

Time Interval	1. Fearful	2. Feeling of Power	3. Stomach Upset	4. Suspicious	5. Sweating	6. Dizzy	
65 minutes	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
7. Craving for cocaine	8. Seeing	9. Irritable	10. Sleepy	11. Tremor	12. Thirsty	13. Excited	14. Jittery
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
15. Tingling	16. Dry Mouth	17. Fidgety	18. Feel a Thrill	19. Nervous	20. Stimulated	21. Drug Effect	22. Numbness
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Time Interval	1. Fearful	2. Feeling of Power	3. Stomach Upset	4. Suspicious	5. Sweating	6. Dizzy	
75 minutes	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
7. Craving for cocaine	8. Seeing	9. Irritable	10. Sleepy	11. Tremor	12. Thirsty	13. Excited	14. Jittery
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
15. Tingling	16. Dry Mouth	17. Fidgety	18. Feel a Thrill	19. Nervous	20. Stimulated	21. Drug Effect	22. Numbness
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Time Interval	1. Fearful	2. Feeling of Power	3. Stomach Upset	4. Suspicious	5. Sweating	6. Dizzy	
85 minutes	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
7. Craving for cocaine	8. Seeing	9. Irritable	10. Sleepy	11. Tremor	12. Thirsty	13. Excited	14. Jittery
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
15. Tingling	16. Dry Mouth	17. Fidgety	18. Feel a Thrill	19. Nervous	20. Stimulated	21. Drug Effect	22. Numbness
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Time Interval	1. Fearful	2. Feeling of Power	3. Stomach Upset	4. Suspicious	5. Sweating	6. Dizzy	
95 minutes	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
7. Craving for cocaine	8. Seeing	9. Irritable	10. Sleepy	11. Tremor	12. Thirsty	13. Excited	14. Jittery
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
15. Tingling	16. Dry Mouth	17. Fidgety	18. Feel a Thrill	19. Nervous	20. Stimulated	21. Drug Effect	22. Numbness
<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):

Protocol Number: NIDA-CPU-0003

RPR 102681 - Cocaine Interaction

Study Day UNSCHD

Site Identification Number: 980101

Subject Identification Number: 0050

Date: / / (mm) (dd) (yyyy)

Form Not Done

ADJECTIVE SCALE

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

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

Table with 6 columns: Not at all, A little bit, Moderately, Quite a bit, Extremely. Each row contains a rating scale from 0 to 4 with checkboxes.

Source Completed By (Initials):

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Site Identification Number: 980101

RPR 102681 - Cocaine Interaction

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ADVERSE EVENTS

Has the subject had any Adverse Events during this study?

Yes No

If yes, please list all Adverse Events below.

Table with 6 columns: Severity, Study Drug Relationship, Action Taken Regarding Investigational Agent, Other Action Taken, Outcome of AE, Serious. It lists various levels of severity (1-6) and corresponding actions and outcomes.

Table for recording adverse events with columns for #, EVENT, Start Date, Stop Date, Continuing, Severity, Relatedness, Action Taken, Other Action, Outcome, Serious, and Initials.

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Study Day UNSCHD

Site Identification Number: 980101

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Date: / /
(mm) (dd) (yyyy)

Form Not Done

ALCOHOL BREATHALYZER TEST

1) Was alcohol breathalyzer test performed? Yes No Unknown

2) Date alcohol breathalyzer test performed / /
(mm) (dd) (yyyy)

3) Blood Alcohol Content (BAC): (mg/ml)

4) Provide comments for any action taken:

Source Completed By (Initials):

ALBREATH v1

27. Less discouraged	<input type="radio"/> True	<input type="radio"/> False
	<input type="radio"/>	<input type="radio"/>
	<input type="radio"/>	<input type="radio"/>
	<input type="radio"/>	<input type="radio"/>
	<input type="radio"/>	<input type="radio"/>
	<input type="radio"/>	<input type="radio"/>
	<input type="radio"/>	<input type="radio"/>
	<input type="radio"/>	<input type="radio"/>
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	<input type="radio"/>	<input type="radio"/>
	<input type="radio"/>	<input type="radio"/>
	<input type="radio"/>	<input type="radio"/>

Source Completed By (Initials):

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Study Day UNSCHD

Form Not Done

Date: / / (mm) (dd) (yyyy)

BRIEF PSYCHIATRIC RATING SCALE

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

Time Interval:

Table with 9 columns: SYMPTOMS, Not Assessed, Not Present, Very Mild, Mild, Moderate, Moderately Severe, Severe, Extremely Severe. Row 1: 1-Somatic Concern. Subsequent rows are empty for symptom names.

