1) Eligibility Criteria
2) Demographics
3) Study Discharge
4) Cocaine Use by Timeline Follow Back Method
5) Physical Exam
6) Medical History
7) 12-lead ECG
8) Echocardiogram
9) Vital Signs Screening Infusions 1 and 2
10) Vital Signs Baseline/Treatment Infusions 3 through 6
11) Vital Signs
12) Urine Toxicology
13) Alcohol Breathalyzer Test
14) Plasma Alcohol
15) Routine Urinalysis
16) Hematology
17) Blood Chemistries / Liver Function Tests
18) Birth Control / Pregnancy Assessment
19) Infectious Disease Panel
20) Blood Samples for Pharmacokinetics Determinations – Cocaine/BE PK
21) Blood Samples for Pharmacokinetics Determinations – GBR 12909 PK and GBR Dosing
22) Adverse Events
23) Prior Medications
24) Concomitant Medications
25) Brief Substance Craving Scale (BSCS)
26) Beck Depression Inventory (BDI)
27) Brief Symptom Inventory (BSI)
28) Profile of Mood States (POMS)
29) Brief Psychiatric Rating Scale (BPRS)
30) HIV Risk-Taking Behavior Scale (HRBS)
31) Barratt Impulsive Scale (BIS-11)
32) Addiction Severity Index (ASI) – Lite
33) Structured Clinical Interview (SCID)
34) Scale Assessments Intake Screening
35) Scale Assessments Day -5
36) Scale Assessments Day -2
37) Scale Assessments Day -1
38) Scale Assessments Day 11
39) Scale Assessments Day 12
40) Scale Assessments Discharge
41) Scale Assessments Day 48
42) Comment Page
43) Investigator Signature Page
44) ARCI (non-scale assessment days)
45) VAS assessments

CRF Book

Day -30 through -8 (Pre-Intake Screening) Page 1

- Demographics
- Cocaine Use by Timeline Follow Back Method
- Physical Exam
- Vital Signs
- Medical History
- Urine Toxicology (6X)
- HIV Risk-Taking Behavior Scale
- Plasma Alcohol
- Routine Urinalysis
- Hematology
- Blood Chemistries / Liver Function Tests
- Birth Control / Pregnancy Assessment
- Infectious Disease Panel
- SCID
- Prior Medications
- Echocardiogram

Day -7 through -6 (Intake Screening) Page 24

- Vital Signs
- Urine Toxicology
- Hematology
- Alcohol Breathalyzer Test
- Birth Control / Pregnancy Assessment
- Brief Substance Craving Scale
- Beck Depression Inventory
- Brief Symptom Inventory
- Profile of Mood States
- Brief Psychiatric Rating Scale
- Barratt Impulsive Scale-11
- Addiction Severity Index – Lite
- Scale Assessments Intake Screening

Day -5 (Screening Infusions) Page 45

- Vital Signs Screening Infusions 1 and 2
- Urine Toxicology
- Brief Substance Craving Scale
- Beck Depression Inventory
- Brief Symptom Inventory
- Profile of Mood States
- Brief Psychiatric Rating Scale
- Brief Psychiatric Rating Scale
- Brief Psychiatric Rating Scale
- Scale Assessments Day -5

Day -3 (Psychometric assessments) Page 59

- Brief Substance Craving Scale
- Beck Depression Inventory
- Brief Symptom Inventory

- Profile of Mood States

Day -2 through -1 (Baseline Infusions) Page 64

- Vital Signs Baseline/Treatment Infusions 3 through 6
- Vital Signs Baseline/Treatment Infusions 3 through 6
- Urine Toxicology
- Birth Control / Pregnancy Assessment
- Brief Substance Craving Scale
- Beck Depression Inventory
- Brief Symptom Inventory
- Profile of Mood States
- Brief Psychiatric Rating Scale
- Brief Psychiatric Rating Scale
- Scale Assessments Day -2
- Scale Assessments Day -1
- Blood Chemistries / Liver Function Tests

Day -1 (Randomization) Page 82

- Eligibility Criteria
- Hematology

Day 1 (Treatment) Page 85

- Brief Substance Craving Scale
- Beck Depression Inventory
- Brief Symptom Inventory
- Profile of Mood States

Day 3 (Treatment) Page 90

- Brief Substance Craving Scale
- Beck Depression Inventory
- Brief Symptom Inventory
- Profile of Mood States

Day 5 (Treatment) Page 95

- Brief Substance Craving Scale
- Beck Depression Inventory
- Brief Symptom Inventory
- Profile of Mood States

Day 7 (Treatment) Page 100

- Hematology
- Brief Substance Craving Scale
- Beck Depression Inventory
- Brief Symptom Inventory
- Profile of Mood States

Day 9 (Treatment) Page 106

- Brief Substance Craving Scale
- Beck Depression Inventory
- Brief Symptom Inventory
- Profile of Mood States

Day 11 (Treatment Infusions) **Page 111**

- Vital Signs Baseline/Treatment Infusions 3 through 6
- Brief Substance Craving Scale
- Beck Depression Inventory
- Brief Symptom Inventory
- Profile of Mood States
- Brief Psychiatric Rating Scale
- Brief Psychiatric Rating Scale
- Scale Assessments Day 11

Day 12 (Treatment Infusions) **Page 122**

- Vital Signs Baseline/Treatment Infusions 3 through 6
- Brief Psychiatric Rating Scale
- Brief Psychiatric Rating Scale
- Scale Assessments Day 12
- Blood Chemistries / Liver Function Tests

Day 13 (Psychometric assessments) **Page 129**

- Brief Substance Craving Scale
- Beck Depression Inventory
- Brief Symptom Inventory
- Profile of Mood States

Day 14 **Page 134**

- Hematology

Day 15 (Psychometric assessments) **Page 135**

- Brief Substance Craving Scale
- Beck Depression Inventory
- Brief Symptom Inventory
- Profile of Mood States

Day 17 (Psychometric assessments) **Page 140**

- Brief Substance Craving Scale
- Beck Depression Inventory
- Brief Symptom Inventory
- Profile of Mood States

Day 19 (Psychometric assessments) **Page 145**

- Brief Substance Craving Scale
- Beck Depression Inventory
- Brief Symptom Inventory
- Profile of Mood States

Day 20 (Discharge / Early Termination) **Page 150**

- Study Discharge
- Vital Signs
- Urine Toxicology
- Hematology
- Blood Chemistries / Liver Function Tests
- Birth Control / Pregnancy Assessment
- HIV Risk-Taking Behavior Scale

- Barratt Impulsive Scale-11
- Scale Assessments Discharge
- Brief Substance Craving Scale
- Beck Depression Inventory
- Brief Symptom Inventory
- Profile of Mood States

Day 27 (Follow up) **Page 166**
- Vital Signs
- Urine Toxicology
- Hematology

Day 34 (Follow up) **Page 169**
- Vital Signs
- Urine Toxicology
- Hematology

Day 41 (Follow up) **Page 172**
- Vital Signs
- Urine Toxicology
- Hematology

Day 48 (Follow up) **Page 175**
- Vital Signs
- Urine Toxicology
- Hematology
- Blood Chemistries / Liver Function Tests
- Birth Control / Pregnancy Assessment
- HIV Risk-Taking Behavior Scale
- Barratt Impulsive Scale-11
- Scale Assessments Day 48

Blood Samples **Page 185**
- Blood Samples for Pharmacokinetics Determinations – Cocaine/BE PK
- Blood Samples for Pharmacokinetics Determinations – GBR 12909 PK and GBR Dosing

ARCI **Page 188**
- ARCI for none-scale-assessment days (2, 4, 6, 8, 13, 15, 18, 27, 34, 41)

Adverse Event / Con Meds **Page 189**
- Adverse Events
- Concomitant Medications

ECG **Page 191**
- 12-Lead ECG

VAS **Page 202**
- VAS for intake, day -5, day -2, day -1, day 11, day 12, discharge, day 48

Study Comments **Page 210**
- Comment Page

- Investigator Signature Page

Date Assessment Completed ___-___-_____ (Day -30 to -8)

Form 2 - Demographics

General

Gender _Male _Female

Date of Birth ___-___-_____

_ Hispanic or Latino

- _ Mexican, Mexican-American, or Chicano
- _ Puerto Rican
- _ Cuban
- _ South or Central American
- _ Other: Specify _____

_ Not Hispanic or Latino

Indicate which single major race/ethnicity applies (*within the single major race/ethnicity that you have selected, mark all that apply*):

_ White

_ Black or African American

_ Asian

(check all that apply)

- _ Asian Indian
- _ Chinese
- _ Filipino
- _ Japanese
- _ Korean
- _ Vietnamese
- _ Other: Specify _____

_ American Indian or Alaska Native

_ Native Hawaiian or Other Pacific Islander

(check all that apply)

- _ Native Hawaiian
- _ Guamanian or Chamorro
- _ Samoan
- _ Other: Specify _____

_ Other: Specify _____

_ Unknown

_ Participant chooses not to answer race/ethnicity questions.

Education

Education Completed (GED = 12 years)	___years ___months

Current employment pattern (past 30 days)					
	Full time (35+ hrs/wk)		Part time (regular hours)		Part time (irregular hrs, day work)
	Student		Military Service		Retired/Disabled
	Homemaker		Unemployed		In Controlled Environment
Past Employment Pattern (Past 3 years)					
	Full time (35+ hrs/wk)		Part time (regular hours)		Part time (irregular hrs, day work)
	Student		Military Service		Retired/Disabled
	Homemaker		Unemployed		In Controlled Environment
	Legally Married		Living with Partner / Cohabiting		Widowed
	Separated		Divorced		Never Married

	# of Days in the Past 30	# of Years Lifetime	Route of Administration*
Alcohol – any use at all			
Alcohol – to intoxication			
Heroin			
Methadone (prescribed)			
Methadone (illicit)			
Other opiates/analgesics			
Barbiturates			
Sedative/hypnotics/tranquilizers			
Cocaine			
Amphetamines			
Cannabis			
Hallucinogens			
Inhalants			
Nicotine			
More than one substance per day (including alcohol)			

*Choose the most common route for each substance. 1 = oral 2 = Nasal 3 = Smoking 4 = Non-IV Injection 5 = IV Injection

According to the interviewer, which substance is the major problem? Check only one.

	No problem		Alcohol - any use at all		Alcohol - to intoxication
	Heroin		Methadone (prescribed)		Methadone (illicit)
	Other opiates/analgesics		Barbiturates		Sedative/hypnotics/tranquilizers
	Cocaine		Amphetamines		Cannabis
	Hallucinogens		Inhalants		Nicotine
	More than one substance per day (including alcohol)				

PI/MD Signature: _____ Date: _____

Date Assessment Completed ___-___-_____ (Day -30 to -8)

Form 4 - Cocaine Use by Timeline Follow Back Method

Days prior to Screening		Amount Used	Unit	Route 1 = Sublingual 4 = Nasal 2 = Intravenous 5 = Other 3 = Inhalation (specify)
1	__ __ / __ __ / __ __ __ __		_____	_____
2	__ __ / __ __ / __ __ __ __		_____	_____
3	__ __ / __ __ / __ __ __ __		_____	_____
4	__ __ / __ __ / __ __ __ __		_____	_____
5	__ __ / __ __ / __ __ __ __		_____	_____
6	__ __ / __ __ / __ __ __ __		_____	_____
7	__ __ / __ __ / __ __ __ __		_____	_____
8	__ __ / __ __ / __ __ __ __		_____	_____
9	__ __ / __ __ / __ __ __ __		_____	_____
10	__ __ / __ __ / __ __ __ __		_____	_____
11	__ __ / __ __ / __ __ __ __		_____	_____
12	__ __ / __ __ / __ __ __ __		_____	_____
13	__ __ / __ __ / __ __ __ __		_____	_____
14	__ __ / __ __ / __ __ __ __		_____	_____
15	__ __ / __ __ / __ __ __ __		_____	_____
16	__ __ / __ __ / __ __ __ __		_____	_____
17	__ __ / __ __ / __ __ __ __		_____	_____
18	__ __ / __ __ / __ __ __ __		_____	_____
19	__ __ / __ __ / __ __ __ __		_____	_____
20	__ __ / __ __ / __ __ __ __		_____	_____
21	__ __ / __ __ / __ __ __ __		_____	_____
22	__ __ / __ __ / __ __ __ __		_____	_____
23	__ __ / __ __ / __ __ __ __		_____	_____

24	__ __ / __ __ / __ __ __ __		_____	_____
25	__ __ / __ __ / __ __ __ __		_____	_____
26	__ __ / __ __ / __ __ __ __		_____	_____
27	__ __ / __ __ / __ __ __ __		_____	_____
28	__ __ / __ __ / __ __ __ __		_____	_____
29	__ __ / __ __ / __ __ __ __		_____	_____
30	__ __ / __ __ / __ __ __ __		_____	_____

Completed by (initials): _____

Date Assessment Completed ___-___-_____ (Day -30 to -8)

Form 5 - Physical Exam

Height: ___ ___ ___ inches			Weight: ___ ___ ___ pounds		
General Exam	Normal	Abnormal	Abnormal Significant	Not Done	If Abnormal, please explain
Oral					
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 _____					

PI/MD Signature: _____ Date: _____

(Day -30 to -8)

Form 11 - Vital Signs	
Date ___-___-_____	Time ___:___
Oral Temperature	___ . _ °C
Sitting Blood Pressure	____/ ____ mm Hg
Sitting Pulse Rate	_____ beats / min
Sitting Respiratory Rate	___ breaths / min
Standing Blood Pressure (1 minute)	_____ / _____ mm Hg
Standing Pulse Rate (1 minute)	_____ beats / min
Standing Blood Pressure (3 minutes)	_____ / _____ mm Hg
Standing Pulse Rate (3 minutes)	_____ beats / min

Completed by (initials): _____

Subject Identification _____

Medical History

Date Assessment Completed ___-___-_____

(Day -30 to -8)

Disorder	No history of disorder	Yes, doesn't exclude	Yes, excludes	Not evaluated	If yes, specify or describe
Allergies: drug					
Allergies: other					
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					
Other					
Specify _____					
Other					
Specify _____					

Surgical History			
Was major surgery ever performed? _Yes _No			
Type of Surgery	Date of Surgery	Excludes	Doesn't Exclude
	___-___-_____		
	___-___-_____		
	___-___-_____		
	___-___-_____		
	___-___-_____		
	___-___-_____		
	___-___-_____		

Tobacco History	
Has subject used any tobacco product (e.g. cigarettes, cigars, pipe, chewing tobacco) in the past week?	_Yes _No
Has subject ever used any tobacco product for at least one year?	_Yes _No
If yes, number of years tobacco used?	___ years
Comments _____ _____ _____ _____ _____	

PI/MD Signature: _____ Date: _____

Subject Identification ________
Urine Toxicology

(Day -30 to -8)

Form 12 - Urine Toxicology			
Date ___-___-______			
Temperature within expected range?	_Yes	_No	_Unknown
If no or unknown, comment ____			
Drug / Test	Positive	Negative	Not Done
Amphetamines			
Cannabinoids (THC)			
Cocaine			
Opiates			

Form 12 - Urine Toxicology			
Date ___-___-______			
Temperature within expected range?	_Yes	_No	_Unknown
If no or unknown, comment ____			
Drug / Test	Positive	Negative	Not Done
Amphetamines			
Cannabinoids (THC)			
Cocaine			
Opiates			

Form 12 - Urine Toxicology			
Date ___-___-______			
Temperature within expected range?	_Yes	_No	_Unknown
If no or unknown, comment ____			
Drug / Test	Positive	Negative	Not Done
Amphetamines			
Cannabinoids (THC)			
Cocaine			
Opiates			

Subject Identification _______
Urine Toxicology
(Day -30 to -8)

Form 12 - Urine Toxicology

Date ___-___-______

Temperature within expected range?	_Yes	_No	_Unknown
If no or unknown, comment ____			
Drug / Test	Positive	Negative	Not Done
Amphetamines			
Cannabinoids (THC)			
Cocaine			
Opiates			

Form 12 - Urine Toxicology

Date ___-___-______

Temperature within expected range?	_Yes	_No	_Unknown
If no or unknown, comment ____			
Drug / Test	Positive	Negative	Not Done
Amphetamines			
Cannabinoids (THC)			
Cocaine			
Opiates			

Form 12 - Urine Toxicology

Date ___-___-______

Temperature within expected range?	_Yes	_No	_Unknown
If no or unknown, comment ____			
Drug / Test	Positive	Negative	Not Done
Amphetamines			
Cannabinoids (THC)			
Cocaine			
Opiates			

Completed by (initials): _________________

Date Assessment Completed ___-___-_____ (Day -30 to -8)

Form 30 - HIV Risk-Taking Behavior Scale (HRBS)

Ask subject to read each of the items and choose only one answer for each question

1. How many times have you hit up (i.e. injected any drugs) in the last month?	
	I haven't hit up (If you have not injected drugs in the last month, go to question 7.)
	Once a week or less
	More than once a week but less than once a day
	Once a day
	2-3 times a day
	More than three times a day
2. How many times in the last month have you used a needle after someone else had already used it?	
	No times
	One time
	Two times
	3-5 times
	6-10 times
	More than 10 times
3. How many different people have used a needle before you in the past month?	
	None
	One person
	Two people
	3-5 people
	6-10 people
	More than 10 people
4. How many times in the last month has someone used a needle after you?	
	No times
	One time
	Two times
	3-5 times
	6-10 times
	More than 10 times

5. How often, in the last month, have you cleaned needles before re-using them?	
	I do not re-use
	Every time
	Often
	Sometimes
	Rarely
	Never
6. Before using needles again, how often in the past month did you use bleach to clean them?	
	I do not re-use
	Every time
	Often
	Sometimes
	Rarely
	Never
7. How many people, including clients, have you had sex with in the last month?	
	None (If you have not had sex in the last month, skip to question 12.)
	One
	Two
	3-5 people
	6-10 people
	More than 10 people
8. How often have you used condoms when having sex with your regular partner(s) in the last month?	
	No regular partner/no penetrative sex
	Every time
	Often
	Sometimes
	Rarely
	Never

9. How often have you used condoms when you had sex with casual partners?	
	No casual partner/no penetrative sex
	Every time
	Often
	Sometimes
	Rarely
	Never
10. How often have you used condoms when you have been paid for sex in the last month?	
	No paid partner/no penetrative sex
	Every time
	Often
	Sometimes
	Rarely
	Never
11. How many times have you had anal sex in the last month?	
	No times
	One time
	Two times
	3-5 times
	6-10 times
	More than 10 times
Everyone should answer question 12.	
12. Have you had an HIV test come back positive?	
	Yes
	No
	Don't know

Completed by (initials): _____

(Day -30 to -8)

Form 14 - Plasma Alcohol	
Was a sample taken for plasma alcohol concentrations?	_Yes _No _Unknown
Date sample was taken	___-___-_____
Plasma Alcohol content	___._____
Provide comments for any action taken	

Completed by (initials): _____

Subject Identification _____
Routine Urinalysis

(Day -30 to -8)

Form 15 - Routine Urinalysis

Date of sample ___-___-_____

	Value	Normal	Abnormal	Abnormal Significant	Not Done	Comments (required for abnormal values)
pH	___.__					
Protein	(+/-)					
Glucose	(+/-)					
Ketones	(+/-)					
Occult Blood	(+/-)					
WBC	*					
RBC	*					
Epithelial Cells	*					

*For WBC, RBC, and Epithelial Cells use the following scale to report values: 1 = None: 0-5 2 = Few: 6-10 3 = Moderate: 11-50 4 = Heavy: >50

PI/MD Signature: _____ Date: _____

(Day -30 to -8)

Form 16 - Hematology

Date of sample ___-___-_____

	Value	Normal	Abnormal	Abnormal Significant	Not Done	Comments (required for abnormal values)
WBC	___.__*					
Hemoglobin	___.__g/dL					
Hematocrit	___.__%					
MCV	fL					
Platelet Count	*					
Neutrophils	%					
Lymphocytes	%					
Monocytes	%					
Eosinophils	%					
Basophils	__.__%					

**x 10^3/uL = thou/cumm = thou/mcl = K/cmm = 1000/uL = x 10^3/cumm*

PI/MD Signature: _____ Date: _____

(Day -30 to -8)

Form 17 - Blood Chemistries / Liver Function Tests

Date of sample ___-___-_____

	Value	Normal	Abnormal	Abnormal Significant	Not Done	Comments (required for abnormal values)
Sodium	mmol/L					
Potassium	__.__ mmol/L					
Chloride	mmol/L					
CO_2	mmol/L					
Bilirubin*	__.__ mg/dL					
ALP*	IU/L					
LDH	IU/L					
SGOT/AST*	IU/L					
SGPT/ALT*	IU/L					
Glucose	mg/dL					
BUN	mg/dL					
Creatinine	_._ mg/dL					
CPK	IU/L					

mmol/L = mEq/L

***Complete liver function tests only at Baseline Infusions (Day -1), and Treatment Infusions (Day 12).**

PI/MD Signature: _____ Date: _____

Date Assessment Completed ___-___-_____ (Day -30 to -8)

Form 18 - Birth Control / Pregnancy Assessment

Is the subject male, postmenopausal, or have they had a hysterectomy or been sterilized?		_Yes _No
If no, is the subject using an acceptable method of birth control?		_Yes _No
What method of birth control is the participant currently using?		
	Complete abstinence from sexual intercourse	
	Diaphragm and condom by partner	
	Intrauterine device and condom by partner: Type _____	
	Sponge and condom by partner	

Note: oral contraceptives, Depo-Provera, Norplant and intrauterine progesterone contraceptive system are not allowed.

Was a serum pregnancy test performed?	_Yes _No
If yes, what was the result?	_Positive _Negative _Unknown
Date and time specimen collected	Date ___-___-_____ Time ___:___

If no, specify reason
_____
_____
_____

PI/MD Signature: _____ Date: _____

(Day -30 to -8)

Form 19 - Infectious Disease Panel

Hepatitis

Date of sample ___-___-_____

		Provide comments for any positive value
Hepatitis B surface antigen result	_Positive _Negative	
Hepatitis C virus antibody result	_Positive _Negative	

Is the subject abusing any drugs intravenously?		_Yes _No
If yes, a PPD test is required. If no, skip to the HIV section of this form.		
Has the subject ever had a positive PPD test?		_Yes _No
If yes, do not perform PPD, leave the rest of the PPD section blank, and skip to the chest x-ray section of this form.		
PPD test administered	Date ___-___-_____	Time ___:___
PPD test read	Date ___-___-_____	Time ___:___
PPD test result	_Negative _Positive _Unknown	
If PPD test is positive or the test was not done, a chest x-ray is required.		

