Protocol Number: NIDA-CPU-0004

GBR 12909 for Cocaine Dependence

Site Identification Number: 980101

Subject Identification Number: 0001

Study Day UNSCHD

ADVERSE EVENTS

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

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

#	EVENT	Start Date	Cont.?	Stop Date	Sev.	Drug Rel.	Action Taken	Other Action	Out.	Serious	Initials
			☐							☐	

Protocol Number: NIDA-CPU-0004

GBR-12909 for Cocaine Dependence

Site Identification Number: 980101

Subject Identification Number: 0001

Study Day UNSCHD

Date: (mm/dd/yyyy)

Form Not Done ☐

ALCOHOL BREATHALYZER TEST

1) Was alcohol breathalyzer test performed? ☐ Yes ☐ No ☐ Unknown

2) Date test performed: (mm/dd/yyyy)

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

4) Provide comment for any action taken:

Source Completed By (Initials):

ALBREATH v1

Protocol Number: NIDA-CPU-0004	**Site Identification Number:** 980101
GBR-12909 for Cocaine Dependence	**Subject Identification Number:** 0001

Study Day UNSCHD **Form Not Done** ☐ **Date:** (mm/dd/yyyy)

ARCI SHORT FORM

These 49 items may or may not describe how you feel right now. Mark T (for true) next to each item that does describe how you feel, and F (for false) for each item that does not describe how you feel.

Actual Time (00:00 - 23:59)

27. Less discouraged	○ True	○ False
	○	○
	○	○
	○	○
	○	○
	○	○
	○	○
	○	○
	○	○
	○	○
	○	○
	○	○
	○	○
	○	○
	○	○
	○	○
	○	○
	○	○
	○	○
	○	○
	○	○
	○	○
	○	○
	○	○
	○	○

Source Completed By (Initials): _____

Protocol Number: NIDA-CPU-0004	**Site Identification Number:** 980101
GBR-12909 for Cocaine Dependence	**Subject Identification Number:** 0001

Study Day UNSCHD **Form Not Done** ☐ **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):

Protocol Number: NIDA-CPU-0004

GBR-12909 for Cocaine Dependence

Site Identification Number: 980101

Subject Identification Number: 0001

Study Day UNSCHD

CONCOMITANT MEDICATIONS

Has the subject taken any Concomitant Medications during this study? ☐ Yes ☐ No *If yes, please list all below:*

Dose	Unit of Medication				Frequency		Route of Administration			
Strength of Medication	CAP	= capsule	PUF	= puff	ONCE	= single dose	PO	= oral	AUR	= auricular
	g	= gram	SPY	= spray/squirt	QD	= once daily	TD	= transdermal	IA	= intra-articular
	GR	= grain	SUP	= suppository	BID	= twice daily	INH	= inhaled	NAS	= nasal
	GTT	= drop	TSP	= teaspoon	TID	= three times a day	IM	= intramuscular	IO	= intraocular
	ug	= microgram	TBS	= tablespoon	QID	= four times a day	IV	= intravenous	UNK	= unknown
	uL	= microliter	TAB	= tablet	QOD	= every other day	REC	= rectal	OTH	= other, specify
	mg	= milligram	UNK	= unknown	PRN	= as needed	VAG	= vaginal		
	mL	= milliliter	OTH	= other, specify	OTH	= other, specify	SQ	= subcutaneous		
	OZ	= ounce					SL	= sublingual		

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

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

Protocol Number: NIDA-CPU-0004	**Site Identification Number:** 980101
GBR-12909 for Cocaine Dependence	**Subject Identification Number:** 0001

Study Day UNSCHD **Form Not Done** ☐ **Date:** (mm/dd/yyyy)

CHANGES IN SEXUAL FUNCTIONING QUESTIONNAIRE (CSFQ-Female)

1)	Compared with the most enjoyable it has ever been, how enjoyable or pleasurable is your sexual life right now?	
2)	How frequently do you engage in sexual activity (sexual intercourse, masturbation, etc.) now?	
3)	How often do you desire to engage in sexual activity?	
4)	How frequently do you engage in sexual thoughts (thinking about sex, sexual fantasies) now?	
5)	Do you enjoy books, movies, music or artwork with sexual content?	
6)	How much pleasure or enjoyment do you get from thinking about and fantasizing about sex?	
7)	How often do become sexually aroused?	
8)	Are you easily aroused?	
9)	Do you have adequate vaginal lubrication during sexual activity?	
10)	How often do you become aroused and then lose interest?	
11)	How often do you experience an orgasm?	
12)	Are you able to have an orgasm when you want to?	
13)	How much pleasure or enjoyment do you get from your orgasms?	
14)	How often do you have painful orgasm?	

