

Site ID _____

NIDA-CTO-0012

Tiagabine

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Subject ID # _____

Subject Initials: ____

Date: ____ / ____ / _____

Screening

Week ____ Visit ____

Form 1 - INFORMED CONSENT

1. Did the subject sign the initial informed consent?

Yes

No

2. Date subject signed informed consent: ____ / ____ / ____
mm/dd/yyyy

Completed by (initials): _____

Date completed: ____ / ____ / _____

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Subject Initials: _____

Date: ____ / ____ / _____

Circle One: Screening/Baseline Treatment Follow Up

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Form 2 - DEMOGRAPHICS

General

1. Gender: Male Female

2. Date of Birth: ____ / ____ / ____
(mm/dd/yyyy)

Race/Ethnicity

3. Indicate which single major race/ethnicity applies:

- White, not of Hispanic Origin
- Hispanic or Latino
- African American, Black, not of Hispanic Origin
- Asian or Pacific Islander
- American Indian or Alaska Native
- Other, specify _____
- Unknown

4. For each of the following, circle Yes for all that apply and No for those that do not.

Yes No White

Yes No Black or African American

Yes No American Indian or Alaskan Native

Yes No Spanish, Hispanic, or Latino (**check all that apply**)
 Mexican, Mexican-American, or Chicano
 Puerto Rican
 Cuban
 Other, specify _____

Yes No Asian (**check all that apply**)
 Asian Indian
 Chinese
 Filipino
 Japanese
 Korean
 Vietnamese
 Other, specify _____

Yes No Native Hawaiian or Pacific Islander (**check all that apply**)
 Native Hawaiian
 Guamanian or Chamorro
 Samoan
 Other, specify _____

Yes No Other, specify _____

Participant chooses not to answer race/ethnicity questions.

Education

1. Education Completed (GED = 12 years): ___ ___ years ___ ___ months

Employment/Support Status

1. Current Employment Pattern (Past 30 Days)

- | | | |
|--|---|---|
| <input type="radio"/> Full Time
<i>(35+ hrs/wk)</i> | <input type="radio"/> Part time
<i>(regular hrs)</i> | <input type="radio"/> Part time
<i>(irregular hrs, day work)</i> |
| <input type="radio"/> Student | <input type="radio"/> Military Service | <input type="radio"/> Retired/Disabled |
| <input type="radio"/> Homemaker | <input type="radio"/> Unemployed | <input type="radio"/> In Controlled Environment |

2. Past Employment Pattern (Past 3 Years)

- | | | |
|--|---|---|
| <input type="radio"/> Full Time
<i>(35+ hrs/wk)</i> | <input type="radio"/> Part time
<i>(regular hrs)</i> | <input type="radio"/> Part time
<i>(irregular hrs, day work)</i> |
| <input type="radio"/> Student | <input type="radio"/> Military Service | <input type="radio"/> Retired/Disabled |
| <input type="radio"/> Homemaker | <input type="radio"/> Unemployed | <input type="radio"/> In Controlled Environment |

Marital Status

- | | | |
|---------------------------------------|---|-------------------------------------|
| <input type="radio"/> Legally Married | <input type="radio"/> Living with Partner/ Cohabiting | <input type="radio"/> Widowed |
| <input type="radio"/> Separated | <input type="radio"/> Divorced | <input type="radio"/> Never Married |

Drug/Alcohol Use

	<u># of Days in the Past 30</u>	<u># of Years Lifetime</u>	<u>Route of Administration*</u>
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 <i>including alcohol</i>	___	___	___

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

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

- | | | |
|--|---|---|
| <input type="radio"/> No problem | <input type="radio"/> Alcohol (any) | <input type="radio"/> Alcohol to intoxication |
| <input type="radio"/> Heroin | <input type="radio"/> Methadone/LAAM
<i>prescribed</i> | <input type="radio"/> Methadone/LAAM
<i>illicit</i> |
| <input type="radio"/> Opiates/analgesics | <input type="radio"/> Barbiturates | <input type="radio"/> Sedatives/Hypnotics/
Tranquilizers/Benzodiazepines |
| <input type="radio"/> Cocaine | <input type="radio"/> Amph./Methamph. | <input type="radio"/> Cannabis |
| <input type="radio"/> Hallucinogens | <input type="radio"/> Inhalants | <input type="radio"/> Nicotine |
| <input type="radio"/> Alcohol and Drug Addiction | <input type="radio"/> Polydrug addiction | |

Completed by (Initials): _____

Date completed: ___ / ___ / _____

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Form 3 - SCID WORKSHEET

Axis I Diagnosis

*Please list all **CURRENT Substance Abuse or Dependence Diagnoses** (Including DSM-IV code)*

____ . ____ _____

____ . ____ _____

____ . ____ _____

____ . ____ _____

*Please list all **PAST Substance Abuse or Dependence Diagnoses** (Including DSM-IV code)*

____ . ____ _____

____ . ____ _____

____ . ____ _____

____ . ____ _____

*Please list all other **CURRENT Axis I Diagnoses** (Including DSM-IV code)*

____ . ____ _____

____ . ____ _____

____ . ____ _____

____ . ____ _____

*Please list all other **PAST Axis I Diagnoses** (Including DSM-IV code)*

____ . ____ _____

____ . ____ _____

____ . ____ _____

____ . ____ _____

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Form 4 - MEDICAL HISTORY

	A. Yes, Excludes	B. Yes, Does Not Exclude	C. No History Of	D. Did Not Evaluate	E. Specify or Describe (Required if yes)
1. Allergies, drug (specify)_____	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	_____
2. Allergies, other (specify)_____	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	_____
3. Sensitivity to study medication or related compounds	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	_____
4. History of asthma	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	_____
5. HEENT Disorder	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	_____
6. Cardiovascular Disorder	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	_____
7. Renal Disorder	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	_____
8. Hepatic Disorder	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	_____
9. Pulmonary Disorder	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	_____
10. Gastrointestinal Disorder	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	_____
11. Musculoskeletal Disorder	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	_____
12. Neurologic Disorder:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	_____
13. Psychiatric Disorder	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	_____
14. Dermatologic Disorder	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	_____
15. Metabolic Disorder	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	_____
16. Hematologic Disorder	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	_____
17. Endocrine Disorder	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	_____
18. Genitourinary Disorder	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	_____
19. Reproductive System	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	_____
20. Seizure	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	_____
21. Infectious Disease	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	_____
22. Other 1 (specify)_____	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	_____
23. Other 2 (specify)_____	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	_____

Surgical History

24. Has patient ever had any major surgery? Yes No

If 'Yes', list major surgeries below.

<u>Type of Surgery</u>	<u>Date of Surgery</u> (mm/dd/yyyy)	<u>Is Surgery Relevant to Study Participation?</u>		
		Yes, Excludes	Yes, Does Not Exclude	No
25. _____	___ / ___ / _____	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
26. _____	___ / ___ / _____	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
27. _____	___ / ___ / _____	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
28. _____	___ / ___ / _____	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
29. _____	___ / ___ / _____	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
30. _____	___ / ___ / _____	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
31. _____	___ / ___ / _____	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Tobacco History

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

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

34. If yes, number of years tobacco product used: ___

Comments:

Physician Signature: _____

Date: ___ / ___ / _____

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Form 5 - PRIOR MEDICATIONS

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Has the subject taken any medications in the PAST 30 DAYS? ___ Yes ___ No

(If yes, please complete table)

Unit of Medication		Frequency		Route of Administration			
CAP = capsule	mg = milligram	SUP = suppository	ONCE = one dose	QID = 4 times/day	PO = oral	REC = rectal	IA = intra-articular
g = gram	mL = milliliter	TSP = teaspoon	QD = once daily	QOD = every other day	TD = transdermal	VAG = vaginal	NAS = nasal
GR = grain	oz = ounce	TBS = tablespoon	BID = twice daily	PRN = as needed	INH = inhaled	SQ = subcutaneous	IO = intraocular
GTT = drop	PUF = puff	TAB = tablet	TID = 3 times/day	OTH = other (specify)	IM = intramuscular	SL = sublingual	UNK = unknown
ug = microgram	SPY = spray/squirt	UNK = unknown			IV = intravenous	AUR = auricular	OTH = other (specify)
uL = microliter		OTH = other (specify)					