Comments (required for any positive value)

Chest X-Ray	**Infectious Disease Panel**
Was a chest X-ray performed?	_Yes _No
Date chest X-ray performed	___-___-_____
Results of chest X-ray	
	Normal
	Abnormal, not significant
	Abnormal, significant
	Indeterminate
	Not assessed
Provide comments for any abnormal finding	

HIV			
Was an HIV test performed?	_Yes	_No	
If yes, what was the result of the HIV type 1 test?	_Positive	_Negative	
If yes, what was the result of the HIV type 2 test?	_Positive	_Negative	

RPR result	_Reactive	_Nonreactive	
If reactive, FTA-abs, MHA-TP, or TP-PA result	_Positive	_Negative	

PI/MD Signature: _____ Date: _____

Date Assessment Completed ___-___-_____ (Day -30 to -8)

Form 33 - Structured Clinical Interview (SCID)

DSM-IV Code	Diagnosis
Please list all CURRENT Substance Abuse or Dependence Diagnoses	
_____-_____	_____
_____-_____	_____
_____-_____	_____
_____-_____	_____
_____-_____	_____
_____-_____	_____
Please list all PAST Substance Abuse or Dependence Diagnoses	
_____-_____	_____
_____-_____	_____
_____-_____	_____
_____-_____	_____
_____-_____	_____
_____-_____	_____
Please list all other CURRENT Axis I Diagnoses	
_____-_____	_____
_____-_____	_____
_____-_____	_____
_____-_____	_____
_____-_____	_____
_____-_____	_____
Please list all other PAST Axis I Diagnoses	
_____-_____	_____
_____-_____	_____
_____-_____	_____
_____-_____	_____
_____-_____	_____
_____-_____	_____

Completed by (initials): _____

Form 23 - Prior Medications

Has the subject taken any prescription medication for 14 days or non-prescription medications for 7 days prior to signing informed consent? __Yes __No

Unit of Medication			Frequency		Route of Administration		
1 = capsule 2 = gram 3 = grain 4 = drop 5 = microgram 6 = microliter	7 = milligram 8 = milliliter 9 = ounce 10 = puff 11 = spray/squirt	12 = suppository 13 = teaspoon 14 = tablespoon 15 = tablet 16 = unknown	1 = one dose 2 = once daily 3 = twice daily 4 = 3 times/day	5 = 4 times/day 6 = every other day 7 = as needed	1 = oral 2 = Transdermal 3 = inhaled 4 = intramuscular 5 = intravenous	6 = rectal 7 = vaginal 8 = subcutaneous 9 = sublingual 10 = auricular	11 = intra-articular 12 = nasal 13 = intraocular 14 = unknown

Medication	Dose	Units	Freq.	Route	Start Date	Stop Date	Cont.	Indication
					__ __/__ __/__ __ __ __	__ __/__ __/__ __ __ __		
					__ __/__ __/__ __ __ __	__ __/__ __/__ __ __ __		
					__ __/__ __/__ __ __ __	__ __/__ __/__ __ __ __		
					__ __/__ __/__ __ __ __	__ __/__ __/__ __ __ __		
					__ __/__ __/__ __ __ __	__ __/__ __/__ __ __ __		
					__ __/__ __/__ __ __ __	__ __/__ __/__ __ __ __		
					__ __/__ __/__ __ __ __	__ __/__ __/__ __ __ __		
					__ __/__ __/__ __ __ __	__ __/__ __/__ __ __ __		
					__ __/__ __/__ __ __ __	__ __/__ __/__ __ __ __		
					__ __/__ __/__ __ __ __	__ __/__ __/__ __ __ __		
					__ __/__ __/__ __ __ __	__ __/__ __/__ __ __ __		
					__ __/__ __/__ __ __ __	__ __/__ __/__ __ __ __		
					__ __/__ __/__ __ __ __	__ __/__ __/__ __ __ __		

PI/MD Signature: ____________________________ Date: _______________

Date Echocardiogram Completed ___-___-_____ (Day -30 to -8)

Form 8 - Echocardiogram

Echocardiogram is:	_ Normal	_Abnormal(NCS)	_Abnormal (CS)	
Is subject eligible to participate in this study:		_Yes	_No	

Comments (required for abnormal result):

_____

_____

_____

_____

PI/MD Signature: _____ Date: _____

(Day -7 to -6)

Form 11 - Vital Signs	
Date ___-___-_____	Time ___:___
Oral Temperature	_____ . ___ °C
Sitting Blood Pressure	_____ /_____ mm Hg
Sitting Pulse Rate	_____ beats / min
Sitting Respiratory Rate	_____ breaths / min
Standing Blood Pressure (1 minute)	_____ / _____ mm Hg
Standing Pulse Rate (1 minute)	_____ beats / min
Standing Blood Pressure (3 minutes)	_____ / _____ mm Hg
Standing Pulse Rate (3 minutes)	_____ beats / min

Completed by (initials): _____

(Day -7 to -6)

Form 12 - Urine Toxicology			
Date ___-___-_____			
Temperature within expected range?	_Yes	_No	_Unknown
If no or unknown, comment _____			
Drug / Test	Positive	Negative	Not Done
Amphetamines			
Cannabinoids (THC)			
Cocaine			
Opiates			

Completed by (initials): _____

Subject Identification_____
Hematology

(Day -7 to -6)

Form 16 - Hematology

Date of sample ___-___-_____

	Value	Normal	Abnormal	Abnormal Significant	Not Done	Comments (required for abnormal values)
WBC	_____.___*					
Hemoglobin	_____.___g/dL					
Hematocrit	_____.___%					
MCV	_____fL					
Platelet Count	_____*					
Neutrophils	_____%					
Lymphocytes	_____%					
Monocytes	_____%					
Eosinophils	_____%					
Basophils	___.___%					

**x 10^3/uL = thou/cumm = thou/mcl = K/cmm = 1000/uL = x 10^3/cumm*

PI/MD Signature: _____ Date: _____

Subject Identification _____
Alcohol Breathalyzer Test

(Day -7 to -6)

Form 13 - Alcohol Breathalyzer Test	
Was alcohol breathalyzer test performed?	_Yes _No _Unknown
Date alcohol breathalyzer test performed	___-___-_____
Blood Alcohol content (BAC)	_._____
Provide comments for any action taken	

Completed by (initials): _____

Date Assessment Completed ___-___-_____ (Day -7 to -6)

Form 18 - Birth Control / Pregnancy Assessment

Is the subject male, postmenopausal, or have they had a hysterectomy or been sterilized?		_Yes _No
If no, is the subject using an acceptable method of birth control?		_Yes _No
What method of birth control is the participant currently using?		
	Complete abstinence from sexual intercourse	
	Diaphragm and condom by partner	
	Intrauterine device and condom by partner: Type _____	
	Sponge and condom by partner	

Note: oral contraceptives, Depo-Provera, Norplant and intrauterine progesterone contraceptive system are not allowed.

Was a serum pregnancy test performed?	_Yes _No
If yes, what was the result?	_Positive _Negative _Unknown
Date and time specimen collected	Date ___-___-_____ Time _____:_____

If no, specify reason

_____

_____

_____

PI/MD Signature: _____ Date: _____

Date Assessment Completed ___-___-_____ (Day -7 to -6)

Form 25 - Brief Substance Craving Scale (BSCS)

Cocaine				
1. The intensity of my craving, that is, how much I desired cocaine in the past 24 hours was				
_None at all	_Slight	_Moderate	_Considerable	_Extreme
2. The frequency of my craving, that is, how often I desired cocaine in the past 24 hours was				
_ Never	_Almost never	_Several times	_Regularly	_ Almost constantly
3. The length of time I spent craving for cocaine during the past 24 hours was				
_None at all	_Very short	_Short	_Somewhat long	_Very long
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. The worst day: During the past week my most intense craving occurred on the following day				
_Sunday	_Monday	_Tuesday	_Wednesday	
_Thursday	_Friday	_Saturday	_All days the same (go to question 8)	
7. The date for that day was ___-___-_____				
8. The intensity of my craving, that is, how much I desired cocaine on that worst day was				
_None at all	_Slight	_Moderate	_Considerable	_Extreme
9. A 2nd craved drug during the past 24 hours was (Mark only one of the following. If no 2nd craved drug, mark "None" and leave the rest of this form blank.)				
_None	_Downers or Sedatives (Barbiturates, etc.)		_Benzodiazepines (Valium, Xanax, etc.	_Nicotine
_Alcohol	_Heroin or other Opiates		_Marijuana	_Other Specify _____
10. The intensity of my craving, that is, how much I desired this **second** drug in the past 24 hours was				
_None at all	_Slight	_Moderate	_Considerable	_Extreme
11. The frequency of my craving, that is, how often I desired this **second** drug in the past 24 hours was				
_Never	_Almost never	_Several times	_Regularly	_Almost constantly
12. The length of time I spent in craving for this **second** drug during the past 24 hours was				
_None at all	_Very short	_Short	_Somewhat long	_Very long

Third Drug				
13. A **3rd** craved drug during the past 24 hours was (Mark only one of the following. If no 3rd craved drug, mark "None" and leave questions 14-16 blank.)				
_ None	_Downers or Sedatives (Barbiturates, etc.)		_Benzodiazepines (Valium, Xanax, etc.	_Nicotine
_Alcohol	_Heroin or other Opiates		_Marijuana	_Other Specify _____
14. The intensity of my craving, that is, how much I desired this **third** drug in the past 24 hours was				
_None at all	_Slight	_Moderate	_Considerable	_Extreme
15. The frequency of my craving, that is, how often I desired this **third** drug in the past 24 hours was				
_Never	_Almost never	_Several times	_Regularly	_Almost constantly
16. The length of time I spent in craving for this third drug during the past 24 hours was				
_None at all	_Very short	_Short	_Somewhat long	_Very long

Completed by (initials): _____

Date Assessment Completed ___-___-_____ (Day -7 to -6)

Form 26 - Beck Depression Inventory (BDI)

Please enter the total score:

Total BDI Score: _____ _____

Completed by (initials): _____

Date Assessment Completed ___-___-_____ (Day -7 to -6)

Form 27 - Brief Symptom Inventory (BSI)

Please enter the T score for each symptom dimension:

Somatization _____ _____. _____ _____

Obsession-Compulsion _____ _____. _____ _____

Interpersonal Sensitivity _____ _____. _____ _____

Depression _____ _____. _____ _____

Anxiety _____ _____. _____ _____

Hostility _____ _____. _____ _____

Phobic Anxiety _____ _____. _____ _____

Paranoid Ideation _____ _____. _____ _____

Psychoticism _____ _____. _____ _____

Please enter the T score for each global index of distress:

Global Severity Index (GSI) _____ _____. _____ _____

Positive Symptom Total (PST) _____ _____. _____ _____

Positive Symptom Distress Index (PSDI) _____ _____. _____ _____

Completed by (initials): _____

Subject Identification _____
Profile of Mood States

Date Assessment Completed ___-___-_____ (Day -7 to -6)

Form 28 - Profile of Mood States (POMS)		
Please enter the total score for each category:		
1.	Tension	__ __
2.	Depression	__ __
3.	Anger	__ __
4.	Vigor	__ __
5.	Fatigue	__ __
6.	Confusion	__ __
Total Mood Disturbance		__ __ __

Completed by (initials): _____

Date Assessment Completed ___-___-_____ Time ___:___ (Day -7 to -6)

Form 29 - Brief Psychiatric Rating Scale (BPRS)

Symptoms	Not Assessed	Not Present	Very Mild	Mild	Moderate	Moderately Severe	Severe	Extremely Severe
Somatic Concern	_1	_2	_3	_4	_5	_6	_7	_8
Anxiety	_1	_2	_3	_4	_5	_6	_7	_8
Depression	_1	_2	_3	_4	_5	_6	_7	_8
Guilt	_1	_2	_3	_4	_5	_6	_7	_8
Hostility	_1	_2	_3	_4	_5	_6	_7	_8
Suspiciousness	_1	_2	_3	_4	_5	_6	_7	_8
Unusual thought content	_1	_2	_3	_4	_5	_6	_7	_8
Grandiosity	_1	_2	_3	_4	_5	_6	_7	_8
Hallucinations	_1	_2	_3	_4	_5	_6	_7	_8
Disorientation	_1	_2	_3	_4	_5	_6	_7	_8
Conceptual Disorganization.	_1	_2	_3	_4	_5	_6	_7	_8
Excitement	_1	_2	_3	_4	_5	_6	_7	_8
Motor retardation	_1	_2	_3	_4	_5	_6	_7	_8
Blunt Affect	_1	_2	_3	_4	_5	_6	_7	_8
Tension	_1	_2	_3	_4	_5	_6	_7	_8
Mannerisms / Posturing	_1	_2	_3	_4	_5	_6	_7	_8
Uncooperativeness	_1	_2	_3	_4	_5	_6	_7	_8
Emotional withdrawal	_1	_2	_3	_4	_5	_6	_7	_8
Suicidality	_1	_2	_3	_4	_5	_6	_7	_8
Self-neglect	_1	_2	_3	_4	_5	_6	_7	_8
Bizarre behavior	_1	_2	_3	_4	_5	_6	_7	_8
Elated Mood	_1	_2	_3	_4	_5	_6	_7	_8
Motor hyperactivity	_1	_2	_3	_4	_5	_6	_7	_8
Distractability	_1	_2	_3	_4	_5	_6	_7	_8

Completed by (initials): _____

Subject Identification _____
Barratt Impulsive Scale - 11

Date Assessment Completed ___-___-_____ (Day -7 to -6)

Form 31 - Barratt Impulsive Scale (BIS) - 11

This is a test to measure some of the ways you think and act. Read each statement, and circle either (1 – rarely/never), (2 – once in a while), (3 – often), or (4 – almost always/always). Circle only one number for each statement. Do not spend too much time on any statement. Answer quickly and honestly.	Rarely / Never	One in a while	Often	Almost Always / Always
1. I plan tasks carefully.	1	2	3	4
2. I do things without thinking.	1	2	3	4
3. I make up my mind quickly.	1	2	3	4
4. I am happy-go-lucky.	1	2	3	4
5. I don't "pay attention."	1	2	3	4
6. I have "racing" thoughts.	1	2	3	4
7. I plan trips well ahead of time.	1	2	3	4
8. I am self-controlled.	1	2	3	4
9. I concentrate easily.	1	2	3	4
10. I save regularly.	1	2	3	4
11. I "squirm" at plays or lectures (speeches).	1	2	3	4
12. I am a careful thinker.	1	2	3	4
13. I plan for job security.	1	2	3	4
14. I say things without thinking.	1	2	3	4
15. I like to think about complex (hard) problems.	1	2	3	4
16. I change jobs.	1	2	3	4
17. I act "on impulse."	1	2	3	4
18. I get easily bored when solving thought problems.	1	2	3	4
19. I act on the spur of the moment.	1	2	3	4
20. I am a steady thinker.	1	2	3	4
21. I change residences (where I live).	1	2	3	4
22. I buy things on impulse.	1	2	3	4
23. I can only think about one problem at a time.	1	2	3	4
24. I change hobbies.	1	2	3	4
25. I spend or charge more than I earn.	1	2	3	4
26. I have extraneous (outside) thoughts when thinking.	1	2	3	4
27. I am more interested in the present than the future.	1	2	3	4
28. I am restless at the theater or lectures.	1	2	3	4
29. I like puzzles.	1	2	3	4
30. I am future oriented.	1	2	3	4

Completed by (initials): _____

Date Assessment Completed ___-___-_____ (Day -7 to -6)

Form 32 - Addiction Severity Index (ASI) - Lite

G4. Date of admission	___-___-_____		
G8. Class	_Intake	_Follow-up	
G9. Contact code	_In person	_Telephone	_Mail
G10. Gender	_Male	_Female	
G12. Special	_Terminated	_Refused	_Unable to respond
G14. How long have you lived at your current address?		___Years, ___Months	
G16. Date of birth	___-___-_____		
G17. Of what race do you consider yourself?		_White (not Hispanic)	_Hispanic - Mexican
		_Black (not Hispanic)	_Hispanic – Puerto Rican
		_American Indian	_Hispanic - Cuban
		_Alaskan Native	_Other - Hispanic
		_Asian/Pacific Islander	
G18. Do you have a religious preference?		_Protestant	_Islamic
		_Catholic	_Other
		_Jewish	_None
G19. Have you been in a controlled environment in the last 30 days?		_No	_Medical treatment
		_Jail	_Psychiatric treatment
		_Alcohol/drug treatment	_Other _____
G20. How many days? _____			

M1. How many times in your life have you been hospitalized for medical problems?	_____	
M3. Do you have any chronic medical problem(s) which continue to interfere with your life?	_Yes	_No
If yes, please specify in the comment section below.		
M4. Are you taking any prescribed medication on a regular basis for a physical problem?	_Yes	_No
If yes, please specify in the comment section below.		
M5. Do you receive a pension for a physical disability? (Exclude psychiatric disabilities.)	_Yes	_No
If yes, please specify in the comment section below.		
M6. How many days have you experienced medical problems in the past 30 days?	_____	
M7. How troubled or bothered have you been by these medical problems in the past 30 days?		
_0 = Not at all _1 = Slightly _2 = Moderately _3 = Considerably _4 = Extremely		

M8. How important to you now is treatment for these medical problems?		
_0 = Not at all _1 = Slightly _2 = Moderately _3 = Considerably _4 = Extremely		
Confidence Ratings		
Is the above information significantly distorted by		
M10. Subject's misrepresentation?	_Yes	_No
M11. Subject's inability to understand?	_Yes	_No
Comments _____ _____		

E1. Education completed (GED = 12 years)	_____Years	_____Months
E2. Training or technical education completed		_____Months
E4. Do you have a driver's license?	___Yes	___No
E5. Do you have an automobile available for use?	___Yes	___No
E6. How long was your longest full-time job?	_____Years	_____Months
E7. Usual (or last) occupation _____		
Hollingshead occupational category		
_1 = Higher execs, major professionals, owners of large businesses		
_2 = Managers of medium sized businesses, nurses, opticians, pharmacists, social workers, teachers		
_3 = Administrative personnel, managers, owners/proprietors of small businesses (bakery, car dealership, engraving business, florist, decorator, actor, reporter, travel agent)		
_4 = Clerical and sales, technicians, bank teller, bookkeeper, clerk, draftsperson, timekeeper, secretary		
_5 = Skilled manual – usually having had training (baker, barber, brakeperson, chef, electrician, fireperson, lineperson, machinist, mechanic, paperhanger, painter, repairperson, tailor, welder, policeperson, plumber)		
_6 = Semi-skilled (hospital aide, painter, bartender, bus driver, cutter, cook, drill press, garage guard, checker, waiter, spot welder, machine operator)		
_7 = Unskilled (attendant, janitor, construction helper, unspecified labor, porter)		
_8 = Homemaker		
_9 = Student, disabled, no occupation		
E9. Does someone contribute the majority of your support?	_Yes	_No
E10. Usual employment pattern, past 3 years		
_1 = full time (35+ hrs/week) _5 = military service		
_2 = part time (regular hours) _6 = retired/disabled		
_3 = part time (irregular hours) _7 = unemployed		
_4 = student _8 = in controlled environment		

E11. How many days were you paid for working in the past 30 days?	_____	
How much money did you receive from the following sources in the past 30 days?		
E12. Employment (net income)	$$_____.____	
E13. Unemployment compensation	$_____.____	
E14. Welfare	$_____.____	
E15. Pension, benefits or social security	$_____.____	
E16. Mate, family or friends (money for personal expenses)	$_____.____	
E17. Illegal	$_____.____	
E18. How many people depend on you for the majority of their food, shelter, etc.?		
E19. How many days have you experienced employment problems in the past 30 days?		
E20. How troubled or bothered have you been by these employment problems in the past 30 days?		
_0 = Not at all _1 = Slightly _2 = Moderately _3 = Considerably _4 = Extremely		
E21. How important to you now is counseling for these employment problems?		
_0 = Not at all _1 = Slightly _2 = Moderately _3 = Considerably _4 = Extremely		
Confidence Ratings		
Is the above information significantly distorted by:		
E23. Subject's misrepresentation?	_Yes	_No
E24. Subject's inability to understand?	_Yes	_No
Comments _____ _____		

Drug/Alcohol Abuse			
	Days in Past 30 Days	Lifetime Years	Route of Administration 1 = Oral 2 = nasal 3 = smoking 4 = non iv inj. 5 = iv inj.
D1. Alcohol – any use at all			
D2. Alcohol – to intoxication			
D3. Heroin			
D4. Methadone			
D5. Other opiates/analgesics			
D6. Barbiturates			
D7. Other sedatives/hypnotics/tranquilizers			
D8. Cocaine			
D9. Amphetamines			
D10. Cannabis			
D11. Hallucinogens			
D12. Inhalants			
D13. More than one substance per day (incl. Alcohol)			
D17. How many times have you had alcohol DTs?			
How many times in your life have you been treated for			
D19. Alcohol abuse			
D20. Drug abuse			
How many of these times were detox only?			
D21. Alcohol			
D22. Drugs			
How much would you say you spend in the past 30 days on:			
D23. Alcohol	$_,____		
D24. Drugs	$_,____		
D25. How many days have you been treated as an outpatient for alcohol or drugs in the past 30 days? (Include NA, AA)			
How many days in the past 30 days have you experienced:			
D26. Alcohol problems			
D27. Drug problems			

How troubled or bothered have you been in the past 30 days by these?			
D28. Alcohol problems			
0 = Not at all 1 = Slightly 2 = Moderately 3 = Considerably 4 = Extremely			
D29. Drug problems			
0 = Not at all 1 = Slightly 2 = Moderately 3 = Considerably 4 = Extremely			
How important to you now is treatment for these:			
D30. Alcohol problems			
0 = Not at all 1 = Slightly 2 = Moderately 3 = Considerably 4 = Extremely			
D31. Drug problems			
0 = Not at all 1 = Slightly 2 = Moderately 3 = Considerably 4 = Extremely			
Confidence Ratings			

Is the above information significantly distorted by:			
D34. Subject's misrepresentation?	_Yes	_No	
D35. Subject's inability to understand?	_Yes	_No	

Comments

_____

_____

L1. Was this admission prompted or suggested by the criminal justice system (judge, probation/parole officer, etc.)?			_Yes _No
L2. Are you on probation or parole?			_Yes _No
How many times in your life have you been arrested and charged with the following:			
L3. Shoplifting/vandalism		L10. Assault	
L4. Parole/probation violation(s)		L11. Arson	
L5. Drug charge(s)		L12. Rape	
L6. Forgery		L13. Homicide, manslaughter	
L7. Weapons offense		L14. Prostitution	
L8. Burglary, larceny, breaking and entering		L15. Contempt of court	
L9. Robbery		L16. Other, specify _____	
		L17. How many of these charges resulted in conviction?	

How many times in your life have you been charged with the following:	
L18. Disorderly conduct, vagrancy, public intoxication	
L19. Driving while intoxicated	
L20. Major driving violations (reckless driving, speeding, no license, etc.)	
L21. How many months were you incarcerated in your life?	
L24. Are you presently awaiting charges, trial, or sentence?	_Yes _No
L25. What for?	
L26. How many days in the past 30 were you detained or incarcerated?	
L27. How many days in the past 30 have you engaged in illegal activities for profit?	
L28. How serious do you feel your present legal problems are?	
0 = Not at all 1 = Slightly 2 = Moderately 3 = Considerably 4 = Extremely	
L29. How important to you now is counseling or referral for these legal problems?	
0 = Not at all 1 = Slightly 2 = Moderately 3 = Considerably 4 = Extremely	

Confidence Ratings	
Is the above information significantly distorted by:	
L31. Subject's misrepresentation?	Yes No
L32. Subject's inability to understand?	Yes No

Comments

_____

_____

F1. Marital status			
Married Remarried Widowed Separated Divorced Never Married			
F3. Are you satisfied with this situation?	Yes	No	Indifferent
F4 Usual living arrangements (past three years)			
1 = with sexual partner and children 2 = with sexual partner alone 3 = with children alone			
4 = with parents 5 = with family 6 = with friends 7 = alone 8 = controlled environment			
9 = no stable arrangements			
F6. Are you satisfied with these living arrangements?	Yes	No	Indifferent
Do you live with anyone who			
F7. Has a current alcohol problem	Yes	No	
F8. Uses non-prescribed drugs	Yes	No	
F9. With whom do you spend most of your free time?	Family	Friends	Alone
F10. Are you satisfied with spending your free time this way?	Yes	No	Indifferent

Have you had any significant periods in which you have experienced serious problems getting along with:	In the past 30 days			Lifetime		
	Yes	No	N/A	Yes	No	N/A
F18. Mother						
F19. Father						
F20. Siblings						
F21. Sexual partner/spouse						
F22. Children						
F23. Other significant family (specify _____)						
F24. Close friends						
F25. Neighbors						
F26. Co-workers						
Did anyone abuse you?						
F28. Physically (caused you physical harm)						
In the past 30 days	Yes	No	Lifetime	Yes	No	
F29. Sexually (forced sexual advances or sexual acts)						
In the past 30 days	Yes	No	Lifetime	Yes	No	
How many days in the past 30 have you had serious conflicts						
F30. With your family						
F31. With other people excluding family						
How troubled or bothered have you been in the past 30 days by these?						
F32. Family problems						
0 = Not at all 1 = Slightly 2 = Moderately 3 = Considerably 4 = Extremely						
F33. Social problems						
0 = Not at all 1 = Slightly 2 = Moderately 3 = Considerably 4 = Extremely						
How important to you now is treatment or counseling for these?						
F34. Family problems						
0 = Not at all 1 = Slightly 2 = Moderately 3 = Considerably 4 = Extremely						
F35. Social problems						
0 = Not at all 1 = Slightly 2 = Moderately 3 = Considerably 4 = Extremely						
Confidence Ratings						
Is the above information significantly distorted by						
F37. Subject's misrepresentation	Yes	No				
F38. Subject's inability to understand	Yes	No				

Comments

Psychiatric Status

How many times have you been treated for any psychological or emotional problem(s)?