Source Completed By (Initials):

BPRSTIME v1

Protocol Number: NIDA-CPU-0003

RPR 102681 - Cocaine Interaction

Study Day UNSCHD

Form Not Done

Site Identification Number: 980101

Subject Identification Number: 0050

Date: / / (mm) (dd) (yyyy)

BRIEF PHYSICAL EXAM

Temperature: (oral) F C

Respiratory Rate breaths/minute

Pulse Rate beats/minute

Blood Pressure mm/hg

Table with 5 columns: General Exam, Normal, Abnormal, Abnormal Significant, Not Done, and If Abnormal, explain below. Rows include Neurological, Cardiovascular, Respiratory, Gastrointestinal, Skin, and Other, specify.

Source Completed By (Initials):

BRIEFPE v1

Protocol Number: NIDA-CPU-0003

RPR 102681 - Cocaine Interaction

Study Day UNSCHD

Form Not Done

Site Identification Number: 980101

Subject Identification Number: 0050

Date: [] / [] / []
(mm) (dd) (yyyy)

BRIEF SUBSTANCE CRAVING SCALE (BSCS)

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

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

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

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

5) Write in the total TIME spent craving cocaine during the past 24 hours: [] HOURS [] MINUTES

6) WORST day: During the past week my most intense craving occurred on the following day: []

7) The date for that day was: [] / [] / [] (mm/dd/yyyy) *(If "All days the same, then skip to Question #8)*

8) The INTENSITY of my craving, that is, how much I desired cocaine on that WORST day was: []

9) A 2nd craved drug during the past 24 hours was: []

[] Other (specify)

10) The INTENSITY of my craving, that is, how much I desired this second drug in the past 24 hrs was: []

11) The FREQUENCY of my craving, that is, how often I desired this second drug in the past 24 hrs was: []

12) The LENGTH of time I spent in craving for this second drug during the past 24 hrs was: []

13) A 3rd craved drug during the past 24 hours was: []

[] Other (specify)

14) The INTENSITY of my craving, that is, how much I desired this third drug in the past 24 hrs was: []

15) The FREQUENCY of my craving, that is, how often I desired this third drug in the past 24 hrs was: []

16) The LENGTH of time I spent in craving for this third drug during the past 24 hrs was: []

Source Completed By (Initials): []

BSCS v1

Protocol Number: NIDA-CPU-0003

RPR 102681 - Cocaine Interaction

Study Day UNSCHD

Site Identification Number: 980101

Subject Identification Number: 0050

Date: / / (mm) (dd) (yyyy)

COCAINE TIMELINE FOLLOW BACK

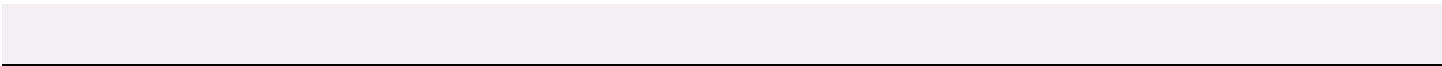
Consent Date: / / (mm/dd/yyyy)

Date 30 Days Prior to Consent Date: / / (mm/dd/yyyy)

Day 1 is yesterday, Day 2 is the day before yesterday, etc.

Table with 3 columns and 28 rows for data entry, each cell containing a radio button.

Source Completed By (Initials):



Protocol Number: NIDA-CPU-0003

RPR 102681 - Cocaine Interaction

Study Day UNSCHD

Site Identification Number: 980101

Subject Identification Number: 0050

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?

[Text input field for primary cause of death]

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

[Text input field for narrative description of death]

Source Completed By (Initials): [Text input field]

Protocol Number: NIDA-CPU-0003

RPR 102681 - Cocaine Interaction

Study Day UNSCHD

Site Identification Number: 980101

Subject Identification Number: 0050

Date: (mm) / (dd) / (yyyy)

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 or African American
Yes/No American Indian or Alaskan Native
Yes/No Spanish, Hispanic, or Latino (check all that apply)
Mexican, Mexican-American, or Chicano
Cuban
Puerto Rican
Other (specify)
Yes/No Asian (check all that apply)
Asian Indian
Korean
Chinese
Vietnamese
Filipino
Other (specify)
Japanese
Yes/No Native Hawaiian or Pacific Islander (check all that apply)
Native Hawaiian
Samoan
Guamanian or Chamorro
Other (specify)
Yes/No Other (specify)
Participant chooses not to answer

EMPLOYMENT/SUPPORT STATUS

1) Education completed (GED = 12 years): (years) (months)

2) Usual employment pattern, past 30 days:

- Full time (35+ hours/week)
Part time (regular hours)
Part time (irregular hours, day work)
Student
Military Service
Retired/Disabled
Homemaker
Unemployed
In controlled environment

3) Usual employment pattern, past 3 years:

- Full time (35+ hours/week)
- Student
- Homemaker
- Part time (regular hours)
- Military Service
- Unemployed
- Part time (irregular hours, day work)
- Retired/Disabled
- In controlled environment

4) Marital Status:

- Legally married
- Separated
- Living with partner/cohabitating
- Divorced
- Widowed
- Never Married

DRUG/ALCOHOL USE

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

- No problem
- Heroin
- Opiates/analgesics
- Cocaine
- Cannabis
- Nicotine
- Alcohol (any)
- Methadone/LAAM (presc.)
- Barbiturates
- Amphetamines
- Hallucinogens
- Alcohol and Drug Addiction
- Alcohol to intoxication
- Methadone/LAAM (illicit)
- Sed./Hyp./Tranq./Benzos.
- Methamphetamine
- Inhalants
- Polydrug addiction

Source Completed By (Initials):

DEMOG v1

Protocol Number: NIDA-CPU-0003

RPR 102681 - Cocaine Interaction

Study Day UNSCHD

Site Identification Number: 980101

Subject Identification Number: 0050

Date: / / (mm) (dd) (yyyy)

Form Not Done

12 LEAD ECG

Indicate if any result was ABNORMAL but does not exclude the subject from participation in the study, or ABNORMAL SIGNIFICANT and does preclude entry or (continued) participation in the study.

Test Type	Time (00:00-23:59)	VR (bpm)	PR (msec)	QT (msec)	QRS (msec)	R-R (msec)	QTc (msec)	ECG Abnormal?
12-Lead								<input type="checkbox"/> Yes <input type="checkbox"/> No

If Abnormal, Clinically Significant?

Yes No

Specify Abnormality as recorded on ECG tracing

Source Completed By (Initials):

ECG1 v1

Protocol Number: NIDA-CPU-0003

Site Identification Number: 980101

RPR 102681 - Cocaine Interaction

Subject Identification Number: 0050

Study Day UNSCHD

Date: / / (mm) (dd) (yyyy)

Form Not Done

12 LEAD ECG

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 9 columns: Time Interval, Time (00:00-23:59), VR (bpm), PR (msec), QT (msec), QRS (msec), R-R (msec), QTc (msec), ECG Abnormal?. It contains 5 rows of data entry fields for ECG readings at different time intervals.

Source Completed By (Initials):

ECGPRFL1 v1

Protocol Number: NIDA-CPU-0003

Site Identification Number: 980101

RPR 102681 - Cocaine Interaction

Subject Identification Number: 0050

Study Day UNSCHD

END OF TRIAL

1) Study Termination Date: [mm] / [dd] / [yyyy] Last Date of Study Drug: [mm] / [dd] / [yyyy]

2) Reason for study termination (CHECK ONLY ONE):

- A. Subject completed the study
B. Subject was a screen failure

If "B" is checked, please check primary reason for screen failure below (only check one)

- He/she did not meet study criteria
He/she did not complete screening process
C. Subject did not complete the study

If "C" is checked, please check primary reason for withdrawal below (only check one)

- Subject was determined after enrollment to be ineligible. (Provide comments)
Subject requested to withdraw. (Provide comments)
Subject experienced intercurrent illness, unrelated medical condition, or clinically significant adverse events, which, in the judgement of the investigator, prompted early termination. (If subject experienced adverse event(s), an Adverse Event Case Report Form(s) must be completed.) (Provide comments.)
Subject terminated for administrative reasons. (Include protocol non-compliance in this category. Provide comments)
Subject transferred to another treatment program (check type)
Methadone LAAM Drug Free Inpatient Detox or Treatment
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. (Complete Death Report CRF)
Subject can no longer attend clinic.
Subject no longer attends clinic.
Subject is in a controlled environment.
Other (Provide comments)

Comments:

[Large empty box for comments]

Source Completed By (Initials): []

Protocol Number: NIDA-CPU-0003

RPR 102681 - Cocaine Interaction

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Site Identification Number: 980101

Subject Identification Number: 0050

ENROLLMENT

Is the subject eligible for the study based on Inclusion and Exclusion Criteria? Yes No

If yes:

Was the subject enrolled? Yes No

If enrolled:

Date enrolled (hospital admission date): / / (mm/dd/yyyy)

If eligible and not enrolled, check reason:

- failed to return
- declined participation
- other, specify:

Source Completed By (Initials):

ENROLL v1

Protocol Number: NIDA-CPU-0003

RPR 102681 - Cocaine Interaction

Study Day UNSCHD

Site Identification Number: 980101

Subject Identification Number: 0050

Date: / /
(mm) (dd) (yyyy)

EXCLUSION CRITERIA

Participant must not:

- | | |
|--|--|
| 1. Have a current or past history of seizure disorder, including alcohol- or stimulant-related seizure, febrile seizure, or significant family history of idiopathic seizure disorder. | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 2. Have a previous medically adverse reaction to cocaine, including loss of consciousness, chest pain, or seizure. | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 3. According to DSM-IV criteria as determined by structured clinical interview (SCID), have any history of major psychiatric illness, such as bipolar disorder, depression, manic or dysthymic illness, other than drug dependence or disorders secondary to drug use as determined by a National Institute of Mental Health trained technician. | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 4. Be pregnant or lactating. | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 5. Have a history of liver disease or current elevation of aspartate aminotransferase (AST) or alanine aminotransferase (ALT) exceeding the upper limit of normal. | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 6. Have donated a unit of blood or participated in any other clinical investigation within 4 weeks of enrolling on the study. | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 7. Have a history of any illness, or a family history of early significant cardiovascular disease, or a history of behavior, that in the opinion of the investigator might confound the results of the study or pose additional risk in administering the investigational agents to the subject. | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 8. Be seropositive for hepatitis B surface antigen, hepatitis C antibody, or human immunodeficiency virus (HIV) type 1. | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 9. Have a diagnosis of adult onset asthma (i.e., 21 years or older), or chronic obstructive pulmonary disease (COPD), 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. | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 10. Have any illness, condition, and use of medications, that in the opinion of the principal investigator and the admitting physician, would preclude safe and/or successful completion of the study. | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 11. Currently use illicit drugs besides cocaine and marijuana. | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 12. Have used any prescription drugs within 14 days of the start or non-prescription drugs within 7 days of the start of the study. | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 13. Be unable to distinguish between a 20 mg and 40 mg dose of cocaine intravenously during the administration of screening infusions. | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 14. Have had prior exposure to radiation for a research study. This excludes having x-rays for medical purposes. | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 15. Have had tattoos within the last 6 months. | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 16. Have a metallic body art (such as eye rings, navel rings) that cannot be removed. | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 17. Have an abnormal MRI finding discovered as part of the PET Scan procedure.
(Subjects will be notified immediately of results and advised to contact their primary care physician.) | <input type="checkbox"/> Yes <input type="checkbox"/> No |

To be included in the trial, all answers to Exclusion Criteria must be NO.

Source Completed By (Initials):

(EXCLUS v1)

Protocol Number: NIDA-CPU-0003

RPR 102681 - Cocaine Interaction

Site Identification Number: 980101

Subject Identification Number: 0050

Study Day UNSCHD

Date: [mm] / [dd] / [yyyy]

Form Not Done []

FOLLOW-UP

1) Has contact been made with the subject? [Yes] [No] (If Yes, skip to Question #4)

If so, date: [mm] / [dd] / [yyyy] (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).

Table with 4 columns: DRUG, Days Used, DRUG, Days Used. Rows include Cocaine, Methamphetamines, Amphetamines, Benzodiazepines, Alcohol, Marijuana, Sedatives, Nicotine, Opiates, Barbiturates, None, Other.

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-CPU-0003

RPR 102681 - Cocaine Interaction

Study Day UNSCHD

Site Identification Number: 980101

Subject Identification Number: 0050

Date: / /
(mm) (dd) (yyyy)

INFUSION BLOOD SPECIMEN TRACKING (DAY 0)

Actual Time (00:00 - 23:59)	Serum Prolactin Assay Blood Drawn	Comments	Initials
	<input type="radio"/> Yes <input type="radio"/> No		

INBLDSP1 v1

Protocol Number: NIDA-CPU-0003

RPR 102681 - Cocaine Interaction

Study Day UNSCHD

Site Identification Number: 980101

Subject Identification Number: 0050

Date: / /
(mm) (dd) (yyyy)

INFUSION BLOOD SPECIMEN TRACKING (DAY 8)

Time Point	Actual Time (00:00 - 23:59)	LFT Blood Drawn	Actual Time (00:00 - 23:59)	Cocaine PK Blood Drawn	Comments	Initials
-25 min		<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Yes <input type="checkbox"/> No		
		<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"/>		

Protocol Number: NIDA-CPU-0003

RPR 102681 - Cocaine Interaction

Study Day UNSCHD

Site Identification Number: 980101

Subject Identification Number: 0050

Date: / /
(mm) (dd) (yyyy)

INCLUSION CRITERIA

Participant must:

- | | |
|--|--|
| 1. Be volunteers who are not seeking treatment at the time of the study. | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 2. Be between 18 and 45 years of age and within 20% of ideal body weight according to the Metropolitan Height and Weight Chart, and weigh at least 45 kg. | <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. Must currently use cocaine by the smoked or i.v. route, and this use must be confirmed by s positive BE urine test once within 30 days prior to entering the study. | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 5. Be able to verbalize understanding of consent form, able to provide written informed consent, and verbalize willingness to complete study procedures. | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 6. If female and have a negative pregnancy test within 72 hours prior to receiving the first dose of investigational agent and agree to use one of the following methods of birth control, or be postmenopausal, or have had hysterectomy, or have been sterilized, or be male.

a) complete abstinence from sexual intercourse
b) diaphragm and condom by partner
c) intrauterine device and condom by partner
d) sponge and condom by partner

<u>Note:</u> oral contraceptives, Depo-Provera, Norplant and intrauterine progesterone contraceptive system are not allowed. | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 7. Have a history and physical examination that demonstrate no clinically significant contraindication for participating in the study. | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 8. Be able to comply with protocol requirements, Clinical Pharmacology Unit (CPU) rules and regulations, and be likely to complete all the study treatments. | <input type="checkbox"/> Yes <input type="checkbox"/> No |

To be included in the trial, all answers to Inclusion Criteria must be YES

Source Completed By (Initials):

(INCLUS V1)

Protocol Number: NIDA-CPU-0003

RPR 102681 - Cocaine Interaction

Study Day UNSCHD

Site Identification Number: 980101

Subject Identification Number: 0050

INFORMED CONSENT DATE

Date Informed Consent was signed: / /
(mm) (dd) (yyyy)

Completed by (initials):

INCONSNT v1

Protocol Number: NIDA-CPU-0003

RPR 102681 - Cocaine Interaction

Study Day UNSCHD

Site Identification Number: 980101

Subject Identification Number: 0050

Date: / /
(mm) (dd) (yyyy)

INFUSION BLOOD SPECIMEN TRACKING (DAY 13, 20 AND 27)

Actual Time (00:00 - 23:59)	RPR 102681PK Blood Drawn	Comments	Initials
12:12	<input type="checkbox"/> Yes <input type="checkbox"/> No		
	<input type="checkbox"/> <input type="checkbox"/>		

Protocol Number: NIDA-CPU-0003

RPR 102681 - Cocaine Interaction

Study Day UNSCHD

Site Identification Number: 980101

Subject Identification Number: 0050

Date: / /
(mm) (dd) (yyyy)

INFUSION BLOOD SPECIMEN TRACKING (DAY 14, 21 AND 28)

Time Point	Actual Time (00:00 - 23:59)	RPR 102681PK Blood Drawn	Comments	Initials
-20 min		<input type="checkbox"/> Yes <input type="checkbox"/> No		
		<input type="checkbox"/> <input type="checkbox"/>		

Protocol Number: NIDA-CPU-0003

RPR 102681 - Cocaine Interaction

Study Day UNSCHD

Site Identification Number: 980101

Subject Identification Number: 0050

Date: / / (mm) (dd) (yyyy)

INFUSION BLOOD SPECIMEN TRACKING (DAY 15, 22 AND 29)

Table with 11 columns: Time Point, Actual Time (00:00 - 23:59), LFT Blood Drawn (Yes/No), Actual Time (00:00 - 23:59), Cocaine PK Blood Drawn (Yes/No), Actual Time (00:00 - 23:59), RPR 102681PK Blood Drawn (Yes/No), Actual Time (00:00 - 23:59), Serum Prolactin Assay Blood Drawn (Yes/No), Comments, Initials. The table contains 15 rows of empty data entry fields.

Protocol Number: NIDA-CPU-0003

Site Identification Number: 980101

RPR 102681 - Cocaine Interaction

Subject Identification Number: 0050

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.

Date of Hepatitis Specimen: [] / [] / [] (mm/dd/yyyy)

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-CPU-0003

RPR 102681 - Cocaine Interaction

Study Day UNSCHD

Site Identification Number: 980101

Subject Identification Number: 0050

Form Not Done

Date: / / (mm) (dd) (yyyy)

INFUSION MONITORING

Cocaine 20mg/Saline Cocaine 40mg/Saline

Infusion 1: Start Time: Stop Time: Administered By: (Initials)

Infusion 2: Start Time: Stop Time: Administered By: (Initials)

Table with 6 columns: Time Interval, Actual Time, Blood Pressure, Heart Rate, Comments, Initials. Includes a row for -15 min and multiple empty rows for data entry.

90 min	(00:00-23:59)	(sys)	/	(dias)	(beats/min)	

Protocol Number: NIDA-CPU-0003

RPR 102681 - Cocaine Interaction

Study Day UNSCHD

Site Identification Number: 980101

Subject Identification Number: 0050

Date: / /
(mm) (dd) (yyyy)

INTAKE SCREENING LAB TRACKING FORM

Check to indicate whether tests were done.