Medication	Dose	Units		Frequency		Route of Administration		Start Date	Stop Date	Continuing? (check if yes)	Indication
			Other		Other		Other				
_____	_____	_____	_____	_____	_____	_____	_____	___/___/___	___/___/___	___	_____
_____	_____	_____	_____	_____	_____	_____	_____	___/___/___	___/___/___	___	_____
_____	_____	_____	_____	_____	_____	_____	_____	___/___/___	___/___/___	___	_____
_____	_____	_____	_____	_____	_____	_____	_____	___/___/___	___/___/___	___	_____
_____	_____	_____	_____	_____	_____	_____	_____	___/___/___	___/___/___	___	_____
_____	_____	_____	_____	_____	_____	_____	_____	___/___/___	___/___/___	___	_____
_____	_____	_____	_____	_____	_____	_____	_____	___/___/___	___/___/___	___	_____
_____	_____	_____	_____	_____	_____	_____	_____	___/___/___	___/___/___	___	_____
_____	_____	_____	_____	_____	_____	_____	_____	___/___/___	___/___/___	___	_____
_____	_____	_____	_____	_____	_____	_____	_____	___/___/___	___/___/___	___	_____
_____	_____	_____	_____	_____	_____	_____	_____	___/___/___	___/___/___	___	_____
_____	_____	_____	_____	_____	_____	_____	_____	___/___/___	___/___/___	___	_____
_____	_____	_____	_____	_____	_____	_____	_____	___/___/___	___/___/___	___	_____

Physician Signature: _____

Date completed: ___/___/_____

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Circle One: Screening/Baseline Treatment Follow Up

Week ____ Visit ____

Form 6 - INFECTIOUS DISEASE ASSESSMENT

Hepatitis

Provide comments for any positive value.

Hepatitis B surface antigen result

- Negative
- Positive
- Positive, significant
- Indeterminate
- Not assessed

Hepatitis B surface antibody result

- Negative
- Positive
- Positive, significant
- Indeterminate
- Not assessed

Hepatitis B core antibody result

- Negative
- Positive
- Positive, significant
- Indeterminate
- Not assessed

Hepatitis C virus antibody result

- Negative
- Positive
- Positive, significant
- Indeterminate
- Not assessed

Purified Protein Derivative (PPD) Test

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 and leave the rest of the PPD section blank, **however** a chest X-ray is **required**.*

PPD test administered:

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

Time ____ : ____
(24-hour clock)

PPD test read:

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

Time ____ : ____
(24-hour clock)

PPD test result: Negative Positive Unknown Test not done

If PPD test is positive or the test was not done, a chest X-ray is required.

Comments:

Required for any positive value.

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Date: ____ / ____ / ____

Circle One: Screening/Baseline Treatment Follow Up

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Form 7 - SYPHILIS TEST

Rapid plasma reagin (RPR) test result: negative
 positive
 indeterminant
 not done

If RPR test is not done, state reason: _____

If RPR test is positive, fluorescent treponemal antibody absorbent (FTA-abs) confirmatory test is required. If RPR test is indeterminant, it must be repeated.

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

FTA-abs test result: negative
 positive
 indeterminant
 not done

If FTA-abs test is not done, state reason: _____

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

If the subject is unwilling to undergo treatment for active syphilis, they are ineligible to participate in this research study.

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

Comments:

Completed by (Initials): _____

Date completed: ____ / ____ / ____

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Circle One: Screening/Baseline Treatment Follow Up

Week _____ Visit _____

Form 8 - PHYSICAL EXAM

1. Height _____ . _____ inches

2. Weight _____ pounds

	A. Normal	B. Abnormal	C. Abnormal Significant	D. Not Done	E. Comments (required for abnormal values)
3. Oral (mouth)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	_____
4. Head and Neck	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	_____
5. Eyes, ears, nose/throat	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	_____
6. Cardiovascular	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	_____
7. Chest	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	_____
8. Lungs	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	_____
9. Abdomen (include liver/spleen)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	_____
10. Extremities	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	_____
11. Skin, hair, nails	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	_____
12. Neuropsychiatric mental status	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	_____
13. Neuropsychiatric sensory/motor	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	_____
14. Musculoskeletal	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	_____
15. General appearance	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	_____
16. Rectal	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	_____
17. Prostate	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	_____
18. Breast	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	_____
19. Lymph	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	_____
20. Genital	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	_____
21. Pelvic	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	_____
22. Other, specify _____	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	_____
23. Other, specify _____	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	_____

Physician Signature: _____

Date: ____ / ____ / _____

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Circle One: Screening/Baseline Treatment Follow Up Week _____

Form 9 - VITAL SIGNS

First Study Visit of Week

Vital signs not assessed at this visit

Date ____/____/_____
(mm/dd/yyyy)

Time Vital Signs taken ____ : ____
(24 hour clock)

Temperature (oral) ____ . ____ °F

Blood Pressure (sitting) ____ / ____ mm Hg

Pulse Rate (sitting) ____ (beats/min)

Respiratory Rate (sitting) ____ (breaths/min)

Completed by (Initials): _____

Second Study Visit of Week

Vital signs not assessed at this visit

Date ____/____/_____
(mm/dd/yyyy)

Time Vital Signs taken ____ : ____
(24 hour clock)

Temperature (oral) ____ . ____ °F

Blood Pressure (sitting) ____ / ____ mm Hg

Pulse Rate (sitting) ____ (beats/min)

Respiratory Rate (sitting) ____ (breaths/min)

Completed by (Initials): _____

Third Study Visit of Week

Vital signs not assessed at this visit

Date ____/____/_____
(mm/dd/yyyy)

Time Vital Signs taken ____ : ____
(24 hour clock)

Temperature (oral) ____ . ____ °F

Blood Pressure (sitting) ____ / ____ mm Hg

Pulse Rate (sitting) ____ (beats/min)

Respiratory Rate (sitting) ____ (breaths/min)

Completed by (Initials): _____

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Circle One: Screening/Baseline Treatment Follow Up

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Form 10 - HEMATOLOGY

	Value	Normal	Abnormal*	Abnormal* Significant	Not Done	Comments (required for abnormal values)
1. Hemoglobin	__ . __ g/dL	___	___	___	___	_____
2. Hematocrit	__ . __ %	___	___	___	___	_____
3. RBC	__ . __ M/uL	___	___	___	___	_____
4. Platelet count	__ __ K/uL	___	___	___	___	_____
5. WBC	__ __ K/uL	___	___	___	___	_____
6. Neutrophils	__ . __ %	___	___	___	___	_____
7. Lymphocytes	__ . __ %	___	___	___	___	_____
8. Monocytes	__ . __ %	___	___	___	___	_____
9. Eosinophils	__ . __ %	___	___	___	___	_____
10. Basophils	__ . __ %	___	___	___	___	_____

Please refer to Appendix I of the protocol when determining the significance of abnormal values.

***Abnormal" is any value outside the normal laboratory range.*

million/uL = mil/cumm = mill/mcl = M/cmm = x10⁶/cumm

x 10³/uL = thou/cumm = thou/mcl = K/cmm = 1000/uL = x 10³/cumm

Physician Signature: _____

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Form 11 - BLOOD CHEMISTRY

	Value	Normal	Abnormal*	Abnormal*	Not	Comments
			Significant	Done		(Required for Abnormal values)
1. Sodium	__ __ mmol/L	___	___	___	___	_____
2. Potassium	__ . __ mmol/L	___	___	___	___	_____
3. Chloride	__ __ mmol/L	___	___	___	___	_____
4. CO2	__ . __ mmol/L	___	___	___	___	_____
5. Glucose	__ __ mg/dL	___	___	___	___	_____
6. Creatinine	__ . __ mg/dL	___	___	___	___	_____
7. Albumin	__ . __ g/dL	___	___	___	___	_____
8. Total protein	__ . __ g/dL	___	___	___	___	_____
9. SGOT/AST	__ __ U/L	___	___	___	___	_____
10. SGPT/ALT	__ __ U/L	___	___	___	___	_____
11. GGT	__ __ U/L	___	___	___	___	_____
12. Bilirubin	__ . __ mg/dL	___	___	___	___	_____
13. BUN	__ __ mg/dL	___	___	___	___	_____

Please refer to Appendix I of the protocol when determining significance of abnormal values.

