Protocol Number: NIDA-MDS-Disulfiram-0001

Disulfiram, Cocaine and Alcohol Interaction

Site Identification Number: 980202

Subject Identification Number:

Study Day UNSCHD

Date: (mm/dd/yyyy)

ACETALDEHYDE PHARMACOKINETICS

Time Point	Actual Time (00:00-23:59)	Acetaldehyde PK Blood Drawn	Barcode	Comments	Initials

ACEPK v1

Protocol Number: NIDA-MDS-Disulfiram-0001

Disulfiram, Cocaine and Alcohol Interaction

Site Identification Number: 980202

Subject Identification Number: 0001

Study Day UNSCHD

Date: (mm/dd/yyyy)

☐ **Form Not Done**

ADJECTIVE SELF-ASSESSMENT SCALE FOR DER SYMPTOMS (DAY -3)

Instructions: Listed below are symptoms that you may experience in this study.

For each item, please choose one number to indicate how much you feel that way **"right now".**

Time Interval	Actual Time	Good	Bad	Nauseous	Hot or Flushed	Dizzy	Heart is Racing	Short of Breath	Headache	Sick
-15 min	(00:00 - 23:59)									

Time Interval	Actual Time	Good	Bad	Nauseous	Hot or Flushed	Dizzy
64 min	(00:00 - 23:59)	Heart is Racing	Short of Breath	Headache	Sick	

Source Completed By (Initials):

ADJSDER1 v1

Protocol Number: NIDA-MDS-Disulfiram-0001	**Site Identification Number:** 980203
Disulfiram, Cocaine and Alcohol Interaction	**Subject Identification Number:** 0001
Study Day UNSCHD	**Date:** (mm/dd/yyyy)

☐ **Form Not Done**

ADJECTIVE SELF-ASSESSMENT SCALE FOR DER SYMPTOMS (DAY -2 TO 7)

Instructions: Listed below are symptoms that you may experience in this study.
For each item, please choose one number to indicate how much you feel that way **"right now".**

Time Interval	Actual Time	Good	Bad	Nauseous	Hot or Flushed	Dizzy
-120 min	(00:00 - 23:59)	Heart is Racing	Short of Breath	Headache	Sick	

Time Interval	Actual Time	Good	Bad	Nauseous	Hot or Flushed	Dizzy
30 min	(00:00 - 23:59)	Heart is Racing	Short of Breath	Headache	Sick	

Source Completed By (Initials):

ADJSDER2 v1

Protocol Number: NIDA-MDS-Disulfiram-0001

Disulfiram, Cocaine and Alcohol Interaction

Site Identification Number: 980202

Subject Identification Number: 0001

Study Day UNSCHD

ADVERSE EVENTS

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

Severity	Study Drug Relationship	Action Taken Regarding Investigational Agent	Other Action Taken	Outcome of AE	Serious
1 = Mild 2 = Moderate 3 = Severe	1 = Definitely 2 = Probably 3 = Possibly 4 = Remotely 5 = Definitely Not 6 = Unknown	1 = None 2 = Discontinued Perm. 3 = Discontinued Temp. 4 = Reduced Dose 5 = Increased Dose 6 = Delayed Dose	1 = None 2 = Remedial Therapy-pharm 3 = Remedial Therapy-nonpharm 4 = Hospitalization	1 = Resolved, No Sequelae 2 = AE still present - no tx 3 = AE still present - being tx 4 = Residual effects present-no tx 5 = Residual effects present being-tx 6 = Death 7 = Unknown	1 = Yes 2 = No (If yes, complete SAE form)

#	EVENT	Start Date (mm / dd / yyyy)	Stop Date (mm / dd / yyyy)	Continuing
1		/ /	/ /	☐

Severity	Relatedness	Action Taken	Other Action	Outcome	Serious	Initials
					☐ Yes ☐ No	

Protocol Number: NIDA-MDS-Disulfiram-0001

Disulfiram, Cocaine and Alcohol Interaction

Site Identification Number: 980202

Subject Identification Number: 0001

Study Day UNSCHD

Date: (mm/dd/yyyy)

☐ **Form Not Done**

ALCOHOL BREATHALYZER TEST (DAY -3)

Time Administered	Actual Time (00:00-23:59)	Was alcohol breathalyzer test performed?	Breath Alcohol Content	Provide comments for any action taken
		◉ ◉		
		◉ ◉		
		◉ ◉		

Source Completed By (Initials):

ALBRTH1 v1

Protocol Number: NIDA-MDS-Disulfiram-0001

Disulfiram, Cocaine and Alcohol Interaction

Site Identification Number: 980202

Subject Identification Number: 0001

Study Day UNSCHD

Date: (mm/dd/yyyy)

☐ **Form Not Done**

ALCOHOL BREATHALYZER TEST (DAY -2 TO 7)

Time Administered	Actual Time (00:00-23:59)	Was alcohol breathalyzer test performed?	Breath Alcohol Content	Provide comments for any action taken
		◎ ◎		
		◎ ◎		
		◎ ◎		
		◎ ◎		
		◎ ◎		
		◎ ◎		
		◎ ◎		
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		◎ ◎		
		◎ ◎		
		◎ ◎		
		◎ ◎		
		◎ ◎		
		◎ ◎		