Source Completed By (Initials): **TOTAL SCORE:**

Protocol Number: NIDA-CPU-0004	**Site Identification Number:** 980101
GBR-12909 for Cocaine Dependence	**Subject Identification Number:** 0001

Study Day UNSCHD **Form Not Done** ☐ **Date:** (mm/dd/yyyy)

CHANGES IN SEXUAL FUNCTIONING QUESTIONNAIRE (CSFQ-Male)

1)	Compared with the most enjoyable it has ever been, how enjoyable or pleasurable is your sexual life right now?	
2)	How frequently do you engage in sexual activity (sexual intercourse, masturbation, etc.) now?	
3)	How often do you desire to engage in sexual activity?	
4)	How frequently do you engage in sexual thoughts (thinking about sex, sexual fantasies) now?	
5)	Do you enjoy books, movies, music or artwork with sexual content?	
6)	How much pleasure or enjoyment do you get from thinking about and fantasizing about sex?	
7)	How often do you have an erection related or unrelated to sexual activity?	
8)	Do you get an erection easily?	
9)	Are you able to maintain an erection?	
10)	How often do you experience painful prolonged erections?	
11)	How often do you have an ejaculation?	
12)	Are you able to ejaculate when you want to?	
13)	How much pleasure or enjoyment do you get from your orgasms?	
14)	How often do you have painful orgasm?	

Source Completed By (Initials): **TOTAL SCORE:**

CSFQMALE v1

Protocol Number: NIDA-CPU-0004

GBR-12909 for Cocaine Dependence

Site Identification Number: 980101

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-CPU-0004

GBR-12909 for Cocaine Dependence

Site Identification Number: 980101

Subject Identification Number: 0001

Study Day UNSCHD

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, African American, or Negro

☐ Yes ☐ No American Indian or Alaskan Native

☐ Yes ☐ No Spanish, Hispanic, or Latino (mark all that apply)

- ☐ Mexican, Mexican-American, or Chicano
- ☐ Puerto Rican
- ☐ Cuban
- ☐ Other (specify)

☐ Yes ☐ No Asian (mark all that apply)

- ☐ Asian Indian
- ☐ Chinese
- ☐ Filipino
- ☐ Japanese
- ☐ Korean
- ☐ Vietnamese
- ☐ Other (specify)

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

- ☐ Native Hawaiian
- ☐ Guamanian or Chamorro
- ☐ Samoan
- ☐ Other (specify)

☐ Yes ☐ No Other (specify)

☐ **Participant chooses not to answer**

EMPLOYMENT/SUPPORT STATUS

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

2) Usual employment pattern, past 30 days:

- ☐ 1 - Full time (35+ hours/week)
- ☐ 2 - Part time (regular hours)
- ☐ 3 - Part time (irregular hours, day work)
- ☐ 4 - Student
- ☐ 5 - Military Service
- ☐ 6 - Retired/Disabled
- ☐ 7 - Homemaker
- ☐ 8 - Unemployed
- ☐ 9 - In controlled environment

3) Usual employment pattern, past 3 years:

- ☐ 1 - Full time (35+ hours/week)
- ☐ 2 - Part time (regular hours)
- ☐ 3 - Part time (irregular hours, day work)
- ☐ 4 - Student
- ☐ 5 - Military Service
- ☐ 6 - Retired/Disabled
- ☐ 7 - Homemaker
- ☐ 8 - Unemployed
- ☐ 9 - In controlled environment

4) Marital Status:

- ☐ 1 - Legally married
- ☐ 2 - Living with partner/cohabitating
- ☐ 3 - Widowed
- ☐ 4 - Separated
- ☐ 5 - Divorced
- ☐ 6 - Never Married

DRUG / ALCOHOL USE

	Days in Past 30 Days	Lifetime Years	ROUTE OF ADMINISTRATION oral	nasal	smoking	injection	N/A
			☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐

According to the interviewer, which substance is the major problem? (Select only one item.)

- ☐ 0 - No problem
- ☐ 1 - Alcohol (any)
- ☐ 2 - Alcohol to intoxication
- ☐ 3 - Heroin
- ☐ 4 - Methadone/LAAM (presc.)
- ☐ 5 - Methadone/LAAM (illicit)
- ☐ 6 - Opiates/analgesics
- ☐ 7 - Barbiturates
- ☐ 8 - Sed./hyp./tranq./benzos.
- ☐ 9 - Cocaine
- ☐ 10- Amph./methamph.
- ☐ 11 - Cannabis
- ☐ 12 - Hallucinogens
- ☐ 13 - Inhalants
- ☐ 14 - Nicotine
- ☐ 15 - Alcohol and Drug addictiion
- ☐ 16 - Polydrug addiction

Source Completed By (Initials): ______

DEMOG v1

Protocol Number: NIDA-CPU-0004

GBR-12909 for Cocaine Dependence

Site Identification Number: 980101

Subject Identification Number: 0001

Study Day UNSCHD

Date: (mm/dd/yyyy)

Form Not Done ☐

12-Lead ELECTROCARDIOGRAM

Normal Intervals	
PR:	120 - 200 msec
QT:	360 - 440 msec
QRS:	60 - 100 msec

Hour ECG	Test Type	Time (00:00-23:59)	Heart Rate Beats/minute	PR (msec)	QT (msec)	QRS (msec)	R-R (msec)	QTc (msec)	ECG Abnormal?	If Abnormal, Clinically Significant?
	12-Lead								☐ Yes ☐ No	☐ Yes ☐ No

Specify Abnormality as recorded on ECG tracing

Source Completed By (Initials):

ECG1 v1

Protocol Number: NIDA-CPU-0004

GBR-12909 for Cocaine Dependence

Site Identification Number: 980101

Subject Identification Number: 0001

Study Day UNSCHD

Form Not Done ☐

Date: (mm/dd/yyyy)

