

Protocol Number: NIDA-CTO-0002

Subject Identification Number: 0001

Modafinil for Cocaine Dependence

Study Day UNSCHD

ADVERSE EVENTS

Has the subject had any Adverse Experiences during this study?

Yes No

If yes, please list all Adverse Experiences below:

Table with 6 columns: Severity, Study Drug Relationship, Action Taken Regarding Investigational Agent, Other Action Taken, Outcome of AE, Serious. Includes legend for severity levels and outcomes.

Main table for recording adverse events with columns: #, EVENT, Start Date, Stop Date, Sev., Drug Rel., Action Taken, Other Action, Out., Serious, Initials.

Protocol Number: NIDA-CTO-0002

Subject Identification Number: 0001

Modafinil for Cocaine Dependence

Date: (mm/dd/yyyy)

Study Day UNSCHD

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:

- 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:

- | | In the past 30 days | Lifetime |
|--|----------------------------|----------------------|
| 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?

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-0002

Subject Identification Number: 0009

Modafinil for Cocaine Dependence

Date: (mm/dd/yyyy)

Study Day DAY4

Form Not Done

BRIEF PSYCHIATRIC RATING SCALE

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

SYMPTOMS	Not Assessed	Not Present	Very Mild	Mild	Moderate	Moderately Severe	Severe	Extremely Severe
1-Somatic Concern	<input type="checkbox"/> NA	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="checkbox"/> 6	<input type="checkbox"/> 7
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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"/>
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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"/>				

Protocol Number: NIDA-CTO-0002

Subject Identification Number: 0001

Modafinil 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:

Legend table for medication units, frequencies, and routes of administration. Includes abbreviations like CAP, g, GR, GTT, ug, uL, mg, mL, OZ, PUF, SPY, SUP, TSP, TBS, TAB, UNK, OTH, ONCE, QD, BID, TID, QID, QOD, PRN, OTH, PO, TD, INH, IM, IV, REC, VAG, SQ, SL, AUR, IA, NAS, IO, UNK, OTH.

Main data table for concomitant medications with columns: No., Medication, Dose, Unit, Other, Frequency, Other, Route, Other, Date Started, Date Stopped, Cont.?, Indication, Initials.

Protocol Number: NIDA-CTO-0002

Modafinil for Cocaine Dependence

Subject Identification Number: 0002

Study Day UNSCHD

DEATH REPORT

Subject Date of Death (mm/dd/yyyy)

Was autopsy performed? Yes No Unknown

If yes, is autopsy report available? Yes No

Is cause of death known? Yes No

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

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

Source Completed By (Initials):

DEATH v1

Protocol Number: NIDA-CTO-0002

Subject Identification Number: 0002

Modafinil 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

Protocol Number: NIDA-CTO-0002

Subject Identification Number: 0001

Modafinil for Cocaine Dependence

Date: (mm/dd/yyyy)

Study Day UNSCHD

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.

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

ECG v1

Protocol Number: NIDA-CTO-0002

Subject Identification Number: 0001

Modafinil 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-0002

Subject Identification Number: 0002

Modafinil 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-0002

Modafinil for Cocaine Dependence

Subject Identification Number: 0001

Date: (mm/dd/yyyy)

Study Day DAY0

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 a history of significant hepatic, renal, endocrine, cardiac, (i.e., arrhythmia requiring medication, angina pectoris, myocardial infarction, left ventricular hypertrophy as determined by electrocardiogram or clinical data), 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 modafinil or drugs of the same class. 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 clinically significant abnormal laboratory measurements in liver function tests (AST and ALT levels greater than 3 times the upper limit of normal), hematology (CBC, differential, platelet count), serum chemistries (SMA-24) and EKG. 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 modafinil. Yes No
- 8. Have active hypertension as defined by American Heart Association criteria. Yes No
- 9. Currently receive any medications for the treatment of any medical conditions, specifically, subjects with an FEV1 of less than 75% of predicted values, any history of current or past asthma and/or the use of albuterol or other beta-agonist inhalers will be excluded. Yes No
- 10. Be suffering from or have any history of migraines. Yes No
- 11. Have any medical history or condition considered by the investigator(s) to place the subject at increased risk. Yes No
- 12. Do not actively meet the inclusion criteria at the time of the screening. 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-0002
Modafinil 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="text"/>	<input type="checkbox"/> Sedatives	<input type="text"/>
<input type="checkbox"/> Methamphetamines	<input type="text"/>	<input type="checkbox"/> Nicotine	<input type="text"/>
<input type="checkbox"/> Amphetamines	<input type="text"/>	<input type="checkbox"/> Opiates	<input type="text"/>
<input type="checkbox"/> Benzodiazepines	<input type="text"/>	<input type="checkbox"/> Barbiturates	<input type="text"/>
<input type="checkbox"/> Alcohol	<input type="text"/>	<input type="checkbox"/> None	<input type="text"/>
<input type="checkbox"/> Marijuana	<input type="text"/>	<input type="checkbox"/> Other	<input type="text"/> (specify) <input type="text"/>