** "Abnormal" is any value outside the normal laboratory range.*

mmol/L = mEq/L

Physician Signature: _____

Date: ____ / ____ / _____

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Form 12 - URINALYSIS

	Value	Normal	Abnormal*	Abnormal* Significant	Not Done	Comments (required for abnormal values)
1. Specific gravity	__ . ____	____	____	____	____	_____
2. pH	____ . ____	____	____	____	____	_____
3. Glucose	____	____	____	____	____	_____
4. Protein	____	____	____	____	____	_____
5. Ketones	____	____	____	____	____	_____
6. Occult Blood	____	____	____	____	____	_____
7. WBC	____	____	____	____	____	_____
8. RBC	____	____	____	____	____	_____
9. Epithelial Cells	____	____	____	____	____	_____

***"Abnormal" is any value outside the normal laboratory range.**

For Glucose, Protein, Ketones, and Occult Blood use the following scale to report Values:

- 1 = Absent
- 0 = Trace
- 1
- 2
- 3
- 4

For WBC, RBC, and Epithelial Cells use the following scale to report Values:

- 1 = None (1 - 5)
- 2 = Few (6 - 10)
- 3 = Moderate (11 - 50)
- 4 = Heavy (>50)

Completed by (Initials): _____

Date completed: ____ / ____ / _____

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Form 13 - ELECTROCARDIOGRAM

- A. ECG overall results were: Normal
 Abnormal

If ECG is Normal please skip to Question C.

- B. If ECG is abnormal, check below for all abnormalities.

	<u>Abnormal</u>	<u>Abnormal Significant</u>		<u>Abnormal</u>	<u>Abnormal Significant</u>
1. Increased QRS voltage	<input type="radio"/>	<input type="radio"/>	17. Supraventricular premature beat	<input type="radio"/>	<input type="radio"/>
2. Qtc prolongation	<input type="radio"/>	<input type="radio"/>	18. Ventricular premature beat	<input type="radio"/>	<input type="radio"/>
3. Left atrial hypertrophy	<input type="radio"/>	<input type="radio"/>	19. Supraventricular tachycardia	<input type="radio"/>	<input type="radio"/>
4. Right atrial hypertrophy	<input type="radio"/>	<input type="radio"/>	20. Ventricular tachycardia	<input type="radio"/>	<input type="radio"/>
5. Left ventricular hypertrophy	<input type="radio"/>	<input type="radio"/>	21. Atrial fibrillation	<input type="radio"/>	<input type="radio"/>
6. Right ventricular hypertrophy	<input type="radio"/>	<input type="radio"/>	22. Atrial flutter	<input type="radio"/>	<input type="radio"/>
7. Acute infarction	<input type="radio"/>	<input type="radio"/>	23. Other rhythm abnormalities	<input type="radio"/>	<input type="radio"/>
8. Subacute infarction	<input type="radio"/>	<input type="radio"/>	24. Implanted pacemaker	<input type="radio"/>	<input type="radio"/>
9. Old infarction	<input type="radio"/>	<input type="radio"/>	25. 1 st degree A-V block	<input type="radio"/>	<input type="radio"/>
10. Myocardial ischemia	<input type="radio"/>	<input type="radio"/>	26. 2 nd degree A-V block	<input type="radio"/>	<input type="radio"/>
11. Digitalis effect	<input type="radio"/>	<input type="radio"/>	27. 3 rd degree A-V block	<input type="radio"/>	<input type="radio"/>
12. Symmetrical T-wave inversions	<input type="radio"/>	<input type="radio"/>	28. LBB block	<input type="radio"/>	<input type="radio"/>
13. Poor R-wave progression	<input type="radio"/>	<input type="radio"/>	29. RBB block	<input type="radio"/>	<input type="radio"/>
14. Other nonspecific ST/T	<input type="radio"/>	<input type="radio"/>	30. Pre-excitation syndrome	<input type="radio"/>	<input type="radio"/>
15. Sinus tachycardia	<input type="radio"/>	<input type="radio"/>	31. Other intraventricular condition	<input type="radio"/>	<input type="radio"/>
16. Sinus bradycardia	<input type="radio"/>	<input type="radio"/>	32. Other, specify _____	<input type="radio"/>	<input type="radio"/>

C. Ventricular rate (bpm) _____

E. QRS (ms) _____

D. PR (ms) _____

F. QTC (ms) _____

Are there any abnormalities noted above that preclude the subject from safe entry into or continuation in the study? Yes No

Physician Signature: _____

Date: ____ / ____ / ____

Site ID _____

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Tiagabine

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Subject ID # _____

Subject Initials: ____

Date: ____ / ____ / ____

Circle One: Screening/Baseline Treatment Follow Up

Week ____ Visit ____

Form 14 - BIRTH CONTROL/PREGNANCY ASSESSMENT

This form is to be filled out for female subjects only. All female subjects must be tested at Screening/Baseline and have a negative pregnancy test in order to be eligible for this study.

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

What method of birth control is the participant currently using?

- Oral contraceptive
- Barrier (diaphragm or condom plus spermicide)
- Levonorgestrel implant (Norplant)
- Intrauterine Contraceptive system (IUD)
- Medroxyprogesterone Acetate Contraceptive injection (Depo-Provera)
- Complete abstinence
- Surgical Sterilization (Hysterectomy / Tubal ligation)

If 'Yes', circle one.

Was a pregnancy test performed? Yes No

If yes, what was the result? Positive Negative Unknown

Date specimen collected ____ / ____ / ____
(mm/dd/yyyy)

If no, specify reason.

Is the subject lactating? Yes No

Comments:

Completed by (Initials): _____

Date completed: ____ / ____ / ____

Site ID _____

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Subject ID # _____

Subject Initials: ____

Date: ____ / ____ / ____

Circle One: Screening/Baseline Treatment Follow Up

Week ____ Visit ____

Form 15 - HAMILTON DEPRESSION RATING SCALE

1. Depressed Mood

(sad, hopeless, helpless, worthless)

- 0 = Absent
- 1 = These feeling states indicated only on questioning.
- 2 = These feeling states spontaneously reported verbally.
- 3 = Communicates feeling states nonverbally – i.e., through facial expression, posture, voice, and tendency to weep.
- 4 = Subject reports virtually only these feeling states in his/her spontaneous verbal and nonverbal communication.

2. Feelings of Guilt

- 0 = Absent
- 1 = Self-reproach, feels s/he has let people down.
- 2 = Ideas of guilt or rumination over past errors or sinful deeds.
- 3 = Present illness is a punishment. Delusions of guilt.
- 4 = Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations.

3. Suicide

- 0 = Absent
- 1 = Feels life is not worth living.
- 2 = Wishes s/he were dead or any thoughts of possible death to self.
- 3 = Suicide ideas or gesture.
- 4 = Attempts at suicide (any serious attempt rates 4).

4. Insomnia Early

- 0 = No difficulty falling asleep.
- 1 = Complains of occasional difficulty falling asleep. (i.e., more than ½ hour)
- 2 = Complains of nightly difficulty falling asleep.

5. Insomnia Middle

- 0 = No difficulty.
- 1 = Subject complains of being restless and disturbed during the night.
- 2 = Waking during the night – any getting out of bed rates 2 (*except for purposes of voiding*).

6. Insomnia Late

- 0 = No difficulty.
- 1 = Waking in early hours of the morning but goes back to sleep.
- 2 = Unable to fall asleep again if gets out of bed.

7. Work and Activities

- 0 = No difficulty
- 1 = Thoughts and feelings of incapacity, fatigue, or weakness related to activities; work or hobbies.
- 2 = Loss of interest in activity; hobbies or work – either directly reported by patient, or indirect in listlessness, indecision and vacillation (*feels s/he has to push self to work or activities*).
- 3 = Decrease in actual time spent in activities or decrease in productivity.
- 4 = Stopped working because of present illness.