Source Completed By (Initials):

Protocol Number: NIDA-MDS-Disulfiram-0001

Disulfiram, Cocaine and Alcohol Interaction

Site Identification Number: 980202

Subject Identification Number: 0001

Study Day UNSCHD

Date: (mm/dd/yyyy)

☐ **Form Not Done**

CHEMISTRIES

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

Provide comments for any abnormal value(s)

Source Completed By (Initials):

Protocol Number: NIDA-MDS-Disulfiram-0001

Disulfiram, Cocaine and Alcohol Interaction

Site Identification Number: 980202

Subject Identification Number: 0001

Study Day UNSCHD

Date: (mm/dd/yyyy)

COCAINE PHARMACOKINETICS

Time Point	Actual Time (00:00-23:59)	Cocaine PK Blood Drawn	Barcode	Comments	Initials

COCPK v1

Protocol Number: NIDA-MDS-Disulfiram-0001	**Site Identification Number:** 980202
Disulfiram, Cocaine and Alcohol Interaction	**Subject Identification Number:** 0001
Study Day UNSCHD	**Date:** ______ (mm/dd/yyyy)

COCAINE TIMELINE FOLLOW BACK

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

Date 42 Days Prior to Consent Date: ____ / ____ / ____ (mm/dd/yyyy)

Day	Cocaine Use		Alcohol Use	
	○	○	○	○
	○	○	○	○
	○	○	○	○
	○	○	○	○
	○	○	○	○
	○	○	○	○
	○	○	○	○
	○	○	○	○
	○	○	○	○
	○	○	○	○
	○	○	○	○
	○	○	○	○
	○	○	○	○
	○	○	○	○
	○	○	○	○
	○	○	○	○
	○	○	○	○
	○	○	○	○
	○	○	○	○
	○	○	○	○
	○	○	○	○
	○	○	○	○
	○	○	○	○
	○	○	○	○
	○	○	○	○
	○	○	○	○
	○	○	○	○
	○	○	○	○
	○	○	○	○
	○	○	○	○
	○	○	○	○
	○	○	○	○
	○	○	○	○

Day 34	Yes	No	Yes	No

Source Completed By (Initials):

COCTIME v1

Protocol Number: NIDA-MDS-Disulfiram-0001

Disulfiram, Cocaine and Alcohol Interaction

Site Identification Number: 980202

Subject Identification Number: 0001

Study Day UNSCHD

CONCOMITANT MEDICATIONS

Has the subject taken any concomitant medications during this study? ☐ Yes ☐ No *If yes, please complete table*

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			QHS	= at bedtime	SL	= sublingual		

No.	Medication	Dose	Unit	Other (specify)	Frequency	Other (specify)	Route	Other (specify)
1								

Start Date (mm / dd / yyyy)	Stop Date (mm / dd / yyyy)	Cont.?	Indication	Related to an AE?	Initials
/ /	/ /	☐		☐ Yes ☐ No	

CONMED v1

Protocol Number: NIDA-MDS-Disulfiram-0001

Disulfiram, Cocaine and Alcohol Interaction

Site Identification Number: 980202

Subject Identification Number: 0001

Study Day UNSCHD

DEATH REPORT

Subject Date of Death: ____ / ____ / ____
(mm) (dd) (yyyy)

Was autopsy performed? ☐ Yes ☐ No ☐ Unknown

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

Is cause of death known? ☐ Yes ☐ No

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

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

Source Completed By (Initials): ____

Protocol Number: NIDA-MDS-Disulfiram-0001	**Site Identification Number:** 980202
Disulfiram, Cocaine and Alcohol Interaction	**Subject Identification Number:** 0001

Study Day UNSCHD

Date: (mm/dd/yyyy)

☐ **Form Not Done**

DEMOGRAPHICS

Informed Consent Signed: / / (mm/dd/yyyy)

1) Gender ☐ Male ☐ Female

2) Date of Birth / / (mm/dd/yyyy)

3a) Ethnicity:

☐ Spanish origin, Hispanic or Latino

☐ Not of Spanish origin, Hispanic or Latino (Skip to question 4)

3b) Ethnicity Specification:

If Hispanic or Latino, answer Yes to ALL THAT APPLY and No to those that do not.

☐ Yes ☐ No Mexican, Mexican-American, or Chicano

☐ Yes ☐ No Puerto Rican

☐ Yes ☐ No Cuban

☐ Yes ☐ No Hispanic or Latino other, specify

4) Race:

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 Asian (check all that apply)

- ☐ Asian Indian
- ☐ Chinese
- ☐ Filipino
- ☐ Japanese
- ☐ Korean
- ☐ Vietnamese
- ☐ Other, specify

☐ Yes ☐ No Native Hawaiian or Pacific Islander (check all that apply)

- ☐ Native Hawaiian
- ☐ Guamanian or Chamorro
- ☐ Samoan
- ☐ Other, specify

☐ Yes ☐ No Other, specify

☐ **Participant chooses not to answer**

☐ **Unknown**

Source Completed By (Initials): _____

Protocol Number: NIDA-MDS-Disulfiram-0001

Disulfiram, Cocaine and Alcohol Interaction

Site Identification Number: 980202

Subject Identification Number: 0001

Study Day UNSCHD

Date: (mm/dd/yyyy)

☐ **Form Not Done**

DISULFIRAM ETHANOL REACTION (DAY -3)

Clinical signs of early DER include conjunctival injection, flushing; more extensive reactions include vomiting, and headache. Document the extent of DER by referring to the key below and choosing only ONE answer.