P1. In a hospital or inpatient setting				
P2. As an outpatient or private patient				
P3. Do you receive a pension for a psychiatric disability?		Yes	No	

Have you had a significant period (that was not a direct result of drug/alcohol use) in which you have

	Past 30 days		Lifetime	
P4. Experienced serious depression	Yes	No	Yes	No
P5. Experienced serious anxiety or tension	Yes	No	Yes	No
P6. Experienced hallucinations	Yes	No	Yes	No
P7. Experienced trouble understanding, concentrating or remembering	Yes	No	Yes	No
P8. Experienced trouble controlling violent behavior	Yes	No	Yes	No
P9. Experienced serious thoughts of suicide	Yes	No	Yes	No
P10. Attempted suicide	Yes	No	Yes	No
P11. Been prescribed medication for any psychological emotional problem	Yes	No	Yes	No
P12. How many days in the past 30 have you experienced these psychological or emotional problems?				

P13. How much have you been troubled or bothered by these psychological or emotional problems in the past 30 days?

0 = Not at all 1 = Slightly 2 = Moderately 3 = Considerably 4 = Extremely

P14. How important to you now is treatment for these psychological problems?

0 = Not at all 1 = Slightly 2 = Moderately 3 = Considerably 4 = Extremely

Confidence Ratings				
Is the above information significantly distorted by				
P22. Subject's misrepresentation	Yes	No		
P23. Subject's inability to understand	Yes	No		

Comment

Completed by (initials): _____

(Day -7 to -6)

Date Assessments Completed ___-___-_____			
Time Point	Actual Time	VAS	IMT/DMT
Intake Screening	___:___	___:___	___:___

Completed by (initials): _____

Subject Identification _____
Vital Signs Screening Infusions 1 and 2

Date Assessment Completed ___-___-_____ (Day -5)

Form 9 - Vital Signs

Time Point	Actual Time (00:00-23:59)	Heart Rate (beats/minute)	Blood Pressure (mmHg)	
			(systolic)	(diastolic)
-10	_____:_____			
-8	_____:_____			
-6	_____:_____			
-4	_____:_____			
-2	_____:_____			
0 20 mg cocaine	_____:_____			
2	_____:_____			
4	_____:_____			
6	_____:_____			
8	_____:_____			
10	_____:_____			
15	_____:_____			
20	_____:_____			
25	_____:_____			
30	_____:_____			
35	_____:_____			
40	_____:_____			
50	_____:_____			
55	_____:_____			
60	_____:_____			

Time Point	Actual Time (00:00-23:59)	Heart Rate (beats/minute)	Blood Pressure (mmHg)	
			(systolic)	(diastolic)
90	_____:_____			
110	_____:_____			
120 min Saline i.v.	_____:_____			
122	_____:_____			
124	_____:_____			
126	_____:_____			
128	_____:_____			
130	_____:_____			
135	_____:_____			
140	_____:_____			
145	_____:_____			
150	_____:_____			
155	_____:_____			
160	_____:_____			
170	_____:_____			
180	_____:_____			
210	_____:_____			
230	_____:_____			
240 min 40 mg cocaine	_____:_____			
242	_____:_____			

Subject Identification _____
Vital Signs Screening Infusions 1 and 2

Time Point	Actual Time (00:00-23:59)	Heart Rate (beats/minute)	Blood Pressure (mmHg)	
			(systolic)	(diastolic)
244	_____:_____			
246	_____:_____			
248	_____:_____			
250	_____:_____			
255	_____:_____			
260	_____:_____			
265	_____:_____			
270	_____:_____			
275	_____:_____			
280	_____:_____			
290	_____:_____			
295	_____:_____			
300	_____:_____			
330	_____:_____			
360	_____:_____			
390	_____:_____			
420	_____:_____			
450	_____:_____			
480	_____:_____			
510	_____:_____			
540	_____:_____			
570	_____:_____			
600	_____:_____			

Did the vital signs revert to being within 10% of the baseline? _Yes _No	
If yes, at what time point?	_____minutes
If no, provide comment _____ _____ _____	

Completed by (initials): _____

(Day -5)

Form 12 - Urine Toxicology

Date ___-___-_____

Temperature within expected range?	_Yes	_No	_Unknown
If no or unknown, comment _____			
Drug / Test	Positive	Negative	Not Done
Amphetamines			
Cannabinoids (THC)			
Cocaine			
Opiates			

Completed by (initials): _____

Date Assessment Completed ___-___-_____ (Day -5)

Form 25 - Brief Substance Craving Scale (BSCS)

Cocaine				
1. The intensity of my craving, that is, how much I desired cocaine in the past 24 hours was				
None at all	Slight	Moderate	Considerable	Extreme
2. The frequency of my craving, that is, how often I desired cocaine in the past 24 hours was				
Never	Almost never	Several times	Regularly	Almost constantly
3. The length of time I spent craving for cocaine during the past 24 hours was				
None at all	Very short	Short	Somewhat long	Very long
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. The worst day: During the past week my most intense craving occurred on the following day				
Sunday	Monday	Tuesday	Wednesday	
Thursday	Friday	Saturday	All days the same (go to question 8)	
7. The date for that day was ___-___-_____				
8. The intensity of my craving, that is, how much I desired cocaine on that worst day was				
None at all	Slight	Moderate	Considerable	Extreme
9. A 2nd craved drug during the past 24 hours was (Mark only one of the following. If no 2nd craved drug, mark "None" and leave the rest of this form blank.)				
None	Downers or Sedatives (Barbiturates, etc.)		Benzodiazepines (Valium, Xanax, etc.	Nicotine
Alcohol	Heroin or other Opiates		Marijuana	Other Specify _____
10. The intensity of my craving, that is, how much I desired this **second** drug in the past 24 hours was				
None at all	Slight	Moderate	Considerable	Extreme
11. The frequency of my craving, that is, how often I desired this **second** drug in the past 24 hours was				
Never	Almost never	Several times	Regularly	Almost constantly
12. The length of time I spent in craving for this **second** drug during the past 24 hours was				
None at all	Very short	Short	Somewhat long	Very long

Third Drug				
13. A **3rd** craved drug during the past 24 hours was (Mark only one of the following. If no 3rd craved drug, mark "None" and leave questions 14-16 blank.)				
None	Downers or Sedatives (Barbiturates, etc.)		Benzodiazepines (Valium, Xanax, etc.	Nicotine
Alcohol	Heroin or other Opiates		Marijuana	Other Specify _____
14. The intensity of my craving, that is, how much I desired this **third** drug in the past 24 hours was				
None at all	Slight	Moderate	Considerable	Extreme
15. The frequency of my craving, that is, how often I desired this **third** drug in the past 24 hours was				
Never	Almost never	Several times	Regularly	Almost constantly
16. The length of time I spent in craving for this third drug during the past 24 hours was				
None at all	Very short	Short	Somewhat long	Very long

Completed by (initials): _____

Date Assessment Completed ___-___-_____ (Day -5)

Form 26 - Beck Depression Inventory (BDI)

Please enter the total score:

Total BDI Score: _____ _____

Completed by (initials): _____

Date Assessment Completed ___-___-_____ (Day -5)

Form 27 - Brief Symptom Inventory (BSI)

Please enter the T score for each symptom dimension:

Somatization _____ _____. _____ _____

Obsession-Compulsion _____ _____. _____ _____

Interpersonal Sensitivity _____ _____. _____ _____

Depression _____ _____. _____ _____

Anxiety _____ _____. _____ _____

Hostility _____ _____. _____ _____

Phobic Anxiety _____ _____. _____ _____

Paranoid Ideation _____ _____. _____ _____

Psychoticism _____ _____. _____ _____

Please enter the T score for each global index of distress:

Global Severity Index (GSI) _____ _____. _____ _____

Positive Symptom Total (PST) _____ _____. _____ _____

Positive Symptom Distress Index (PSDI) _____ _____. _____ _____

Completed by (initials): _____

Subject Identification _____
Profile of Mood States

Date Assessment Completed ___-___-_____ (Day -5)

Form 28 - Profile of Mood States (POMS)	
Please enter the total score for each category:	
1. Tension	__ __
2. Depression	__ __
3. Anger	__ __
4. Vigor	__ __
5. Fatigue	__ __
6. Confusion	__ __
Total Mood Disturbance	__ __ __

Completed by (initials): _____

Date Assessment Completed ___-___-_____ Time _____:_____ (Day -5)

Form 29 - Brief Psychiatric Rating Scale (BPRS)

Symptoms	Not Assessed	Not Present	Very Mild	Mild	Moderate	Moderately Severe	Severe	Extremely Severe
Somatic Concern	1	2	3	4	5	6	7	8
Anxiety	1	2	3	4	5	6	7	8
Depression	1	2	3	4	5	6	7	8
Guilt	1	2	3	4	5	6	7	8
Hostility	1	2	3	4	5	6	7	8
Suspiciousness	1	2	3	4	5	6	7	8
Unusual thought content	1	2	3	4	5	6	7	8
Grandiosity	1	2	3	4	5	6	7	8
Hallucinations	1	2	3	4	5	6	7	8
Disorientation	1	2	3	4	5	6	7	8
Conceptual Disorganization.	1	2	3	4	5	6	7	8
Excitement	1	2	3	4	5	6	7	8
Motor retardation	1	2	3	4	5	6	7	8
Blunt Affect	1	2	3	4	5	6	7	8
Tension	1	2	3	4	5	6	7	8
Mannerisms / Posturing	1	2	3	4	5	6	7	8
Uncooperativeness	1	2	3	4	5	6	7	8
Emotional withdrawal	1	2	3	4	5	6	7	8
Suicidality	1	2	3	4	5	6	7	8
Self-neglect	1	2	3	4	5	6	7	8
Bizarre behavior	1	2	3	4	5	6	7	8
Elated Mood	1	2	3	4	5	6	7	8
Motor hyperactivity	1	2	3	4	5	6	7	8
Distractability	1	2	3	4	5	6	7	8

Completed by (initials): _____

Date Assessment Completed ___-___-_____ Time_____:____ (Day -5)

Form 29 - Brief Psychiatric Rating Scale (BPRS)

Symptoms	Not Assessed	Not Present	Very Mild	Mild	Moderate	Moderately Severe	Severe	Extremely Severe
Somatic Concern	1	2	3	4	5	6	7	8
Anxiety	1	2	3	4	5	6	7	8
Depression	1	2	3	4	5	6	7	8
Guilt	1	2	3	4	5	6	7	8
Hostility	1	2	3	4	5	6	7	8
Suspiciousness	1	2	3	4	5	6	7	8
Unusual thought content	1	2	3	4	5	6	7	8
Grandiosity	1	2	3	4	5	6	7	8
Hallucinations	1	2	3	4	5	6	7	8
Disorientation	1	2	3	4	5	6	7	8
Conceptual Disorganization.	1	2	3	4	5	6	7	8
Excitement	1	2	3	4	5	6	7	8
Motor retardation	1	2	3	4	5	6	7	8
Blunt Affect	1	2	3	4	5	6	7	8
Tension	1	2	3	4	5	6	7	8
Mannerisms / Posturing	1	2	3	4	5	6	7	8
Uncooperativeness	1	2	3	4	5	6	7	8
Emotional withdrawal	1	2	3	4	5	6	7	8
Suicidality	1	2	3	4	5	6	7	8
Self-neglect	1	2	3	4	5	6	7	8
Bizarre behavior	1	2	3	4	5	6	7	8
Elated Mood	1	2	3	4	5	6	7	8
Motor hyperactivity	1	2	3	4	5	6	7	8
Distractability	1	2	3	4	5	6	7	8

Completed by (initials): _____

Date Assessment Completed ___-___-_____ Time _____:_____ (Day -5)

Form 29 - Brief Psychiatric Rating Scale (BPRS)

Symptoms	Not Assessed	Not Present	Very Mild	Mild	Moderate	Moderately Severe	Severe	Extremely Severe
Somatic Concern	1	2	3	4	5	6	7	8
Anxiety	1	2	3	4	5	6	7	8
Depression	1	2	3	4	5	6	7	8
Guilt	1	2	3	4	5	6	7	8
Hostility	1	2	3	4	5	6	7	8
Suspiciousness	1	2	3	4	5	6	7	8
Unusual thought content	1	2	3	4	5	6	7	8
Grandiosity	1	2	3	4	5	6	7	8
Hallucinations	1	2	3	4	5	6	7	8
Disorientation	1	2	3	4	5	6	7	8
Conceptual Disorganization.	1	2	3	4	5	6	7	8
Excitement	1	2	3	4	5	6	7	8
Motor retardation	1	2	3	4	5	6	7	8
Blunt Affect	1	2	3	4	5	6	7	8
Tension	1	2	3	4	5	6	7	8
Mannerisms / Posturing	1	2	3	4	5	6	7	8
Uncooperativeness	1	2	3	4	5	6	7	8
Emotional withdrawal	1	2	3	4	5	6	7	8
Suicidality	1	2	3	4	5	6	7	8
Self-neglect	1	2	3	4	5	6	7	8
Bizarre behavior	1	2	3	4	5	6	7	8
Elated Mood	1	2	3	4	5	6	7	8
Motor hyperactivity	1	2	3	4	5	6	7	8
Distractability	1	2	3	4	5	6	7	8

Completed by (initials): _____

Form 35 - Scale Assessments Day -5			
Date of Infusion 1 and 2 ___-___-_____			
Time Point	Actual Time	VAS	IMT/DMT
-15	_____:_____	_____:_____	
Infusion 1 (0 min)			
5	_____:_____	_____:_____	
10	_____:_____		_____:_____
15	_____:_____	_____:_____	
25	_____:_____	_____:_____	
35	_____:_____	_____:_____	
45	_____:_____	_____:_____	
Infusion 1a (120 min)			
65	_____:_____	_____:_____	
75	_____:_____	_____:_____	
85	_____:_____	_____:_____	
95	_____:_____	_____:_____	
105	_____:_____	_____:_____	
130	_____:_____		_____:_____
Infusion 2 (240 min)			
250	_____:_____		_____:_____

Completed by (initials): _____

Date Assessment Completed ___-___-_____ (Day -3)

Form 25 - Brief Substance Craving Scale (BSCS)

Cocaine				
1. The intensity of my craving, that is, how much I desired cocaine in the past 24 hours was				
None at all	Slight	Moderate	Considerable	Extreme
2. The frequency of my craving, that is, how often I desired cocaine in the past 24 hours was				
Never	Almost never	Several times	Regularly	Almost constantly
3. The length of time I spent craving for cocaine during the past 24 hours was				
None at all	Very short	Short	Somewhat long	Very long
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. The worst day: During the past week my most intense craving occurred on the following day				
_Sunday	_Monday	_Tuesday	_Wednesday	
_Thursday	_Friday	_Saturday	_All days the same (go to question 8)	
7. The date for that day was ___-___-_____				
8. The intensity of my craving, that is, how much I desired cocaine on that worst day was				
_None at all	_Slight	_Moderate	_Considerable	_Extreme
9. A 2nd craved drug during the past 24 hours was (Mark only one of the following. If no 2nd craved drug, mark "None" and leave the rest of this form blank.)				
_ None	_Downers or Sedatives (Barbiturates, etc.)		_Benzodiazepines (Valium, Xanax, etc.	_Nicotine
_Alcohol	_Heroin or other Opiates		_Marijuana	_Other Specify _____
10. The intensity of my craving, that is, how much I desired this **second** drug in the past 24 hours was				
_None at all	_Slight	_Moderate	_Considerable	_Extreme
11. The frequency of my craving, that is, how often I desired this **second** drug in the past 24 hours was				
_Never	_Almost never	_Several times	_Regularly	_Almost constantly
12. The length of time I spent in craving for this **second** drug during the past 24 hours was				
_None at all	_Very short	_Short	_Somewhat long	_Very long

Third Drug				
13. A **3rd** craved drug during the past 24 hours was (Mark only one of the following. If no 3rd craved drug, mark "None" and leave questions 14-16 blank.)				
_ None	_Downers or Sedatives (Barbiturates, etc.)		_Benzodiazepines (Valium, Xanax, etc.	_Nicotine
_Alcohol	_Heroin or other Opiates		_Marijuana	_Other Specify _____
14. The intensity of my craving, that is, how much I desired this **third** drug in the past 24 hours was				
_None at all	_Slight	_Moderate	_Considerable	_Extreme
15. The frequency of my craving, that is, how often I desired this **third** drug in the past 24 hours was				
_Never	_Almost never	_Several times	_Regularly	_Almost constantly
16. The length of time I spent in craving for this third drug during the past 24 hours was				
_None at all	_Very short	_Short	_Somewhat long	_Very long

Completed by (initials): _____

Date Assessment Completed ___-___-_____ (Day -3)

Form 26 - Beck Depression Inventory (BDI)

Please enter the total score:

Total BDI Score: _____ _____

Completed by (initials): _____

Date Assessment Completed ___-___-_____ (Day -3)

Form 27 - Brief Symptom Inventory (BSI)

Please enter the T score for each symptom dimension:

Somatization _____ _____. _____ _____

Obsession-Compulsion _____ _____. _____ _____

Interpersonal Sensitivity _____ _____. _____ _____

Depression _____ _____. _____ _____

Anxiety _____ _____. _____ _____

Hostility _____ _____. _____ _____

Phobic Anxiety _____ _____. _____ _____

Paranoid Ideation _____ _____. _____ _____

Psychoticism _____ _____. _____ _____

Please enter the T score for each global index of distress:

Global Severity Index (GSI) _____ _____. _____ _____

Positive Symptom Total (PST) _____ _____. _____ _____

Positive Symptom Distress Index (PSDI) _____ _____. _____ _____

Completed by (initials): _____

Subject Identification _____
Profile of Mood States

Date Assessment Completed ___-___-_____ (Day -3)

Form 28 - Profile of Mood States (POMS)	
Please enter the total score for each category:	
1. Tension	__ __
2. Depression	__ __
3. Anger	__ __
4. Vigor	__ __
5. Fatigue	__ __
6. Confusion	__ __
Total Mood Disturbance	__ __ __

Completed by (initials): _____

Date Assessment Completed ___-___-_____ (Day -2)

Form 10 - Vital Signs

Time Point	Actual Time (00:00-23:59)	Heart Rate (beats/minute)	Blood Pressure (mmHg) (systolic)	(diastolic)
-10	_____:_____			
-8	_____:_____			
-6	_____:_____			
-4	_____:_____			
-2	_____:_____			
0 Saline / Cocaine I.V.	_____:_____			
2	_____:_____			
4	_____:_____			
6	_____:_____			
8	_____:_____			
10	_____:_____			
15	_____:_____			
20	_____:_____			
25	_____:_____			
30	_____:_____			
35	_____:_____			
40	_____:_____			
50	_____:_____			
55	_____:_____			

Subject Identification _____
Vital Signs Baseline/Treatment Infusions 3-6

Time Point	Actual Time (00:00-23:59)	Heart Rate (beats/minute)	Blood Pressure (mmHg) (systolic)	(diastolic)
60 min Cocaine / Saline I.V.	_____:_____			
62	_____:_____			
64	_____:_____			
66	_____:_____			
68	_____:_____			
70	_____:_____			
75	_____:_____			
80	_____:_____			
85	_____:_____			
90	_____:_____			
95	_____:_____			
100	_____:_____			
110	_____:_____			
115	_____:_____			
120	_____:_____			
150	_____:_____			
180	_____:_____			
210	_____:_____			
240	_____:_____			
270	_____:_____			

Time Point	Actual Time (00:00-23:59)	Heart Rate (beats/minute)	Blood Pressure (mmHg) (systolic)	(diastolic)
300	_____:_____			
330	_____:_____			
360	_____:_____			
390	_____:_____			
420	_____:_____			

Did the vital signs revert to being within 10% of the baseline? _Yes _No	
If yes, at what time point?	_____minutes
If no, provide comment _____ _____ _____	

Completed by (initials): _____

Date Assessment Completed ___-___-_____ (Day -1)

Form 10 - Vital Signs

Time Point	Actual Time (00:00-23:59)	Heart Rate (beats/minute)	Blood Pressure (mmHg) (systolic)	(diastolic)
-10	_____:_____			
-8	_____:_____			
-6	_____:_____			
-4	_____:_____			
-2	_____:_____			
0 Saline / Cocaine I.V.	_____:_____			
2	_____:_____			
4	_____:_____			
6	_____:_____			
8	_____:_____			
10	_____:_____			
15	_____:_____			
20	_____:_____			
25	_____:_____			
30	_____:_____			
35	_____:_____			
40	_____:_____			
50	_____:_____			
55	_____:_____			

Subject Identification _____
Vital Signs Baseline/Treatment Infusions 3-6

Time Point	Actual Time (00:00-23:59)	Heart Rate (beats/minute)	Blood Pressure (mmHg) (systolic)	(diastolic)
60 min Cocaine / Saline I.V.	_____:_____			
62	_____:_____			
64	_____:_____			
66	_____:_____			
68	_____:_____			
70	_____:_____			
75	_____:_____			
80	_____:_____			
85	_____:_____			
90	_____:_____			
95	_____:_____			
100	_____:_____			
110	_____:_____			
115	_____:_____			
120	_____:_____			
150	_____:_____			
180	_____:_____			
210	_____:_____			
240	_____:_____			
270	_____:_____			

Subject Identification _____
Vital Signs Baseline/Treatment Infusions 3-6

Time Point	Actual Time (00:00-23:59)	Heart Rate (beats/minute)	Blood Pressure (mmHg) (systolic)	(diastolic)
300	_____:_____			
330	_____:_____			
360	_____:_____			
390	_____:_____			
420	_____:_____			

Did the vital signs revert to being within 10% of the baseline? _Yes _No	
If yes, at what time point?	_____minutes
If no, provide comment _____ _____ _____	

Completed by (initials): _____

(Day -2 to -1)

Form 12 - Urine Toxicology			
Date ___-___-_____			
Temperature within expected range?	_Yes	_No	_Unknown
If no or unknown, comment _____			
Drug / Test	Positive	Negative	Not Done
Amphetamines			
Cannabinoids (THC)			
Cocaine			
Opiates			

Completed by (initials): _____

Date Assessment Completed ___-___-_____ (Day -2 to -1)

Form 18 - Birth Control / Pregnancy Assessment

Is the subject male, postmenopausal, or have they had a hysterectomy or been sterilized?		_Yes _No
If no, is the subject using an acceptable method of birth control?		_Yes _No
What method of birth control is the participant currently using?		
	Complete abstinence from sexual intercourse	
	Diaphragm and condom by partner	
	Intrauterine device and condom by partner: Type _____	
	Sponge and condom by partner	

Note: oral contraceptives, Depo-Provera, Norplant and intrauterine progesterone contraceptive system are not allowed.