8. Retardation

(slowness of thought and speech; impaired ability to concentrate; decreased motor activity)

- 0 = Normal speech and thought
- 1 = Slight retardation at interview
- 2 = Obvious retardation at interview
- 3 = Interview difficult
- 4 = Complete stupor

9. Agitation

- 0 = None
- 1 = Fidgetiness
- 2 = Playing with hands, hair, etc.
- 3 = Moving about, can't sit still
- 4 = Hand-wringing, nail-biting, hair-pulling, biting of lips

10. Anxiety Psychic

- 0 = No difficulty
- 1 = Subjective tension and irritability
- 2 = Worrying about minor matters
- 3 = Apprehensive attitude apparent in face or speech
- 4 = Fears expressed without questioning

11. Anxiety Somatic

(Physiological concomitants of anxiety such as: Gastrointestinal: dry mouth, wind, indigestion, diarrhea, cramps, belching. Cardiovascular: palpitations, headaches. Respiratory: hyperventilation, sighing. Urinary frequency. Sweating.)

- 0 = Absent
- 1 = Mild
- 2 = Moderate
- 3 = Severe
- 4 = Incapacitating

12. Somatic Symptoms Gastrointestinal

- 0 = None
- 1 = Loss of appetite but eating without encouragement. Heavy feelings in abdomen.
- 2 = Difficulty eating without urging. Requests or requires laxatives or medication for bowels or medication for G.I. symptoms.

13. Somatic Symptoms General

- 0 = None
- 1 = Heaviness in limbs, back or head. Backaches, headache, muscle aches. Loss of energy and fatigability.
- 2 = Any clear-cut symptom rates 2.

14. Genital Symptoms

(such as loss of libido and menstrual disturbances)

- 0 = Absent
- 1 = Mild
- 2 = Severe

15. Hypochondriasis

- 0 = Not present
- 1 = Self-absorption (bodily)
- 2 = Preoccupation with health
- 3 = Frequent complaints, requests for help, etc.
- 4 = Hypochondriacal delusions

16. Loss of Weight

- 0 = No weight loss
- 1 = Probable weight loss associated with present illness.
- 2 = Definite weight loss (according to subject)

17. Insight

- 0 = Acknowledges being depressed and ill.
- 1 = Acknowledges illness but attributes cause to bad food, climate, overwork, virus, need for rest, etc.
- 2 = Denies being ill at all

18. Diurnal Variation

- 0 = No variation
 - 1 = (Mild) Doubtful or slight variation
 - 2 = (Severe) Clear or marked variation
- If answer is 1 or 2, note whether the symptoms are worse in: A.M. P.M.

19. Depersonalization and Derealization

(symptoms such as feelings of unreality and nihilistic ideas)

- 0 = Absent
- 1 = Mild
- 2 = Moderate
- 3 = Severe
- 4 = Incapacitating

20. Paranoid Symptoms

- 0 = None
- 1 = Suspicious
- 2 = Ideas of reference
- 3 = Delusions of reference and persecution

21. Obsessive and Compulsive Symptoms

- 0 = Absent
- 1 = Mild
- 2 = Severe

22. Helplessness

- 0 = Not present
- 1 = Subjective feelings which are elicited only by inquiry.
- 2 = Subject volunteers his helpless feelings.
- 3 = Requires urging, guidance and reassurance to accomplish chores or personal hygiene.
- 4 = Despite urging, does not perform necessary chores or personal hygiene.

23. Hopelessness

- 0 = Not present
- 1 = Intermittently doubts that "things will improve" but can be reassured.
- 2 = Consistently feels "hopeless" but accepts reassurances.
- 3 = Expresses feelings of discouragement, despair, pessimism about future, which cannot be dispelled.
- 4 = Spontaneously and inappropriately perseverates, "I'll never get well," or its equivalent

24. Worthlessness

(ranges from mild loss of self-esteem, feelings of inferiority, self-depreciation (loss of self-esteem) to delusion notions of worthlessness)

- 0 = Not present
- 1 = Indicates feelings of worthlessness (loss of self esteem) only on questioning.
- 2 = Spontaneously indicates feelings of worthlessness (loss of self esteem).
- 3 = Different from 2 by degree: Subject volunteers that s/he is "no good," "inferior," etc.
- 4 = Expresses feelings of total worthlessness – e.g. "I am a heap of garbage" or equivalent

Completed by (Initials): _____

Date completed: ___ / ___ / _____

Site ID _____

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Tiagabine

Subject ID # _____

Subject Initials: _ _ _

Page ___ of ___

Form 16 - ADVERSE EVENTS

Has the subject had any Adverse Events during the time period evaluated? ___ Yes ___ No *(If yes, please list below).*

D: Severity

- 1 = Mild
- 2 = Moderate
- 3 = Severe

E: Relationship

- 1 = Definitely
- 2 = Probably
- 3 = Possibly
- 4 = Remotely
- 5 = Definitely Not
- 6 = Unknown

F: Action Taken Regarding Study Drug

- 1 = None
- 2 = Discontinued Perm.
- 3 = Discontinued Temp
- 4 = Reduced Dose
- 5 = Increased Dose
- 6 = Delayed Dose

G: Other Action Taken

- 1 = None
- 2 = Pharmacologic Therapy
- 3 = Nonpharm. Therapy
- 4 = Hospitalization

H: Outcome of AE

- 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

I: Serious?

- 1 = Yes
 - 0 = No
- (If yes, complete SAE Form)***

A Adverse Event	B Start Date	C Stop Date	D Severity	E Related	F Action	G Other Act.	H Outcome	I SAE?	J Initials
_____	___/___/___	___/___/___	___	___	___	___	___	___	_____
_____	___/___/___	___/___/___	___	___	___	___	___	___	_____
_____	___/___/___	___/___/___	___	___	___	___	___	___	_____
_____	___/___/___	___/___/___	___	___	___	___	___	___	_____
_____	___/___/___	___/___/___	___	___	___	___	___	___	_____
_____	___/___/___	___/___/___	___	___	___	___	___	___	_____
_____	___/___/___	___/___/___	___	___	___	___	___	___	_____

Physician Signature: _____

___/___/___

Site ID _____

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Subject ID # _____

Subject Initials: _____

Date: ____ / ____ / _____

Circle One: Screening/Baseline Treatment Follow Up

Week ____ Visit ____

Form 17 - SERIOUS ADVERSE EVENTS

Demographic Information

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

Gender: Male Female

Date of Birth: ____ / ____ / _____
(mm/dd/yyyy)

Height: ____ . ____ in Weight: _____ lb

Race:

- White, not of Hispanic Origin
- Hispanic or Latino
- African American, Black, not of Hispanic Origin
- Asian or Pacific Islander
- American Indian or Alaska Native
- Other, specify _____
- Unknown

Serious Adverse Event

Description of the Serious Adverse Event (make sure the description and date are consistent with the AE Form):

Onset date: ____ / ____ / _____
(mm/dd/yyyy)

Reported to FDA by: _____

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

Reported to Sponsor by: _____

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

Reported to NIDA by: _____

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

Severity Grade: Mild Moderate Severe

Was the SAE related to the investigational agent?

- Definitely
- Probably
- Possibly
- Remotely
- Definitely Not
- Unknown

Action Taken regarding investigational agent:

- None
- Discontinued permanently
- Discontinued temporarily
- Reduced dose
- Increased dose
- Delayed dose

Other actions taken:

- None
- Remedial therapy – pharmacologic
- Remedial therapy – nonpharmacologic
- Hospitalization -new or prolonged

Outcome

- Death
- Life-threatening event
- Hospitalization
- Disability
- Congenital anomaly
- Other, specify _____

Concomitant medications: _____

Relevant tests/laboratory data, including dates: _____

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

Date of SAE Resolution: ____/____/____
(mm/dd/yyyy) continuing

Investigational Agent Administration

Is the investigational agent information known? Yes No

If yes, investigational agent name _____ Lot number: _____

Expiration date: ____/____/____
(mm/dd/yyyy)

Quantity: _____ Units: _____ Frequency: _____ Route of Administration: _____
Codes listed below.