0 = no change from baseline
1 = localized flushing around the eyes or conjunctival injection
2 = extensive facial flushing
3 = Flushing extending to the neck and upper thorax
4 = Flushing extending to the back and arms

Time Administered	Actual Time (00:00-23:59)	DER Results

Source Completed By (Initials):

Protocol Number: NIDA-MDS-Disulfiram-0001	**Site Identification Number:** 980202
Disulfiram, Cocaine and Alcohol Interaction	**Subject Identification Number:** 0001

Study Day UNSCHD

Date: (mm/dd/yyyy)

☐ **Form Not Done**

DISULFIRAM ETHANOL REACTION (DAY -2 TO 7)

Clinical signs of early DER include conjunctival injection, flushing; more extensive reactions include vomiting, and headache.
Document the extent of DER by referring to the key below and choosing only ONE answer.

0 = no change from baseline
1 = localized flushing around the eyes or conjunctival injection
2 = extensive facial flushing
3 = Flushing extending to the neck and upper thorax
4 = Flushing extending to the back and arms

Time Administered	Actual Time (00:00-23:59)	DER Results

Source Completed By (Initials):

Protocol Number: NIDA-MDS-Disulfiram-0001

Disulfiram, Cocaine and Alcohol Interaction

Site Identification Number: 980202

Subject Identification Number: 0001

Study Day UNSCHD

Form Not Done ☐

Date: (mm/dd/yyyy)

ELECTROCARDIOGRAM 12-LEAD

A. ECG overall results were: ☐ Normal ☐ Abnormal

If ECG was normal, skip to question B; otherwise indicate if any result was ABNORMAL but does not exclude the subject from participation in the study, or ABNORMAL SIGNIFICANT and does preclude (continued) participation in the study.

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

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

B. Ventricular rate (bpm):

C. PR (ms):

D. QRS (ms):

E. QTc (ms):

Source Completed By (Initials)

Protocol Number: NIDA-MDS-Disulfiram-0001

Disulfiram, Cocaine and Alcohol Interaction

Site Identification Number: 980203

Subject Identification Number: 0005

Study Day DAY-2

Date: (mm/dd/yyyy)

Form Not Done ☐

ETHANOL INFUSION CALCULATED DOSE

Calculated Ethanol Infusion Volume (total mls D5E10): (Column A of Spreadsheet)

Infusion Minutes: (Column B of Spreadsheet)

Actual Ethanol Volume Infused (mls):

Actual Ethanol Infusion Minutes:

Source Completed By (Initials):

(EICD v1)

Protocol Number: NIDA-MDS-Disulfiram-0001	**Site Identification Number:** 980202
Disulfiram, Cocaine and Alcohol Interaction	**Subject Identification Number:** 0001

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 ONE ONLY):

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

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

- ☐ 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 (check one only)

- ☐ 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 judgment 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:

Source Completed By (Initials): ____

Protocol Number: NIDA-MDS-Disulfiram-0001

Disulfiram, Cocaine and Alcohol Interaction

Site Identification Number: 980202

Subject Identification Number: 0001

Study Day UNSCHD

ENROLLMENT (DAY-3)

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

(If no leave the rest of the form blank)

Did the subject successfully complete the screening infusions? ☐ Yes ☐ No

If no:

Did the subject meet stopping criteria? ☐ Yes ☐ No

Was the subject able to discern between saline and cocaine? ☐ Yes ☐ No

- Was the subject enrolled? ☐ Yes ☐ No
- If enrolled:

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

- If eligible and not enrolled, check reason:

  ☐ failed to return
  ☐ declined participation
  ☐ other, specify: ____

Source Completed By (Initials): ____

Protocol Number: NIDA-MDS-Disulfiram-0001

Disulfiram, Cocaine and Alcohol Interaction

Site Identification Number: 980202

Subject Identification Number: 0001

Study Day UNSCHD

Date: (mm/dd/yyyy)

ENZYME ASSAYS

Time Point	Actual Time (00:00-23:59)	Cholinesterase Assay Blood Drawn (yes/no)	Cholinesterase Assay Barcode	Actual Time (00:00-23:59)	Aldehyde dehydrogenase Assay Blood Drawn (yes/no)	Aldehyde dehydrogenase Assay Barcode	Comments	Initials
-30 min		Yes No			Yes No			