12 LEAD ECG and DIGITAL ACQUISITION ECG

Hour	Test Type	Time (00:00-23:59)	Heart Rate Beats/minute	PR (msec)	QT (msec)	QRS (msec)	R-R (msec)	QTc (msec)	ECG Abnormal?	If Abnormal, Clinically Significant?
									☐ ☐	☐ ☐

Source Completed By (Initials):

ECGDIGIT v1

Protocol Number: NIDA-CPU-0004

GBR-12909 for Cocaine Dependence

Site Identification Number: 980101

Subject Identification Number: 0001

Study Day UNSCHD

Form Not Done ☐

Date: (mm/dd/yyyy)

12 LEAD ECG and DIGITAL ACQUISITION ECG (DAYS 0 AND 11)

Hour	Test Type	Time (00:00-23:59)	PR (msec)	QT (msec)	QRS (msec)	R-R (msec)	QTc (msec)	ECG Abnormal?	If Abnormal, Clinically Significant?
								☐ ☐	☐ ☐

Source Completed By (Initials):

ECGPRFL1 v1

Protocol Number: NIDA-CPU-0004

GBR-12909 for Cocaine Dependence

Site Identification Number: 980101

Subject Identification Number: 0001

Study Day UNSCHD

Form Not Done ☐

Date: (mm/dd/yyyy)

12 LEAD ECG and DIGITAL ACQUISITION ECG (DAYS 12 - 18)

Hour since last dose/Day	Test Type	Time (00:00-23:59)	PR (msec)	QT (msec)	QRS (msec)	R-R (msec)	QTc (msec)	ECG Abnormal?	If Abnormal, Clinically Significant?
								☐ ☐	☐ ☐

Source Completed By (Initials):

ECGPRFL2 v1

Protocol Number: NIDA-CPU-0004	**Site Identification Number:** 980101
GBR-12909 for Cocaine Dependence	**Subject Identification Number:** 0001

Study Day UNSCHD

END OF TRIAL

1) Date of last visit? (mm/dd/yyyy)

2) Was the subject terminated early from the trial? ☐ Yes ☐ No

Reason subject's participation has ended (Mark all that apply):

- ☐ Subject completed study without a re-challenge phase.
- ☐ Subject completed study with a re-challenge phase.
- ☐ Subject was determined after enrollment to be ineligible. (Provide comments)
- ☐ Subject requested to withdraw. (Provide comments)
- ☐ Subject experienced an intercurrent illness, unrelated medical condition, or clinically significant adverse events which prompted early termination. (Complete AE form, provide comments)
- ☐ Subject terminated for administrative reasons. (Include protocol non-compliance in this category. Provide comments)
- ☐ Subject transferred to another treatment program (check all that apply)
  - ☐ Methadone ☐ Drug Free ☐ Inpatient Detox or Treatment
  - ☐ LAAM ☐ Therapeutic Community ☐ Other (specify)
- ☐ Subject was incarcerated.
- ☐ Subject became pregnant.
- ☐ Subject developed sensitivity to study agent.
- ☐ Subject was lost to follow-up.
- ☐ Subject moved from area.
- ☐ Subject died. (If subject died, a Death Report Case Report Form must be completed)
- ☐ Subject can no longer attend clinic.
- ☐ Subject no longer attends clinic.
- ☐ Subject is in a controlled environment.
- ☐ Subject is a screen failure.
- ☐ Other (Provide comments)

Comments:

Source Completed By (Initials):

Protocol Number: NIDA-CPU-0004

GBR-12909 for Cocaine Dependence

Site Identification Number: 980101

Subject Identification Number: 0001

Study Day UNSCHD

ENROLLMENT

Is subject eligible for participation based on the Eligibility Criteria? ☐ Yes ☐ No

If yes, was subject enrolled into the study? ☐ Yes ☐ No

If subject was enrolled in the study, date enrolled: _____ (mm/dd/yyyy)

If not enrolled, indicate reason

- ☐ failed to return to clinic
- ☐ declined study participation
- ☐ other, specify: _____

Source Completed By (Initials): _____

Protocol Number: NIDA-CPU-0004	**Site Identification Number:** 980101
GBR-12909 for Cocaine Dependence	**Subject Identification Number:** 0001
Study Day UNSCHD	**Date:** (mm/dd/yyyy)

EXCLUSION CRITERIA

Participant must not:

1. According to DSM-IV criteria as determined by structured clinical interview (SCID), have any current diagnosis or history of major psychiatric illness other than drug dependence or disorders secondary to drug use or be mentally or legally incapacitated.	☐ Yes ☐ No
2. According to DSM-IV criteria be dependent upon or abusing drugs other than cocaine, marijuana, nicotine, and alcohol or have physiological dependence upon alcohol requiring medical detoxification.	☐ Yes ☐ No
3. Currently be physically dependent on illicit drugs besides cocaine and marijuana as determined by the SCID. Note: The subjects that are not physically dependent on other illicit substances but during pre-study screening have a positive urine drug screen for amphetamines, barbiturates, benzodiazepines, methadone, opiates, PCP, or propoxyphene will be allowed to participate after a wash-out period and providing a negative urine drug screen.	☐ Yes ☐ No
4. Use any prescription drugs within 14 days of enrollment or non-prescription drugs within 7 days of enrollment, or if female, have used an oral contraceptive, Depo-Provera, Norplant or intrauterine progesterone contraceptive system within 30 days of enrollment.	☐ Yes ☐ No
5. Be pregnant or lactating.	☐ Yes ☐ No
6. Have a history of liver disease or of any elevation of aspartate aminotransferase (AST) or alanine aminotransferase (ALT) exceeding the upper limit of normal.	☐ Yes ☐ No
7. Have donated a unit of blood or participated in any other clinical investigation within 4 weeks of enrolling on the study.	☐ Yes ☐ No
8. Have a history of any illness, 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.	☐ Yes ☐ No
9. Be seropositive for hepatitis B surface antigen, hepatitis C antibody, or human immunodeficiency virus (HIV) types 1.	☐ Yes ☐ No
10. Have a diagnosis of adult (i.e., 21 years or older) asthma, 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.	☐ Yes ☐ No
11. Have a mean baseline absolute neutrophil count (from Days -2, -1, and 0) of less than 1000 cells/mcL and a mean total white blood cell count of less that 2 x 10^3 cells/mcL.	☐ Yes ☐ No

Note: All answers to EXCLUSION CRITERIA must be NO.

Source Completed By (Initials):

Protocol Number: NIDA-CPU-0004

GBR-12909 for Cocaine Dependence

Site Identification Number: 980101

Subject Identification Number: 0001

Study Day UNSCHD

Form Not Done ☐

Date: (mm/dd/yyyy)

FOLLOW-UP

1) Has contact been made with the subject? ◯ Yes ◯ No

If so, date: (mm/dd/yyyy)

2) If unable to reach subject, has contact been made with someone who can verify his/her status? ◯ Yes ◯ No

If yes, has the subject died? ◯ Yes ◯ No *(If the subject died, a Death Report CRF must be completed)*

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

4) Does subject report use of any of the following and if so, for how many days in the last week? *(Check all that apply).*

DRUG	Days Used	DRUG	Days Used
☐ Cocaine		☐ Sedatives	
☐ Methamphetamine		☐ Nicotine	
☐ Amphetamines		☐ Opiates	
☐ Benzodiazepines		☐ Barbiturates	
☐ Alcohol		☐ None	
☐ Marijuana		☐ Other	*(specify)*

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

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

7) Have any adverse events occurred? ◯ Yes ◯ No

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

9) Additional comments:

Source Completed By (Initials):

Protocol Number: NIDA-CPU-0004

GBR-12909 for Cocaine Dependence

Site Identification Number: 980101

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
Hemoglobin				☐	☐	☐	☐
				☐	☐	☐	☐
				☐	☐	☐	☐
				☐	☐	☐	☐
				☐	☐	☐	☐
				☐	☐	☐	☐
				☐	☐	☐	☐
				☐	☐	☐	☐
				☐	☐	☐	☐
				☐	☐	☐	☐
				☐	☐	☐	☐
				☐	☐	☐	☐

Provide comments for any abnormal value(s)

Source Completed By (Initials):

HEMAT v1

Protocol Number: NIDA-CPU-0004	**Site Identification Number:** 980101
GBR-12909 for Cocaine Dependence	**Subject Identification Number:** 0001
Study Day UNSCHD	**Date:** (mm/dd/yyyy)

INCLUSION CRITERIA

Participant must:

1. Be African American between 18 and 45 years-of-age.	☐ Yes ☐ No
2. Be within 20% of ideal body weight and must weigh at least 45 kg.	☐ Yes ☐ No
3. Understand the study procedures and provide written informed consent.	☐ Yes ☐ No
4. Be volunteers who are dependent on or abusing cocaine according to DSM-IV criteria and are non-treatment seeking at time of study.	☐ Yes ☐ No
5. Currently use cocaine as determined by self report and positive urine test for BE within 30 days of the start of the study.	☐ Yes ☐ No
6. Be 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, have had hysterectomy or have been sterilized, or be male. a. complete abstinence from sexual intercouse b. diaphragm and condom by partner c. intrauterine device and condom by partner d. sponge and condom by partner Note: oral contraceptives, Depo-Provera, Norplant and intrauterine progesterone contraceptive system are not allowed.	☐ Yes ☐ No
7. Be judged by the examining physician or his/her designee after a history and physical examination to be in good health, without clinically significant abnormalities.	☐ Yes ☐ No
8. Have an ECG performed that demonstrates normal sinus rhythm and no clinically significant arrhythmias.	☐ Yes ☐ No

Note: All answers to INCLUSION CRITERIA must be YES.

Source Completed By (Initials):

Protocol Number: NIDA-CPU-0004	**Site Identification Number:** 980101
GBR-12909 for Cocaine Dependence	**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		
HIV type 1		
HIV type 2		

Source Completed By (Initials):

Protocol Number: NIDA-CPU-0004

GBR-12909 for Cocaine Dependence

Site Identification Number: 980101

Subject Identification Number: 0001

Study Day UNSCHD

Form Not Done ☐

INVESTIGATIONAL AGENT ADMINISTRATION

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

Source Completed By (Initials):