Unit of Medication		Frequency	Route of Administration	
CAP = capsule	oz = ounce	ONCE = one dose	PO = oral	SL = sublingual
g = gram	PUF = puff	QD = once daily	TD = transdermal	AUR = auricular
GR = grain	SPY = spray/squirt	BID = twice daily	INH = inhaled	IA = intra-articular
GTT = drop	SUP = suppository	TID = 3 times/day	IM = intramuscular	NAS = nasal
ug = microgram	TSP = teaspoon	QID = 4 times/day	IV = intravenous	IO = intraocular
uL = microliter	TBS = tablespoon	QOD = every other day	REC = rectal	UNK = unknown
mg = milligram	TAB = tablet	PRN = as needed	VAG = vaginal	OTH = other
mL = milliliter	UNK = unknown	OTH = other (specify)	SQ = subcutaneous	(specify)
OTH = other (specify)				

Start date: ____/____/____ Stop date: ____/____/____
(mm/dd/yyyy) (mm/dd/yyyy)

Comments: _____

Physician Signature: _____ Date signed: ____/____/____

Site ID _____

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Tiagabine

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Subject ID # _____

Subject Initials: ___ ___

Date: ___ / ___ / _____

Circle One: Screening/Baseline Treatment Follow Up

Week _____ Visit _____

Form 19 - ENTRY CRITERIA

Inclusion Criteria

- Yes No 1. Subject is at least 18 years-of-age.
- Yes No 2. Subject has a DSM-IV diagnosis of cocaine dependence as determined by SCID.
- Yes No 3. Subject is seeking treatment for cocaine dependence.
- Yes No 4. Subject had at least 1 positive urine BE specimen (>300 ng/mL) within the two-week baseline period prior to randomization with a minimum of four samples tested.
- Yes No 5. Subject has the ability to understand, and having understood, has provided written informed consent.
- Yes No N/A Male 6. If female, the subject agrees to use one of the following methods of birth control:
- a. oral contraceptives
 - b. barrier (diaphragm or condom)
 - c. intrauterine contraceptive system
 - d. levonorgestrel implant
 - e. medroxyprogesterone acetate contraceptive injection
 - f. surgical sterilization
 - g. complete abstinence from sexual intercourse

If any of Questions 1-6 above are answered “No” the subject is ineligible. Please proceed to the end of this form and complete the final questions.

Exclusion Criteria

- Yes No 1. Subject has current dependence, defined by DSM-IV criteria, on any psychoactive substance other than cocaine, alcohol, nicotine, or marijuana or physiological dependence on alcohol requiring medical detoxification.
- Yes No 2. Subject is mandated by the court to obtain treatment for cocaine-dependence.
- Yes No 3. Subject has been enrolled in an opiate-substitution program (methadone, LAAM, buprenorphine) within 2 months of screening.
- Yes No 4. Subject is someone who, in the opinion of the investigator, would not be expected to complete the study protocol due to probable incarceration or relocation from the clinic area.

- Yes No 5. Subject has a psychiatric disorder, as assessed by the SCID, or a neurological disorder, brain disease, dementia or any disorder that, in the opinion of the study physician requires ongoing treatment that would make study participation unsafe or which would make treatment compliance difficult.
- Yes No 6. Subject has had electroconvulsive therapy within the past 3 months preceding screening.
- Yes No 7. Subject has a current suicidal ideation or plan (within the past 30 days) as assessed by the SCID.
- Yes No 8. Subject is pregnant or lactating.
- Yes No 9. Subject has a serious medical illnesses including, but not limited to,
- a) uncontrolled hypertension,
 - b) significant heart disease (including myocardial infarction within one year of enrollment), or any clinically significant cardiovascular abnormality (ECG),
 - c) angina,
 - d) hepatic, renal or gastrointestinal disorders that could result in altered metabolism or excretion of the study agent,
 - e) current or historical diagnosis of chronic disease of the gastrointestinal tract (e.g., ulcerative colitis, regional enteritis, or gastrointestinal bleeding),
 - f) potentially life-threatening or progressive medical illness other than addiction that may compromise subject safety or study conduct.
- Yes No 10. Subject has clinically significant abnormal laboratory values, per protocol (Appendix I).
- Yes No 11. Subject has AIDS according to the current CDC criteria for AIDS MMWR 1999; 48 (No.RR-13:29-31).
- Yes No 12. Subject has active syphilis that has not been treated or refuses treatment for syphilis (see note below).
- Yes No 13. Subject has 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 3 months) treatment with inhaled or oral beta-agonist or steroid therapy (because of potential serious adverse interactions with cocaine).
- Yes No 14. Subject is actively using albuterol or other beta agonist medications, regardless of formal diagnosis of asthma. (Inhalers are sometimes used by cocaine addicts to enhance cocaine delivery to the lungs). A subject without respiratory disease who will consent to discontinue beta-agonist use, may be considered for inclusion.

- Yes No 15. Subject has received a drug with known potential for toxicity to a major organ system within 30 days prior to study entry (e.g. isoniazid, methotrexate).
- Yes No 16. Subject has the need or the intention to use concurrently with dosing or within two weeks prior to dosing, any of the following medications: carbamazepine, phenytoin, phenobarbital, primidone, valproic acid, and ketoconazole. In addition, other substances, which affect the enzyme CYP3A4 (as inhibitors, substrates, or inducers) should be used with caution. The research physician will decide on this issue. A listing of these substances may be found in protocol Appendix VI.
- Yes No 17. Subject has participated in any experimental study within 2 months preceding screening.
- Yes No 18. Subject has a known or suspected hypersensitivity to tiagabine.
- Yes No 19. Subject is taking tiagabine for any reason.

If any of Questions 1-20 above are answered "Yes" the subject is ineligible. Please proceed to the end of this form and complete the final questions.

Notes on inclusion/exclusion criterion: Although AIDS is an exclusion criteria, a positive antibody titer to HIV is not. Prospective subjects will be offered HIV testing during screening but may not have the test performed until after enrollment. This test is offered as a courtesy to the prospective subject along with HIV education.

Prospective subjects who are positive for syphilis by the RPR test will have a fluorescent treponemal antibody absorption assay (FTA-abs) confirmatory test performed. If this test is positive, prospective subjects must be treated for syphilis to be enrolled on the study or provide evidence of previous treatment for syphilis.

The infectious disease panel for hepatitis is performed as an aid to determine if the prospective subject has been exposed to the hepatitis virus. Positive hepatitis results do not exclude a prospective subject from participation. However, if liver function tests (e.g. ALT and AST) are over three times normal it is presumptive evidence that the subject has active hepatitis and should be excluded from the study (exclusion criterion #10). Tuberculin test (PPD) is performed only on subjects that are intravenous abusers of any drug. A positive PPD result does not exclude a prospective subject from participation, but if diagnostic tests (e.g. chest x-ray) indicate that active disease is present, subjects will be excluded from participation.

Yes No **Is the subject eligible for randomization based on the above criteria?**

If "Yes, please assign the subject a Subject ID # and record it in the header on this form and have the physician sign the form below.

If "No", please record the subject's Screening number in the Subject ID # field of the header on this form, complete the End of Trial form, and have the physician sign the form below.

Yes No **Was the subject randomized?**

If "No", please indicate the reason on the End of Trial form and have the physician sign the form below:

Physician Signature: _____

Date: ____ / ____ / ____

Subject ID # _____

Subject Initials: ____

Date: ____ / ____ / ____

Circle One: Screening/Baseline Treatment Follow Up

Week ____ Visit ____

Form 21 - ADDICTION SEVERITY INDEX: LITE**General Information**G4. Date of admission _____ / _____ / _____
(mm/dd/yyyy)G8. Class Intake Follow-upG9. Contact code In person Telephone MailG10. Gender Male FemaleG12. Special Terminated Refused Unable to respond

G14. How long have you lived at your current address? ____ Years, ____ Months

G16. Date of birth: _____ / _____ / _____
(mm/dd/yyyy)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 Hispanic - Other
 Asian/Pacific IslanderG18. Do you have a religious preference? Protestant Islamic
 Catholic Other
 Jewish NoneG19. 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? _____

MEDICAL STATUS

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" to #M1-2, please specify in 'Comments'.*M4. Are you taking any prescribed medication on a regular basis for a physical problem?
If "Yes", please specify in 'Comments'. Yes No

M5 Do you receive a pension for a physical disability? (Exclude psychiatric disabilities.)
 Yes No
If yes to #M5, please specify in Comments section below.