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-0002

Subject Identification Number: 0001

Modafinil for Cocaine Dependence

Date:

Study Day UNSCHD

Form Not Done

(mm/dd/yyyy)

HEMATOLOGY

<u>Complete</u> Blood Count	<u>Std.</u> Quantity	<u>Standard</u> Unit	<u>Other</u> Unit	Normal	Abnormal	Abnormal Significant	Not Done
Hemoglobin				<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-0002

Modafinil for Cocaine Dependence

Study Day

Subject Identification Number:

Date:
(mm/dd/yyyy)

INCLUSION CRITERIA

Potential subjects must:

- | | |
|---|--|
| 1. Be volunteers who are dependent on cocaine and are non-treatment seeking at the time of the study. | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 2. Be male or female of any race, between 18 and 45 years of age. | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 3. Meet DSM-IV criteria for cocaine abuse or dependence. | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 4. Currently use cocaine by the smoked or intravenous route of administration and confirmed by positive urine screen for benzoylecgonine within 2 weeks prior to study entry. The subjects who currently use cocaine by smoked route must have a history of intravenous exposure to drugs of abuse. | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 5. Be in stable physical and mental health as judged by interview and physical examinations. | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 6. For female subjects, test non-pregnant and use adequate birth control. All female subjects will have a urine pregnancy test performed prior to the first dose of study medication. All females will have a second urine pregnancy test the morning of the day of discharge from the hospital. | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 7. Be capable of providing written informed consent to participate in this study. | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 8. Be able to comply with protocol requirements and be likely to complete all study treatments. | <input type="checkbox"/> Yes <input type="checkbox"/> No |

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

Source Completed By (Initials):

(INCLUS V1)

Protocol Number: NIDA-CTO-0002

Subject Identification Number: 0001

Modafinil for Cocaine Dependence

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-0002

Modafinil for Cocaine Dependence

Subject Identification Number: 0002

Date: []

(mm/dd/yyyy)

Study Day UNSCHD

Form Not Done

INFUSION MONITORING Placebo/20mg: 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	Oxygen Saturation	Oral Temp	Comments	Init.
Infusion #2	[] (00:00-23:59)	[] [] (sys) (dias)	[] (beats/min)	[]	[]	[]	[]
63 min	[] (00:00-23:59)	[] [] (sys) (dias)	[] (beats/min)	[]	[]	[]	[]
66 min	[] (00:00-23:59)	[] [] (sys) (dias)	[] (beats/min)	[]	[]	[]	[]
69 min	[] (00:00-23:59)	[] [] (sys) (dias)	[] (beats/min)	[]	[]	[]	[]
72 min	[] (00:00-23:59)	[] [] (sys) (dias)	[] (beats/min)	[]	[]	[]	[]
75 min	[] (00:00-23:59)	[] [] (sys) (dias)	[] (beats/min)	[]	[]	[]	[]
78 min	[] (00:00-23:59)	[] [] (sys) (dias)	[] (beats/min)	[]	[]	[]	[]
81 min	[] (00:00-23:59)	[] [] (sys) (dias)	[] (beats/min)	[]	[]	[]	[]
85 min	[] (00:00-23:59)	[] [] (sys) (dias)	[] (beats/min)	[]	[]	[]	[]
90 min	[] (00:00-23:59)	[] [] (sys) (dias)	[] (beats/min)	[]	[]	[]	[]

Protocol Number: NIDA-CTO-0002

Subject Identification Number: 0001

Modafinil 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-0002

Modafinil for Cocaine Dependence

Subject Identification Number: 0001

Date:
(mm/dd/yyyy)

Study Day DAY6

Form Not Done

OFF-SITE LAB TEST TRACKING FORM (Day 6 and 7)