INVAGT v1

Protocol Number: NIDA-CPU-0004

GBR-12909 for Cocaine Dependence

Site Identification Number: 980101

Subject Identification Number: 0001

Study Day UNSCHD

Form Not Done ☐

LAB TRACKING

Date: (mm/dd/yyyy)	**Tests:**	**Barcode / Tracking #**	**Barcode / Tracking # For Lab Corp**	**Actual Time** (00:00-23:59)	**Completed By** (Initials)
	☐ Plasma Alcohol				
	☐ GBR 12909 Assay				
	☐ Urine Specimen				
	☐ Hematology				
	☐ Chemistry				
	☐ Urinalysis				

Comments:

LABTRACK v1

Protocol Number: NIDA-CPU-0004

GBR-12909 for Cocaine Dependence

Site Identification Number: 980101

Subject Identification Number: 0001

Study Day UNSCHD

Form Not Done ☐

Date: (mm/dd/yyyy)

LAB TRACKING PK FOR GBR 12909 (DAY 11-18)

Time of Dosing	GBR Assay	Actual Time (00:00-23:59)
Prior to GBR 12909 Administration/ Day 11	☐	
	☐	
	☐	
	☐	
	☐	
	☐	
	☐	
	☐	
	☐	
	☐	
	☐	
	☐	
	☐	
	☐	
	☐	
	☐	
	☐	
	☐	
	☐	

Source Completed By (Initials):

Protocol Number: NIDA-CPU-0004

GBR-12909 for Cocaine Dependence

Site Identification Number: 980101

Subject Identification Number: 0001

Study Day UNSCHD

Date: (mm/dd/yyyy)

Form Not Done ☐

MEDICAL HISTORY

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

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

	Type of Surgery	Date of Surgery (mm/dd/yyyy)	Yes excludes	Yes doesn't exclude	No
25.	test		☐	☐	☐
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-CPU-0004	**Site Identification Number:** 980101
GBR-12909 for Cocaine Dependence	**Subject Identification Number:** 0001

Study Day UNSCHD **Form Not Done** ☐ **Date:** (mm/dd/yyyy)

McLEAN HOSPITAL
OVERT AGGRESSION SYMPTOM CHECK LIST

Indicate with an appropriate check mark whether or not you have engaged in any of the following behaviors during -

☐ the past day. ☐ the past week.
☐ the past month. ☐ the past year.
☐ any time in your life.

I. VERBAL AGGRESSION

1. I have made loud noises, or shouted angrily	☐ Yes ☐ No
2. I have yelled mild personal insults (e.g., "You're stupid")	☐ Yes ☐ No
3. I have cursed viciously, or used foul language in anger	☐ Yes ☐ No
4. I have made clear threats of violence to myself or others	☐ Yes ☐ No

II. PHYSICAL AGGRESSION TOWARD SELF

1. I have picked or scratched at my skin, hit myself, pulled my hair, or hurt myself without causing any actual injury.	☐ Yes ☐ No
2. I have banged my head, hit my fist into objects, thrown myself down, or hurt myself in such a way as to inflict minor injury	☐ Yes ☐ No
3. I have made small cuts, bruises, or burns on my body, or have hurt myself in such a way as to visibly damage my skin	☐ Yes ☐ No
4. I have cut myself deeply, bit myself till I bled, inflicted internal injury, broke bones, or hurt myself in a potentially serious way	☐ Yes ☐ No

III. PHYSICAL AGGRESSION TOWARD OBJECTS

1. I have slammed doors, scattered my clothes, or made a mess out of anger	☐ Yes ☐ No
2. I have thrown objects down, kicked furniture without breaking it, or have marked walls	☐ Yes ☐ No
3. I have broken objects or smashed windows	☐ Yes ☐ No
4. I have set a destructive fire, or damaged valuable property	☐ Yes ☐ No

IV. PHYSICAL AGGRESSION TOWARD OTHERS

1. I have made threatening gestures, swung at someone, or grabbed at someone's clothing out of anger	☐ Yes ☐ No
2. I have hit, kicked pushed someone or pulled their hair, without injuring them	☐ Yes ☐ No
3. I have attacked someone, causing mild-to-moderate physical injury (bruises, sprains, welts), or threatened someone with a dangerous weapon	☐ Yes ☐ No
4. I have attacked someone, causing severe physical injury (e.g., broken bones, deep cuts, internal injury)	☐ Yes ☐ No

V. SUICIDALITY

1. I have daydreamed or fantasized about committing suicide	☐ Yes ☐ No
2. I have formulated a detailed suicide plan, but did not make an attempt	☐ Yes ☐ No
3. I have taken an overdose of medications, mixed alcohol and pills, or engaged in other hazardous behavior to escape from my feelings, with little concern for my personal safety, but without an absolutely certain intent to die	☐ Yes ☐ No
4. I have taken a massive overdose, tried to hang myself, or directly made a nearly lethal suicide attempt with an absolutely certain intent to die	☐ Yes ☐ No

Source Completed By (Initials): _____

Protocol Number: NIDA-CPU-0004

GBR-12909 for Cocaine Dependence

Site Identification Number: 980101

Subject Identification Number: 0001

Study Day UNSCHD

Date: (mm/dd/yyyy)

Form Not Done ☐

ABBREVIATED PHYSICAL EXAMINATION

General Exam	Normal	Abnormal	Abnormal Significant	Not Done	If Abnormal, explain below
Cardiovascular	☐	☐	☐	☐	
Lungs	☐	☐	☐	☐	
Neuropsychiatric mental status	☐	☐	☐	☐	
Neuropsychiatric sensory/motor	☐	☐	☐	☐	
Skin	☐	☐	☐	☐	