ENZYME v1

Protocol Number: NIDA-MDS-Disulfiram-0001	**Site Identification Number:** 980202
Disulfiram, Cocaine and Alcohol Interaction	**Subject Identification Number:** 0001
Study Day UNSCHD	**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, significant family history of idiopathic seizure disorder.	☐ Yes ☐ No
2.	Have a history of head trauma that resulted in neurological sequellae (e.g., loss of memory for greater than 5 minutes or that required hospitalization).	☐ Yes ☐ No
3.	Have a physiological dependence on alcohol, sedative-hypnotics (e.g., benzodiazepine, barbiturates) or opiates that requires medical detoxification based on the clinical signs of withdrawal in the presence of negative alcohol breath samples and negative drug urine samples.	☐ Yes ☐ No
4.	Have any previous medically serious adverse reaction to cocaine or Antabuse including loss of consciousness, chest pain, seizure, or psychosis resulting in hospitalization.	☐ Yes ☐ No
5.	Meet the diagnostic criteria for the following Axis I disorders: psychosis, bipolar I disorder, organic brain disease, dementia, major depression, schizoaffective disorder, or schizophrenia.	☐ Yes ☐ No
6.	Have any evidence of clinically significant heart disease, hypertension, or other significant medical illness, including diabetes.	☐ Yes ☐ No
7.	Be pregnant or nursing.	☐ Yes ☐ No
8.	Have a diagnosis of adult asthma, including a history of acute asthma within the past two years, or current or recent (past 2 years) treatment with inhaled or oral beta-agonist or steroid therapy (due to potential serious adverse interactions with cocaine).	☐ Yes ☐ No
9.	Be actively using albuterol or other beta agonist medications, regardless of formal diagnosis of asthma. (Inhalers are sometimes used by cocaine addicts to enhance cocaine delivery to the lungs.) If respiratory disease is excluded and the subject will consent to discontinue agonist use, s/he may be considered for inclusion.	☐ Yes ☐ No
10.	For subjects suspect for asthma but without formal diagnosis, 1) have a history of coughing, and/or wheezing, 2) have a history of asthma and/or asthma treatment two or more years before, 3) have a history of other respiratory illness, e.g., complications of pulmonary disease (exclude if on beta agonists), 4) use over-the-counter agonist or allergy medication for respiratory problems (e.g., Primatene Mist); a detailed history and physical exam, pulmonary consult, pulmonary function tests should be performed prior to including or excluding from the study or 5) have a FEV <70%.	☐ Yes ☐ No
11.	Have any illness, condition, and/or use of medications that in the opinion of the site investigator and the admitting physician would preclude safe and/or successful completion of the study. Excluded medications include any which affect the CNS, are psychoactive, affect the cardiovascular system, or produce pharmacological interactions with cocaine, alcohol, or disulfiram.	☐ Yes ☐ No
12.	Have active syphilis that has not been treated or refuse treatment for syphilis (see note).	☐ Yes ☐ No
13.	Be undergoing HIV treatment with antiviral and/or non-antiviral therapy.	☐ Yes ☐ No
14.	Have AIDS according to the current CDC criteria for AIDS - MMWR 1999; 48 (no. RR- 13: 29-31).	☐ Yes ☐ No
15.	Have peripheral neuropathy or other significant neurological disorders.	☐ Yes ☐ No
16.	Have a history of allergic responses to rubber or latex products.	☐ Yes ☐ No
17.	Be using disulfiram or any medication that could interact adversely with disulfiram within the following time of beginning of administration of disulfiram based on the longest time interval of A, B, or C, below or as otherwise specified:	☐ Yes ☐ No

A) Five half lives of other medication or active metabolite(s), whichever is longer

B) Two weeks

C) Interval recommended by other medication's product labeling

Medications that fall into category include:

a. Disulfiram (Antabuse)™ used during the past 30 days

b. Antidepressants including monoamine oxidase (MAO) inhibitors (GlaxoSmithKlein recommends 14 days after stopping MAO inhibitors)

c. Neuroleptics

d. Anticoagulants, i.e. coumadin

e. Phenytoin

f. Psychotropics

g. Systemic corticosteroids

h. Xanthines, i.e., theophilline, theophilline sodium glycinate and aminophylline

i. Drugs that lower seizure threshold

All Exclusion Criteria must be answered NO.

Source Completed By (Initials): _____

(EXCLUS v1)

Protocol Number: NIDA-MDS-Disulfiram-0001	**Site Identification Number:** 980202
Disulfiram, Cocaine and Alcohol Interaction	**Subject Identification Number:** 0001

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)

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 has died, a Death Report Case Report Form must be completed.

3) If contact has not been made with the subject, explain:

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

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

6) Have any adverse events occurred? ○ Yes ○ No

7) Have any serious adverse events occurred? ○ Yes*** ○ No

***If yes, a Serious Adverse Event Case Report Form must be completed.

8) Additional comments:

Source Completed By (Initials):

FOLLOWUP v1

Protocol Number: NIDA-MDS-Disulfiram-0001

Disulfiram, Cocaine and Alcohol Interaction

Site Identification Number: 980202

Subject Identification Number: 0001

Study Day UNSCHD

Date: (mm/dd/yyyy)

☐ **Form Not Done**

HEMATOLOGY

Complete Blood Count	Std. Quantity	Standard Unit	Other Unit	Normal	Abnormal	Abnormal Significant	Not Done
				☐	☐	☐	☐
				☐	☐	☐	☐
				☐	☐	☐	☐
				☐	☐	☐	☐
				☐	☐	☐	☐
				☐	☐	☐	☐
				☐	☐	☐	☐
				☐	☐	☐	☐
				☐	☐	☐	☐
				☐	☐	☐	☐
				☐	☐	☐	☐
				☐	☐	☐	☐

Provide comments for any abnormal value(s)

Source Completed By (Initials):