Chemistry plus Liver function tests

Not Done Done

Comments

Source Completed By (Initials):

INLABTRK v1

Protocol Number: NIDA-CPU-0003

RPR 102681 - Cocaine Interaction

Study Day: UNSCHD

Site Identification Number: 980101

Subject Identification Number: 0050

Date Administered: / /
(mm) (dd) (yyyy)

Form Not Done

INVESTIGATIONAL AGENT ADMINISTRATION

Line No.	No. of Capsules Administered	RPR 102681/ Placebo Dose	Time Administered	Comments	Administered By
1.			(00:00-23:59)		(Initials)
2.			(00:00-23:59)		(Initials)

Source Completed By (Initials):

INVAGT v1

Protocol Number: NIDA-CPU-0003

RPR 102681 - Cocaine Interaction

Study Day UNSCHD

Site Identification Number: 980101

Subject Identification Number: 0050

Date: / /
(mm) (dd) (yyyy)

LAB TRACKING FORM

Check to indicate whether tests were done.

Comments

Hematology Not Done Done

Chemistry plus Liver function tests Not Done Done

Source Completed By (Initials):

LABTRACK v1

Protocol Number: NIDA-CPU-0003

RPR 102681 - Cocaine Interaction

Study Day UNSCHD

Site Identification Number: 980101

Subject Identification Number: 0050

Date: / / (mm) (dd) (yyyy)

MEDICAL HISTORY

Table with 6 columns: Disorder, Yes excludes, Yes doesn't exclude, No history of disorder, Not evaluated, If yes, specify or describe. Rows include Allergies, Sensitivity to Agent/Compounds, History of Asthma, HEENT, Cardiovascular, Renal, Hepatic, Pulmonary, Gastrointestinal, Musculoskeletal, Neurologic, Psychiatric, Dermatologic, Metabolic, Hematologic, Endocrine, Genitourinary, Reproductive System, Seizure, Infectious Disease, and Other 1/2.

24. Was major surgery ever performed?

Yes No

(If Yes, list surgeries:)

Is surgery relevant to study participation?

	Type of Surgery	Date of Surgery (mm/dd/yyyy)	Is surgery relevant to study participation?		
			Yes excludes	Yes doesn't exclude	No
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-CPU-0003

Site Identification Number: 980101

RPR 102681 - Cocaine Interaction

Subject Identification Number: 0050

Study Day: UNSCHD

Date: / / (mm) (dd) (yyyy)

PHYSICAL EXAMINATION

Height: inches centimeters

Weight: pounds kilograms

Temperature: (oral) F C

Respiratory Rate: breaths/minute

Pulse Rate: beats/minute

Blood Pressure: mm/hg

Table with columns: General Exam, Normal, Abnormal, Abnormal Significant, Not Done, If Abnormal, explain below. Rows include Oral (mouth), Head, Eyes, ears, nose/throat, Cardiovascular, Lungs, Abdomen (include liver/spleen), Extremities, Skin, Neuropsychiatric mental status, Neuropsychiatric sensory/motor, Musculoskeletal, General Appearance, Other, specify.

Source Completed By (Initials):

PHYSEXAM v1

Protocol Number: NIDA-CPU-0003

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Subject Identification Number: 0050

PLASMA ALCOHOL TEST

Plasma Alcohol Test Done Not Done

If done:

Date: / /
(mm) (dd) (yyyy)

Source Completed By: (initials)

PLASMA v1

Protocol Number: NIDA-CPU-0003

RPR 102681 - Cocaine Interaction

Study Day UNSCHD

Site Identification Number: 980101

Subject Identification Number: 0050

Date: / / (mm) (dd) (yyyy)

Form Not Done

PROFILE OF MOOD STATES (POMS)

How have you been feeling during the past two days?

Table with columns: FEELINGS, Not at all, A Little Bit, Moderately, Quite a bit, Extremely. Row 1: 1. Friendly. Subsequent rows are empty for input.

Protocol Number: NIDA-CPU-0003

RPR 102681 - Cocaine Interaction

Study Day UNSCHD

Site Identification Number: 980101

Subject Identification Number: 0050

Date: / /
(mm) (dd) (yyyy)

PREGNANCY

1) Was a pregnancy test performed? Yes
 No
 N/A subject is male (If N/A, the rest of the form should be blank)

2) Pregnancy test result: Positive
 Negative

3) Pregnancy test comments:

4) Is the subject lactating? Yes No Not Applicable

5) Is the subject using an acceptable method of birth control? Yes No

6) What method of birth control is the subject using?

