consent to participate in this study, able to comply with protocol requirements, and likely to complete all study treatments. Yes No
- 7. Have basal cortisol and ACTH levels within normal range. Yes No

All Inclusion Criteria must be answered YES to be eligible for the study.

Source Completed By (Initials):

(INCLUS V1)

Protocol Number: NIDA-CTO-0006

Metyrapone 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.

Table with 3 columns: Infectious Disease, Result, Provide comments for any abnormal value. Rows include 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-0006

Metyrapone for Cocaine Dependence

Subject Identification Number: 0001

Date:

(mm/dd/yyyy)

Study Day UNSCHD

Form Not Done

INITIATION INFUSION MONITORING 20mg.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	Heart Rate	Standing Blood Pressure	Standing Heart Rate	Blood Draw Actual Time	Comments	Init.
<input type="text"/>	<input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

INFUSN2 v1

Protocol Number: NIDA-CTO-0006

Metyrapone for Cocaine Dependence

Study Day UNSCHD

Subject Identification Number: 0001

Date:
(mm/dd/yyyy)

Form Not Done

INITIATION INFUSION MONITORING 40mg.Cocaine: Infusion #3

Infusion Start Time:

(00:00 - 23:59)

Infusion Stop Time:

(00:00 - 23:59)

Infusion Administered By:

(Initials)

Time Interval	Actual Time	Blood Pressure	Heart Rate	Standing Blood Pressure	Standing Heart Rate	Blood Draw Actual Time	Comments	Init.
<input type="text"/>	<input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

INFUSN3 v1

Protocol Number: NIDA-CTO-0006

Subject Identification Number: 0001

Metyrapone for Cocaine Dependence

Date: (mm/dd/yyyy)

Study Day UNSCHD

Form Not Done

INFUSION MONITORING 40mg. Cocaine/Placebo: Infusion #4

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

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

Infusion Administered By: (Initials)

Table with 9 columns: Time Interval, Actual Time, Blood Pressure, Heart Rate, Standing Blood Pressure, Standing Heart Rate, Blood Draw Actual Time, Comments, Init. The table contains 14 empty rows for data entry.

Protocol Number: NIDA-CTO-0006

Metyrapone for Cocaine Dependence

Study Day UNSCHD

Form Not Done

Subject Identification Number: 0001

Date:
(mm/dd/yyyy)

INITIATION INFUSION MONITORING 20mg. Cocaine: 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	Heart Rate	Standing Blood Pressure	Standing Heart Rate	Blood Draw Actual Time	Comments	Init.
<input type="text"/>	<input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

INFUSN1 v1

Protocol Number: NIDA-CTO-0006

Subject Identification Number: 0001

Metyrapone for Cocaine Dependence

Study Day UNSCHD

Form Not Done

INVESTIGATIONAL AGENT ADMINISTRATION

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

Source Completed By (Initials):

INVAGT v1

Protocol Number: NIDA-CTO-0006

Metyrapone for Cocaine Dependence

Subject Identification Number: 0001

Date:
(mm/dd/yyyy)

Study Day HOSPD11

Form Not Done

LAB TEST TRACKING FORM (Day 11)

<u>Time of Test</u>	Blood draw for Cortisol	Cortisol Time	Blood draw for ACTH	ACTH Time
<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/> (

Source Completed By (Initials):

Protocol Number: NIDA-CTO-0006

Subject Identification Number: 0001

Metyrapone for Cocaine Dependence

Date:
(mm/dd/yyyy)

Study Day HOSPD10

Form Not Done

LAB TEST TRACKING FORM

Time of Infusion	Blood draw for Cortisol	Cortisol Time	Blood draw for ACTH	ACTH Time	Blood draw for Cocaine BE	Cocaine BE Time
<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>
<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>
<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>
<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>
<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>
<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>
<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>
<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>
<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>	<input type="text"/>

Source Completed By (Initials):

LABTRACK v1

Protocol Number: NIDA-CTO-0006

Subject Identification Number: 0001

Metyrapone for Cocaine Dependence

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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
2. Allergies: other, specify <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3. Sensitivity to Agent/Compounds	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4. History of Asthma	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
5. HEENT	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
6. Cardiovascular	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
7. Renal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
8. Hepatic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
9. Pulmonary	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
10. Gastrointestinal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
11. Musculoskeletal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
12. Neurologic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
13. Psychiatric	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
14. Dermatologic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
15. Metabolic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
16. Hematologic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
17. Endocrine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
18. Genitourinary	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
19. Reproductive System	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
20. Seizure	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
21. Infectious Disease	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
22. Other 1, specify: <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
23. Other 2, specify: <input type="text"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

24. Was major surgery ever performed?

Yes No

(If Yes, list surgeries:)