Time of Infusion	Cocaine PK	Cocaine PK Time (00:00-23:59)
Pre-Dose	<input type="checkbox"/>	<input type="text"/>
<input type="text"/>	<input type="checkbox"/>	<input type="text"/>
<input type="text"/>	<input type="checkbox"/>	<input type="text"/>
<input type="text"/>	<input type="checkbox"/>	<input type="text"/>
<input type="text"/>	<input type="checkbox"/>	<input type="text"/>
<input type="text"/>	<input type="checkbox"/>	<input type="text"/>
<input type="text"/>	<input type="checkbox"/>	<input type="text"/>
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<input type="text"/>	<input type="checkbox"/>	<input type="text"/>
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<input type="text"/>	<input type="checkbox"/>	<input type="text"/>
<input type="text"/>	<input type="checkbox"/>	<input type="text"/>
<input type="text"/>	<input type="checkbox"/>	<input type="text"/>

Source Completed By (Initials):

Protocol Number: NIDA-CTO-0002

Modafinil for Cocaine Dependence

Subject Identification Number: 0001

Date:
(mm/dd/yyyy)

Study Day DAY10

Form Not Done

OFF-SITE LAB TEST TRACKING FORM (Day 10, 11, 12, 17, 18 and 19)

	Modafinil PK	Modafinil PK Time (00:00-23:59)	
<input type="text"/>	<input type="checkbox"/>	<input type="text"/>	

Source Completed By (Initials):

LABMODAF v1

Protocol Number: NIDA-CTO-0002

Subject Identification Number: 0001

Modafinil for Cocaine Dependence

Date:
(mm/dd/yyyy)

Study Day UNSCHD

Form Not Done

OFF-SITE LAB TEST TRACKING FORM (Day 20 and 21)

<u>Time of Infusion</u>	Cocaine PK and Modafinil PK	Cocaine PK + Modafinil PK Time (00:00-23:59)
<input type="text"/>	<input type="checkbox"/>	<input type="text"/>

Source Completed By (Initials):

Protocol Number: NIDA-CTO-0002

Modafinil for Cocaine Dependence

Subject Identification Number: 0001

Date:

(mm/dd/yyyy)

Study Day UNSCHD

Form Not Done

MEDICAL HISTORY

Disorder	Yes		No		If yes, specify or describe
	excludes	doesn't exclude	history of disorder	Not evaluated	
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):

MEDHIST v1

Protocol Number: NIDA-CTO-0002

Subject Identification Number: 0001

Modafinil 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):

Protocol Number: NIDA-CTO-0002

Subject Identification Number: 0001

Modafinil 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-0002

Subject Identification Number: 0002

Modafinil 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:

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
	(specify)	(mm / dd / yyyy)	(mm / dd / yyyy)	<input type="checkbox"/>		

Protocol Number: NIDA-CTO-0002

Subject Identification Number: 0001

Modafinil 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-0002

Subject Identification Number: 0001

Modafinil 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-0002

Subject Identification Number: 0002

Modafinil for Cocaine Dependence

Study Day UNSCHD

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	Negative	Not Reported
	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Source Completed By (Initials):

URINEBE v1

Protocol Number: NIDA-CTO-0002

Modafinil for Cocaine Dependence

Subject Identification Number: 0001

Date: (mm/dd/yyyy)

Study Day UNSCHD

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 of subject from study.

Dipstick Urinalysis:

Specific gravity

pH

Lab	Levels	Result	Comments for Abnormal Values
Blood			

Source Completed By (Initials):

URINE v1

Protocol Number: NIDA-CTO-0002

Modafinil for Cocaine Dependence

Subject Identification Number: 0002

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"/>
	<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"/>
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):

Protocol Number: NIDA-CTO-0002

Subject Identification Number: 0001

Modafinil for Cocaine Dependence

Date:
(mm/dd/yyyy)

Study Day

Form Not Done

VITAL SIGNS

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-0002

Subject Identification Number: 0001

Modafinil for Cocaine Dependence

Date: (mm/dd/yyyy)

Study Day UNSCHD

Form Not Done

VITAL SIGNS FOR INITIAL DOSE OF MODAFINIL

Dose of modafinil: 200 mg 400 mg

Time of modafinil dose: (00:00-23:59)

Administered by: (Initials)

Table with 7 columns: Time Interval, Actual Time (00:00 - 23:59), BP (mm/Hg) (sys / (dias), Heart Rate, Temp (oral) Fahrenheit or Celcius, Comments, Comp.By: (Initials). The table contains 16 rows for data entry.