M6 How many days have you experienced medical problems in the past 30 days? _____
For #M7 and M8 please ask the subject to use the subject rating scale.

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: _____

Employment/Support Status

E1* Education completed (GED = 12 years): _____ Years, _____ Months

E2* Training or technical education completed: _____ Months

E4 Do you have a valid driver's license? Yes No

E5 Do you have an automobile available for use? Yes No
Answer "no" if no valid driver's license.

E6. How long was your longest full-time job? _____ Years, _____ Months

E7 Usual (or last) occupation: _____

Hollingshead occupational category: 1 2 3 4 5 6 7 8 9

- 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, draftsman, 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.

- | | |
|---|---|
| <input type="radio"/> 1 = full time (35+ hrs/week) | <input type="radio"/> 5 = military service |
| <input type="radio"/> 2 = part time (regular hours) | <input type="radio"/> 6 = retired/disabled |
| <input type="radio"/> 3 = part time (irregular hours) | <input type="radio"/> 7 = unemployed |
| <input type="radio"/> 4 = student | <input type="radio"/> 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? ___ ___

For Questions E20 and E21 please ask the subject to use the subject rating scale.

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.)
<input type="text"/>	Alcohol – any use at all	___	___	
<input type="text" value="D2"/>	Alcohol – to intoxication	___	___	
<input type="text" value="D3"/>	Heroin	___	___	_____
<input type="text" value="D4"/>	Methadone	___	___	_____
<input type="text"/>	Other opiates/analgesics	___	___	_____
<input type="text" value="D6"/>	Barbiturates	___	___	_____
<input type="text"/>	Other sedatives/hypnotics/tranquilizers	___	___	_____
<input type="text" value="D8"/>	Cocaine	___	___	_____
<input type="text"/>	Amphetamines	___	___	_____
<input type="text" value="D10"/>	Cannabis	___	___	_____
<input type="text"/>	Hallucinogens	___	___	_____
<input type="text" value="D12"/>	Inhalants	___	___	_____
<input type="text"/>	More than one substance per day (including alcohol)	___	___	
<input type="text" value="D17"/>	How many times have you had alcohol DTs?		___	

How many times in your life have you been treated for:

<input type="text" value="D19*"/>	Alcohol abuse	___
<input type="text" value="D20*"/>	Drug abuse	___

How many times of these were detox only?

<input type="text" value="D21"/>	Alcohol	___
<input type="text" value="D22"/>	Drugs	___

Enter "NN" if answers to Question D19 or D20 = "00"

How much money would you say you spent in the past 30 days on:

<input type="text" value="D23"/>	Alcohol	\$ _____
<input type="text" value="D24"/>	Drugs	\$ _____

<input type="text" value="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:

Alcohol problems _____

Drug problems _____

For Questions D28-31 please ask the subject to use the subject rating scale.

How troubled or bothered have you been in the past 30 days by these:

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

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

How important to you now is treatment for these:

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

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

Confidence Ratings

Is the above information significantly distorted by:

Subject's misrepresentation? Yes No

Subject's inability to understand? Yes No

Comments: _____

Legal Status

L1. Was this admission prompted or suggested by the criminal justice system (judge, probation/parole officer, etc.)? Yes No

Are you on probation or parole? Yes No

How many times in your life have you been arrested and charged with the following:

Shoplifting/vandalism _____

Parole/probation violation(s) _____

Drug charge(s) _____

Forgery _____

Weapons offense _____

Burglary, larceny, breaking and entering _____

Robbery _____

- L10* Assault _____
- L11* Arson _____
- L12* Rape _____
- L13* Homicide, manslaughter _____
- L14* Prostitution _____
- L15* Contempt of court _____
- L16* Other, specify: _____
- L17* How many of these charges resulted in conviction? _____

Enter "NN" if no arrests or charges.

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? _____ months
- L24 Are you presently awaiting charges, trial or sentence? Yes No
- L25 What for? _____

If multiple charges, use the number of the most severe from above(L3-L16), or use the following codes: 18=disorderly conduct, 19=driving while intoxicated, 20=major driving violation.

- 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? _____

For Questions L28 and L29 please ask the subject to use the subject rating scale.

- 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: _____

Family/Social Relationships

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 4 = with parents 7 = alone
 2 = with sexual partner alone 5 = with family 8 = controlled environment
 3 = with children alone 6 = with friends 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:

		<u>In the past 30 days</u>			<u>Lifetime</u>		
		Yes	No	N/A	Yes	No	N/A
F18	Mother	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
F19	Father	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
F20	Siblings	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
F21	Sexual partner/ spouse	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
F22	Children	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
F23	Other significant family	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Please specify if "Yes": _____

F24 Close friends Yes No N/A Yes No N/A

F25 Neighbors Yes No N/A Yes No N/A

F26 Co-workers Yes No N/A Yes No N/A

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

In the past 30 days

Lifetime

P4 Experienced serious depression (sadness, hopelessness, loss of interest, difficulty with daily functioning)? Yes No Yes No

P5 Experienced serious anxiety/tension (uptight, unreasonably worried, inability to feel relaxed)? Yes No Yes No

P6 Experienced hallucinations (saw things or heard voices that were not there)? Yes No Yes No

P7 Experienced trouble understanding, concentrating, or remembering? Yes No Yes No

For Questions P8-10, Subject can have been under the influence of alcohol/drugs.

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 or emotional problem? Yes No Yes No

P12 How many days in the past 30 have you experienced these psychological or emotional problems? _____

For Questions P13 and P14 please ask the subject to use the subject rating scale.

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

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Form 23 - SUBSTANCE USE INVENTORY

Indicate whether the subject has used any amount of the listed substance on each given day since the last visit and the most common route of administration for each. Begin with yesterday and work back to the last visit. Date of last visit: ____/____/_____
(mm/dd/yyyy)

Day of week

Date

____/____/____

| | <u>Used?</u> | <u>ROA</u> |
|-----------------|--------------|------------|--------------|------------|--------------|------------|--------------|------------|--------------|------------|--------------|------------|--------------|------------|--------------|------------|--------------|------------|
| Cocaine | Y/N | ____ |
| Alcohol | Y/N | ____ |
| Nicotine | Y/N | ____ |
| Marijuana | Y/N | ____ |
| Amphetamines | Y/N | ____ |
| Methamphetamine | Y/N | ____ |
| Opiates | Y/N | ____ |
| PCP | Y/N | ____ |
| Propoxyphene | Y/N | ____ |
| Barbiturates | Y/N | ____ |
| Benzodiazepines | Y/N | ____ |

Route of administration (ROA) codes: 1 = oral, 2 = nasal, 3 = smoking, 4 = non-intravenous injection, 5 = intravenous injection

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Form 25 - HIV RISK-TAKING BEHAVIOR SCALE

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

Drug Use

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

Sexual Behavior

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

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Form 26 - BRIEF SUBSTANCE CRAVING SCALE

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 Q. 8)

7. The date for that day was: ___ / ___ / _____
(mm/dd/yyyy)

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

Second Drug

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 Questions 10-16 blank.

- None
 Downers or Sedatives (Barbiturates, etc.)
 Benzos (Valium, Xanax, etc.)
 Nicotine
 Alcohol
 Heroin or other Opiates (Morphine, etc.)
 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.