	<u>Type of Surgery</u>	<u>Date of Surgery</u> (mm/dd/yyyy)	<u>Yes</u> <u>excludes</u>	<u>Yes</u> <u>doesn't exclude</u>	<u>No</u>
25.			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
26.			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
27.			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
28.			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
29.			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
30.			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
31.			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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-0006

Subject Identification Number: 0001

Metypone for Cocaine Dependence

Date: (mm/dd/yyyy)

Study Day UNSCHD

Form Not Done

PHYSICAL EXAMINATION

Height: inches centimeters

Weight: pounds kilograms

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

Source Completed By (Initials):

PHYSEXAM v1

Protocol Number: NIDA-CTO-0006

Subject Identification Number: 0001

Metyrapone for Cocaine Dependence

Date:
(mm/dd/yyyy)

Study Day UNSCHD

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):

PREGNANT v1

Protocol Number: NIDA-CTO-0006

Subject Identification Number: 0001

Metyrapone for Cocaine Dependence

Study Day UNSCHD

PRIOR MEDICATIONS

Has the subject taken any medications in the PAST 30 DAYS?

Yes No

If yes, please list all below:

Legend table for medication abbreviations: Dose, Unit of Medication, Frequency, Route of Administration.

Main medication entry table with columns: No., Medication, Dose, Unit, Other, Frequency, Other, Route, Other, Date Started, Date Stopped, Cont.?, Indication, Initials.

Protocol Number: NIDA-CTO-0006

Subject Identification Number: 0001

Metyrapone for Cocaine Dependence

Date: (mm/dd/yyyy)

Study Day UNSCHD

Form Not Done

INITIATION RHYTHM STRIPS: Infusion #1

- RHYTHM CODES**
- 01 - Normal Sinus Rhythm
 - 02 - Sinus Tachycardia
 - 03 - Sinus Bradycardia
 - 04 - PAC's
 - 05 - PVC's
 - 06 - 1st Degree A-V Block
 - 07 - 2nd Degree A-V Block, type 1
 - 08 - 2nd degree A-V Block, type 2
 - 09 - 3rd Degree A-V Block
 - 10 - Atrial Fibrillation
 - 11 - Atrial Flutter
 - 12 - Ventricular Tachycardia
 - 13 - Ventricular Fibrillation

Time Interval	Actual Time	Rhythm	Rate	Comments	Initials

(RHYTHM1 v1)

Protocol Number: NIDA-CTO-0006

Subject Identification Number: 0001

Metyrapone for Cocaine Dependence

Date:
(mm/dd/yyyy)

Study Day UNSCHD

Form Not Done

INITIATION RHYTHM STRIPS: Infusion #2

RHYTHM CODES

- 01 - Normal Sinus Rhythm
- 02 - Sinus Tachycardia
- 03 - Sinus Bradycardia
- 04 - PAC's
- 05 - PVC's
- 06 - 1st Degree A-V Block
- 07 - 2nd Degree A-V Block, type 1
- 08 - 2nd degree A-V Block, type 2
- 09 - 3rd Degree A-V Block
- 10 - Atrial Fibrillation
- 11 - Atrial Flutter
- 12 - Ventricular Tachycardia
- 13 - Ventricular Fibrillation

Time Interval	Actual Time	Rhythm	Rate	Comments	Initials
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

(RHYTHM2 v1)

Protocol Number: NIDA-CTO-0006

Subject Identification Number: 0001

Metyrapone for Cocaine Dependence

Date: (mm/dd/yyyy)

Study Day UNSCHD

Form Not Done

INITIATION RHYTHM STRIPS: Infusion #3

- RHYTHM CODES**
- 01 - Normal Sinus Rhythm
 - 02 - Sinus Tachycardia
 - 03 - Sinus Bradycardia
 - 04 - PAC's
 - 05 - PVC's
 - 06 - 1st Degree A-V Block
 - 07 - 2nd Degree A-V Block, type 1
 - 08 - 2nd degree A-V Block, type 2
 - 09 - 3rd Degree A-V Block
 - 10 - Atrial Fibrillation
 - 11 - Atrial Flutter
 - 12 - Ventricular Tachycardia
 - 13 - Ventricular Fibrillation

Time Interval	Actual Time	Rhythm	Rate	Comments	Initials

Protocol Number: NIDA-CTO-0006

Subject Identification Number: 0001

Metyrapone for Cocaine Dependence

Date:
(mm/dd/yyyy)

Study Day HOSPD10

Form Not Done

RHYTHM STRIPS

RHYTHM CODES

- 01 - Normal Sinus Rhythm
- 02 - Sinus Tachycardia
- 03 - Sinus Bradycardia
- 04 - PAC's
- 05 - PVC's
- 06 - 1st Degree A-V Block
- 07 - 2nd Degree A-V Block, type 1
- 08 - 2nd degree A-V Block, type 2
- 09 - 3rd Degree A-V Block
- 10 - Atrial Fibrillation
- 11 - Atrial Flutter
- 12 - Ventricular Tachycardia
- 13 - Ventricular Fibrillation