Protocol Number: NIDA-MDS-Disulfiram-0001

Disulfiram, Cocaine and Alcohol Interaction

Site Identification Number: 980202

Subject Identification Number: 0001

Study Day UNSCHD

Date: (mm/dd/yyyy)

IMMUNE PARAMETERS

Time Point	Actual Time (00:00-23:59)	Immune Parameter Blood Drawn	Barcode	Comments	Initials
		☐ ☐			
		☐ ☐			
		☐ ☐			

IMMPARAM v1

Protocol Number: NIDA-MDS-Disulfiram-0001	**Site Identification Number:** 980202
Disulfiram, Cocaine and Alcohol Interaction	**Subject Identification Number:** 0001
Study Day UNSCHD	**Date:** (mm/dd/yyyy)

INCLUSION CRITERIA

Participant must:

1.	Be volunteers who meet DSM-IV criteria for cocaine abuse or dependence and are not seeking treatment at time of study.	☐ Yes ☐ No
2.	Be between 18-50 years of age.	☐ Yes ☐ No
3.	Be able to verbalize understanding of consent form, able to provide written informed consent, and verbalize willingness to complete study procedures.	☐ Yes ☐ No
4.	Use cocaine by the smoked or i.v. route and drink at least two drinks of alcohol on average at least twice per week for at least four of the past six weeks.	☐ Yes ☐ No
5.	Have a history and physical examination that demonstrate no clinically significant contraindication for participating in the study, in the judgment of the admitting physician and the site investigators.	☐ Yes ☐ No
6.	Have resting vital signs as follows: heart rate between 50 and 90bpm, systolic BP below 150mm Hg and diastolic BP below 90mm Hg.	☐ Yes ☐ No
7.	Have electrolytes (Na, K, Cl, HCO) and hematocrit that is clinically normal (+/- 10% of laboratory limits).	☐ Yes ☐ No
8.	Have liver function tests (total bilirubin, ALT, AST, and alkaline phosphatase) less than three times the upper limit of normal.	☐ Yes ☐ No
9.	Have kidney function tests (creatinine and BUN) less than twice the upper limit of normal.	☐ Yes ☐ No
10.	Have an ECG performed that demonstrates no clinically significant arrhythmia or deviations from a normal sinus rhythm and conduction.	☐ Yes ☐ No
11.	Be male or female and have a negative pregnancy test and be postmenopausal, or have had a hysterectomy or have been sterilized, or agree to use the following methods of birth control: a. oral contraceptives b. barrier (diaphragm or condom) with spermicide c. intrauterine progesterone contraceptive system d. levonorgesterel implant e. medroxyprogesterone acetate contraceptive injection f. complete abstinence from sexual intercourse	☐ Yes ☐ No

All Inclusion Criteria must be answered YES

Source Completed By (Initials): _____

Protocol Number: NIDA-MDS-Disulfiram-0001	**Site Identification Number:** 980202
Disulfiram, Cocaine and Alcohol Interaction	**Subject Identification Number:** 0001

Study Day UNSCHD

INFORMED CONSENT DATE

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

Completed by (initials): ____

INCONSNT v1

Protocol Number: NIDA-MDS-Disulfiram-0001	**Site Identification Number:** 980202
Disulfiram, Cocaine and Alcohol Interaction	**Subject Identification Number:** 0001

Study Day UNSCHD **Date:** (mm/dd/yyyy)

☐ **Form Not Done**

INFECTIOUS DISEASE ASSESSMENT

Indicate whether the laboratory value is NEGATIVE: negative test result, POSITIVE: but DOES NOT EXCLUDE subject from participation or continued study participation, POSITIVE SIGNIFICANT: significant during screening means subject is ineligible for study; significant while on study means consider reporting result as adverse event if unexpected and at least possibly related to investigational agent or early termination of the subject from study, INDETERMINANT: result was not interpretable.

Infectious Disease	Result	Provide comments for any abnormal value
Hepatitis B surface antigen result		
Hepatitis B surface antibody result		
Hepatitis B core antibody result		
Hepatitis C virus antibody result		

Date PPD test administered / / (mm/dd/yyyy)

Time PPD test administered (00:00 - 23:59)

Date PPD test read / / (mm/dd/yyyy)

Time PPD test read (00:00 - 23:59)

☐ **PPD Previously Positive**
*(Test not done, chest X-ray required)

PPD test result *If positive, chest X-ray is 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):

INFECDIS v1

Protocol Number: NIDA-MDS-Disulfiram-0001

Disulfiram, Cocaine and Alcohol Interaction

Site Identification Number: 980202

Subject Identification Number: 0001

Study Day UNSCHD

Date: (mm/dd/yyyy)

☐ **Form Not Done**

INFUSION MONITORING (DAY -3)

Saline Infusion 1 Start Time: (00:00-23:59)

Saline Infusion 1 Administered by (initials):

Cocaine 30mg Infusion 2 Start Time: (00:00-23:59)

Cocaine 30mg Infusion 2 Administered by (initials):

Time Interval	Actual Time (00:00-23:59)	Blood Pressure (systolic/diastolic)		Heart Rate Beats/minute	Comments	Initials