Was a serum pregnancy test performed?	_Yes _No
If yes, what was the result?	_Positive _Negative _Unknown
Date and time specimen collected	Date ___-___-_____ Time _____:_____

If no, specify reason

_____

_____

_____

PI/MD Signature: _____ Date: _____

Subject Identification _____
Brief Substance Craving Scale

Date Assessment Completed ___-___-_____ (Day -2 to -1)

Form 25 - Brief Substance Craving Scale (BSCS)

Cocaine

1. The intensity of my craving, that is, how much I desired cocaine in the past 24 hours was				
_None at all	_Slight	_Moderate	_Considerable	_Extreme
2. The frequency of my craving, that is, how often I desired cocaine in the past 24 hours was				
_Never	_Almost never	_Several times	_Regularly	_Almost constantly
3. The length of time I spent craving for cocaine during the past 24 hours was				
_None at all	_Very short	_Short	_Somewhat long	_Very long
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. The worst day: During the past week my most intense craving occurred on the following day				
_Sunday	_Monday	_Tuesday	_Wednesday	
_Thursday	_Friday	_Saturday	_All days the same (go to question 8)	
7. The date for that day was ___-___-_____				
8. The intensity of my craving, that is, how much I desired cocaine on that worst day was				
_None at all	_Slight	_Moderate	_Considerable	_Extreme
9. A 2nd craved drug during the past 24 hours was (Mark only one of the following. If no 2nd craved drug, mark "None" and leave the rest of this form blank.)				
_ None	_Downers or Sedatives (Barbiturates, etc.)		_Benzodiazepines (Valium, Xanax, etc.	_Nicotine
_Alcohol	_Heroin or other Opiates		_Marijuana	_Other Specify _____
10. The intensity of my craving, that is, how much I desired this **second** drug in the past 24 hours was				
_None at all	_Slight	_Moderate	_Considerable	_Extreme
11. The frequency of my craving, that is, how often I desired this **second** drug in the past 24 hours was				
_Never	_Almost never	_Several times	_Regularly	_Almost constantly
12. The length of time I spent in craving for this **second** drug during the past 24 hours was				
_None at all	_Very short	_Short	_Somewhat long	_Very long

Third Drug				
13. A **3rd** craved drug during the past 24 hours was (Mark only one of the following. If no 3rd craved drug, mark "None" and leave questions 14-16 blank.)				
_ None	_Downers or Sedatives (Barbiturates, etc.)		_Benzodiazepines (Valium, Xanax, etc.	_Nicotine
_Alcohol	_Heroin or other Opiates		_Marijuana	_Other Specify _____
14. The intensity of my craving, that is, how much I desired this **third** drug in the past 24 hours was				
_None at all	_Slight	_Moderate	_Considerable	_Extreme
15. The frequency of my craving, that is, how often I desired this **third** drug in the past 24 hours was				
_Never	_Almost never	_Several times	_Regularly	_Almost constantly
16. The length of time I spent in craving for this third drug during the past 24 hours was				
_None at all	_Very short	_Short	_Somewhat long	_Very long

Completed by (initials): _____

Date Assessment Completed ___-___-_____ (Day -2 to -1)

Form 26 - Beck Depression Inventory (BDI)

Please enter the total score:

Total BDI Score: _____ _____

Completed by (initials): _____

Date Assessment Completed ___-___-_____ (Day -2 to -1)

Form 27 - Brief Symptom Inventory (BSI)

Please enter the T score for each symptom dimension:

Somatization _____ _____. _____ _____

Obsession-Compulsion _____ _____. _____ _____

Interpersonal Sensitivity _____ _____. _____ _____

Depression _____ _____. _____ _____

Anxiety _____ _____. _____ _____

Hostility _____ _____. _____ _____

Phobic Anxiety _____ _____. _____ _____

Paranoid Ideation _____ _____. _____ _____

Psychoticism _____ _____. _____ _____

Please enter the T score for each global index of distress:

Global Severity Index (GSI) _____ _____. _____ _____

Positive Symptom Total (PST) _____ _____. _____ _____

Positive Symptom Distress Index (PSDI) _____ _____. _____ _____

Completed by (initials): _____

Subject Identification _____
Profile of Mood States

Date Assessment Completed ___-___-_____ (Day -2 to -1)

Form 28 - Profile of Mood States (POMS)		
Please enter the total score for each category:		
1.	Tension	__ __
2.	Depression	__ __
3.	Anger	__ __
4.	Vigor	__ __
5.	Fatigue	__ __
6.	Confusion	__ __
Total Mood Disturbance		__ __ __

Completed by (initials): _____

Subject Identification _____
Brief Psychiatric Rating Scale

Date Assessment Completed ___-___-_____ Time _____:_____ (Day -2 to -1)

Form 29 - Brief Psychiatric Rating Scale (BPRS)

Symptoms	Not Assessed	Not Present	Very Mild	Mild	Moderate	Moderately Severe	Severe	Extremely Severe
Somatic Concern	1	2	3	4	5	6	7	8
Anxiety	1	2	3	4	5	6	7	8
Depression	1	2	3	4	5	6	7	8
Guilt	1	2	3	4	5	6	7	8
Hostility	1	2	3	4	5	6	7	8
Suspiciousness	1	2	3	4	5	6	7	8
Unusual thought content	1	2	3	4	5	6	7	8
Grandiosity	1	2	3	4	5	6	7	8
Hallucinations	1	2	3	4	5	6	7	8
Disorientation	1	2	3	4	5	6	7	8
Conceptual Disorganization.	1	2	3	4	5	6	7	8
Excitement	1	2	3	4	5	6	7	8
Motor retardation	1	2	3	4	5	6	7	8
Blunt Affect	1	2	3	4	5	6	7	8
Tension	1	2	3	4	5	6	7	8
Mannerisms / Posturing	1	2	3	4	5	6	7	8
Uncooperativeness	1	2	3	4	5	6	7	8
Emotional withdrawal	1	2	3	4	5	6	7	8
Suicidality	1	2	3	4	5	6	7	8
Self-neglect	1	2	3	4	5	6	7	8
Bizarre behavior	1	2	3	4	5	6	7	8
Elated Mood	1	2	3	4	5	6	7	8
Motor hyperactivity	1	2	3	4	5	6	7	8
Distractability	1	2	3	4	5	6	7	8

Completed by (initials): _____

Subject Identification _____
Brief Psychiatric Rating Scale

Date Assessment Completed ___-___-_____ Time _____:_____ (Day -2 to -1)

Form 29 - Brief Psychiatric Rating Scale (BPRS)

Symptoms	Not Assessed	Not Present	Very Mild	Mild	Moderate	Moderately Severe	Severe	Extremely Severe
Somatic Concern	1	2	3	4	5	6	7	8
Anxiety	1	2	3	4	5	6	7	8
Depression	1	2	3	4	5	6	7	8
Guilt	1	2	3	4	5	6	7	8
Hostility	1	2	3	4	5	6	7	8
Suspiciousness	1	2	3	4	5	6	7	8
Unusual thought content	1	2	3	4	5	6	7	8
Grandiosity	1	2	3	4	5	6	7	8
Hallucinations	1	2	3	4	5	6	7	8
Disorientation	1	2	3	4	5	6	7	8
Conceptual Disorganization.	1	2	3	4	5	6	7	8
Excitement	1	2	3	4	5	6	7	8
Motor retardation	1	2	3	4	5	6	7	8
Blunt Affect	1	2	3	4	5	6	7	8
Tension	1	2	3	4	5	6	7	8
Mannerisms / Posturing	1	2	3	4	5	6	7	8
Uncooperativeness	1	2	3	4	5	6	7	8
Emotional withdrawal	1	2	3	4	5	6	7	8
Suicidality	1	2	3	4	5	6	7	8
Self-neglect	1	2	3	4	5	6	7	8
Bizarre behavior	1	2	3	4	5	6	7	8
Elated Mood	1	2	3	4	5	6	7	8
Motor hyperactivity	1	2	3	4	5	6	7	8
Distractibility	1	2	3	4	5	6	7	8

Completed by (initials): _____

Form 36 - Scale Assessments Day -2

Date of Infusion 3 ___-___-_____

Time Point	Actual Time	VAS	IMT/DMT
-15	_____:_____	_____:_____	
Infusion 3 (0 min)			
5	_____:_____	_____:_____	
10	_____:_____		_____:_____
15	_____:_____	_____:_____	
25	_____:_____	_____:_____	
35	_____:_____	_____:_____	
45	_____:_____	_____:_____	
Infusion 3a (60 min)			
65	_____:_____	_____:_____	
70	_____:_____		_____:_____
75	_____:_____	_____:_____	
85	_____:_____	_____:_____	
95	_____:_____	_____:_____	
105	_____:_____	_____:_____	

Completed by (initials): _____

Form 37 - Scale Assessments Day -1				
Date of Infusion 4 __-__-____				
Time Point	Actual Time	VAS	ARCI	IMT/DMT
-90	_____:_____		_____:_____	
-15	_____:_____	_____:_____		
Infusion 4 (0 min)				
5	_____:_____	_____:_____		
10	_____:_____			_____:_____
15	_____:_____	_____:_____		
25	_____:_____	_____:_____		
35	_____:_____	_____:_____		
45	_____:_____	_____:_____		
Infusion 4a (60 min)				
65	_____:_____	_____:_____		
70	_____:_____			_____:_____
75	_____:_____	_____:_____		
85	_____:_____	_____:_____		
95	_____:_____	_____:_____		
105	_____:_____	_____:_____		

Completed by (initials): _____

Subject Identification _____
Blood Chemistries / Liver Function Tests

(Day -1)

Form 17 - Blood Chemistries / Liver Function Tests

Date of sample ____-____-_____

	Value	Normal	Abnormal	Abnormal Significant	Not Done	Comments (required for abnormal values)
Sodium	_____mmol/L					
Potassium	___.___mmol/L					
Chloride	_____mmol/L					
CO_2	_____mmol/L					
Bilirubin*	___.___mg/dL					
ALP*	_____IU/L					
LDH	_____IU/L					
SGOT/AST*	_____IU/L					
SGPT/ALT*	_____IU/L					
Glucose	_____mg/dL					
BUN	_____mg/dL					
Creatinine	___.___mg/dL					
CPK	_____IU/L					

mmol/L = mEq/L

***Complete liver function tests only at Baseline Infusions (Day -1), and Treatment Infusions (Day 12).**

PI/MD Signature: _____ Date: _____

Form 1 - Eligibility Criteria

Inclusion Criteria (All inclusion criteria must be answered "yes" for the subject to qualify for the study.)	Yes	No
1. Be between 18 and 45 years-of-age inclusive.		
2. Be within 20% of ideal body weight and must weigh at least 45 kg. (MetLifeInsTable)		
3. Understand the study procedures and provide written informed consent.		
4. Be volunteers who are dependent on or abusing cocaine according to DSM-IV criteria and are non-treatment seeking at time of study.		
5. Currently use cocaine as determined by self report and a positive urine test for BE within 30 days of the start of the study.		
6. Be male, or if female, 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. 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 Note: oral contraceptives, Depo-Provera, Norplant and intrauterine progesterone contraceptive system are not allowed.		
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.		
8. Have an ECG performed that demonstrates normal sinus rhythm and no clinically significant abnormalities.		
Note: Recent intermittent alcohol or other illicit drug use without physical dependence is allowable.		
Exclusion Criteria (All exclusion criteria must be answered "no" for the subject to qualify for the study.)		
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.		
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.		
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.		
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 (in the case of DP or Norplant, if within the past 3 months).		
5. Be pregnant or lactating.		
6. Have a history of liver disease or current elevation of aspartate aminotransferase (AST) or alanine aminotransferase (ALT) exceeding the upper limit of normal.		
7. Have donated a unit of blood or participated in any other clinical investigation within 4 weeks of enrolling on the study.		

8. 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.		
9. Be seropositive for hepatitis B surface antigen, hepatitis C antibody, or human immunodeficiency virus (HIV) types 1 and 2.		
10. Be seropositive for syphilis by rapid plasma reagin (RPR) test or have active tuberculosis with positive purified protein derivative (PPD) skin test confirmed by chest x-ray.		
11. 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.		
12. Be unable to distinguish between a 20 mg and 40 mg dose of cocaine intravenously.		
13. On standard 12-lead ECG, show a QTc interval >440 ms for males and >450 ms for females.		

Was the informed consent signed?	_Yes _No
Date Consented	___-___-_____

Is subject eligible for participation based on the Eligibility Checklist?	_Yes _No
If yes, was subject randomized into the study?	_Yes _No
Date randomized	___-___-_____
If no, complete the discharge form.	

PI/MD Signature: _____ Date: _____

Subject Identification _____
Hematology

(Day -1)

Form 16 - Hematology

Date of sample ___-___-_____

	Value	Normal	Abnormal	Abnormal Significant	Not Done	Comments (required for abnormal values)
WBC	_____.___*					
Hemoglobin	_____.___g/dL					
Hematocrit	_____.___%					
MCV	_____fL					
Platelet Count	_____*					
Neutrophils	_____%					
Lymphocytes	_____%					
Monocytes	_____%					
Eosinophils	_____%					
Basophils	___.___%					

**x 10^3/uL = thou/cumm = thou/mcl = K/cmm = 1000/uL = x 10^3/cumm*

PI/MD Signature: _____ Date: _____

Date Assessment Completed ___-___-_____ (Day 1)

Form 25 - Brief Substance Craving Scale (BSCS)

Cocaine				
1. The intensity of my craving, that is, how much I desired cocaine in the past 24 hours was				
_None at all	_Slight	_Moderate	_Considerable	_Extreme
2. The frequency of my craving, that is, how often I desired cocaine in the past 24 hours was				
_Never	_Almost never	_Several times	_Regularly	_Almost constantly
3. The length of time I spent craving for cocaine during the past 24 hours was				
_None at all	_Very short	_Short	_Somewhat long	_Very long
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. The worst day: During the past week my most intense craving occurred on the following day				
_Sunday	_Monday	_Tuesday	_Wednesday	
_Thursday	_Friday	_Saturday	_All days the same (go to question 8)	
7. The date for that day was ___-___-_____				
8. The intensity of my craving, that is, how much I desired cocaine on that worst day was				
_None at all	_Slight	_Moderate	_Considerable	_Extreme
9. A 2nd craved drug during the past 24 hours was (Mark only one of the following. If no 2nd craved drug, mark "None" and leave the rest of this form blank.)				
_ None	_Downers or Sedatives (Barbiturates, etc.)		_Benzodiazepines (Valium, Xanax, etc.	_Nicotine
_Alcohol	_Heroin or other Opiates		_Marijuana	_Other Specify _____
10. The intensity of my craving, that is, how much I desired this **second** drug in the past 24 hours was				
_None at all	_Slight	_Moderate	_Considerable	_Extreme
11. The frequency of my craving, that is, how often I desired this **second** drug in the past 24 hours was				
_Never	_Almost never	_Several times	_Regularly	_Almost constantly
12. The length of time I spent in craving for this **second** drug during the past 24 hours was				
_None at all	_Very short	_Short	_Somewhat long	_Very long

Third Drug				
13. A **3rd** craved drug during the past 24 hours was (Mark only one of the following. If no 3rd craved drug, mark "None" and leave questions 14-16 blank.)				
_ None	_Downers or Sedatives (Barbiturates, etc.)		_Benzodiazepines (Valium, Xanax, etc.	_Nicotine
_Alcohol	_Heroin or other Opiates		_Marijuana	_Other Specify _____
14. The intensity of my craving, that is, how much I desired this **third** drug in the past 24 hours was				
_None at all	_Slight	_Moderate	_Considerable	_Extreme
15. The frequency of my craving, that is, how often I desired this **third** drug in the past 24 hours was				
_Never	_Almost never	_Several times	_Regularly	_Almost constantly
16. The length of time I spent in craving for this third drug during the past 24 hours was				
_None at all	_Very short	_Short	_Somewhat long	_Very long

Completed by (initials): _____

Date Assessment Completed ___-___-_____ (Day 1)

Form 26 - Beck Depression Inventory (BDI)

Please enter the total score:

Total BDI Score: _____ _____

Completed by (initials): _____

Date Assessment Completed ___-___-_____ (Day 1)

Form 27 - Brief Symptom Inventory (BSI)

Please enter the T score for each symptom dimension:

Somatization _____ _____. _____ _____

Obsession-Compulsion _____ _____. _____ _____

Interpersonal Sensitivity _____ _____. _____ _____

Depression _____ _____. _____ _____

Anxiety _____ _____. _____ _____

Hostility _____ _____. _____ _____

Phobic Anxiety _____ _____. _____ _____

Paranoid Ideation _____ _____. _____ _____

Psychoticism _____ _____. _____ _____

Please enter the T score for each global index of distress:

Global Severity Index (GSI) _____ _____. _____ _____

Positive Symptom Total (PST) _____ _____. _____ _____

Positive Symptom Distress Index (PSDI) _____ _____. _____ _____

Completed by (initials): _____

Subject Identification _____
Profile of Mood States

Date Assessment Completed ___-___-_____ (Day 1)

Form 28 - Profile of Mood States (POMS)		
Please enter the total score for each category:		
1.	Tension	__ __
2.	Depression	__ __
3.	Anger	__ __
4.	Vigor	__ __
5.	Fatigue	__ __
6.	Confusion	__ __
Total Mood Disturbance		__ __ __

Completed by (initials): _____

Date Assessment Completed ___-___-_____ (Day 3)

Form 25 - Brief Substance Craving Scale (BSCS)

Cocaine				
1. The intensity of my craving, that is, how much I desired cocaine in the past 24 hours was				
_None at all	_Slight	_Moderate	_Considerable	_Extreme
2. The frequency of my craving, that is, how often I desired cocaine in the past 24 hours was				
_Never	_Almost never	_Several times	_Regularly	_Almost constantly
3. The length of time I spent craving for cocaine during the past 24 hours was				
_None at all	_Very short	_Short	_Somewhat long	_Very long
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. The worst day: During the past week my most intense craving occurred on the following day				
_Sunday	_Monday	_Tuesday	_Wednesday	
_Thursday	_Friday	_Saturday	_All days the same (go to question 8)	
7. The date for that day was ___-___-_____				
8. The intensity of my craving, that is, how much I desired cocaine on that worst day was				
_None at all	_Slight	_Moderate	_Considerable	_Extreme
9. A 2nd craved drug during the past 24 hours was (Mark only one of the following. If no 2nd craved drug, mark "None" and leave the rest of this form blank.)				
_ None	_Downers or Sedatives (Barbiturates, etc.)		_Benzodiazepines (Valium, Xanax, etc.	_Nicotine
_Alcohol	_Heroin or other Opiates		_Marijuana	_Other Specify _____
10. The intensity of my craving, that is, how much I desired this **second** drug in the past 24 hours was				
_None at all	_Slight	_Moderate	_Considerable	_Extreme
11. The frequency of my craving, that is, how often I desired this **second** drug in the past 24 hours was				
_Never	_Almost never	_Several times	_Regularly	_Almost constantly
12. The length of time I spent in craving for this **second** drug during the past 24 hours was				
_None at all	_Very short	_Short	_Somewhat long	_Very long

Third Drug				
13. A **3rd** craved drug during the past 24 hours was (Mark only one of the following. If no 3rd craved drug, mark "None" and leave questions 14-16 blank.)				
_ None	_Downers or Sedatives (Barbiturates, etc.)		_Benzodiazepines (Valium, Xanax, etc.	_Nicotine
_Alcohol	_Heroin or other Opiates		_Marijuana	_Other Specify _____
14. The intensity of my craving, that is, how much I desired this **third** drug in the past 24 hours was				
_None at all	_Slight	_Moderate	_Considerable	_Extreme
15. The frequency of my craving, that is, how often I desired this **third** drug in the past 24 hours was				
_Never	_Almost never	_Several times	_Regularly	_Almost constantly
16. The length of time I spent in craving for this third drug during the past 24 hours was				
_None at all	_Very short	_Short	_Somewhat long	_Very long

Completed by (initials): _____

Date Assessment Completed ___-___-_____ (Day 3)

Form 26 - Beck Depression Inventory (BDI)

Please enter the total score:

Total BDI Score: _____ _____

Completed by (initials): _____

Date Assessment Completed ___-___-_____ (Day 3)

Form 27 - Brief Symptom Inventory (BSI)

Please enter the T score for each symptom dimension:

Somatization _____ _____. _____ _____

Obsession-Compulsion _____ _____. _____ _____

Interpersonal Sensitivity _____ _____. _____ _____

Depression _____ _____. _____ _____

Anxiety _____ _____. _____ _____

Hostility _____ _____. _____ _____

Phobic Anxiety _____ _____. _____ _____

Paranoid Ideation _____ _____. _____ _____

Psychoticism _____ _____. _____ _____

Please enter the T score for each global index of distress:

Global Severity Index (GSI) _____ _____. _____ _____

Positive Symptom Total (PST) _____ _____. _____ _____

Positive Symptom Distress Index (PSDI) _____ _____. _____ _____

Completed by (initials): _____

Subject Identification _____
Profile of Mood States

Date Assessment Completed ___-___-_____ (Day 3)

Form 28 - Profile of Mood States (POMS)		
Please enter the total score for each category:		
1.	Tension	__ __
2.	Depression	__ __
3.	Anger	__ __
4.	Vigor	__ __
5.	Fatigue	__ __
6.	Confusion	__ __
Total Mood Disturbance		__ __ __

Completed by (initials): _____

Date Assessment Completed ___-___-_____ (Day 5)

Form 25 - Brief Substance Craving Scale (BSCS)

Cocaine				
1. The intensity of my craving, that is, how much I desired cocaine in the past 24 hours was				
_None at all	_Slight	_Moderate	_Considerable	_Extreme
2. The frequency of my craving, that is, how often I desired cocaine in the past 24 hours was				
_Never	_Almost never	_Several times	_Regularly	_Almost constantly
3. The length of time I spent craving for cocaine during the past 24 hours was				
_None at all	_Very short	_Short	_Somewhat long	_Very long
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. The worst day: During the past week my most intense craving occurred on the following day				
_Sunday	_Monday	_Tuesday	_Wednesday	
_Thursday	_Friday	_Saturday	_All days the same (go to question 8)	
7. The date for that day was ___-___-_____				
8. The intensity of my craving, that is, how much I desired cocaine on that worst day was				
_None at all	_Slight	_Moderate	_Considerable	_Extreme
9. A 2nd craved drug during the past 24 hours was (Mark only one of the following. If no 2nd craved drug, mark "None" and leave the rest of this form blank.)				
_ None	_Downers or Sedatives (Barbiturates, etc.)		_Benzodiazepines (Valium, Xanax, etc.	_Nicotine
_Alcohol	_Heroin or other Opiates		_Marijuana	_Other Specify _____
10. The intensity of my craving, that is, how much I desired this **second** drug in the past 24 hours was				
_None at all	_Slight	_Moderate	_Considerable	_Extreme
11. The frequency of my craving, that is, how often I desired this **second** drug in the past 24 hours was				
_Never	_Almost never	_Several times	_Regularly	_Almost constantly
12. The length of time I spent in craving for this **second** drug during the past 24 hours was				
_None at all	_Very short	_Short	_Somewhat long	_Very long

Third Drug				
13. A **3rd** craved drug during the past 24 hours was (Mark only one of the following. If no 3rd craved drug, mark "None" and leave questions 14-16 blank.)				
_ None	_Downers or Sedatives (Barbiturates, etc.)		_Benzodiazepines (Valium, Xanax, etc.	_Nicotine
_Alcohol	_Heroin or other Opiates		_Marijuana	_Other Specify _____
14. The intensity of my craving, that is, how much I desired this **third** drug in the past 24 hours was				
_None at all	_Slight	_Moderate	_Considerable	_Extreme
15. The frequency of my craving, that is, how often I desired this **third** drug in the past 24 hours was				
_Never	_Almost never	_Several times	_Regularly	_Almost constantly
16. The length of time I spent in craving for this third drug during the past 24 hours was				
_None at all	_Very short	_Short	_Somewhat long	_Very long

Completed by (initials): _____

Date Assessment Completed ___-___-_____ (Day 5)

Form 26 - Beck Depression Inventory (BDI)

Please enter the total score:

Total BDI Score: _____ _____

Completed by (initials): _____

Date Assessment Completed ___-___-_____ (Day 5)

Form 27 - Brief Symptom Inventory (BSI)

Please enter the T score for each symptom dimension:

Somatization _____ _____. _____ _____

Obsession-Compulsion _____ _____. _____ _____

Interpersonal Sensitivity _____ _____. _____ _____

Depression _____ _____. _____ _____

Anxiety _____ _____. _____ _____

Hostility _____ _____. _____ _____

Phobic Anxiety _____ _____. _____ _____

Paranoid Ideation _____ _____. _____ _____

Psychoticism _____ _____. _____ _____

Please enter the T score for each global index of distress:

Global Severity Index (GSI) _____ _____. _____ _____

Positive Symptom Total (PST) _____ _____. _____ _____

Positive Symptom Distress Index (PSDI) _____ _____. _____ _____

Completed by (initials): _____

Subject Identification _____
Profile of Mood States

Date Assessment Completed ___-___-_____ (Day 5)

Form 28 - Profile of Mood States (POMS)		
Please enter the total score for each category:		
1.	Tension	__ __
2.	Depression	__ __
3.	Anger	__ __
4.	Vigor	__ __
5.	Fatigue	__ __
6.	Confusion	__ __
Total Mood Disturbance		__ __ __

Completed by (initials): _____

(Day 7)

Form 16 - Hematology

Date of sample ___-___-_____

	Value	Normal	Abnormal	Abnormal Significant	Not Done	Comments (required for abnormal values)
WBC	_____.___*					
Hemoglobin	_____.___g/dL					
Hematocrit	_____.___%					
MCV	_____fL					
Platelet Count	_____*					
Neutrophils	_____%					
Lymphocytes	_____%					
Monocytes	_____%					
Eosinophils	_____%					
Basophils	___.___%					

**x 10^3/uL = thou/cumm = thou/mcl = K/cmm = 1000/uL = x 10^3/cumm*

PI/MD Signature: _____ Date: _____

Date Assessment Completed ___-___-_____ (Day 7)

Form 25 - Brief Substance Craving Scale (BSCS)