Source Completed By (Initials):

PHYEXAM2 v1

Protocol Number: NIDA-CPU-0004

GBR-12909 for Cocaine Dependence

Site Identification Number: 980101

Subject Identification Number: 0001

Study Day UNSCHD

Date: (mm/dd/yyyy)

Form Not Done ☐

PHYSICAL EXAMINATION

Height: ☐ inches ☐ centimeters

Weight: ☐ pounds ☐ kilograms

General Exam	Normal	Abnormal	Abnormal Significant	Not Done	If Abnormal, explain below
Oral (mouth)	☐	☐	☐	☐	
Head and Neck	☐	☐	☐	☐	
EENT	☐	☐	☐	☐	
Cardiovascular	☐	☐	☐	☐	
Chest	☐	☐	☐	☐	
Lungs	☐	☐	☐	☐	
Abdomen (include liver/spleen)	☐	☐	☐	☐	
Extremities	☐	☐	☐	☐	
Skin, Hair, Nails	☐	☐	☐	☐	
Neuropsychiatric mental status	☐	☐	☐	☐	
Neuropsychiatric sensory/motor	☐	☐	☐	☐	
Musculoskeletal	☐	☐	☐	☐	
General Appearance	☐	☐	☐	☐	
Rectal	☐	☐	☐	☐	
Prostate	☐	☐	☐	☐	
Breast	☐	☐	☐	☐	
Lymph	☐	☐	☐	☐	
Genital	☐	☐	☐	☐	
Pelvic	☐	☐	☐	☐	
Other *(specify)*	☐	☐	☐	☐	
Other *(specify)*	☐	☐	☐	☐	

Source Completed By (Initials):

PHYSEXAM v1

Protocol Number: NIDA-CPU-0004

GBR-12909 for Cocaine Dependence

Site Identification Number: 980101

Subject Identification Number: 0001

Study Day UNSCHD

Date: (mm/dd/yyyy)

Form Not Done ☐

PREGNANCY

Was a pregnancy test performed? ○ Yes ○ No

IF Yes, type: ○ Urine ○ Serum

(If no, skip to birth control method)

Pregnancy test result:

- ○ Positive
- ○ Negative
- ○ Unknown
- ○ Not applicable, subject is male

Pregnancy test comments:

Is the subject lactating? ○ Yes ○ No ○ Not Applicable

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

What method of birth control is the subject using?

- ○ Barrier (diaphragm or condom) with spermicide
- ○ Intrauterine progesterone contraceptive system (IUD)
- ○ Lovenorgestrel implant (Norplant)
- ○ Medroxyprogesterone acetate contraceptive injection
- ○ Complete abstinence from sexual intercourse
- ○ Transdermal patch (Ortho Evra)
- ○ Vaginal insert (Nuva Ring)
- ○ Same sex partner
- ○ Surgical sterilization

Source Completed By (Initials):

Protocol Number: NIDA-CPU-0004

GBR-12909 for Cocaine Dependence

Site Identification Number: 980101

Subject Identification Number: 0001

Study Day UNSCHD

PRIOR MEDICATIONS

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

Dose	Unit of Medication				Frequency		Route of Administration			
Strength of Medication	CAP	= capsule	PUF	= puff	ONCE	= single dose	PO	= oral	AUR	= auricular
	g	= gram	SPY	= spray/squirt	QD	= once daily	TD	= transdermal	IA	= intra-articular
	GR	= grain	SUP	= suppository	BID	= twice daily	INH	= inhaled	NAS	= nasal
	GTT	= drop	TSP	= teaspoon	TID	= three times a day	IM	= intramuscular	IO	= intraocular
	ug	= microgram	TBS	= tablespoon	QID	= four times a day	IV	= intravenous	UNK	= unknown
	uL	= microliter	TAB	= tablet	QOD	= every other day	REC	= rectal	OTH	= other, specify
	mg	= milligram	UNK	= unknown	PRN	= as needed	VAG	= vaginal		
	mL	= milliliter	OTH	= other, specify	OTH	= other, specify	SQ	= subcutaneous		
	OZ	= ounce					SL	= sublingual		

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

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

Protocol Number: NIDA-CPU-0004

GBR-12909 for Cocaine Dependence

Site Identification Number: 980101

Subject Identification Number: 0001

Study Day UNSCHD

SERIOUS ADVERSE EVENT

DEMOGRAPHIC INFORMATION

Enrollment Date (mm/dd/yyyy) **Gender** ☐ Male ☐ Female

Date of Birth (mm/dd/yyyy)

Race

☐ White, not of Hispanic Origin
☐ Hispanic or Latino
☐ African American, Black, not of Hispanic Origin
☐ Asian or Pacific Islander
☐ American Indian or Alaska Native
☐ Other, (specify):
☐ Unknown

Height ☐ inches ☐ centimeters **Weight** ☐ pounds ☐ kilograms

AE/Diagnosis:

SERIOUS ADVERSE EVENT

SAE Description

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 Case Report Form must be completed.