- | | | | |
|-------------------------------|--|---|--|
| <input type="radio"/> None | <input type="radio"/> Downers or Sedatives
(Barbiturates, etc.) | <input type="radio"/> Benzos
(Valium, Xanax, etc.) | <input type="radio"/> Nicotine |
| <input type="radio"/> Alcohol | <input type="radio"/> Heroin or other Opiates
(Morphine, etc.) | <input type="radio"/> Marijuana | <input type="radio"/> 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

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Form 27 - COCAINE CRAVING QUESTIONNAIRE

*Indicate how much you agree or disagree with each of the following statements by circling the number which best shows how you feel. The lower the number, the more you disagree; the higher the number, the more you agree with the statement. Please complete every item. We are interested in how you are thinking or feeling **RIGHT NOW** as you are filling out the questionnaire.*

	<u>Strongly Disagree</u>							<u>Strongly Agree</u>
1. If I were using cocaine, I could think more clearly.	1	2	3	4	5	6	7	
2. Right now I am not making plans to use "coke."	1	2	3	4	5	6	7	
3. My desire to use cocaine seems overpowering.	1	2	3	4	5	6	7	
4. I am thinking of ways to get cocaine.	1	2	3	4	5	6	7	
5. I don't want to use "coke".	1	2	3	4	5	6	7	
6. If I were offered some "coke", I would use it immediately.	1	2	3	4	5	6	7	
7. Using cocaine would make me feel less depressed.	1	2	3	4	5	6	7	
8. I could easily control how much cocaine I use right now.	1	2	3	4	5	6	7	
9. I crave "coke" right now.	1	2	3	4	5	6	7	
10. Using cocaine would make me feel powerful.	1	2	3	4	5	6	7	
11. If there were cocaine in front of me, it would be hard not to use it.	1	2	3	4	5	6	7	
12. Using cocaine would not help me calm down right now.	1	2	3	4	5	6	7	
13. I would feel very alert if I used cocaine right now.	1	2	3	4	5	6	7	
14. If I had the chance to use "coke", I don't think I would use it.	1	2	3	4	5	6	7	
15. I would not enjoy using cocaine right now.	1	2	3	4	5	6	7	
16. I would do almost anything for cocaine right now.	1	2	3	4	5	6	7	
17. I could control things better right now if I could use cocaine.	1	2	3	4	5	6	7	
18. Even if it were possible, I probably would not use cocaine right now.	1	2	3	4	5	6	7	
19. Using "coke" would not be pleasant.	1	2	3	4	5	6	7	
20. I think that I could resist using "coke" right now.	1	2	3	4	5	6	7	
21. I have an urge for cocaine.	1	2	3	4	5	6	7	

	<u>Strongly Disagree</u>						<u>Strongly Agree</u>
22. I would not be able to control how much cocaine I used if I had some here.	1	2	3	4	5	6	7
23. Starting now, I could go without using cocaine for long time.	1	2	3	4	5	6	7
24. I would be less irritable now if I could use cocaine.	1	2	3	4	5	6	7
25. I would feel energetic if I used cocaine.	1	2	3	4	5	6	7
26. All I want to use right now is cocaine.	1	2	3	4	5	6	7
27. Using cocaine would not sharpen my concentration.	1	2	3	4	5	6	7
28. I do not need to use cocaine now.	1	2	3	4	5	6	7
29. It would be difficult to turn down cocaine this minute.	1	2	3	4	5	6	7
30. If I use cocaine right now, I would not feel less restless.	1	2	3	4	5	6	7
31. I will use cocaine as soon as I get a chance.	1	2	3	4	5	6	7
32. Using cocaine now would make things seem just perfect.	1	2	3	4	5	6	7
33. I want to use cocaine so bad that I can almost taste it.	1	2	3	4	5	6	7
34. Nothing would be better than using "coke" right now.	1	2	3	4	5	6	7
35. If I used cocaine, my anger would not decrease.	1	2	3	4	5	6	7
36. It would be easy to pass up the chance to use cocaine.	1	2	3	4	5	6	7
37. I am going to use cocaine as soon as possible.	1	2	3	4	5	6	7
38. I have no desire for cocaine right now.	1	2	3	4	5	6	7
39. I could not stop myself from using cocaine if I had some here now.	1	2	3	4	5	6	7
40. Using "coke" right now would make me feel less tired.	1	2	3	4	5	6	7
41. Using cocaine would not be very satisfying right now.	1	2	3	4	5	6	7
42. If I tried a little "coke" now, I would not be able to stop using more of it.	1	2	3	4	5	6	7
43. I would not feel less anxious if I used "coke".	1	2	3	4	5	6	7
44. I am not missing using cocaine now.	1	2	3	4	5	6	7
45. If I had some "coke" with me right now, I probably would not use it.	1	2	3	4	5	6	7

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Form 28 - CLINICAL GLOBAL IMPRESSION-SELF

Cocaine Global Severity

At this time, how would you rate yourself overall for cocaine use and cocaine related problems?

- No problems
- Borderline problems
- Mild problems
- Moderate problems
- Marked problems
- Severe symptoms
- Most extreme problems possible

Global Improvement of Cocaine Dependence

How would you rate yourself for changes in cocaine use and cocaine related problems since the beginning of this study?

- Not assessed, first rating
- Very much improved
- Much improved
- Minimally improved
- No change
- Minimally worse
- Much worse
- Very much worse

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Circle One: Screening/Baseline Treatment Follow Up Week _____ Visit _____

Form 29 - CLINICAL GLOBAL IMPRESSION--OBSERVER

Current Severity

Please rate the subject's current severity in the eight specific problem areas below.

	<u>None, Least Severe</u>						<u>Most Severe</u>
Reported Cocaine Use: (frequency and amount of cocaine used)	1	2	3	4	5	6	7
Cocaine Seeking: (craving for cocaine, effort to stop, and drug seeking behavior)	1	2	3	4	5	6	7
Reported Use of Other Drugs: (frequency and amount of non-cocaine drug/alcohol use)	1	2	3	4	5	6	7
Observable Psychiatric Symptoms: (orientation, memory, comprehension, disorganized thinking, rapid/retarded speech, agitation, grooming, hostility, irritability, affective disturbance)	1	2	3	4	5	6	7
Reported Psychiatric Symptoms: (mood disturbance, depression, anxiety, inner restlessness, covert anger, somatic symptoms, energy level, motivation, sleep, appetite, libido, anhedonia)	1	2	3	4	5	6	7
Physical/Medical Problems: (those that have emerged or gotten worse after drug use)	1	2	3	4	5	6	7
Maladaptive Coping in the Family/Social area: (movement away from healthy relationships)	1	2	3	4	5	6	7
Maladaptive Coping in Other areas: (e.g., employment, legal, housing, etc. movement away from problem solving in those areas)	1	2	3	4	5	6	7

Global Severity of Cocaine Dependence

Considering your total clinical experience with the cocaine dependent population, how severe are this subject's cocaine dependence symptoms at this time?

- Normal, no symptoms
- Borderline symptoms
- Mild symptoms
- Moderate symptoms
- Marked symptoms
- Severe symptoms
- Most extreme symptoms possible

Global Improvement of Cocaine Dependence

Rate the total improvement in the participant's cocaine dependence symptoms whether or not, in your judgment, it is due entirely to drug treatment. Compared to the subject's admission to the project, how much has the subject changed?

- Not assessed, first rating
- Very much improved
- Much improved
- Minimally improved
- No change
- Minimally worse
- Much worse
- Very much worse

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Form 30 - COCAINE SELECTIVE SEVERITY ASSESSMENT

All questions except 4 and 5 are assessed by properly trained personnel. The subject is asked about each of the items in lay language and the response is recorded on a scale of 0-7 with 0 being normal or no symptoms. For question 4 and 5, the subject is asked to mark the appropriate place on the line (on page 2) that describes each of the questions. The rater then transcribes that as the response to those questions.

Date of last cocaine use: _____ / _____ / _____
(mm/dd/yyyy)

1. Hyperphagia _____

- 0 = normal appetite
- 3-4 = eats a lot more than usual
- 7 = eats more than twice usual amount of food

2. Hypophagia _____

- 0 = normal appetite
- 3-4 = eats less than half of normal amount of food
- 7 = no appetite at all

3. Carbohydrate Craving _____

- 0 = no craving
- 3-4 = strong craving for sweets, cakes, and cookies half the time
- 7 = strong craving for sweets, cakes, and cookies all the time

4. Cocaine Craving Intensity _____

Please use subject intensity rating from pg. 3 of this form.

5. Cocaine Craving Frequency _____

Please use subject frequency rating from pg. 3 of this form.

6. Bradycardia _____

Please use scale below.