13 min		Systolic	/ Diastolic			

83 min		Systolic / Diastolic				

Protocol Number: NIDA-MDS-Disulfiram-0001

Disulfiram, Cocaine and Alcohol Interaction

Site Identification Number: 980202

Subject Identification Number: 0001

Study Day UNSCHD

Date: (mm/dd/yyyy)

☐ **Form Not Done**

INFUSION MONITORING (DAY -2 TO 7)

Infusion 1: ☐ **Cocaine 30mg** ☐ **Saline**

Infusion 1: Start Time: (00:00-23:59)

Infusion 1: Administered by (initials):

Infusion 2: ☐ **Ethanol** ☐ **Glucose**

Infusion 2: Start Time: (00:00-23:59)

Infusion 2: Stop Time: (00:00-23:59)

Infusion 2: Administered by (initials):

Time Interval	Actual Time (00:00-23:59)	Blood Pressure (systolic/diastolic)	Heart Rate Beats/minute	Comments	Initials

7 min		Systolic / Diastolic				

Protocol Number: NIDA-MDS-Disulfiram-0001

Disulfiram, Cocaine and Alcohol Interaction

Site Identification Number: 980202

Subject Identification Number: 0001

Study Day UNSCHD

INVESTIGATIONAL AGENT ADMINISTRATION

#	Study Day	Disulfiram 250mg/ Placebo dose administered?	Date Administered (mm/dd/yyyy)	Number of capsules administered	Time Administered (00:00-23:59)	Administered by (initials)	Comments
		☐ ☐					

INVAGT v1

Protocol Number: NIDA-MDS-Disulfiram-0001	**Site Identification Number:** 980202
Disulfiram, Cocaine and Alcohol Interaction	**Subject Identification Number:** 0001
Study Day UNSCHD	**Date:** (mm/dd/yyyy)

MEDICAL HISTORY

Disorder	Yes excludes	Yes doesn't exclude	No history of disorder	Not evaluated	If yes, specify or describe
1. Allergies: drug	☐	☐	☐	☐	
2. Allergies: other, specify	☐	☐	☐	☐	
3. Sensitivity to Agent/Compounds	☐	☐	☐	☐	
4. History of Asthma	☐	☐	☐	☐	
5. HEENT	☐	☐	☐	☐	
6. Cardiovascular	☐	☐	☐	☐	
7. Renal	☐	☐	☐	☐	
8. Hepatic	☐	☐	☐	☐	
9. Pulmonary	☐	☐	☐	☐	
10. Gastrointestinal	☐	☐	☐	☐	
11. Musculoskeletal	☐	☐	☐	☐	
12. Neurologic	☐	☐	☐	☐	
13. Psychiatric	☐	☐	☐	☐	
14. Dermatologic	☐	☐	☐	☐	
15. Metabolic	☐	☐	☐	☐	
16. Hematologic	☐	☐	☐	☐	
17. Endocrine	☐	☐	☐	☐	
18. Genitourinary	☐	☐	☐	☐	
19. Reproductive System	☐	☐	☐	☐	
20. Seizure	☐	☐	☐	☐	
21. Infectious Disease	☐	☐	☐	☐	
22. Other 1, specify:	☐	☐	☐	☐	
23. Other 2, specify:	☐	☐	☐	☐	

24. **Was major surgery ever performed?** ☐ Yes ☐ No ***(If Yes, list surgeries:)***

	Type of Surgery	Date of Surgery (mm/dd/yyyy)	Is surgery relevant to study participation? Yes excludes	Yes doesn't exclude	No
25.		/ /	☐	☐	☐
26.		/ /	☐	☐	☐
27.		/ /	☐	☐	☐
28.		/ /	☐	☐	☐
29.		/ /	☐	☐	☐
30.		/ /	☐	☐	☐
31.		/ /	☐	☐	☐

TOBACCO HISTORY

32. Has subject used any tobacco product (e.g. cigarettes, cigars, pipe, chewing tobacco) in the past week? ☐ Yes ☐ No

33. Has subject ever used any tobacco product for at least one year? ☐ Yes ☐ No

34. If yes, number of years tobacco used? ____

COMMENTS

Source Completed By (Initials): ____

MEDHIST v1

Protocol Number: NIDA-MDS-Disulfiram-0001	**Site Identification Number:** 980202
Disulfiram, Cocaine and Alcohol Interaction	**Subject Identification Number:** 0001

Study Day UNSCHD

☐ **Form Not Done**

Date: (mm/dd/yyyy)

MODIFIED POSITIVE SYMPTOM RATING SCALE (mPSRS)

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

Instructions: This form consists of 4 symptoms constructs, each to be rated on a 7 point scale of severity ranging from "not present" to "extremely severe". If a specific symptom is not rated, mark "NA" (not assessed). Choose the number by the term that best describes the subject's present condition.