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

Concomitant Medications

Relevant tests/laboratory data, including dates

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

SAE resolution date (mm/dd/yyyy) or ☐ continuing

INVESTIGATIONAL AGENT ADMINISTRATION

Is the investigational agent information known? ☐ Yes ☐ No

If yes, investigational agent name

Lot number

Expiration date (mm/dd/yyyy)

Quantity

Unit Code **Other unit**

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

Route of administration

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

Frequency

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

Comments

Source Completed by:

Protocol Number: NIDA-CPU-0004

GBR 12909 for Cocaine Dependence

Site Identification Number: 980101

Subject Identification Number: 0001

Study Day UNSCHD

Form Not Done ☐

Date: (mm/dd/yyyy)

SAFTEE GI-COMBINE (Page 1)

Complete at all visits for participants that are assigned to MM. For further instructions, see SAFTEE guidelines in the MM manual.

PATTERN	SEVERITY	DRUG RELATED	ACTION TAKEN
IS = Isolated	MN = Minimal	N = No	N = None
IN = Intermittent	MI = Mild	DR = Dose-response	IS = Increased surveillance
CO = Continuous	MO = Moderate	TO = Timing of onset	C = Contra active RX
	S = Severe	K = Known drug effect	SU = Suspend RX
		O = Other (specify)	DC = Discontinue RX
		X = Don't Know	O = Other
			R = Dose Reduction
			I = Dose Increased

Line #	EVENT	Date of Onset (Month)	Date of Onset (Day)	Duration (Days)	Pattern	Severity	Drug Related	Action Taken
1								

Drug Related Specify:

Description*

Source Completed By (Initials):

SAFTEE1 v1

Protocol Number: NIDA-CPU-0004

GBR 12909 for Cocaine Dependence

Site Identification Number: 980101

Subject Identification Number: 0001

Study Day UNSCHD

Form Not Done ☐

Date: (mm/dd/yyyy)

SAFTEE GI-COMBINE (Page 2)

Complete at all visits for participants that are assigned to MM. For further instructions, see SAFTEE guidelines in the MM manual.

PATTERN	SEVERITY	DRUG RELATED	ACTION TAKEN
IS = Isolated	MN = Minimal	N = No	N = None
IN = Intermittent	MI = Mild	DR = Dose-response	IS = Increased surveillance
CO = Continuous	MO = Moderate	TO = Timing of onset	C = Contra active RX
	S = Severe	K = Known drug effect	SU = Suspend RX
		O = Other (specify)	DC = Discontinue RX
		X = Don't Know	O = Other
			R = Dose Reduction
			I = Dose Increased

Study Specific Events	EVENT	Date of Onset (Month)	Date of Onset (Day)	Duration (Days)	Pattern	Severity	Drug Related	Action Taken
1. Nausea								

Drug Related Specify: | Description*

Study Specific Events	EVENT	Date of Onset (Month)	Date of Onset (Day)	Duration (Days)	Pattern	Severity	Drug Related	Action Taken
2. Vomiting								

Drug Related Specify: | Description*

Study Specific Events	EVENT	Date of Onset (Month)	Date of Onset (Day)	Duration (Days)	Pattern	Severity	Drug Related	Action Taken
3. Diarrhea								

Drug Related Specify: | Description*

Study Specific Events	EVENT	Date of Onset (Month)	Date of Onset (Day)	Duration (Days)	Pattern	Severity	Drug Related	Action Taken
4. Abdominal Pain								

Drug Related Specify: | Description*

Study Specific Events	EVENT	Date of Onset (Month)	Date of Onset (Day)	Duration (Days)	Pattern	Severity	Drug Related	Action Taken
5. Decreased Appetite								

Drug Related Specify: | Description*

Study Specific Events	EVENT	Date of Onset (Month)	Date of Onset (Day)	Duration (Days)	Pattern	Severity	Drug Related	Action Taken
6. Increased Appetite								

Drug Related Specify:

Description*

Study Specific Events	EVENT	Date of Onset (Month)	Date of Onset (Day)	Duration (Days)	Pattern	Severity	Drug Related	Action Taken
7. Headache								

Drug Related Specify:

Description*

Study Specific Events	EVENT	Date of Onset (Month)	Date of Onset (Day)	Duration (Days)	Pattern	Severity	Drug Related	Action Taken
8. Dizziness								

Drug Related Specify:

Description*

Study Specific Events	EVENT	Date of Onset (Month)	Date of Onset (Day)	Duration (Days)	Pattern	Severity	Drug Related	Action Taken
9. Fatigue								

Drug Related Specify:

Description*

Study Specific Events	EVENT	Date of Onset (Month)	Date of Onset (Day)	Duration (Days)	Pattern	Severity	Drug Related	Action Taken
10. Nervousness/anxiety								

Drug Related Specify:

Description*

Study Specific Events	EVENT	Date of Onset (Month)	Date of Onset (Day)	Duration (Days)	Pattern	Severity	Drug Related	Action Taken
11. Insomnia								

Drug Related Specify:

Description*

Study Specific Events	EVENT	Date of Onset (Month)	Date of Onset (Day)	Duration (Days)	Pattern	Severity	Drug Related	Action Taken
12. Somnolence								

Drug Related Specify:

Description*

Study Specific Events	EVENT	Date of Onset (Month)	Date of Onset (Day)	Duration (Days)	Pattern	Severity	Drug Related	Action Taken
13. Depression**								

Drug Related Specify:

Description*

Study Specific Events	EVENT	Date of Onset (Month)	Date of Onset (Day)	Duration (Days)	Pattern	Severity	Drug Related	Action Taken
14. Itching								