- Subject is postmenopausal
- Subject had a hysterectomy
- Subject is sterile
- Complete abstinence from sexual intercourse
- Diaphragm and condom by partner
- Intrauterine device and condom by partner
- Sponge and condom by partner

Source Completed By (Initials):

PREGNANT v1

Protocol Number: NIDA-CPU-0003

Site Identification Number: 980101

RPR 102681 - Cocaine Interaction

Subject Identification Number: 0050

Study Day UNSCHD

PRIOR AND CONCOMITANT MEDICATIONS

Has the subject taken any prescription or OTC medications 30 days prior to or during the study?

Yes No If yes, please complete table

Legend table for medication units, frequencies, and routes of administration.

Main medication entry form with fields for No., Medication, Dose, Unit, Other, Frequency, Other, Route, Other, Start Date, Stop Date, Cont.?, Indication, Related to an AE?, and Initials.

Protocol Number: NIDA-CPU-0003

RPR 102681 - Cocaine Interaction

Study Day UNSCHD

Site Identification Number: 980101

Subject Identification Number: 0050

Date: / /
(mm) (dd) (yyyy)

PRE-INTAKE SCREENING LAB TRACKING FORM

Check to indicate whether tests were done.

Comments

Hematology Not Done Done

Chemistry plus Liver function tests Not Done Done

Urinalysis Not Done Done

Source Completed By (Initials):

PRLABTRK v1

Protocol Number: NIDA-CPU-0003

RPR 102681 - Cocaine Interaction

Study Day UNSCHD

Site Identification Number: 980101

Subject Identification Number: 0050

RANDOMIZATION

Was the subject randomized? Yes No

If randomized:

Date randomized: / / (mm/dd/yyyy)

Random Dose Code Number:

If randomized, did the subject receive the first dose of study drug? Yes No

If eligible and not randomized, check reason:

declined participation other, specify:

Source Completed By (Initials):

RANDOM v1

Protocol Number: NIDA-CPU-0003

Site Identification Number: 980101

RPR 102681 - Cocaine Interaction

Subject Identification Number: 0050

Study Day UNSCHD

SERIOUS ADVERSE EVENTS

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

Multiple empty text boxes for SAE description.

Onset Date [] / [] / [] (mm/dd/yyyy)

Reported to FDA by: [] Initial Date reported to FDA: [] / [] / [] (mm/dd/yyyy)

Reported to Sponsor by: [] Date reported to sponsor: [] / [] / [] (mm/dd/yyyy)

Reported to NIDA by: [] Initial Date reported to NIDA: [] / [] / [] (mm/dd/yyyy)

Severity grade [] mild [] moderate [] severe

Was SAE related to investigational agent?

- definitely probably possibly remotely definitely not unknown

Action taken regarding investigational agent

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

Other action(s) taken

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

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

- death life-threatening event hospitalization disability congenital anomaly other (specify)

Concomitant Medications

Empty text box for 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) OR 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

- | | |
|--|--|
| <input type="checkbox"/> auricular | <input type="checkbox"/> rectal |
| <input type="checkbox"/> inhaled | <input type="checkbox"/> subcutaneous |
| <input type="checkbox"/> intra-articular | <input type="checkbox"/> sublingual |
| <input type="checkbox"/> intramuscular | <input type="checkbox"/> transdermal |
| <input type="checkbox"/> intraocular | <input type="checkbox"/> vaginal |
| <input type="checkbox"/> intravenous | <input type="checkbox"/> unknown |
| <input type="checkbox"/> nasal | <input type="checkbox"/> other (specify) |
| <input type="checkbox"/> oral | <input type="text"/> |

Frequency

- | |
|--|
| <input type="checkbox"/> single dose |
| <input type="checkbox"/> once daily |
| <input type="checkbox"/> every other day |
| <input type="checkbox"/> twice daily |
| <input type="checkbox"/> three times a day |
| <input type="checkbox"/> four times a day |
| <input type="checkbox"/> as needed |
| <input type="checkbox"/> other (specify) |
| <input type="text"/> |

Comments

Source Completed By (Initials):

Protocol Number: NIDA-CPU-0003

RPR 102681 - Cocaine Interaction

Study Day UNSCHD

Site Identification Number: 980101

Subject Identification Number: 0050

Date: / / (mm) (dd) (yyyy)

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-CPU-0003

RPR 102681 - Cocaine Interaction

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Site Identification Number: 980101

Subject Identification Number: 0050

Date: / /
(mm) (dd) (yyyy)

Form Not Done

URINE TOXICOLOGY

Urine temperature within expected range?