Cocaine				
1. The intensity of my craving, that is, how much I desired cocaine in the past 24 hours was				
_None at all	_Slight	_Moderate	_Considerable	_Extreme
2. The frequency of my craving, that is, how often I desired cocaine in the past 24 hours was				
_Never	_Almost never	_Several times	_Regularly	_Almost constantly
3. The length of time I spent craving for cocaine during the past 24 hours was				
_None at all	_Very short	_Short	_Somewhat long	_Very long
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. The worst day: During the past week my most intense craving occurred on the following day				
_Sunday	_Monday	_Tuesday	_Wednesday	
_Thursday	_Friday	_Saturday	_All days the same (go to question 8)	
7. The date for that day was ___-___-_____				
8. The intensity of my craving, that is, how much I desired cocaine on that worst day was				
_None at all	_Slight	_Moderate	_Considerable	_Extreme
9. A 2nd craved drug during the past 24 hours was (Mark only one of the following. If no 2nd craved drug, mark "None" and leave the rest of this form blank.)				
_ None	_Downers or Sedatives (Barbiturates, etc.)		_Benzodiazepines (Valium, Xanax, etc.	_Nicotine
_Alcohol	_Heroin or other Opiates		_Marijuana	_Other Specify _____
10. The intensity of my craving, that is, how much I desired this **second** drug in the past 24 hours was				
_None at all	_Slight	_Moderate	_Considerable	_Extreme
11. The frequency of my craving, that is, how often I desired this **second** drug in the past 24 hours was				
_Never	_Almost never	_Several times	_Regularly	_Almost constantly
12. The length of time I spent in craving for this **second** drug during the past 24 hours was				
_None at all	_Very short	_Short	_Somewhat long	_Very long

Third Drug				
13. A **3rd** craved drug during the past 24 hours was (Mark only one of the following. If no 3rd craved drug, mark "None" and leave questions 14-16 blank.)				
_ None	_Downers or Sedatives (Barbiturates, etc.)		_Benzodiazepines (Valium, Xanax, etc.	_Nicotine
_Alcohol	_Heroin or other Opiates		_Marijuana	_Other Specify _____
14. The intensity of my craving, that is, how much I desired this **third** drug in the past 24 hours was				
_None at all	_Slight	_Moderate	_Considerable	_Extreme
15. The frequency of my craving, that is, how often I desired this **third** drug in the past 24 hours was				
_Never	_Almost never	_Several times	_Regularly	_Almost constantly
16. The length of time I spent in craving for this third drug during the past 24 hours was				
_None at all	_Very short	_Short	_Somewhat long	_Very long

Completed by (initials): _____

Date Assessment Completed ___-___-_____ (Day 7)

Form 26 - Beck Depression Inventory (BDI)

Please enter the total score:

Total BDI Score: _____ _____

Completed by (initials): _____

Date Assessment Completed ___-___-_____ (Day 7)

Form 27 - Brief Symptom Inventory (BSI)

Please enter the T score for each symptom dimension:

Somatization _____ _____. _____ _____

Obsession-Compulsion _____ _____. _____ _____

Interpersonal Sensitivity _____ _____. _____ _____

Depression _____ _____. _____ _____

Anxiety _____ _____. _____ _____

Hostility _____ _____. _____ _____

Phobic Anxiety _____ _____. _____ _____

Paranoid Ideation _____ _____. _____ _____

Psychoticism _____ _____. _____ _____

Please enter the T score for each global index of distress:

Global Severity Index (GSI) _____ _____. _____ _____

Positive Symptom Total (PST) _____ _____. _____ _____

Positive Symptom Distress Index (PSDI) _____ _____. _____ _____

Completed by (initials): _____

Subject Identification _____
Profile of Mood States

Date Assessment Completed ___-___-_____ (Day 7)

Form 28 - Profile of Mood States (POMS)

Please enter the total score for each category:		
1.	Tension	__ __
2.	Depression	__ __
3.	Anger	__ __
4.	Vigor	__ __
5.	Fatigue	__ __
6.	Confusion	__ __
Total Mood Disturbance		__ __ __

Completed by (initials): _____

Date Assessment Completed ___-___-_____ (Day 9)

Form 25 - Brief Substance Craving Scale (BSCS)

Cocaine				
1. The intensity of my craving, that is, how much I desired cocaine in the past 24 hours was				
_None at all	_Slight	_Moderate	_Considerable	_Extreme
2. The frequency of my craving, that is, how often I desired cocaine in the past 24 hours was				
_Never	_Almost never	_Several times	_Regularly	_Almost constantly
3. The length of time I spent craving for cocaine during the past 24 hours was				
_None at all	_Very short	_Short	_Somewhat long	_Very long
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. The worst day: During the past week my most intense craving occurred on the following day				
_Sunday	_Monday	_Tuesday	_Wednesday	
_Thursday	_Friday	_Saturday	_All days the same (go to question 8)	
7. The date for that day was ___-___-_____				
8. The intensity of my craving, that is, how much I desired cocaine on that worst day was				
_None at all	_Slight	_Moderate	_Considerable	_Extreme
9. A 2nd craved drug during the past 24 hours was (Mark only one of the following. If no 2nd craved drug, mark "None" and leave the rest of this form blank.)				
_ None	_Downers or Sedatives (Barbiturates, etc.)		_Benzodiazepines (Valium, Xanax, etc.	_Nicotine
_Alcohol	_Heroin or other Opiates		_Marijuana	_Other Specify _____
10. The intensity of my craving, that is, how much I desired this **second** drug in the past 24 hours was				
_None at all	_Slight	_Moderate	_Considerable	_Extreme
11. The frequency of my craving, that is, how often I desired this **second** drug in the past 24 hours was				
_Never	_Almost never	_Several times	_Regularly	_Almost constantly
12. The length of time I spent in craving for this **second** drug during the past 24 hours was				
_None at all	_Very short	_Short	_Somewhat long	_Very long

Third Drug				
13. A **3rd** craved drug during the past 24 hours was (Mark only one of the following. If no 3rd craved drug, mark "None" and leave questions 14-16 blank.)				
_ None	_Downers or Sedatives (Barbiturates, etc.)		_Benzodiazepines (Valium, Xanax, etc.	_Nicotine
_Alcohol	_Heroin or other Opiates		_Marijuana	_Other Specify _____
14. The intensity of my craving, that is, how much I desired this **third** drug in the past 24 hours was				
_None at all	_Slight	_Moderate	_Considerable	_Extreme
15. The frequency of my craving, that is, how often I desired this **third** drug in the past 24 hours was				
_Never	_Almost never	_Several times	_Regularly	_Almost constantly
16. The length of time I spent in craving for this third drug during the past 24 hours was				
_None at all	_Very short	_Short	_Somewhat long	_Very long

Completed by (initials): _____

Date Assessment Completed ___-___-_____ (Day 9)

Form 26 - Beck Depression Inventory (BDI)

Please enter the total score:

Total BDI Score: _____ _____

Completed by (initials): _____

Date Assessment Completed ___-___-_____ (Day 9)

Form 27 - Brief Symptom Inventory (BSI)

Please enter the T score for each symptom dimension:

Somatization _____ _____. _____ _____

Obsession-Compulsion _____ _____. _____ _____

Interpersonal Sensitivity _____ _____. _____ _____

Depression _____ _____. _____ _____

Anxiety _____ _____. _____ _____

Hostility _____ _____. _____ _____

Phobic Anxiety _____ _____. _____ _____

Paranoid Ideation _____ _____. _____ _____

Psychoticism _____ _____. _____ _____

Please enter the T score for each global index of distress:

Global Severity Index (GSI) _____ _____. _____ _____

Positive Symptom Total (PST) _____ _____. _____ _____

Positive Symptom Distress Index (PSDI) _____ _____. _____ _____

Completed by (initials): _____

Subject Identification _____
Profile of Mood States

Date Assessment Completed ___-___-_____ (Day 9)

Form 28 - Profile of Mood States (POMS)		
Please enter the total score for each category:		
1.	Tension	__ __
2.	Depression	__ __
3.	Anger	__ __
4.	Vigor	__ __
5.	Fatigue	__ __
6.	Confusion	__ __
Total Mood Disturbance		__ __ __

Completed by (initials): _____

Subject Identification _____
Vital Signs Baseline/Treatment Infusions 3-6

Date Assessment Completed ___-___-_____ (Day 11)

Form 10 - Vital Signs

Time Point	Actual Time (00:00-23:59)	Heart Rate (beats/minute)	Blood Pressure (mmHg) (systolic)	(diastolic)
-10	_____:_____			
-8	_____:_____			
-6	_____:_____			
-4	_____:_____			
-2	_____:_____			
0 Saline / Cocaine I.V.	_____:_____			
2	_____:_____			
4	_____:_____			
6	_____:_____			
8	_____:_____			
10	_____:_____			
15	_____:_____			
20	_____:_____			
25	_____:_____			
30	_____:_____			
35	_____:_____			
40	_____:_____			
50	_____:_____			
55	_____:_____			

Subject Identification _____
Vital Signs Baseline/Treatment Infusions 3-6

Time Point	Actual Time (00:00-23:59)	Heart Rate (beats/minute)	Blood Pressure (mmHg) (systolic)	(diastolic)
60 min Cocaine / Saline I.V.	_____:_____			
62	_____:_____			
64	_____:_____			
66	_____:_____			
68	_____:_____			
70	_____:_____			
75	_____:_____			
80	_____:_____			
85	_____:_____			
90	_____:_____			
95	_____:_____			
100	_____:_____			
110	_____:_____			
115	_____:_____			
120	_____:_____			
150	_____:_____			
180	_____:_____			
210	_____:_____			
240	_____:_____			
270	_____:_____			

Subject Identification _____
Vital Signs Baseline/Treatment Infusions 3-6

Time Point	Actual Time (00:00-23:59)	Heart Rate (beats/minute)	Blood Pressure (mmHg) (systolic)	(diastolic)
300	_____:_____			
330	_____:_____			
360	_____:_____			
390	_____:_____			
420	_____:_____			

Did the vital signs revert to being within 10% of the baseline? _Yes _No	
If yes, at what time point?	_____minutes
If no, provide comment _____ _____ _____	

Completed by (initials): _____

Date Assessment Completed ___-___-_____ (Day 11)

Form 25 - Brief Substance Craving Scale (BSCS)

Cocaine				
1. The intensity of my craving, that is, how much I desired cocaine in the past 24 hours was				
_None at all	_Slight	_Moderate	_Considerable	_Extreme
2. The frequency of my craving, that is, how often I desired cocaine in the past 24 hours was				
_Never	_Almost never	_Several times	_Regularly	_Almost constantly
3. The length of time I spent craving for cocaine during the past 24 hours was				
_None at all	_Very short	_Short	_Somewhat long	_Very long
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. The worst day: During the past week my most intense craving occurred on the following day				
_Sunday	_Monday	_Tuesday	_Wednesday	
_Thursday	_Friday	_Saturday	_All days the same (go to question 8)	
7. The date for that day was ___-___-_____				
8. The intensity of my craving, that is, how much I desired cocaine on that worst day was				
_None at all	_Slight	_Moderate	_Considerable	_Extreme
9. A 2nd craved drug during the past 24 hours was (Mark only one of the following. If no 2nd craved drug, mark "None" and leave the rest of this form blank.)				
_ None	_Downers or Sedatives (Barbiturates, etc.)		_Benzodiazepines (Valium, Xanax, etc.	_Nicotine
_Alcohol	_Heroin or other Opiates		_Marijuana	_Other Specify _____
10. The intensity of my craving, that is, how much I desired this **second** drug in the past 24 hours was				
_None at all	_Slight	_Moderate	_Considerable	_Extreme
11. The frequency of my craving, that is, how often I desired this **second** drug in the past 24 hours was				
_Never	_Almost never	_Several times	_Regularly	_Almost constantly
12. The length of time I spent in craving for this **second** drug during the past 24 hours was				
_None at all	_Very short	_Short	_Somewhat long	_Very long

Subject Identification _____
Brief Substance Craving Scale

13. A **3rd** craved drug during the past 24 hours was (Mark only one of the following. If no 3rd craved drug, mark "None" and leave questions 14-16 blank.)				
_ None	_Downers or Sedatives (Barbiturates, etc.)		_Benzodiazepines (Valium, Xanax, etc.	_Nicotine
_Alcohol	_Heroin or other Opiates		_Marijuana	_Other Specify _____
14. The intensity of my craving, that is, how much I desired this **third** drug in the past 24 hours was				
_None at all	_Slight	_Moderate	_Considerable	_Extreme
15. The frequency of my craving, that is, how often I desired this **third** drug in the past 24 hours was				
_Never	_Almost never	_Several times	_Regularly	_Almost constantly
16. The length of time I spent in craving for this third drug during the past 24 hours was				
_None at all	_Very short	_Short	_Somewhat long	_Very long

Completed by (initials): _____

Date Assessment Completed ___-___-_____ (Day 11)

Form 26 - Beck Depression Inventory (BDI)

Please enter the total score:

Total BDI Score: _____ _____

Completed by (initials): _____

Date Assessment Completed ___-___-_____ (Day 11)

Form 27 - Brief Symptom Inventory (BSI)

Please enter the T score for each symptom dimension:

Somatization _____ _____. _____ _____

Obsession-Compulsion _____ _____. _____ _____

Interpersonal Sensitivity _____ _____. _____ _____

Depression _____ _____. _____ _____

Anxiety _____ _____. _____ _____

Hostility _____ _____. _____ _____

Phobic Anxiety _____ _____. _____ _____

Paranoid Ideation _____ _____. _____ _____

Psychoticism _____ _____. _____ _____

Please enter the T score for each global index of distress:

Global Severity Index (GSI) _____ _____. _____ _____

Positive Symptom Total (PST) _____ _____. _____ _____

Positive Symptom Distress Index (PSDI) _____ _____. _____ _____

Completed by (initials): _____

Subject Identification _____
Profile of Mood States

Date Assessment Completed ___-___-_____ (Day 11)

Form 28 - Profile of Mood States (POMS)		
Please enter the total score for each category:		
1.	Tension	__ __
2.	Depression	__ __
3.	Anger	__ __
4.	Vigor	__ __
5.	Fatigue	__ __
6.	Confusion	__ __
Total Mood Disturbance		__ __ __

Completed by (initials): _____

Date Assessment Completed ___-___-_____ Time ____:____ (Day 11)

Form 29 - Brief Psychiatric Rating Scale (BPRS)

Symptoms	Not Assessed	Not Present	Very Mild	Mild	Moderate	Moderately Severe	Severe	Extremely Severe
Somatic Concern	1	2	3	4	5	6	7	8
Anxiety	1	2	3	4	5	6	7	8
Depression	1	2	3	4	5	6	7	8
Guilt	1	2	3	4	5	6	7	8
Hostility	1	2	3	4	5	6	7	8
Suspiciousness	1	2	3	4	5	6	7	8
Unusual thought content	1	2	3	4	5	6	7	8
Grandiosity	1	2	3	4	5	6	7	8
Hallucinations	1	2	3	4	5	6	7	8
Disorientation	1	2	3	4	5	6	7	8
Conceptual Disorganization.	1	2	3	4	5	6	7	8
Excitement	1	2	3	4	5	6	7	8
Motor retardation	1	2	3	4	5	6	7	8
Blunt Affect	1	2	3	4	5	6	7	8
Tension	1	2	3	4	5	6	7	8
Mannerisms / Posturing	1	2	3	4	5	6	7	8
Uncooperativeness	1	2	3	4	5	6	7	8
Emotional withdrawal	1	2	3	4	5	6	7	8
Suicidality	1	2	3	4	5	6	7	8
Self-neglect	1	2	3	4	5	6	7	8
Bizarre behavior	1	2	3	4	5	6	7	8
Elated Mood	1	2	3	4	5	6	7	8
Motor hyperactivity	1	2	3	4	5	6	7	8
Distractability	1	2	3	4	5	6	7	8

Completed by (initials): _____

Subject Identification _____
Brief Psychiatric Rating Scale

Date Assessment Completed ___-___-_____ Time _____:_____ (Day 11)

Form 29 - Brief Psychiatric Rating Scale (BPRS)

Symptoms	Not Assessed	Not Present	Very Mild	Mild	Moderate	Moderately Severe	Severe	Extremely Severe
Somatic Concern	1	2	3	4	5	6	7	8
Anxiety	1	2	3	4	5	6	7	8
Depression	1	2	3	4	5	6	7	8
Guilt	1	2	3	4	5	6	7	8
Hostility	1	2	3	4	5	6	7	8
Suspiciousness	1	2	3	4	5	6	7	8
Unusual thought content	1	2	3	4	5	6	7	8
Grandiosity	1	2	3	4	5	6	7	8
Hallucinations	1	2	3	4	5	6	7	8
Disorientation	1	2	3	4	5	6	7	8
Conceptual Disorganization.	1	2	3	4	5	6	7	8
Excitement	1	2	3	4	5	6	7	8
Motor retardation	1	2	3	4	5	6	7	8
Blunt Affect	1	2	3	4	5	6	7	8
Tension	1	2	3	4	5	6	7	8
Mannerisms / Posturing	1	2	3	4	5	6	7	8
Uncooperativeness	1	2	3	4	5	6	7	8
Emotional withdrawal	1	2	3	4	5	6	7	8
Suicidality	1	2	3	4	5	6	7	8
Self-neglect	1	2	3	4	5	6	7	8
Bizarre behavior	1	2	3	4	5	6	7	8
Elated Mood	1	2	3	4	5	6	7	8
Motor hyperactivity	1	2	3	4	5	6	7	8
Distractability	1	2	3	4	5	6	7	8

Completed by (initials): _____

Form 38 - Scale Assessments Day 11				
Date of Infusion 5 ___-___-_____				
Time Point	Actual Time	VAS	ARCI	IMT/DMT
-90	_____:_____		_____:_____	
-15	_____:_____	_____:_____		
Infusion 5 (0 min)				
5	_____:_____	_____:_____		
10	_____:_____			_____:_____
15	_____:_____	_____:_____		
25	_____:_____	_____:_____		
35	_____:_____	_____:_____		
45	_____:_____	_____:_____		
Infusion 5a (60 min)				
65	_____:_____	_____:_____		
70	_____:_____			_____:_____
75	_____:_____	_____:_____		
85	_____:_____	_____:_____		
95	_____:_____	_____:_____		
105	_____:_____	_____:_____		

Completed by (initials): _____

Date Assessment Completed ___-___-_____ (Day 12)

Form 10 - Vital Signs

Time Point	Actual Time (00:00-23:59)	Heart Rate (beats/minute)	Blood Pressure (mmHg) (systolic)	(diastolic)
-10	_____:_____			
-8	_____:_____			
-6	_____:_____			
-4	_____:_____			
-2	_____:_____			
0 Saline / Cocaine I.V.	_____:_____			
2	_____:_____			
4	_____:_____			
6	_____:_____			
8	_____:_____			
10	_____:_____			
15	_____:_____			
20	_____:_____			
25	_____:_____			
30	_____:_____			
35	_____:_____			
40	_____:_____			
50	_____:_____			
55	_____:_____			

Subject Identification _____
Vital Signs Baseline/Treatment Infusions 3-6

Time Point	Actual Time (00:00-23:59)	Heart Rate (beats/minute)	Blood Pressure (mmHg) (systolic)	(diastolic)
60 min Cocaine / Saline I.V.	_____:_____			
62	_____:_____			
64	_____:_____			
66	_____:_____			
68	_____:_____			
70	_____:_____			
75	_____:_____			
80	_____:_____			
85	_____:_____			
90	_____:_____			
95	_____:_____			
100	_____:_____			
110	_____:_____			
115	_____:_____			
120	_____:_____			
150	_____:_____			
180	_____:_____			
210	_____:_____			
240	_____:_____			
270	_____:_____			

Subject Identification _____
Vital Signs Baseline/Treatment Infusions 3-6

Time Point	Actual Time (00:00-23:59)	Heart Rate (beats/minute)	Blood Pressure (mmHg) (systolic)	(diastolic)
300	_____:_____			
330	_____:_____			
360	_____:_____			
390	_____:_____			
420	_____:_____			

Did the vital signs revert to being within 10% of the baseline? _Yes _No	
If yes, at what time point?	_____minutes
If no, provide comment _____ _____ _____	

Completed by (initials): _____

Subject Identification _____
Brief Psychiatric Rating Scale

Date Assessment Completed ___-___-_____ Time _____:_____ (Day 12)

Form 29 - Brief Psychiatric Rating Scale (BPRS)

Symptoms	Not Assessed	Not Present	Very Mild	Mild	Moderate	Moderately Severe	Severe	Extremely Severe
Somatic Concern	1	2	3	4	5	6	7	8
Anxiety	1	2	3	4	5	6	7	8
Depression	1	2	3	4	5	6	7	8
Guilt	1	2	3	4	5	6	7	8
Hostility	1	2	3	4	5	6	7	8
Suspiciousness	1	2	3	4	5	6	7	8
Unusual thought content	1	2	3	4	5	6	7	8
Grandiosity	1	2	3	4	5	6	7	8
Hallucinations	1	2	3	4	5	6	7	8
Disorientation	1	2	3	4	5	6	7	8
Conceptual Disorganization.	1	2	3	4	5	6	7	8
Excitement	1	2	3	4	5	6	7	8
Motor retardation	1	2	3	4	5	6	7	8
Blunt Affect	1	2	3	4	5	6	7	8
Tension	1	2	3	4	5	6	7	8
Mannerisms / Posturing	1	2	3	4	5	6	7	8
Uncooperativeness	1	2	3	4	5	6	7	8
Emotional withdrawal	1	2	3	4	5	6	7	8
Suicidality	1	2	3	4	5	6	7	8
Self-neglect	1	2	3	4	5	6	7	8
Bizarre behavior	1	2	3	4	5	6	7	8
Elated Mood	1	2	3	4	5	6	7	8
Motor hyperactivity	1	2	3	4	5	6	7	8
Distractability	1	2	3	4	5	6	7	8

Completed by (initials): _____

Subject Identification _____
Brief Psychiatric Rating Scale

Date Assessment Completed ___-___-_____ Time _____:_____ (Day 12)

Form 29 - Brief Psychiatric Rating Scale (BPRS)

Symptoms	Not Assessed	Not Present	Very Mild	Mild	Moderate	Moderately Severe	Severe	Extremely Severe
Somatic Concern	1	2	3	4	5	6	7	8
Anxiety	1	2	3	4	5	6	7	8
Depression	1	2	3	4	5	6	7	8
Guilt	1	2	3	4	5	6	7	8
Hostility	1	2	3	4	5	6	7	8
Suspiciousness	1	2	3	4	5	6	7	8
Unusual thought content	1	2	3	4	5	6	7	8
Grandiosity	1	2	3	4	5	6	7	8
Hallucinations	1	2	3	4	5	6	7	8
Disorientation	1	2	3	4	5	6	7	8
Conceptual Disorganization.	1	2	3	4	5	6	7	8
Excitement	1	2	3	4	5	6	7	8
Motor retardation	1	2	3	4	5	6	7	8
Blunt Affect	1	2	3	4	5	6	7	8
Tension	1	2	3	4	5	6	7	8
Mannerisms / Posturing	1	2	3	4	5	6	7	8
Uncooperativeness	1	2	3	4	5	6	7	8
Emotional withdrawal	1	2	3	4	5	6	7	8
Suicidality	1	2	3	4	5	6	7	8
Self-neglect	1	2	3	4	5	6	7	8
Bizarre behavior	1	2	3	4	5	6	7	8
Elated Mood	1	2	3	4	5	6	7	8
Motor hyperactivity	1	2	3	4	5	6	7	8
Distractability	1	2	3	4	5	6	7	8

Completed by (initials): _____

Form 39 - Scale Assessments Day 12			
Date of Infusion 6 ___-___-_____			
Time Point	Actual Time	VAS	IMT/DMT
-15	_____:_____	_____:_____	
Infusion 6 (0 min)			
5	_____:_____	_____:_____	
10	_____:_____		_____:_____
15	_____:_____	_____:_____	
25	_____:_____	_____:_____	
35	_____:_____	_____:_____	
45	_____:_____	_____:_____	
Infusion 6a (60 min)			
65	_____:_____	_____:_____	
70	_____:_____		_____:_____
75	_____:_____	_____:_____	
85	_____:_____	_____:_____	
95	_____:_____	_____:_____	
105	_____:_____	_____:_____	

Completed by (initials): _____

Subject Identification _____
Blood Chemistries / Liver Function Tests

(Day 12)