1. Suspiciousness
2. Unusual Thought Content
3. Hallucinations
4. Conceptual Disorganization

Source Completed By (Initials):

Protocol Number: NIDA-MDS-Disulfiram-0001

Disulfiram, Cocaine and Alcohol Interaction

Site Identification Number: 980202

Subject Identification Number: 0001

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 (Systolic) (Diastolic)

General Exam	Normal	Abnormal	Abnormal Significant	Not Done	If Abnormal, explain below
Oral (mouth)	☐	☐	☐	☐	
Head	☐	☐	☐	☐	
Eyes, ears, nose/throat	☐	☐	☐	☐	
Cardiovascular	☐	☐	☐	☐	
Lungs	☐	☐	☐	☐	
Abdomen (include liver/spleen)	☐	☐	☐	☐	
Extremities	☐	☐	☐	☐	
Skin	☐	☐	☐	☐	
Neuropsychiatric mental status	☐	☐	☐	☐	
Neuropsychiatric sensory/motor	☐	☐	☐	☐	
Musculoskeletal	☐	☐	☐	☐	
General Appearance	☐	☐	☐	☐	
FEV [1]	☐	☐	☐	☐	
Other, *specify:*	☐	☐	☐	☐	

Source Completed By (Initials):

PHYSEXAM v1

Protocol Number: NIDA-MDS-Disulfiram-0001

Disulfiram, Cocaine and Alcohol Interaction

Site Identification Number: 980202

Subject Identification Number: 0001

Study Day UNSCHD

☐ **Form Not Done**

Date: ____________ (mm/dd/yyyy)

PROFILE OF MOOD STATES (POMS)

How have you been feeling today?

FEELINGS	Not at all	A Little Bit	Moderately	Quite a bit	Extremely
	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐
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	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐

31. Annoyed	0	1	2	3	4
32. Discouraged	0	1	2	3	4
33. Resentful	0	1	2	3	4
34. Nervous	0	1	2	3	4
35. Lonely	0	1	2	3	4
36. Miserable	0	1	2	3	4
37. Muddled	0	1	2	3	4
38. Cheerful	0	1	2	3	4
39. Bitter	0	1	2	3	4
40. Exhausted	0	1	2	3	4
41. Anxious	0	1	2	3	4
42. Ready to fight	0	1	2	3	4
43. Good natured	0	1	2	3	4
44. Gloomy	0	1	2	3	4
45. Desperate	0	1	2	3	4
46. Sluggish	0	1	2	3	4
47. Rebellious	0	1	2	3	4
48. Helpless	0	1	2	3	4
49. Weary	0	1	2	3	4
50. Bewildered	0	1	2	3	4
51. Alert	0	1	2	3	4
52. Deceived	0	1	2	3	4
53. Furious	0	1	2	3	4
54. Efficient	0	1	2	3	4
55. Trusting	0	1	2	3	4
56. Full of pep	0	1	2	3	4
57. Bad-tempered	0	1	2	3	4
58. Worthless	0	1	2	3	4
59. Forgetful	0	1	2	3	4
60. Carefree	0	1	2	3	4
61. Terrified	0	1	2	3	4
62. Guilty	0	1	2	3	4
63. Vigorous	0	1	2	3	4
64. Uncertain about things	0	1	2	3	4
65. Bushed	0	1	2	3	4

Source Completed By (Initials):

Protocol Number: NIDA-MDS-Disulfiram-0001

Disulfiram, Cocaine and Alcohol Interaction

Site Identification Number: 980202

Subject Identification Number: 0001

Study Day UNSCHD

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
- ◯ Oral contraceptives
- ◯ Barrier (diaphragm and condom) with spermicide
- ◯ Intrauterine progesterone contraceptive system
- ◯ Levonorgestrel implant
- ◯ Medroxyprogesterone acetate contraceptive injection
- ◯ Complete abstinence from sexual intercourse

Source Completed By (Initials):

Protocol Number: NIDA-MDS-Disulfiram-0001

Disulfiram, Cocaine and Alcohol Interaction

Site Identification Number: 980202

Subject Identification Number: 0001

Study Day UNSCHD

Date: (mm/dd/yyyy)

☐ **Form Not Done**

QUANTITY AND FREQUENCY DRUG HISTORY (QFI)

		LIFE QUERY				CURRENT PATTERN (recent, past 12 months)							LIFETIME PATTERN					
#	**Drug Class**	Ever Used	Types Used	When Last Used	Life Use Total	Main Type	Usual Route	# Days use Past 7	# Days use Past 30	Estimate Quantity Freq.	Duration of Pattern	Typical Freq.	Age First Began	Age Last Used	Patient Problem Y or N?	Heaviest Lifetime Pattern: Usual route	Heaviest Lifetime Pattern: Estimate Quan./Freq.	Heaviest Lifetime Pattern: Duration of pattern
		◎				◎												
		◎				◎												

Source Completed By (Initials):

Protocol Number: NIDA-MDS-Disulfiram-0001	**Site Identification Number:** 980202
Disulfiram, Cocaine and Alcohol Interaction	**Subject Identification Number:** 0001

Study Day UNSCHD

RANDOMIZATION

- Was the subject randomized? ☐ Yes ☐ No
- If randomized:
  - o Date randomized: ____ / ____ / ____ (mm/dd/yyyy)
  - o Random Dose Code Number: ____
  - o 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): ____

Protocol Number: NIDA-MDS-Disulfiram-0001

Disulfiram, Cocaine and Alcohol Interaction

Site Identification Number: 980202

Subject Identification Number: 0001

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

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

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

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

Frequency

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

Comments

Source Completed By (Initials):

Protocol Number: NIDA-MDS-Disulfiram-0001	**Site Identification Number:** 980202
Disulfiram, Cocaine and Alcohol Interaction	**Subject Identification Number:** 0001