Drug Related Specify:

Description*

Study Specific Events	EVENT	Date of Onset (Month)	Date of Onset (Day)	Duration (Days)	Pattern	Severity	Drug Related	Action Taken
15. Rash								

Drug Related Specify:

Description*

Study Specific Events	EVENT	Date of Onset (Month)	Date of Onset (Day)	Duration (Days)	Pattern	Severity	Drug Related	Action Taken
16. Decreased Libido								

Drug Related Specify:

Description*

Study Specific Events	EVENT	Date of Onset (Month)	Date of Onset (Day)	Duration (Days)	Pattern	Severity	Drug Related	Action Taken
17. Increased Libido								

Drug Related Specify:

Description*

Study Specific Events	EVENT	Date of Onset (Month)	Date of Onset (Day)	Duration (Days)	Pattern	Severity	Drug Related	Action Taken
18. Missed menses								

Drug Related Specify:

Description*

Study Specific Events	EVENT	Date of Onset (Month)	Date of Onset (Day)	Duration (Days)	Pattern	Severity	Drug Related	Action Taken
19. Significant Lab Abnormalities (describe)								

Drug Related Specify:

Description*

Study Specific Events	EVENT	Date of Onset (Month)	Date of Onset (Day)	Duration (Days)	Pattern	Severity	Drug Related	Action Taken
20. Other (describe)								

Drug Related Specify:

Description*

Study Specific Events	EVENT	Date of Onset (Month)	Date of Onset (Day)	Duration (Days)	Pattern	Severity	Drug Related	Action Taken
21. Other (describe)								

Drug Related Specify:

Description*

Study Specific Events	EVENT	Date of Onset (Month)	Date of Onset (Day)	Duration (Days)	Pattern	Severity	Drug Related	Action Taken
22. Other (describe)								

Drug Related Specify:

Description*

Study Specific Events	EVENT	Date of Onset (Month)	Date of Onset (Day)	Duration (Days)	Pattern	Severity	Drug Related	Action Taken
23. Other (describe)								

Drug Related Specify:

Description*

Source Completed By (Initials):

Protocol Number: NIDA-CPU-0004

GBR-12909 for Cocaine Dependence

Site Identification Number: 980101

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-CPU-0004

GBR-12909 for Cocaine Dependence

Site Identification Number: 980101

Subject Identification Number: 0001

Study Day UNSCHD

Date: (mm/dd/yyyy)

Form Not Done ☐

COLLECTION OF URINE SPECIMENS FOR GBR 12909 ELIMINATION PHARMACOKINETICS

Time	Start Time (00:00 - 23:59)	Stop Time (00:00 - 23:59)	Total Volume Collected
0 - 8 hours			ml
8 - 16 hours			ml
16 - 24 hours			ml

Source Completed By (Initials):

URINE11 v1

Protocol Number: NIDA-CPU-0004

GBR-12909 for Cocaine Dependence

Site Identification Number: 980101

Subject Identification Number: 0001

Study Day UNSCHD

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; significant while on study means consider reporting result as adverse event if unexpected and at least possibly related to investigational agent, or requires early termination from study.

Dipstick Urinalysis:

Specific gravity

pH

Color

Appearance

___	_____		

Source Completed By (Initials):

Protocol Number: NIDA-CPU-0004

GBR-12909 for Cocaine Dependence

Site Identification Number: 980101

Subject Identification Number: 0001

Study Day UNSCHD

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	☐	☐	☐
Barbiturates		☐	☐
Benzodiazepines		☐	☐
Cannabinoids (THC)		☐	☐
Cocaine metabolites		☐	☐
Methadone		☐	☐
Methamphetamine		☐	☐
Methaqualone		☐	☐
Opiates		☐	☐
Phencyclidine (PCP)		☐	☐
Propoxyphene		☐	☐

Source Completed By (Initials):

Protocol Number: NIDA-CPU-0004

GBR-12909 for Cocaine Dependence

Site Identification Number: 980101

Subject Identification Number: 0001

Study Day UNSCHD

Date: (mm/dd/yyyy)

Form Not Done ☐

VITAL SIGNS (Days 1-11)

Hour	Time (00:00 - 23:59)	Temp (oral) Fahrenheit or Celcius	Resp. Rate (Breaths/Min)	Pulse Rate (Beats/Min)	Blood Pressure (systolic) / (diastolic)	Comp.By: (Initials)
0		☐F ☐C			/	
		☐ ☐			/	
		☐ ☐			/	
		☐ ☐			/	
		☐ ☐			/	
		☐ ☐			/	
		☐ ☐			/	
		☐ ☐			/	

VITALS v1

Protocol Number: NIDA-CPU-0004

GBR-12909 for Cocaine Dependence

Site Identification Number: 980101

Subject Identification Number: 0001

Study Day UNSCHD

Date: (mm/dd/yyyy)

Form Not Done ☐

VITAL SIGNS (Screening / Days 12-47)

Time (00:00 - 23:59)	Temp (oral) Fahrenheit or Celcius	Resp. Rate (Breaths/Min)	Pulse Rate (Beats/Min)	Blood Pressure (systolic) / (diastolic)	Comp.By: (Initials)
	☐F ☐C			/	

VITALS2 v1