Form 17 - Blood Chemistries / Liver Function Tests

Date of sample ___-___-_____

	Value	Normal	Abnormal	Abnormal Significant	Not Done	Comments (required for abnormal values)
Sodium	_____mmol/L					
Potassium	___.___mmol/L					
Chloride	_____mmol/L					
CO_2	_____mmol/L					
Bilirubin*	___.___mg/dL					
ALP*	_____IU/L					
LDH	_____IU/L					
SGOT/AST*	_____IU/L					
SGPT/ALT*	_____IU/L					
Glucose	_____mg/dL					
BUN	_____mg/dL					
Creatinine	___.___mg/dL					
CPK	_____IU/L					

mmol/L = mEq/L

***Complete liver function tests only at Baseline Infusions (Day -1), and Treatment Infusions (Day 12).**

PI/MD Signature: _____ Date: _____

Date Assessment Completed ___-___-_____ (Day 13)

Form 25 - Brief Substance Craving Scale (BSCS)

Cocaine				
1. The intensity of my craving, that is, how much I desired cocaine in the past 24 hours was				
_None at all	_Slight	_Moderate	_Considerable	_Extreme
2. The frequency of my craving, that is, how often I desired cocaine in the past 24 hours was				
_Never	_Almost never	_Several times	_Regularly	_Almost constantly
3. The length of time I spent craving for cocaine during the past 24 hours was				
_None at all	_Very short	_Short	_Somewhat long	_Very long
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. The worst day: During the past week my most intense craving occurred on the following day				
_Sunday	_Monday	_Tuesday	_Wednesday	
_Thursday	_Friday	_Saturday	_All days the same (go to question 8)	
7. The date for that day was ___-___-_____				
8. The intensity of my craving, that is, how much I desired cocaine on that worst day was				
_None at all	_Slight	_Moderate	_Considerable	_Extreme
9. A 2nd craved drug during the past 24 hours was (Mark only one of the following. If no 2nd craved drug, mark "None" and leave the rest of this form blank.)				
_ None	_Downers or Sedatives (Barbiturates, etc.)		_Benzodiazepines (Valium, Xanax, etc.	_Nicotine
_Alcohol	_Heroin or other Opiates		_Marijuana	_Other Specify _____
10. The intensity of my craving, that is, how much I desired this **second** drug in the past 24 hours was				
_None at all	_Slight	_Moderate	_Considerable	_Extreme
11. The frequency of my craving, that is, how often I desired this **second** drug in the past 24 hours was				
_Never	_Almost never	_Several times	_Regularly	_Almost constantly
12. The length of time I spent in craving for this **second** drug during the past 24 hours was				
_None at all	_Very short	_Short	_Somewhat long	_Very long

Third Drug				
13. A **3rd** craved drug during the past 24 hours was (Mark only one of the following. If no 3rd craved drug, mark "None" and leave questions 14-16 blank.)				
_ None	_Downers or Sedatives (Barbiturates, etc.)		_Benzodiazepines (Valium, Xanax, etc.	_Nicotine
_Alcohol	_Heroin or other Opiates		_Marijuana	_Other Specify _____
14. The intensity of my craving, that is, how much I desired this **third** drug in the past 24 hours was				
_None at all	_Slight	_Moderate	_Considerable	_Extreme
15. The frequency of my craving, that is, how often I desired this **third** drug in the past 24 hours was				
_Never	_Almost never	_Several times	_Regularly	_Almost constantly
16. The length of time I spent in craving for this third drug during the past 24 hours was				
_None at all	_Very short	_Short	_Somewhat long	_Very long

Completed by (initials): _____

Subject Identification _____
Beck Depression Inventory

Date Assessment Completed ___-___-_____ (Day 13)

Form 26 - Beck Depression Inventory (BDI)

Please enter the total score:

Total BDI Score: _____ _____

Completed by (initials): _____

Date Assessment Completed ___-___-_____ (Day 13)

Form 27 - Brief Symptom Inventory (BSI)

Please enter the T score for each symptom dimension:

Somatization _____ _____. _____ _____

Obsession-Compulsion _____ _____. _____ _____

Interpersonal Sensitivity _____ _____. _____ _____

Depression _____ _____. _____ _____

Anxiety _____ _____. _____ _____

Hostility _____ _____. _____ _____

Phobic Anxiety _____ _____. _____ _____

Paranoid Ideation _____ _____. _____ _____

Psychoticism _____ _____. _____ _____

Please enter the T score for each global index of distress:

Global Severity Index (GSI) _____ _____. _____ _____

Positive Symptom Total (PST) _____ _____. _____ _____

Positive Symptom Distress Index (PSDI) _____ _____. _____ _____

Completed by (initials): _____

Subject Identification _____
Profile of Mood States

Date Assessment Completed ___-___-_____ (Day 13)

Form 28 - Profile of Mood States (POMS)	
Please enter the total score for each category:	
1. Tension	__ __
2. Depression	__ __
3. Anger	__ __
4. Vigor	__ __
5. Fatigue	__ __
6. Confusion	__ __
Total Mood Disturbance	__ __ __

Completed by (initials): _____

Subject Identification _____
Hematology

(Day 14)

Form 16 - Hematology

Date of sample ___-___-_____

	Value	Normal	Abnormal	Abnormal Significant	Not Done	Comments (required for abnormal values)
WBC	_____.___*					
Hemoglobin	_____.___g/dL					
Hematocrit	_____.___%					
MCV	_____fL					
Platelet Count	_____*					
Neutrophils	_____%					
Lymphocytes	_____%					
Monocytes	_____%					
Eosinophils	_____%					
Basophils	___.___%					

**x 10^3/uL = thou/cumm = thou/mcl = K/cmm = 1000/uL = x 10^3/cumm*

PI/MD Signature: _____ Date: _____

Subject Identification _____
Brief Substance Craving Scale

Date Assessment Completed ___-___-_____ (Day 15)

Form 25 - Brief Substance Craving Scale (BSCS)

Cocaine				
1. The intensity of my craving, that is, how much I desired cocaine in the past 24 hours was				
_None at all	_Slight	_Moderate	_Considerable	_Extreme
2. The frequency of my craving, that is, how often I desired cocaine in the past 24 hours was				
_Never	_Almost never	_Several times	_Regularly	_Almost constantly
3. The length of time I spent craving for cocaine during the past 24 hours was				
_None at all	_Very short	_Short	_Somewhat long	_Very long
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. The worst day: During the past week my most intense craving occurred on the following day				
_Sunday	_Monday	_Tuesday	_Wednesday	
_Thursday	_Friday	_Saturday	_All days the same (go to question 8)	
7. The date for that day was ___-___-_____				
8. The intensity of my craving, that is, how much I desired cocaine on that worst day was				
_None at all	_Slight	_Moderate	_Considerable	_Extreme
9. A 2nd craved drug during the past 24 hours was (Mark only one of the following. If no 2nd craved drug, mark "None" and leave the rest of this form blank.)				
_ None	_Downers or Sedatives (Barbiturates, etc.)		_Benzodiazepines (Valium, Xanax, etc.	_Nicotine
_Alcohol	_Heroin or other Opiates		_Marijuana	_Other Specify _____
10. The intensity of my craving, that is, how much I desired this **second** drug in the past 24 hours was				
_None at all	_Slight	_Moderate	_Considerable	_Extreme
11. The frequency of my craving, that is, how often I desired this **second** drug in the past 24 hours was				
_Never	_Almost never	_Several times	_Regularly	_Almost constantly
12. The length of time I spent in craving for this **second** drug during the past 24 hours was				
_None at all	_Very short	_Short	_Somewhat long	_Very long

Third Drug				
13. A **3rd** craved drug during the past 24 hours was (Mark only one of the following. If no 3rd craved drug, mark "None" and leave questions 14-16 blank.)				
_ None	_Downers or Sedatives (Barbiturates, etc.)		_Benzodiazepines (Valium, Xanax, etc.	_Nicotine
_Alcohol	_Heroin or other Opiates		_Marijuana	_Other Specify _____
14. The intensity of my craving, that is, how much I desired this **third** drug in the past 24 hours was				
_None at all	_Slight	_Moderate	_Considerable	_Extreme
15. The frequency of my craving, that is, how often I desired this **third** drug in the past 24 hours was				
_Never	_Almost never	_Several times	_Regularly	_Almost constantly
16. The length of time I spent in craving for this third drug during the past 24 hours was				
_None at all	_Very short	_Short	_Somewhat long	_Very long

Completed by (initials): _____

Date Assessment Completed ___-___-_____ (Day 15)

Form 26 - Beck Depression Inventory (BDI)

Please enter the total score:

Total BDI Score: _____ _____

Completed by (initials): _____

Date Assessment Completed ☐☐-☐☐-☐☐☐☐ (Day 15)

Form 27 - Brief Symptom Inventory (BSI)

Please enter the T score for each symptom dimension:

Somatization _____ _____. _____ _____

Obsession-Compulsion _____ _____. _____ _____

Interpersonal Sensitivity _____ _____. _____ _____

Depression _____ _____. _____ _____

Anxiety _____ _____. _____ _____

Hostility _____ _____. _____ _____

Phobic Anxiety _____ _____. _____ _____

Paranoid Ideation _____ _____. _____ _____

Psychoticism _____ _____. _____ _____

Please enter the T score for each global index of distress:

Global Severity Index (GSI) _____ _____. _____ _____

Positive Symptom Total (PST) _____ _____. _____ _____

Positive Symptom Distress Index (PSDI) _____ _____. _____ _____

Completed by (initials): _____

Subject Identification ☐☐☐☐
Profile of Mood States

Date Assessment Completed ☐☐-☐☐-☐☐☐☐ (Day 15)

Form 28 - Profile of Mood States (POMS)	
Please enter the total score for each category:	
1. Tension	__ __
2. Depression	__ __
3. Anger	__ __
4. Vigor	__ __
5. Fatigue	__ __
6. Confusion	__ __
Total Mood Disturbance	__ __ __

Completed by (initials): _____

Subject Identification ☐☐☐☐
Brief Substance Craving Scale

Date Assessment Completed ☐☐-☐☐-☐☐☐☐ (Day 17)

Form 25 - Brief Substance Craving Scale (BSCS)

Cocaine				
1. The intensity of my craving, that is, how much I desired cocaine in the past 24 hours was				
☐None at all	☐Slight	☐Moderate	☐Considerable	☐Extreme
2. The frequency of my craving, that is, how often I desired cocaine in the past 24 hours was				
☐Never	☐Almost never	☐Several times	☐Regularly	☐Almost constantly
3. The length of time I spent craving for cocaine during the past 24 hours was				
☐None at all	☐Very short	☐Short	☐Somewhat long	☐Very long
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. The worst day: During the past week my most intense craving occurred on the following day				
☐Sunday	☐Monday	☐Tuesday	☐Wednesday	
☐Thursday	☐Friday	☐Saturday	☐All days the same (go to question 8)	
7. The date for that day was ☐☐-☐☐-☐☐☐☐				
8. The intensity of my craving, that is, how much I desired cocaine on that worst day was				
☐None at all	☐Slight	☐Moderate	☐Considerable	☐Extreme
9. A 2nd craved drug during the past 24 hours was (Mark only one of the following. If no 2nd craved drug, mark "None" and leave the rest of this form blank.)				
☐None	☐Downers or Sedatives (Barbiturates, etc.)		☐Benzodiazepines (Valium, Xanax, etc.	☐Nicotine
☐Alcohol	☐Heroin or other Opiates		☐Marijuana	☐Other Specify _____
10. The intensity of my craving, that is, how much I desired this **second** drug in the past 24 hours was				
☐None at all	☐Slight	☐Moderate	☐Considerable	☐Extreme
11. The frequency of my craving, that is, how often I desired this **second** drug in the past 24 hours was				
☐Never	☐Almost never	☐Several times	☐Regularly	☐Almost constantly
12. The length of time I spent in craving for this **second** drug during the past 24 hours was				
☐None at all	☐Very short	☐Short	☐Somewhat long	☐Very long

Third Drug				
13. A **3rd** craved drug during the past 24 hours was (Mark only one of the following. If no 3rd craved drug, mark "None" and leave questions 14-16 blank.)				
☐None	☐Downers or Sedatives (Barbiturates, etc.)		☐Benzodiazepines (Valium, Xanax, etc.	☐Nicotine
☐Alcohol	☐Heroin or other Opiates		☐Marijuana	☐Other Specify _____
14. The intensity of my craving, that is, how much I desired this **third** drug in the past 24 hours was				
☐None at all	☐Slight	☐Moderate	☐Considerable	☐Extreme
15. The frequency of my craving, that is, how often I desired this **third** drug in the past 24 hours was				
☐Never	☐Almost never	☐Several times	☐Regularly	☐Almost constantly
16. The length of time I spent in craving for this third drug during the past 24 hours was				
☐None at all	☐Very short	☐Short	☐Somewhat long	☐Very long

Completed by (initials): _____

Date Assessment Completed ☐☐-☐☐-☐☐☐☐ (Day 17)

Form 26 - Beck Depression Inventory (BDI)

Please enter the total score:

Total BDI Score: _____ _____

Completed by (initials): _____

Date Assessment Completed ☐☐-☐☐-☐☐☐☐ (Day 17)

Form 27 - Brief Symptom Inventory (BSI)

Please enter the T score for each symptom dimension:

Somatization _____ _____. _____ _____

Obsession-Compulsion _____ _____. _____ _____

Interpersonal Sensitivity _____ _____. _____ _____

Depression _____ _____. _____ _____

Anxiety _____ _____. _____ _____

Hostility _____ _____. _____ _____

Phobic Anxiety _____ _____. _____ _____

Paranoid Ideation _____ _____. _____ _____

Psychoticism _____ _____. _____ _____

Please enter the T score for each global index of distress:

Global Severity Index (GSI) _____ _____. _____ _____

Positive Symptom Total (PST) _____ _____. _____ _____

Positive Symptom Distress Index (PSDI) _____ _____. _____ _____

Completed by (initials): _____

Subject Identification ☐☐☐☐
Profile of Mood States

Date Assessment Completed ☐☐-☐☐-☐☐☐☐ (Day 17)

Form 28 - Profile of Mood States (POMS)	
Please enter the total score for each category:	
1. Tension	__ __
2. Depression	__ __
3. Anger	__ __
4. Vigor	__ __
5. Fatigue	__ __
6. Confusion	__ __
Total Mood Disturbance	__ __ __

Completed by (initials): _____

Subject Identification ☐☐☐☐
Brief Substance Craving Scale

Date Assessment Completed ☐☐-☐☐-☐☐☐☐ (Day 19)

Form 25 - Brief Substance Craving Scale (BSCS)

Cocaine				
1. The intensity of my craving, that is, how much I desired cocaine in the past 24 hours was				
☐None at all	☐Slight	☐Moderate	☐Considerable	☐Extreme
2. The frequency of my craving, that is, how often I desired cocaine in the past 24 hours was				
☐Never	☐Almost never	☐Several times	☐Regularly	☐Almost constantly
3. The length of time I spent craving for cocaine during the past 24 hours was				
☐None at all	☐Very short	☐Short	☐Somewhat long	☐Very long
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. The worst day: During the past week my most intense craving occurred on the following day				
☐Sunday	☐Monday	☐Tuesday	☐Wednesday	
☐Thursday	☐Friday	☐Saturday	☐All days the same (go to question 8)	
7. The date for that day was ☐☐-☐☐-☐☐☐☐				
8. The intensity of my craving, that is, how much I desired cocaine on that worst day was				
☐None at all	☐Slight	☐Moderate	☐Considerable	☐Extreme
9. A 2nd craved drug during the past 24 hours was (Mark only one of the following. If no 2nd craved drug, mark "None" and leave the rest of this form blank.)				
☐None	☐Downers or Sedatives (Barbiturates, etc.)		☐Benzodiazepines (Valium, Xanax, etc.	☐Nicotine
☐Alcohol	☐Heroin or other Opiates		☐Marijuana	☐Other Specify _____
10. The intensity of my craving, that is, how much I desired this **second** drug in the past 24 hours was				
☐None at all	☐Slight	☐Moderate	☐Considerable	☐Extreme
11. The frequency of my craving, that is, how often I desired this **second** drug in the past 24 hours was				
☐Never	☐Almost never	☐Several times	☐Regularly	☐Almost constantly
12. The length of time I spent in craving for this **second** drug during the past 24 hours was				
☐None at all	☐Very short	☐Short	☐Somewhat long	☐Very long

Third Drug				
13. A **3rd** craved drug during the past 24 hours was (Mark only one of the following. If no 3rd craved drug, mark "None" and leave questions 14-16 blank.)				
☐None	☐Downers or Sedatives (Barbiturates, etc.)		☐Benzodiazepines (Valium, Xanax, etc.	☐Nicotine
☐Alcohol	☐Heroin or other Opiates		☐Marijuana	☐Other Specify _____
14. The intensity of my craving, that is, how much I desired this **third** drug in the past 24 hours was				
☐None at all	☐Slight	☐Moderate	☐Considerable	☐Extreme
15. The frequency of my craving, that is, how often I desired this **third** drug in the past 24 hours was				
☐Never	☐Almost never	☐Several times	☐Regularly	☐Almost constantly
16. The length of time I spent in craving for this third drug during the past 24 hours was				
☐None at all	☐Very short	☐Short	☐Somewhat long	☐Very long

Completed by (initials): _____

Date Assessment Completed ☐☐-☐☐-☐☐☐☐ (Day 19)

Form 26 - Beck Depression Inventory (BDI)

Please enter the total score:

Total BDI Score: _____ _____

Completed by (initials): _____

Date Assessment Completed ☐☐-☐☐-☐☐☐☐ (Day 19)

Form 27 - Brief Symptom Inventory (BSI)

Please enter the T score for each symptom dimension:

Somatization _____ _____. _____ _____

Obsession-Compulsion _____ _____. _____ _____

Interpersonal Sensitivity _____ _____. _____ _____

Depression _____ _____. _____ _____

Anxiety _____ _____. _____ _____

Hostility _____ _____. _____ _____

Phobic Anxiety _____ _____. _____ _____

Paranoid Ideation _____ _____. _____ _____

Psychoticism _____ _____. _____ _____

Please enter the T score for each global index of distress:

Global Severity Index (GSI) _____ _____. _____ _____

Positive Symptom Total (PST) _____ _____. _____ _____

Positive Symptom Distress Index (PSDI) _____ _____. _____ _____

Completed by (initials): _____

Subject Identification ☐☐☐☐
Profile of Mood States

Date Assessment Completed ☐☐-☐☐-☐☐☐☐ (Day 19)

Form 28 - Profile of Mood States (POMS)	
Please enter the total score for each category:	
1. Tension	__ __
2. Depression	__ __
3. Anger	__ __
4. Vigor	__ __
5. Fatigue	__ __
6. Confusion	__ __
Total Mood Disturbance	__ __ __

Completed by (initials): _____

Form 3 - Study Discharge

Date of last clinic visit (not follow up)	☐☐-☐☐-☐☐☐☐	
Corresponding study day	☐☐	
Follow up Dates: 1) ☐☐-☐☐-☐☐☐☐	3) ☐☐-☐☐-☐☐☐☐	
2) ☐☐-☐☐-☐☐☐☐	4) ☐☐-☐☐-☐☐☐☐	
Was the subject terminated early from the trial?	☐Yes	☐No

	Reason subject's participation has ended (Mark all that apply)
	Subject completed study
	Subject was determined after enrollment to be ineligible. (Provide comments)
	Subject requested to withdrawal. (Provide comments)
	Subject experienced an intercurrent illness, unrelated medical condition, or clinically significant adverse event which prompted early termination. (Complete AE or SAE form as necessary. Provide comments)
	Subject terminated for administrative reasons. (Including protocol non-compliance. 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. (Complete SAE form. Provide comments)
	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

PI Signature: _____ Date: _____

(Day 20)

Form 11 - Vital Signs	
Date ☐☐-☐☐-☐☐☐☐	Time ☐☐:☐☐
Oral Temperature	☐☐.☐ °C
Sitting Blood Pressure	☐☐☐/☐☐☐ mm Hg
Sitting Pulse Rate	☐☐☐ beats / min
Sitting Respiratory Rate	☐☐ breaths / min
Standing Blood Pressure (1 minute)	☐☐☐/☐☐☐ mm Hg
Standing Pulse Rate (1 minute)	☐☐☐ beats / min
Standing Blood Pressure (3 minutes)	☐☐☐/☐☐☐ mm Hg
Standing Pulse Rate (3 minutes)	☐☐☐ beats / min

Completed by (initials): _____

(Day 20)

Form 12 - Urine Toxicology

Date ☐☐-☐☐-☐☐☐☐

Temperature within expected range?	☐Yes	☐No	☐Unknown
If no or unknown, comment _____			

Drug / Test	Positive	Negative	Not Done
Amphetamines			
Cannabinoids (THC)			
Cocaine			
Opiates			

Completed by (initials): _____

Subject Identification ☐☐☐☐
Hematology

(Day 20)

Form 16 - Hematology

Date of sample ☐☐-☐☐-☐☐☐☐

	Value	Normal	Abnormal	Abnormal Significant	Not Done	Comments (required for abnormal values)
WBC	☐☐.☐*					
Hemoglobin	☐☐.☐g/dL					
Hematocrit	☐☐.☐%					
MCV	☐☐fL					
Platelet Count	☐☐☐*					
Neutrophils	☐☐%					
Lymphocytes	☐☐%					
Monocytes	☐☐%					
Eosinophils	☐☐%					
Basophils	☐.☐%					

**x 10^3/uL = thou/cumm = thou/mcl = K/cmm = 1000/uL = x 10^3/cumm*

PI/MD Signature: _____ Date: _____

Subject Identification ☐☐☐☐
Blood Chemistries / Liver Function Tests

(Day 20)

Form 17 - Blood Chemistries / Liver Function Tests

Date of sample ☐☐-☐☐-☐☐☐☐

	Value	Normal	Abnormal	Abnormal Significant	Not Done	Comments (required for abnormal values)
Sodium	☐☐☐ mmol/L					
Potassium	☐.☐ mmol/L					
Chloride	☐☐☐ mmol/L					
CO_2	☐☐ mmol/L					
Bilirubin*	☐.☐ mg/dL					
ALP*	☐☐☐ IU/L					
LDH	☐☐☐ IU/L					
SGOT/AST*	☐☐ IU/L					
SGPT/ALT*	☐☐ IU/L					
Glucose	☐☐☐ mg/dL					
BUN	☐☐ mg/dL					
Creatinine	☐.☐ mg/dL					
CPK	☐☐☐ IU/L					

mmol/L = mEq/L

***Complete liver function tests only at Baseline Infusions (Day -1), and Treatment Infusions (Day 12).**

PI/MD Signature: _____ Date: _____

Date Assessment Completed ☐☐-☐☐-☐☐☐☐ (Day 20)

Form 18 - Birth Control / Pregnancy Assessment

Is the subject male, postmenopausal, or have they had a hysterectomy or been sterilized?		☐Yes ☐No
If no, is the subject using an acceptable method of birth control?		☐Yes ☐No
What method of birth control is the participant currently using?		
	Complete abstinence from sexual intercourse	
	Diaphragm and condom by partner	
	Intrauterine device and condom by partner: Type _____	
	Sponge and condom by partner	

Note: oral contraceptives, Depo-Provera, Norplant and intrauterine progesterone contraceptive system are not allowed.