Time Interval	Actual Time	Rhythm	Rate	Comments	Initials
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

(RHYTHM v1)

Protocol Number: NIDA-CTO-0006

Subject Identification Number: 0001

Metrapone for Cocaine Dependence

Study Day UNSCHD

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

SAE Description text input area

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 reduced dose
discontinued permanently increased dose
discontinued temporarily 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 disability
life-threatening event congenital anomaly
hospitalization other (specify)

Concomitant Medications

Relevant tests/laboratory data, including dates

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

SAE resolution date (mm/dd/yyyy) continuing

INVESTIGATIONAL AGENT ADMINISTRATION

Is investigational agent information known? Yes No

If yes, investigational agent name

Lot number

Expiration date (mm/dd/yyyy)

Quantity

Unit Code **Other unit**

Start date (mm/dd/yyyy) **Stop date** (mm/dd/yyyy) or continuing

Route of administration

Frequency

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

- 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-0006

Subject Identification Number: 0001

Metyrapone for Cocaine Dependence

Date: (mm/dd/yyyy)

Study Day UNSCHD

Form Not Done

SCID WORKSHEET

AXIS I - Diagnosis

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

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

Source Completed By (Initials):

SCID v1

Protocol Number: NIDA-CTO-0006

Subject Identification Number: 0001

Metyrapone for Cocaine Dependence

Date:

Study Day UNSCHD

Form Not Done

(mm/dd/yyyy)

URINALYSIS

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

Dipstick Urinalysis:

Specific gravity

pH

Lab	Levels	Result	Comments for Abnormal Values
Blood	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Source Completed By (Initials):

URINE v1

Protocol Number: NIDA-CTO-0006

Subject Identification Number: 0001

Metyrapone for Cocaine Dependence

Date: (mm/dd/yyyy)

Study Day UNSCHD

Form Not Done

URINE TOXICOLOGY

Urine temperature within expected range?

Yes No Unknown

(96.4 < or = T < or = 100.4 F)

Drug/Test	Positive	Negative	Not Done
Amphetamines	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Source Completed By (Initials):

URINETOX v1

Time Interval <input type="text"/>	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Time Interval <input type="text"/>	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Time Interval <input type="text"/>	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Source Completed By (Initials):

VISLANA1 v1

Time Interval <input type="text"/>	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Time Interval <input type="text"/>	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Source Completed By (Initials):

VISLANA2 v1

Time Interval <input type="text"/>	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Time Interval <input type="text"/>	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Source Completed By (Initials):

VISLANA3 v1

Time Interval <input type="text"/>	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Time Interval <input type="text"/>	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Time Interval <input type="text"/>	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Time Interval <input type="text"/>	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Time Interval <input type="text"/>	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Time Interval <input type="text"/>	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Source Completed By (Initials):

VISLANA4 v1

Protocol Number: NIDA-CTO-0006

Subject Identification Number: 0001

Metyrapone for Cocaine Dependence

Date:
(mm/dd/yyyy)

Study Day

Form Not Done

VITAL SIGNS - NON INFUSION DAYS

Line No.	Time (00:00 - 23:59)	Temp (oral) Fahrenheit or Celcius	Resp. Rate (Breaths/Min)	Pulse Rate (Beats/Min)	BP (mm/Hg) (systolic) / (diastolic)	Comp.By: (Initials)
<input type="text"/>	<input type="text"/>	<input type="text"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/> / <input type="text"/>	<input type="text"/>

Protocol Number: NIDA-CTO-0006

Metyrapone for Cocaine Dependence

Subject Identification Number: 0001

Date:
(mm/dd/yyyy)

Study Day UNSCHD

Form Not Done

POSTURAL VITAL SIGNS - NON INFUSION DAYS

Post Infusion	Actual Time	Pulse Rate	Blood Pressure (systolic) / (diastolic)	Comp.By: (Initials)
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/> / <input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/> / <input type="text"/>	<input type="text"/>

Protocol Number: NIDA-CTO-0006

Metyrapone for Cocaine Dependence

Site Identification Number: 980404

Subject Identification Number: 0001

Study Day: SCRNG

Form Not Done

Date: (mm/dd/yyyy)

BRIEF PSYCHIATRIC RATING SCALE

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

Table with 9 columns: SYMPTOMS, Not Assessed, Not Present, Very Mild, Mild, Moderate, Moderately Severe, Severe, Extremely Severe. Row 1: 1-Somatic Concern with checkboxes for NA, 1-7.

Source Completed By (Initials):

BPRSTIME v1