Study Day UNSCHD

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):

Protocol Number: NIDA-MDS-Disulfiram-0001

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Site Identification Number: 980202

Subject Identification Number: 0001

Study Day UNSCHD

Date: (mm/dd/yyyy)

☐ **Form Not Done**

SUBSTANCE USE INVENTORY (SUI)

Indicate whether the subject has used any amount of the listed substance since the last visit through today's visit and the most common route of administration. **Begin with yesterday and work back to the last visit.**

Date of last visit: / /

Route of Administration (ROA) codes:

1 = Oral 2 = Nasal 3 = Smoking 4 = non-intravenous injection 5 = intravenous injection

Line No.	Day of Week	Date of Drug Use (mm/dd/yyyy)		Used?	ROA
1		/ /	Cocaine	☐ Yes ☐ No	
			Amphetamines	☐ Yes ☐ No	
			Alcohol	☐ Yes ☐ No	
			Marijuana	☐ Yes ☐ No	
			Opiates	☐ Yes ☐ No	
			Other Specify:	☐ Yes ☐ No	

Source Completed By (Initials):

Protocol Number: NIDA-MDS-Disulfiram-0001

Disulfiram, Cocaine and Alcohol Interaction

Site Identification Number: 980202

Subject Identification Number: 0001

Study Day UNSCHD

Date: (mm/dd/yyyy)

☐ **Form Not Done**

SYPHILIS TEST

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

Rapid plasma reagin (RPR) test result

If RPR test is not done, state reason.

***If positive, fluorescent treponemal antibody absorbent (FTA-abs) confirmatory test is required.**

****If RPR test is indeterminant, it must be repeated.**

Date FTA-abs test administered ___ / ___ / ___ (mm/dd/yyyy)

FTA-abs test result

If test not done, state reason.

+If FTA-abs result is positive, is subject willing to undergo treatment for syphilis? ☐ Yes ☐ No

If treated, date of written proof of treatment: ___ / ___ / ___ (mm/dd/yyyy)

If subject is unwilling to undergo treatment for active syphilis, s/he is ineligible to participate in research study.

Comments:

Source Completed By (Initials):

Protocol Number: NIDA-MDS-Disulfiram-0001

Disulfiram, Cocaine and Alcohol Interaction

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Study Day UNSCHD

Date: (mm/dd/yyyy)

☐ **Form Not Done**

URINE TOXICOLOGY SCREEN ONSITE TESTING DEVICE

Urine temperature within expected range? ☐ Yes ☐ No ☐ Unknown (96.4° F ≤ T ≤ 100.4° F)

Drug/Test	Positive	Negative	Not Done
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐

Source Completed By (Initials):

Protocol Number: NIDA-MDS-Disulfiram-0001

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Site Identification Number: 980202

Subject Identification Number: 0001

Study Day UNSCHD

Date: (mm/dd/yyyy)

☐ **Form Not Done**

VISUAL ANALOG SCALE - SHORT (DAY -3)

Time Interval	ACTUAL TIME (00:00 - 23:59)	FEEL EFFECTS	LIKE DRUG	REALLY GOOD
-15 min	COCAINE HIGH	ALCOHOL BUZZ	CRAVE COCAINE	WANT COCAINE

Time Interval 30 min	ACTUAL TIME (00:00 - 23:59)	FEEL EFFECTS	LIKE DRUG	REALLY GOOD
	COCAINE HIGH	ALCOHOL BUZZ	CRAVE COCAINE	WANT COCAINE

Time Interval	ACTUAL TIME	FEEL EFFECTS	LIKE DRUG	REALLY GOOD
105 min	(00:00 - 23:59)			
	COCAINE HIGH	ALCOHOL BUZZ	CRAVE COCAINE	WANT COCAINE

Source Completed By (Initials):

Protocol Number: NIDA-MDS-Disulfiram-0001	Site Identification Number: 980202
Disulfiram, Cocaine and Alcohol Interaction	Subject Identification Number: 0001

Study Day UNSCHD

☐ **Form Not Done**

Date: ______ (mm/dd/yyyy)

VISUAL ANALOG SCALE - SHORT (DAY -2 to 7)

Time Interval				
	ACTUAL TIME (00:00 - 23:59)	FEEL EFFECTS	LIKE DRUG	REALLY GOOD
-15 min	COCAINE HIGH	ALCOHOL BUZZ	CRAVE COCAINE	WANT COCAINE

Time Interval 60 min	ACTUAL TIME (00:00 - 23:59)	FEEL EFFECTS	LIKE DRUG	REALLY GOOD
	COCAINE HIGH	ALCOHOL BUZZ	CRAVE COCAINE	WANT COCAINE

Source Completed By (Initials):

Protocol Number: NIDA-MDS-Disulfiram-0001

Disulfiram, Cocaine and Alcohol Interaction

Site Identification Number: 980202

Subject Identification Number: 0001

Study Day UNSCHD

Date: (mm/dd/yyyy)

Form Not Done ☐

VITAL SIGNS

Time: (00:00-23:59)

Temp: (oral) ☐ F ☐ C

SITTING:

Respiratory Rate breaths/minute

Heart Rate beats/minute

Blood Pressure / mm/hg
(Systolic) (Diastolic)

Source Completed By (Initials):

VITALS v1