Was a serum pregnancy test performed?	☐Yes ☐No
If yes, what was the result?	☐Positive ☐Negative ☐Unknown
Date and time specimen collected	Date ☐☐-☐☐-☐☐☐☐ Time ☐☐:☐☐

If no, specify reason

_____

_____

_____

PI/MD Signature: _____ Date: _____

Date Assessment Completed ☐☐-☐☐-☐☐☐☐ (Day 20)

Form 30 - HIV Risk-Taking Behavior Scale (HRBS)

Ask subject to read each of the items and choose only one answer for each question

1. How many times have you hit up (i.e. injected any drugs) in the last month?	
	I haven't hit up (If you have not injected drugs in the last month, go to question 7.)
	Once a week or less
	More than once a week but less than once a day
	Once a day
	2-3 times a day
	More than three times a day
2. How many times in the last month have you used a needle after someone else had already used it?	
	No times
	One time
	Two times
	3-5 times
	6-10 times
	More than 10 times
3. How many different people have used a needle before you in the past month?	
	None
	One person
	Two people
	3-5 people
	6-10 people
	More than 10 people
4. How many times in the last month has someone used a needle after you?	
	No times
	One time
	Two times
	3-5 times
	6-10 times
	More than 10 times

5. How often, in the last month, have you cleaned needles before re-using them?	
	I do not re-use
	Every time
	Often
	Sometimes
	Rarely
	Never
6. Before using needles again, how often in the past month did you use bleach to clean them?	
	I do not re-use
	Every time
	Often
	Sometimes
	Rarely
	Never
7. How many people, including clients, have you had sex with in the last month?	
	None (If you have not had sex in the last month, skip to question 12.)
	One
	Two
	3-5 people
	6-10 people
	More than 10 people
8. How often have you used condoms when having sex with your regular partner(s) in the last month?	
	No regular partner/no penetrative sex
	Every time
	Often
	Sometimes
	Rarely
	Never

9. How often have you used condoms when you had sex with casual partners?	
	No casual partner/no penetrative sex
	Every time
	Often
	Sometimes
	Rarely
	Never
10. How often have you used condoms when you have been paid for sex in the last month?	
	No paid partner/no penetrative sex
	Every time
	Often
	Sometimes
	Rarely
	Never
11. How many times have you had anal sex in the last month?	
	No times
	One time
	Two times
	3-5 times
	6-10 times
	More than 10 times
Everyone should answer question 12.	
12. Have you had an HIV test come back positive?	
	Yes
	No
	Don't know

Completed by (initials): _____

Date Assessment Completed ☐☐-☐☐-☐☐☐☐ (Day 20)

Form 31 - Barratt Impulsive Scale (BIS) - 11

This is a test to measure some of the ways you think and act. Read each statement, and circle either (1 – rarely/never), (2 – once in a while), (3 – often), or (4 – almost always/always). Circle only one number for each statement. Do not spend too much time on any statement. Answer quickly and honestly.	Rarely / Never	One in a while	Often	Almost Always / Always
1. I plan tasks carefully.	1	2	3	4
2. I do things without thinking.	1	2	3	4
3. I make up my mind quickly.	1	2	3	4
4. I am happy-go-lucky.	1	2	3	4
5. I don't "pay attention."	1	2	3	4
6. I have "racing" thoughts.	1	2	3	4
7. I plan trips well ahead of time.	1	2	3	4
8. I am self-controlled.	1	2	3	4
9. I concentrate easily.	1	2	3	4
10. I save regularly.	1	2	3	4
11. I "squirm" at plays or lectures (speeches).	1	2	3	4
12. I am a careful thinker.	1	2	3	4
13. I plan for job security.	1	2	3	4
14. I say things without thinking.	1	2	3	4
15. I like to think about complex (hard) problems.	1	2	3	4
16. I change jobs.	1	2	3	4
17. I act "on impulse."	1	2	3	4
18. I get easily bored when solving thought problems.	1	2	3	4
19. I act on the spur of the moment.	1	2	3	4
20. I am a steady thinker.	1	2	3	4
21. I change residences (where I live).	1	2	3	4
22. I buy things on impulse.	1	2	3	4
23. I can only think about one problem at a time.	1	2	3	4
24. I change hobbies.	1	2	3	4
25. I spend or charge more than I earn.	1	2	3	4
26. I have extraneous (outside) thoughts when thinking.	1	2	3	4
27. I am more interested in the present than the future.	1	2	3	4
28. I am restless at the theater or lectures.	1	2	3	4
29. I like puzzles.	1	2	3	4
30. I am future oriented.	1	2	3	4

Completed by (initials): _____

Form 40 - Scale Assessments Discharge				
Date Assessments Completed ☐☐-☐☐-☐☐☐☐				
Time Point	Actual Time	VAS	ARCI	IMT/DMT
Discharge	☐☐:☐☐			☐☐:☐☐

Completed by (initials): _____

Subject Identification ☐☐☐☐
Brief Substance Craving Scale

Date Assessment Completed ☐☐-☐☐-☐☐☐☐ (Day 20)

Form 25 - Brief Substance Craving Scale (BSCS)

Cocaine				
1. The intensity of my craving, that is, how much I desired cocaine in the past 24 hours was				
☐None at all	☐Slight	☐Moderate	☐Considerable	☐Extreme
2. The frequency of my craving, that is, how often I desired cocaine in the past 24 hours was				
☐Never	☐Almost never	☐Several times	☐Regularly	☐Almost constantly
3. The length of time I spent craving for cocaine during the past 24 hours was				
☐None at all	☐Very short	☐Short	☐Somewhat long	☐Very long
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. The worst day: During the past week my most intense craving occurred on the following day				
☐Sunday	☐Monday	☐Tuesday	☐Wednesday	
☐Thursday	☐Friday	☐Saturday	☐All days the same (go to question 8)	
7. The date for that day was ☐☐-☐☐-☐☐☐☐				
8. The intensity of my craving, that is, how much I desired cocaine on that worst day was				
☐None at all	☐Slight	☐Moderate	☐Considerable	☐Extreme
9. A 2nd craved drug during the past 24 hours was (Mark only one of the following. If no 2nd craved drug, mark "None" and leave the rest of this form blank.)				
☐None	☐Downers or Sedatives (Barbiturates, etc.)		☐Benzodiazepines (Valium, Xanax, etc.	☐Nicotine
☐Alcohol	☐Heroin or other Opiates		☐Marijuana	☐Other Specify _____
10. The intensity of my craving, that is, how much I desired this **second** drug in the past 24 hours was				
☐None at all	☐Slight	☐Moderate	☐Considerable	☐Extreme
11. The frequency of my craving, that is, how often I desired this **second** drug in the past 24 hours was				
☐Never	☐Almost never	☐Several times	☐Regularly	☐Almost constantly
12. The length of time I spent in craving for this **second** drug during the past 24 hours was				
☐None at all	☐Very short	☐Short	☐Somewhat long	☐Very long

Third Drug				
13. A **3rd** craved drug during the past 24 hours was (Mark only one of the following. If no 3rd craved drug, mark "None" and leave questions 14-16 blank.)				
☐None	☐Downers or Sedatives (Barbiturates, etc.)		☐Benzodiazepines (Valium, Xanax, etc.	☐Nicotine
☐Alcohol	☐Heroin or other Opiates		☐Marijuana	☐Other Specify _____
14. The intensity of my craving, that is, how much I desired this **third** drug in the past 24 hours was				
☐None at all	☐Slight	☐Moderate	☐Considerable	☐Extreme
15. The frequency of my craving, that is, how often I desired this **third** drug in the past 24 hours was				
☐Never	☐Almost never	☐Several times	☐Regularly	☐Almost constantly
16. The length of time I spent in craving for this third drug during the past 24 hours was				
☐None at all	☐Very short	☐Short	☐Somewhat long	☐Very long

Completed by (initials): _____

Subject Identification ☐☐☐☐
Beck Depression Inventory

Date Assessment Completed ☐☐-☐☐-☐☐☐☐ (Day 20)

Form 26 - Beck Depression Inventory (BDI)

Please enter the total score:

Total BDI Score: _____ _____

Completed by (initials): _____

Date Assessment Completed ☐☐-☐☐-☐☐☐☐ (Day 20)

Form 27 - Brief Symptom Inventory (BSI)

Please enter the T score for each symptom dimension:

Somatization _____ _____. _____ _____

Obsession-Compulsion _____ _____. _____ _____

Interpersonal Sensitivity _____ _____. _____ _____

Depression _____ _____. _____ _____

Anxiety _____ _____. _____ _____

Hostility _____ _____. _____ _____

Phobic Anxiety _____ _____. _____ _____

Paranoid Ideation _____ _____. _____ _____

Psychoticism _____ _____. _____ _____

Please enter the T score for each global index of distress:

Global Severity Index (GSI) _____ _____. _____ _____

Positive Symptom Total (PST) _____ _____. _____ _____

Positive Symptom Distress Index (PSDI) _____ _____. _____ _____

Completed by (initials): _____

Subject Identification ☐☐☐☐
Profile of Mood States

Date Assessment Completed ☐☐-☐☐-☐☐☐☐ (Day 20)

Form 28 - Profile of Mood States (POMS)	
Please enter the total score for each category:	
1. Tension	__ __
2. Depression	__ __
3. Anger	__ __
4. Vigor	__ __
5. Fatigue	__ __
6. Confusion	__ __
Total Mood Disturbance	__ __ __

Completed by (initials): _____

(Day 27)

Form 11 - Vital Signs	
Date ☐☐-☐☐-☐☐☐☐	Time ☐☐:☐☐
Oral Temperature	☐☐.☐ °C
Sitting Blood Pressure	☐☐☐/☐☐☐ mm Hg
Sitting Pulse Rate	☐☐☐ beats / min
Sitting Respiratory Rate	☐☐ breaths / min
Standing Blood Pressure (1 minute)	☐☐☐/☐☐☐ mm Hg
Standing Pulse Rate (1 minute)	☐☐☐ beats / min
Standing Blood Pressure (3 minutes)	☐☐☐/☐☐☐ mm Hg
Standing Pulse Rate (3 minutes)	☐☐☐ beats / min

Completed by (initials): _____

(Day 27)

Form 12 - Urine Toxicology

Date ☐☐-☐☐-☐☐☐☐

Temperature within expected range?	☐Yes	☐No	☐Unknown
If no or unknown, comment _____			
Drug / Test	Positive	Negative	Not Done
Amphetamines			
Cannabinoids (THC)			
Cocaine			
Opiates			

Completed by (initials): _____

(Day 27)

Form 16 - Hematology

Date of sample ☐☐-☐☐-☐☐☐☐

	Value	Normal	Abnormal	Abnormal Significant	Not Done	Comments (required for abnormal values)
WBC	☐☐.☐*					
Hemoglobin	☐☐.☐g/dL					
Hematocrit	☐☐.☐%					
MCV	☐☐fL					
Platelet Count	☐☐☐*					
Neutrophils	☐☐%					
Lymphocytes	☐☐%					
Monocytes	☐☐%					
Eosinophils	☐☐%					
Basophils	☐.☐%					

**x 10^3/uL = thou/cumm = thou/mcl = K/cmm = 1000/uL = x 10^3/cumm*

PI/MD Signature: _____ Date: _____

(Day 34)

Form 11 - Vital Signs	
Date ☐☐-☐☐-☐☐☐☐	Time ☐☐:☐☐
Oral Temperature	☐☐.☐ °C
Sitting Blood Pressure	☐☐☐/☐☐☐ mm Hg
Sitting Pulse Rate	☐☐☐ beats / min
Sitting Respiratory Rate	☐☐ breaths / min
Standing Blood Pressure (1 minute)	☐☐☐/☐☐☐ mm Hg
Standing Pulse Rate (1 minute)	☐☐☐ beats / min
Standing Blood Pressure (3 minutes)	☐☐☐/☐☐☐ mm Hg
Standing Pulse Rate (3 minutes)	☐☐☐ beats / min

Completed by (initials): _____

(Day 34)

Form 12 - Urine Toxicology

Date ☐☐-☐☐-☐☐☐☐

Temperature within expected range?	☐Yes	☐No	☐Unknown
If no or unknown, comment _____			

Drug / Test	Positive	Negative	Not Done
Amphetamines			
Cannabinoids (THC)			
Cocaine			
Opiates			

Completed by (initials): _____

(Day 34)

Form 16 - Hematology

Date of sample ☐☐-☐☐-☐☐☐☐

	Value	Normal	Abnormal	Abnormal Significant	Not Done	Comments (required for abnormal values)
WBC	☐☐.☐*					
Hemoglobin	☐☐.☐g/dL					
Hematocrit	☐☐.☐%					
MCV	☐☐fL					
Platelet Count	☐☐☐*					
Neutrophils	☐☐%					
Lymphocytes	☐☐%					
Monocytes	☐☐%					
Eosinophils	☐☐%					
Basophils	☐.☐%					

**x 10^3/uL = thou/cumm = thou/mcl = K/cmm = 1000/uL = x 10^3/cumm*

PI/MD Signature: _____ Date: _____

(Day 41)

Form 11 - Vital Signs	
Date ☐☐-☐☐-☐☐☐☐	Time ☐☐:☐☐
Oral Temperature	☐☐.☐ °C
Sitting Blood Pressure	☐☐☐/☐☐☐ mm Hg
Sitting Pulse Rate	☐☐☐ beats / min
Sitting Respiratory Rate	☐☐ breaths / min
Standing Blood Pressure (1 minute)	☐☐☐/☐☐☐ mm Hg
Standing Pulse Rate (1 minute)	☐☐☐ beats / min
Standing Blood Pressure (3 minutes)	☐☐☐/☐☐☐ mm Hg
Standing Pulse Rate (3 minutes)	☐☐☐ beats / min

Completed by (initials): _____

(Day 41)

Form 12 - Urine Toxicology

Date ☐☐-☐☐-☐☐☐☐

Temperature within expected range?	☐Yes	☐No	☐Unknown
If no or unknown, comment _____			
Drug / Test	Positive	Negative	Not Done
Amphetamines			
Cannabinoids (THC)			
Cocaine			
Opiates			

Completed by (initials): _____

(Day 41)

Form 16 - Hematology

Date of sample ☐☐-☐☐-☐☐☐☐

	Value	Normal	Abnormal	Abnormal Significant	Not Done	Comments (required for abnormal values)
WBC	☐☐.☐*					
Hemoglobin	☐☐.☐g/dL					
Hematocrit	☐☐.☐%					
MCV	☐☐fL					
Platelet Count	☐☐☐*					
Neutrophils	☐☐%					
Lymphocytes	☐☐%					
Monocytes	☐☐%					
Eosinophils	☐☐%					
Basophils	☐.☐%					

**x 10^3/uL = thou/cumm = thou/mcl = K/cmm = 1000/uL = x 10^3/cumm*

PI/MD Signature: _____ Date: _____

(Day 48)

Form 11 - Vital Signs	
Date ☐☐-☐☐-☐☐☐☐	Time ☐☐:☐☐
Oral Temperature	☐☐.☐ °C
Sitting Blood Pressure	☐☐☐/☐☐☐ mm Hg
Sitting Pulse Rate	☐☐☐ beats / min
Sitting Respiratory Rate	☐☐ breaths / min
Standing Blood Pressure (1 minute)	☐☐☐/☐☐☐ mm Hg
Standing Pulse Rate (1 minute)	☐☐☐ beats / min
Standing Blood Pressure (3 minutes)	☐☐☐/☐☐☐ mm Hg
Standing Pulse Rate (3 minutes)	☐☐☐ beats / min

Completed by (initials): _____

(Day 48)

Form 12 - Urine Toxicology

Date ☐☐-☐☐-☐☐☐☐

Temperature within expected range?	☐Yes	☐No	☐Unknown
If no or unknown, comment _____			

Drug / Test	Positive	Negative	Not Done
Amphetamines			
Cannabinoids (THC)			
Cocaine			
Opiates			

Completed by (initials): _____

Subject Identification ☐☐☐☐
Hematology

(Day 48)

Form 16 - Hematology

Date of sample ☐☐-☐☐-☐☐☐☐

	Value	Normal	Abnormal	Abnormal Significant	Not Done	Comments (required for abnormal values)
WBC	☐☐.☐*					
Hemoglobin	☐☐.☐g/dL					
Hematocrit	☐☐.☐%					
MCV	☐☐fL					
Platelet Count	☐☐☐*					
Neutrophils	☐☐%					
Lymphocytes	☐☐%					
Monocytes	☐☐%					
Eosinophils	☐☐%					
Basophils	☐.☐%					

**x 10^3/uL = thou/cumm = thou/mcl = K/cmm = 1000/uL = x 10^3/cumm*

PI/MD Signature: _____ Date: _____

Subject Identification ☐☐☐☐
Blood Chemistries / Liver Function Tests

(Day 48)

Form 17 - Blood Chemistries / Liver Function Tests

Date of sample ☐☐-☐☐-☐☐☐☐

	Value	Normal	Abnormal	Abnormal Significant	Not Done	Comments (required for abnormal values)
Sodium	☐☐☐ mmol/L					
Potassium	☐.☐ mmol/L					
Chloride	☐☐☐ mmol/L					
CO_2	☐☐ mmol/L					
Bilirubin*	☐.☐ mg/dL					
ALP*	☐☐☐ IU/L					
LDH	☐☐☐ IU/L					
SGOT/AST*	☐☐ IU/L					
SGPT/ALT*	☐☐ IU/L					
Glucose	☐☐☐ mg/dL					
BUN	☐☐ mg/dL					
Creatinine	☐.☐ mg/dL					
CPK	☐☐☐ IU/L					

mmol/L = mEq/L

***Complete liver function tests only at Baseline Infusions (Day -1), and Treatment Infusions (Day 12).**

PI/MD Signature: _____ Date: _____

Date Assessment Completed ☐☐-☐☐-☐☐☐☐ (Day 48)

Form 18 - Birth Control / Pregnancy Assessment

Is the subject male, postmenopausal, or have they had a hysterectomy or been sterilized?		☐Yes ☐No
If no, is the subject using an acceptable method of birth control?		☐Yes ☐No
What method of birth control is the participant currently using?		
☐	Complete abstinence from sexual intercourse	
☐	Diaphragm and condom by partner	
☐	Intrauterine device and condom by partner: Type _____	
☐	Sponge and condom by partner	

Note: oral contraceptives, Depo-Provera, Norplant and intrauterine progesterone contraceptive system are not allowed.

Was a serum pregnancy test performed?	☐Yes ☐No
If yes, what was the result?	☐Positive ☐Negative ☐Unknown
Date and time specimen collected	Date ☐☐-☐☐-☐☐☐☐ Time ☐☐:☐☐

If no, specify reason

_____

_____

_____

PI/MD Signature: _____ Date: _____

Date Assessment Completed ☐☐-☐☐-☐☐☐☐ (Day 48)

Form 30 - HIV Risk-Taking Behavior Scale (HRBS)

Ask subject to read each of the items and choose only one answer for each question

1. How many times have you hit up (i.e. injected any drugs) in the last month?	
	I haven't hit up (If you have not injected drugs in the last month, go to question 7.)
	Once a week or less
	More than once a week but less than once a day
	Once a day
	2-3 times a day
	More than three times a day
2. How many times in the last month have you used a needle after someone else had already used it?	
	No times
	One time
	Two times
	3-5 times
	6-10 times
	More than 10 times
3. How many different people have used a needle before you in the past month?	
	None
	One person
	Two people
	3-5 people
	6-10 people
	More than 10 people
4. How many times in the last month has someone used a needle after you?	
	No times
	One time
	Two times
	3-5 times
	6-10 times
	More than 10 times

5. How often, in the last month, have you cleaned needles before re-using them?	
	I do not re-use
	Every time
	Often
	Sometimes
	Rarely
	Never
6. Before using needles again, how often in the past month did you use bleach to clean them?	
	I do not re-use
	Every time
	Often
	Sometimes
	Rarely
	Never
7. How many people, including clients, have you had sex with in the last month?	
	None (If you have not had sex in the last month, skip to question 12.)
	One
	Two
	3-5 people
	6-10 people
	More than 10 people
8. How often have you used condoms when having sex with your regular partner(s) in the last month?	
	No regular partner/no penetrative sex
	Every time
	Often
	Sometimes
	Rarely
	Never

9. How often have you used condoms when you had sex with casual partners?	
	No casual partner/no penetrative sex
	Every time
	Often
	Sometimes
	Rarely
	Never
10. How often have you used condoms when you have been paid for sex in the last month?	
	No paid partner/no penetrative sex
	Every time
	Often
	Sometimes
	Rarely
	Never
11. How many times have you had anal sex in the last month?	
	No times
	One time
	Two times
	3-5 times
	6-10 times
	More than 10 times
Everyone should answer question 12.	
12. Have you had an HIV test come back positive?	
	Yes
	No
	Don't know

Completed by (initials): _____

Date Assessment Completed ☐☐-☐☐-☐☐☐☐ (Day 48)

Form 31 - Barratt Impulsive Scale (BIS) - 11

This is a test to measure some of the ways you think and act. Read each statement, and circle either (1 – rarely/never), (2 – once in a while), (3 – often), or (4 – almost always/always). Circle only one number for each statement. Do not spend too much time on any statement. Answer quickly and honestly.	Rarely / Never	One in a while	Often	Almost Always / Always
1. I plan tasks carefully.	1	2	3	4
2. I do things without thinking.	1	2	3	4
3. I make up my mind quickly.	1	2	3	4
4. I am happy-go-lucky.	1	2	3	4
5. I don't "pay attention."	1	2	3	4
6. I have "racing" thoughts.	1	2	3	4
7. I plan trips well ahead of time.	1	2	3	4
8. I am self-controlled.	1	2	3	4
9. I concentrate easily.	1	2	3	4
10. I save regularly.	1	2	3	4
11. I "squirm" at plays or lectures (speeches).	1	2	3	4
12. I am a careful thinker.	1	2	3	4
13. I plan for job security.	1	2	3	4
14. I say things without thinking.	1	2	3	4
15. I like to think about complex (hard) problems.	1	2	3	4
16. I change jobs.	1	2	3	4
17. I act "on impulse."	1	2	3	4
18. I get easily bored when solving thought problems.	1	2	3	4
19. I act on the spur of the moment.	1	2	3	4
20. I am a steady thinker.	1	2	3	4
21. I change residences (where I live).	1	2	3	4
22. I buy things on impulse.	1	2	3	4
23. I can only think about one problem at a time.	1	2	3	4
24. I change hobbies.	1	2	3	4
25. I spend or charge more than I earn.	1	2	3	4
26. I have extraneous (outside) thoughts when thinking.	1	2	3	4
27. I am more interested in the present than the future.	1	2	3	4
28. I am restless at the theater or lectures.	1	2	3	4
29. I like puzzles.	1	2	3	4
30. I am future oriented.	1	2	3	4

Completed by (initials): _____

Form 41 - Scale Assessments Day 48				
Date Assessments Completed ☐☐-☐☐-☐☐☐☐				
Time Point	Actual Time	VAS	ARCI	IMT/DMT
Day 48	☐☐:☐☐		☐☐:☐☐	☐☐:☐☐

Completed by (initials): _____

Form 20 - Blood Samples for Pharmacokinetics Determinations –			
Timepoint	Sample Number	Timepoint	Sample Number
-6		-6	
Actual Time ☐☐:☐☐ (Day -1)		**Actual Time ☐☐:☐☐ (Day 12)**	
4		4	
14		14	
30		30	
40		40	
59		59	
64		64	
74		74	
90		90	
100		100	
120		120	
150		150	
180		180	
240		240	
300		300	

PI/MD Signature: _____ Date: _____

Form 21 - Blood Samples for Pharmacokinetics Determinations –

Sample Timepoint	Dose Timepoint	Actual Time	Dose (mg)	Sample Number
Pre Dose Sample Day 1		☐☐:☐☐		
	GBR Dose Day 1	☐☐:☐☐	☐☐☐	
	GBR Dose Day 2	☐☐:☐☐	☐☐☐	
Pre Dose Sample Day 3		☐☐:☐☐		
	GBR Dose Day 3	☐☐:☐☐	☐☐☐	
	GBR Dose Day 4	☐☐:☐☐	☐☐☐	
Pre Dose Sample Day 5		☐☐:☐☐		
	GBR Dose Day 5	☐☐:☐☐	☐☐☐	
	GBR Dose Day 6	☐☐:☐☐	☐☐☐	
	GBR Dose Day 7	☐☐:☐☐	☐☐☐	
Pre Dose Sample Day 8		☐☐:☐☐		
	GBR Dose Day 8	☐☐:☐☐	☐☐☐	
Pre Dose Sample Day 9		☐☐:☐☐		
	GBR Dose Day 9	☐☐:☐☐	☐☐☐	
Pre Dose Sample Day 10		☐☐:☐☐		
	GBR Dose Day 10	☐☐:☐☐	☐☐☐	
0.5 min Pre Dose Sample Day 11		☐☐:☐☐		
	GBR Dose Day 11	☐☐:☐☐	☐☐☐	
0.5 hrs Post Dose Sample		☐☐:☐☐		
1 hrs Post Dose Sample		☐☐:☐☐		
1.5 hrs Post Dose Sample		☐☐:☐☐		

2 hrs Post Dose Sample		☐☐:☐☐		
2.5 hrs Post Dose Sample		☐☐:☐☐		
3 hrs Post Dose Sample		☐☐:☐☐		
4 hrs Post Dose Sample		☐☐:☐☐		
8 hrs Post Dose Sample		☐☐:☐☐		
12 hrs Post Dose Sample		☐☐:☐☐		
Pre Dose Sample Day 12		☐☐:☐☐		
	GBR Dose Day 12	☐☐:☐☐	☐☐☐	
0.5 hrs Post Dose Sample		☐☐:☐☐		
1 hr Post Dose Sample		☐☐:☐☐		
1.5 hrs Post Dose Sample		☐☐:☐☐		
2 hrs Post Dose Sample		☐☐:☐☐		
2.5 hrs Post Dose Sample		☐☐:☐☐		
3 hrs Post Dose Sample		☐☐:☐☐		
4 hrs Post Dose Sample		☐☐:☐☐		
8 hrs Post Dose Sample		☐☐:☐☐		
12 hrs Post Dose Sample		☐☐:☐☐		
21 (Day 13) Post Dose Sample		☐☐:☐☐		
45 (Day 14) Post Dose Sample		☐☐:☐☐		
69 (Day 15) Post Dose Sample		☐☐:☐☐		
93 (Day 16) Post Dose Sample		☐☐:☐☐		
117 (Day 17) Post Dose Sample		☐☐:☐☐		

PI/MD Signature: _____ Date: _____

Form 44 - ARCI

This form captures ARCI that are not otherwise captured on Scale Assessment day CRFs.