Yes No Unknown (96.4 < or = T < or = 100.4 F)

Drug/Test	Positive	Negative	Not Done
Amphetamines	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Barbiturates	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Benzodiazepines	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cannabinoids (THC)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cocaine metabolites	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Methadone	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Methamphetamine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Methaqualone	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Opiates	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Phencyclidine (PCP)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Propoxyphene	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Tricyclics	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Source Completed By (Initials):

URINETOX v1

Protocol Number: NIDA-CPU-0003

RPR 102681 - Cocaine Interaction

Study Day UNSCHD

Site Identification Number: 980101

Subject Identification Number: 0050

Date: / /
(mm) (dd) (yyyy)

Form Not Done

VISUAL ANALOG SCALE

- 1. Do you feel any drug effect?

- 2. How high are you?

- 3. Does the drug have any good effects?

- 4. Does the drug have any bad effects?

- 5. How much do you like the drug?

- 6. How much do you desire the drug right now?

- 7. How depressed do you feel?

- 8. How anxious do you feel?

- 9. How stimulated do you feel?

- 10. If you had access to the drug right now,
how likely would you be to use it?

- 11. How much would you pay for this drug? \$

Source Completed By (Initials):

VAS v1

Protocol Number: NIDA-CPU-0003

Site Identification Number: 980101

RPR 102681 - Cocaine Interaction

Subject Identification Number: 0050

Study Day UNSCHD

Form Not Done

Date: / / (mm) (dd) (yyyy)

VISUAL ANALOG SCALE

Time Interval	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
-15 Minutes						
	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?
Time Interval	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
5 Minutes Post						
	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?
Time Interval	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
15 Minutes Post						
	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?
Time Interval	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
25 Minutes Post						
	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?
Time Interval	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
35 Minutes Post						
	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?

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"/>
Time Interval 75 Minutes Post	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"/>
Time Interval 85 Minutes Post	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"/>
Time Interval 85 Minutes Post	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"/>
Time Interval 95 Minutes Post	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"/>
Time Interval 95 Minutes Post	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"/>

Source Completed By (Initials):

VISLANA1 v1

Protocol Number: NIDA-CPU-0003

RPR 102681 - Cocaine Interaction

Study Day UNSCHD

Site Identification Number: 980101

Subject Identification Number: 0050

Date: / /
(mm) (dd) (yyyy)

Form Not Done

VITAL SIGNS

Time: (00:00-23:59)

Temp: (oral) F C

SITTING:

Respiratory Rate breaths/minute

Pulse Rate beats/minute

Blood Pressure mm/hg

Source Completed By (Initials):

VITALS v1

Protocol Number: NIDA-CPU-0003

RPR 102681 - Cocaine Interaction

Study Day UNSCHD

Site Identification Number: 980101

Subject Identification Number: 0001

Date: / / (mm) (dd) (yyyy)

Form Not Done

CHEMISTRIES

Table with 8 columns: Analyte, Std. Quantity, Standard Unit, Other Specify, Normal, Abnormal, Abnormal Significant, Not Done. Rows include GGT, LDH, SGOT/AST, SGPT/ALT, AlkPhos, Total Bilirubin, Total Protein, Albumin, CPK, Glucose, BUN, Creatinine, Uric Acid, Calcium, Phosphorus, Sodium, Potassium, Chloride, CO2, Cholesterol, Triglycerides, Iron.

Provide comments for any abnormal value(s)

Text input box for comments

Source Completed By (Initials):

Text input box for initials

Protocol Number: NIDA-CPU-0003

Site Identification Number: 980101

RPR 102681 - Cocaine Interaction

Subject Identification Number: 0001

Study Day UNSCHD

Date: / / (mm) (dd) (yyyy)

Form Not Done

HEMATOLOGY

<u>Complete Blood Count</u>	<u>Std. Quantity</u>	<u>Standard Unit</u>	<u>Other Specify</u>	<u>Normal</u>	<u>Abnormal</u>	<u>Abnormal Significant</u>	<u>Not Done</u>
1) WBC				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2) RBC				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3) Hemoglobin				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4) Hematocrit				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5) MCV				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6) Platelet Count				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7) Neutrophils				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8) Lymphocytes				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9) Monocytes				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10) Eosinophils				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11) Basophils				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Provide comments for any abnormal value(s)

Source Completed By (Initials):

Protocol Number: NIDA-CPU-0003

RPR 102681 - Cocaine Interaction

Study Day UNSCHD

Site Identification Number: 980101

Subject Identification Number: 0001

Date: / / (mm) (dd) (yyyy)

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.

Table with 3 columns: Levels, Result, Comments for Abnormal Values. Rows include: 1) Color, 2) Clarity, 3) Specific Gravity, 4) PH, 5) Protein, 6) Glucose, 7) Ketones, 8) Bilirubin, 9) Blood, 10) Leukocyte Esterase, 11) Nitrite, 12) Urobilinogen (mg/dl), 13) WBC, 14) RBC.

Source Completed By (Initials):

URINE v1