Day	Date	Actual Time	ARCI
2	☐☐-☐☐-☐☐☐☐	☐☐:☐☐	☐☐:☐☐
4	☐☐-☐☐-☐☐☐☐	☐☐:☐☐	☐☐:☐☐
6	☐☐-☐☐-☐☐☐☐	☐☐:☐☐	☐☐:☐☐
8	☐☐-☐☐-☐☐☐☐	☐☐:☐☐	☐☐:☐☐
13	☐☐-☐☐-☐☐☐☐	☐☐:☐☐	☐☐:☐☐
15	☐☐-☐☐-☐☐☐☐	☐☐:☐☐	☐☐:☐☐
18	☐☐-☐☐-☐☐☐☐	☐☐:☐☐	☐☐:☐☐
27	☐☐-☐☐-☐☐☐☐	☐☐:☐☐	☐☐:☐☐
34	☐☐-☐☐-☐☐☐☐	☐☐:☐☐	☐☐:☐☐
41	☐☐-☐☐-☐☐☐☐	☐☐:☐☐	☐☐:☐☐

Completed by (initials): _____

Form 22 - Adverse Events

Has the subject had any Adverse Events? ☐Yes ☐No

Severity	Relationship	Action Taken (regarding study drug)	Other Action Taken	Outcome of AE	SAE?
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 Temporarily 4 = Reduced Dose 5 = Increased Dose 6 = Delayed Dose	1 = None 2 = Pharmacologic Therapy 3 = Nonpharm. Therapy 4 = Hospitalization	1 = Resolved, no sequelae 2 = Still present, no treatment 3 = Still present, being treated 4 = Residual effects, no treatment 5 = Residual effects, being treated 6 = Death 7 = Unknown	0 = No 1 = Yes (complete SAE form)

Adverse Event	Start Date	Stop Date	Severity	Relation	Action	Other	Outcome	SAE?
	☐☐-☐☐-☐☐☐☐	☐☐-☐☐-☐☐☐☐						
	☐☐-☐☐-☐☐☐☐	☐☐-☐☐-☐☐☐☐						
	☐☐-☐☐-☐☐☐☐	☐☐-☐☐-☐☐☐☐						
	☐☐-☐☐-☐☐☐☐	☐☐-☐☐-☐☐☐☐						
	☐☐-☐☐-☐☐☐☐	☐☐-☐☐-☐☐☐☐						
	☐☐-☐☐-☐☐☐☐	☐☐-☐☐-☐☐☐☐						
	☐☐-☐☐-☐☐☐☐	☐☐-☐☐-☐☐☐☐						
	☐☐-☐☐-☐☐☐☐	☐☐-☐☐-☐☐☐☐						
	☐☐-☐☐-☐☐☐☐	☐☐-☐☐-☐☐☐☐						
	☐☐-☐☐-☐☐☐☐	☐☐-☐☐-☐☐☐☐						
	☐☐-☐☐-☐☐☐☐	☐☐-☐☐-☐☐☐☐						
	☐☐-☐☐-☐☐☐☐	☐☐-☐☐-☐☐☐☐						

PI/MD Signature: ______________________________ Date: ________________

Form 24 - Concomitant Medications

Has the subject taken any concomitant medications since signing informed consent? ☐Yes ☐No

Record any change from the prior medication form.

Unit of Medication			Frequency		Route of Administration		
1 = capsule 2 = gram 3 = grain 4 = drop 5 = microgram 6 = microliter	7 = milligram 8 = milliliter 9 = ounce 10 = puff 11 = spray/squirt	12 = suppository 13 = teaspoon 14 = tablespoon 15 = tablet 16 = unknown	1 = one dose 2 = once daily 3 = twice daily 4 = 3 times/day	5 = 4 times/day 6 = every other day 7 = as needed	1 = oral 2 = Transdermal 3 = inhaled 4 = intramuscular 5 = intravenous	6 = rectal 7 = vaginal 8 = subcutaneous 9 = sublingual 10 = auricular	11 = intra-articular 12 = nasal 13 = intraocular 14 = unknown

Medication	Dose	Units	Freq.	Route	Start Date	Stop Date	Cont.	Indication
					__ __/ __ __/ __ __ __ __	__ __/ __ __/ __ __ __ __		
					__ __/ __ __/ __ __ __ __	__ __/ __ __/ __ __ __ __		
					__ __/ __ __/ __ __ __ __	__ __/ __ __/ __ __ __ __		
					__ __/ __ __/ __ __ __ __	__ __/ __ __/ __ __ __ __		
					__ __/ __ __/ __ __ __ __	__ __/ __ __/ __ __ __ __		
					__ __/ __ __/ __ __ __ __	__ __/ __ __/ __ __ __ __		
					__ __/ __ __/ __ __ __ __	__ __/ __ __/ __ __ __ __		
					__ __/ __ __/ __ __ __ __	__ __/ __ __/ __ __ __ __		
					__ __/ __ __/ __ __ __ __	__ __/ __ __/ __ __ __ __		
					__ __/ __ __/ __ __ __ __	__ __/ __ __/ __ __ __ __		
					__ __/ __ __/ __ __ __ __	__ __/ __ __/ __ __ __ __		
					__ __/ __ __/ __ __ __ __	__ __/ __ __/ __ __ __ __		
					__ __/ __ __/ __ __ __ __	__ __/ __ __/ __ __ __ __		

PI/MD Signature: ______________________________ Date: ________________

Form 7 - 12-Lead ECG

Pre-Intake Screening

Date	Time (00:00-23:59)	PR (msec)	QT (msec)	QRS (msec)	R-R (msec)	QTc (msec)	ECG Abnormal	If Abnormal, Clinically Significant?
☐☐-☐☐-☐☐☐☐	☐☐:☐☐						☐Yes ☐No	☐Yes ☐No
Specify Abnormalities as recorded on ECG tracing _____								
☐☐-☐☐-☐☐☐☐	☐☐:☐☐						☐Yes ☐No	☐Yes ☐No
Specify Abnormalities as recorded on ECG tracing _____								

Date	Time (00:00-23:59)	PR (msec)	QT (msec)	QRS (msec)	R-R (msec)	QTc (msec)	ECG Abnormal	If Abnormal, Clinically Significant?
☐☐-☐☐-☐☐☐☐	☐☐:☐☐						☐Yes ☐No	☐Yes ☐No
Specify Abnormalities as recorded on ECG tracing _____								
	☐☐:☐☐						☐Yes ☐No	☐Yes ☐No
Specify Abnormalities as recorded on ECG tracing _____								
	☐☐:☐☐						☐Yes ☐No	☐Yes ☐No
Specify Abnormalities as recorded on ECG tracing _____								
	☐☐:☐☐						☐Yes ☐No	☐Yes ☐No
Specify Abnormalities as recorded on ECG tracing _____								

Date	Time (00:00-23:59)	PR (msec)	QT (msec)	QRS (msec)	R-R (msec)	QTc (msec)	ECG Abnormal	If Abnormal, Clinically Significant?
☐☐-☐☐-☐☐☐☐	☐☐:☐☐						☐Yes ☐No	☐Yes ☐No
Specify Abnormalities as recorded on ECG tracing _____								
	☐☐:☐☐						☐Yes ☐No	☐Yes ☐No
Specify Abnormalities as recorded on ECG tracing _____								
	☐☐:☐☐						☐Yes ☐No	☐Yes ☐No
Specify Abnormalities as recorded on ECG tracing _____								
	☐☐:☐☐						☐Yes ☐No	☐Yes ☐No
Specify Abnormalities as recorded on ECG tracing _____								

10 minutes prior to Infusion #2								
Date	Time (00:00-23:59)	PR (msec)	QT (msec)	QRS (msec)	R-R (msec)	QTc (msec)	ECG Abnormal	If Abnormal, Clinically Significant?
☐☐-☐☐-☐☐☐☐	☐☐:☐☐						☐Yes ☐No	☐Yes ☐No
Specify Abnormalities as recorded on ECG tracing _____								
	☐☐:☐☐						☐Yes ☐No	☐Yes ☐No
Specify Abnormalities as recorded on ECG tracing _____								
	☐☐:☐☐						☐Yes ☐No	☐Yes ☐No
Specify Abnormalities as recorded on ECG tracing _____								
	☐☐:☐☐						☐Yes ☐No	☐Yes ☐No
Specify Abnormalities as recorded on ECG tracing _____								

10 minutes prior to Infusion #3								
Date	Time (00:00-23:59)	PR (msec)	QT (msec)	QRS (msec)	R-R (msec)	QTc (msec)	ECG Abnormal	If Abnormal, Clinically Significant?
☐☐-☐☐-☐☐☐☐	☐☐:☐☐						☐Yes ☐No	☐Yes ☐No
Specify Abnormalities as recorded on ECG tracing _____								
	☐☐:☐☐						☐Yes ☐No	☐Yes ☐No
Specify Abnormalities as recorded on ECG tracing _____								
	☐☐:☐☐						☐Yes ☐No	☐Yes ☐No
Specify Abnormalities as recorded on ECG tracing _____								
	☐☐:☐☐						☐Yes ☐No	☐Yes ☐No
Specify Abnormalities as recorded on ECG tracing _____								

10 minutes prior to Infusion #4								
Date	Time (00:00-23:59)	PR (msec)	QT (msec)	QRS (msec)	R-R (msec)	QTc (msec)	ECG Abnormal	If Abnormal, Clinically Significant?
☐☐-☐☐-☐☐☐☐	☐☐:☐☐						☐Yes ☐No	☐Yes ☐No
Specify Abnormalities as recorded on ECG tracing _____								
	☐☐:☐☐						☐Yes ☐No	☐Yes ☐No
Specify Abnormalities as recorded on ECG tracing _____								
	☐☐:☐☐						☐Yes ☐No	☐Yes ☐No
Specify Abnormalities as recorded on ECG tracing _____								
	☐☐:☐☐						☐Yes ☐No	☐Yes ☐No
Specify Abnormalities as recorded on ECG tracing _____								

Daily ECG (Day1)								
Date	Time (00:00-23:59)	PR (msec)	QT (msec)	QRS (msec)	R-R (msec)	QTc (msec)	ECG Abnormal	If Abnormal, Clinically Significant?
☐☐-☐☐-☐☐☐☐	☐☐:☐☐						☐Yes ☐No	☐Yes ☐No
Specify Abnormalities as recorded on ECG tracing ____								
☐☐-☐☐-☐☐☐☐	☐☐:☐☐						☐Yes ☐No	☐Yes ☐No
Specify Abnormalities as recorded on ECG tracing ____								
☐☐-☐☐-☐☐☐☐	☐☐:☐☐						☐Yes ☐No	☐Yes ☐No
Specify Abnormalities as recorded on ECG tracing ____								
☐☐-☐☐-☐☐☐☐	☐☐:☐☐						☐Yes ☐No	☐Yes ☐No
Specify Abnormalities as recorded on ECG tracing ____								
☐☐-☐☐-☐☐☐☐	☐☐:☐☐						☐Yes ☐No	☐Yes ☐No
Specify Abnormalities as recorded on ECG tracing ____								

Daily ECG (Day6)								
Date	Time (00:00-23:59)	PR (msec)	QT (msec)	QRS (msec)	R-R (msec)	QTc (msec)	ECG Abnormal	If Abnormal, Clinically Significant?
☐☐-☐☐-☐☐☐☐	☐☐:☐☐						☐Yes ☐No	☐Yes ☐No
Specify Abnormalities as recorded on ECG tracing ______								
☐☐-☐☐-☐☐☐☐	☐☐:☐☐						☐Yes ☐No	☐Yes ☐No
Specify Abnormalities as recorded on ECG tracing ______								
☐☐-☐☐-☐☐☐☐	☐☐:☐☐						☐Yes ☐No	☐Yes ☐No
Specify Abnormalities as recorded on ECG tracing ______								
☐☐-☐☐-☐☐☐☐	☐☐:☐☐						☐Yes ☐No	☐Yes ☐No
Specify Abnormalities as recorded on ECG tracing ______								
☐☐-☐☐-☐☐☐☐	☐☐:☐☐						☐Yes ☐No	☐Yes ☐No
Specify Abnormalities as recorded on ECG tracing ______								

10 minutes prior to Infusion #5								
Date	Time (00:00-23:59)	PR (msec)	QT (msec)	QRS (msec)	R-R (msec)	QTc (msec)	ECG Abnormal	If Abnormal, Clinically Significant?
☐☐-☐☐-☐☐☐☐	☐☐:☐☐						☐Yes ☐No	☐Yes ☐No
Specify Abnormalities as recorded on ECG tracing _____								
	☐☐:☐☐						☐Yes ☐No	☐Yes ☐No
Specify Abnormalities as recorded on ECG tracing _____								
	☐☐:☐☐						☐Yes ☐No	☐Yes ☐No
Specify Abnormalities as recorded on ECG tracing _____								
	☐☐:☐☐						☐Yes ☐No	☐Yes ☐No
Specify Abnormalities as recorded on ECG tracing _____								

10 minutes prior to Infusion #6								
Date	Time (00:00-23:59)	PR (msec)	QT (msec)	QRS (msec)	R-R (msec)	QTc (msec)	ECG Abnormal	If Abnormal, Clinically Significant?
☐☐-☐☐-☐☐☐☐	☐☐:☐☐						☐Yes ☐No	☐Yes ☐No
Specify Abnormalities as recorded on ECG tracing _____								
	☐☐:☐☐						☐Yes ☐No	☐Yes ☐No
Specify Abnormalities as recorded on ECG tracing _____								
	☐☐:☐☐						☐Yes ☐No	☐Yes ☐No
Specify Abnormalities as recorded on ECG tracing _____								
	☐☐:☐☐						☐Yes ☐No	☐Yes ☐No
Specify Abnormalities as recorded on ECG tracing _____								

Discharge								
Date	Time (00:00-23:59)	PR (msec)	QT (msec)	QRS (msec)	R-R (msec)	QTc (msec)	ECG Abnormal	If Abnormal, Clinically Significant?
☐☐-☐☐-☐☐☐☐	☐☐:☐☐						☐Yes ☐No	☐Yes ☐No
Specify Abnormalities as recorded on ECG tracing ______								
☐☐-☐☐-☐☐☐☐	☐☐:☐☐						☐Yes ☐No	☐Yes ☐No
Specify Abnormalities as recorded on ECG tracing ______								
☐☐-☐☐-☐☐☐☐	☐☐:☐☐						☐Yes ☐No	☐Yes ☐No
Specify Abnormalities as recorded on ECG tracing ______								
☐☐-☐☐-☐☐☐☐	☐☐:☐☐						☐Yes ☐No	☐Yes ☐No
Specify Abnormalities as recorded on ECG tracing ______								
☐☐-☐☐-☐☐☐☐	☐☐:☐☐						☐Yes ☐No	☐Yes ☐No
Specify Abnormalities as recorded on ECG tracing ______								

PI/MD Signature: ______________________ Date: ____________

Subject Identification ☐☐☐☐
VAS

Date Assessment Completed ☐☐-☐☐-☐☐☐☐ (Intake: Day -7 to -6)

Form 45 - VAS	
1. Right now, I feel alert.	
2. Right now, I feel my mind is racing.	
3. Right now, I am getting a buzz or a thrill.	
4. Right now, I feel lethargic.	
5. Right now, I feel restless.	
6. Right now, I feel good.	
7. Right now, I feel content.	
8. Right now, I feel high.	
9. Right now, I feel anxious.	
10. Right now, I dislike the effects of the drugs I have taken.	
11. Right now, I feel sad.	
12. Right now, I am thinking about how I can get cocaine.	
13. Right now, I am thinking about the next time I will use cocaine.	
14. Right now, I feel bothered about what is happening.	
15. Right now, I want to buy cocaine.	
16. Right now, I want to use cocaine.	
17. Right now, if cocaine was offered to me I could not resist.	
18. Right now, I feel I am being treated unfairly.	

Completed by (initials): _____

Subject Identification ☐☐☐☐
VAS

Date Assessment Completed ☐☐-☐☐-☐☐☐☐ (Day -5)

Form 45 - VAS

	Time (minutes post-infusion)										
1. Right now, I feel alert.											
2. Right now, I feel my mind is racing.											
3. Right now, I am getting a buzz or a thrill.											
4. Right now, I feel lethargic.											
5. Right now, I feel restless.											
6. Right now, I feel good.											
7. Right now, I feel content.											
8. Right now, I feel high.											
9. Right now, I feel anxious.											
10. Right now, I dislike the effects of the drugs I have taken.											
11. Right now, I feel sad.											
12. Right now, I am thinking about how I can get cocaine.											
13. Right now, I am thinking about the next time I will use cocaine.											
14. Right now, I feel bothered about what is happening.											
15. Right now, I want to buy cocaine.											
16. Right now, I want to use cocaine.											
17. Right now, if cocaine was offered to me I could not resist.											
18. Right now, I feel I am being treated unfairly.											

Completed by (initials): _____

Subject Identification ☐☐☐☐
VAS

Date Assessment Completed ☐☐-☐☐-☐☐☐☐ (Day -2)

Form 45 - VAS

	Time (minutes post-infusion)										
1. Right now, I feel alert.											
2. Right now, I feel my mind is racing.											
3. Right now, I am getting a buzz or a thrill.											
4. Right now, I feel lethargic.											
5. Right now, I feel restless.											
6. Right now, I feel good.											
7. Right now, I feel content.											
8. Right now, I feel high.											
9. Right now, I feel anxious.											
10. Right now, I dislike the effects of the drugs I have taken.											
11. Right now, I feel sad.											
12. Right now, I am thinking about how I can get cocaine.											
13. Right now, I am thinking about the next time I will use cocaine.											
14. Right now, I feel bothered about what is happening.											
15. Right now, I want to buy cocaine.											
16. Right now, I want to use cocaine.											
17. Right now, if cocaine was offered to me I could not resist.											
18. Right now, I feel I am being treated unfairly.											

Completed by (initials): _____

Subject Identification ☐☐☐☐
VAS

Date Assessment Completed ☐☐-☐☐-☐☐☐☐ (Day -1)

Form 45 - VAS

	Time (minutes post-infusion)										
1. Right now, I feel alert.											
2. Right now, I feel my mind is racing.											
3. Right now, I am getting a buzz or a thrill.											
4. Right now, I feel lethargic.											
5. Right now, I feel restless.											
6. Right now, I feel good.											
7. Right now, I feel content.											
8. Right now, I feel high.											
9. Right now, I feel anxious.											
10. Right now, I dislike the effects of the drugs I have taken.											
11. Right now, I feel sad.											
12. Right now, I am thinking about how I can get cocaine.											
13. Right now, I am thinking about the next time I will use cocaine.											
14. Right now, I feel bothered about what is happening.											
15. Right now, I want to buy cocaine.											
16. Right now, I want to use cocaine.											
17. Right now, if cocaine was offered to me I could not resist.											
18. Right now, I feel I am being treated unfairly.											

Completed by (initials): _____

Subject Identification ☐☐☐☐
VAS

Date Assessment Completed ☐☐-☐☐-☐☐☐☐ (Day 11)

Form 45 - VAS

	Time (minutes post-infusion)										
1. Right now, I feel alert.											
2. Right now, I feel my mind is racing.											
3. Right now, I am getting a buzz or a thrill.											
4. Right now, I feel lethargic.											
5. Right now, I feel restless.											
6. Right now, I feel good.											
7. Right now, I feel content.											
8. Right now, I feel high.											
9. Right now, I feel anxious.											
10. Right now, I dislike the effects of the drugs I have taken.											
11. Right now, I feel sad.											
12. Right now, I am thinking about how I can get cocaine.											
13. Right now, I am thinking about the next time I will use cocaine.											
14. Right now, I feel bothered about what is happening.											
15. Right now, I want to buy cocaine.											
16. Right now, I want to use cocaine.											
17. Right now, if cocaine was offered to me I could not resist.											
18. Right now, I feel I am being treated unfairly.											

Completed by (initials): _____

Subject Identification ☐☐☐☐
VAS

Date Assessment Completed ☐☐-☐☐-☐☐☐☐ (Day 12)

Form 45 - VAS

	Time (minutes post-infusion)										
1. Right now, I feel alert.											
2. Right now, I feel my mind is racing.											
3. Right now, I am getting a buzz or a thrill.											
4. Right now, I feel lethargic.											
5. Right now, I feel restless.											
6. Right now, I feel good.											
7. Right now, I feel content.											
8. Right now, I feel high.											
9. Right now, I feel anxious.											
10. Right now, I dislike the effects of the drugs I have taken.											
11. Right now, I feel sad.											
12. Right now, I am thinking about how I can get cocaine.											
13. Right now, I am thinking about the next time I will use cocaine.											
14. Right now, I feel bothered about what is happening.											
15. Right now, I want to buy cocaine.											
16. Right now, I want to use cocaine.											
17. Right now, if cocaine was offered to me I could not resist.											
18. Right now, I feel I am being treated unfairly.											

Completed by (initials): _____

Date Assessment Completed ☐☐-☐☐-☐☐☐☐ (Discharge: Day 20)

Form 45 - VAS	
1. Right now, I feel alert.	
2. Right now, I feel my mind is racing.	
3. Right now, I am getting a buzz or a thrill.	
4. Right now, I feel lethargic.	
5. Right now, I feel restless.	
6. Right now, I feel good.	
7. Right now, I feel content.	
8. Right now, I feel high.	
9. Right now, I feel anxious.	
10. Right now, I dislike the effects of the drugs I have taken.	
11. Right now, I feel sad.	
12. Right now, I am thinking about how I can get cocaine.	
13. Right now, I am thinking about the next time I will use cocaine.	
14. Right now, I feel bothered about what is happening.	
15. Right now, I want to buy cocaine.	
16. Right now, I want to use cocaine.	
17. Right now, if cocaine was offered to me I could not resist.	
18. Right now, I feel I am being treated unfairly.	

Completed by (initials): _____

Date Assessment Completed ☐☐-☐☐-☐☐☐☐ (Day 48)

Form 45 - VAS	
1. Right now, I feel alert.	
2. Right now, I feel my mind is racing.	
3. Right now, I am getting a buzz or a thrill.	
4. Right now, I feel lethargic.	
5. Right now, I feel restless.	
6. Right now, I feel good.	
7. Right now, I feel content.	
8. Right now, I feel high.	
9. Right now, I feel anxious.	
10. Right now, I dislike the effects of the drugs I have taken.	
11. Right now, I feel sad.	
12. Right now, I am thinking about how I can get cocaine.	
13. Right now, I am thinking about the next time I will use cocaine.	
14. Right now, I feel bothered about what is happening.	
15. Right now, I want to buy cocaine.	
16. Right now, I want to use cocaine.	
17. Right now, if cocaine was offered to me I could not resist.	
18. Right now, I feel I am being treated unfairly.	

Completed by (initials): _____

Form 42 - Comment Page

Date of Comment □□-□□-□□□□	This comment applies to Visit Date:____/____/____ CRF Name ______________________ Field name:____________________________
Comments	

Date of Comment □□-□□-□□□□	This comment applies to Visit Date:____/____/____ CRF Name ______________________ Field name:____________________________
Comments	

Date of Comment □□-□□-□□□□	This comment applies to Visit Date:____/____/____ CRF Name ______________________ Field name:____________________________
Comments	

Date of Comment □□-□□-□□□□	This comment applies to Visit Date:____/____/____ CRF Name ______________________ Field name:____________________________
Comments	

Completed by (initials): ______________

Form 43 - Investigator Signature Page

I have reviewed the data contained in this case report form, and ensure that it is accurate, complete, and consistent.

_____	_____	____/____/_____
Investigator's Name (printed)	Investigator Signature	Date of Signature