	0	1	2	3	4	5	6	7
Apical Pulse (BPM)	>64	64-63	62-61	60-59	58-57	56-55	54-53	<53

7. Insomnia _____

- 0 = normal amount of sleep
- 3-4 = half of normal amount of sleep
- 7 = no sleep at all

8. Hypersomnia _____

- 0 = normal amount of sleep
- 3-4 = could sleep or does sleep half the day
- 7 = sleep or could sleep all the time

9. Anxiety _____

- 0 = usually does not feel anxious
- 3-4 = feels anxious half the time
- 7 = feels anxious all the time

10. Energy Level _____

0 = feels alert and has usual amount of energy
3-4 = feels tired half the time
7 = feels tired all the time

11. Activity Level _____

0 = no change in usual activities
3-4 = participates in half of usual activities
7 = no participation in usual activities

12. Tension _____

0-1 = rarely feel tense
3-4 = feels tense half the time
7 = feels tense most or all the time

13. Attention _____

0 = able to concentrate on reading, conversation, tasks, and make plans without difficulty
3-4 = has difficulty with the above half the time
7 = has difficulty with the above all the time

14. Paranoid Ideation _____

0 = no evidence of paranoid thoughts
3-4 = unable to trust anyone
5 = feels people are out to get him/her
7 = feels a specific person/group is plotting against him/her

15. Anhedonia _____

0 = ability to enjoy themselves remains unchanged
3-4 = able to enjoy themselves half of the time
7 = unable to enjoy themselves at all

16. Depression _____

0 = no feelings related to sadness or depression
3-4 = feels sad or depressed half the time
7 = feels depressed all of the time

17. Suicidality _____

0 = does not think about being dead
3-4 = feels like life is not worth living
7 = feels like actually ending life

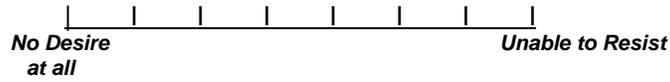
18. Irritability _____

0 = feels that most things are not irritating
3-4 = feels that many things are irritating
7 = feels that mostly everything is irritating and upsetting

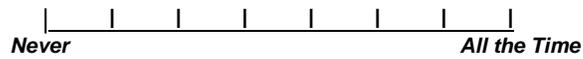
CSSA VISUAL ANALOG SCALE

Please do no mark on upright lines.

Please rate the highest intensity of the desire for cocaine you have felt in the last 24 hours:



Please identify on the line below, how often you have felt the urge to use cocaine in the last 24 hours:



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Form 31 - STATE OF FEELINGS QUESTIONNAIRE

Please take a moment to focus on the feelings or states listed below. Rate your level (or intensity) of each of the feelings during the past 24 hours by filling in the appropriate bubble.

Feeling or state

1. Anxiety

None at All Slight Moderate Considerable Extreme

2. Depression

None at All Slight Moderate Considerable Extreme

3. Restlessness

None at All Slight Moderate Considerable Extreme

4. Anger

None at All Slight Moderate Considerable Extreme

5. Irritability

None at All Slight Moderate Considerable Extreme

6. Frustration

None at All Slight Moderate Considerable Extreme

7. Impatience

None at All Slight Moderate Considerable Extreme

8. Difficulty Concentrating

None at All Slight Moderate Considerable Extreme

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Subject ID # _____

Subject Initials: _____

Date: ____ / ____ / _____

Circle One: Screening/Baseline Treatment Follow Up

Week _____ Visit _____

Form 33 - TREATMENT COMPLIANCE: MEDICATION

Date tablets dispensed _____ / _____ / _____
(mm/dd/yyyy)

Number of tablets dispensed _____

Date unused tablets returned _____ / _____ / _____
(mm/dd/yyyy)

Number of tablets returned _____

Number of tablets reported lost by subject _____

Number of tablets taken:	<u>Date</u> (mm/dd/yyyy)	<u>AM</u>	<u>PM</u>
Monday	____ / ____ / _____	____	____
Tuesday	____ / ____ / _____	____	____
Wednesday	____ / ____ / _____	____	____
Thursday	____ / ____ / _____	____	____
Friday	____ / ____ / _____	____	____
Saturday	____ / ____ / _____	____	____
Sunday	____ / ____ / _____	____	____

Comments:

Completed by (Initials): _____

Date completed: ____ / ____ / _____

Site ID _____

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Subject ID # _____

Subject Initials: ____

Date: ____ / ____ / _____

Circle One: Screening/Baseline Treatment Follow Up

Week ____ Visit ____

Form 34 - TREATMENT COMPLIANCE—PSYCHOTHERAPY

Did subject receive standardized, manual-guided individual psychotherapy this week?

Yes No Unknown

If yes, length of psychotherapy session ____ minutes

Did subject require emergency crisis management sessions this week?

Yes No

If yes, how many? _____

Additional comments:

Completed by (Initials): _____

Date completed: ____ / ____ / _____

Site ID _____

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Subject ID # _____

Subject Initials: ____

Date: ____ / ____ / _____

Circle One: Screening/Baseline Treatment Follow Up

Week ____ Visit ____

Form 37 - FOLLOW-UP

1. Has contact been made with the subject? Yes No

If yes, date of contact: ____ / ____ / ____
(mm/dd/yyyy)

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

	<u>Days Used</u>
____ Cocaine	_____
____ Methamphetamines	_____
____ Amphetamines	_____
____ Benzodiazepines	_____
____ Alcohol	_____
____ Marijuana	_____
____ Sedatives	_____
____ Nicotine	_____
____ Opiates	_____
____ Barbiturates	_____
____ None	_____
____ other _____	_____

3. Does the subject report currently receiving treatment for drug or alcohol abuse/dependence? Yes No

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

5. Have any adverse events occurred? Yes No
If 'Yes', an Adverse Event CRF form must be completed.

6. Have any serious adverse events occurred? Yes No
If 'Yes', a Serious Adverse Event report must be filed.

7. If contact has not been made with the subject, explain:

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

If yes, is the subject still alive? Yes No
If the subject has died, a Serious Adverse Event report must be filed.

9. Additional comments:

Completed by (Initials): _____

Date completed: ____ / ____ / _____

Site ID _____

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Subject ID # _____

Subject Initials: _ _ _

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Form 38 - COMMENT PAGE

Date of Comment: __ __ / __ __ / __ __ __ __ **This Comment Applies to** _____
(mm/dd/yyyy)

Please indicate Week#, Visit#, Visit Date, and CRF# (if applicable).

Comment: _____

Signature _____

Date of Comment: __ __ / __ __ / __ __ __ __ **This Comment Applies to** _____
(mm/dd/yyyy)

Please indicate Week#, Visit#, Visit Date, and CRF# (if applicable).

Comment: _____

Signature _____

Date of Comment: __ __ / __ __ / __ __ __ __ **This Comment Applies to** _____
(mm/dd/yyyy)

Please indicate Week#, Visit#, Visit Date, and CRF# (if applicable).

Comment: _____

Signature _____

Site ID _____

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Subject ID # _____

Subject Initials: ___ ___

Circle One: Screening/Baseline Treatment Follow Up

Week _____

Visit _____

Form 39 - END OF TRIAL

This form must be completed for every consented subject.

1. Date of last clinic visit

___ / ___ / ___
(mm/dd/yyyy)

2. Was the subject randomized?

Yes

No

If "No", indicate below reason(s) not randomized.

If "Yes", indicate below reason(s) subject is no longer in study.

Reason(s) subject's participation has ended:

Mark all that apply.

Subject completed study.

Subject failed to meet Inclusion/Exclusion criteria. **Entry Criteria form must indicate which criteria were/were not met.**

Subject declined to participate (during Screening).

Subject requested to withdraw from study

Subject reports drug not working

Other **Please specify below.**

Subject developed sensitivity to study drug or experienced intercurrent illness, unrelated medical condition, or clinically significant adverse events which, in the judgment of the investigator, prompted early termination.

If subject experienced adverse event(s), an Adverse Event Case Report Form(s) must be completed. Please specify which Adverse Event(s) is(are) involved.

Subject terminated for administrative reasons. **Include protocol non-compliance in this Category. Provide comments.**

Subject transferred to another treatment program (circle type)

Methadone

LAAM

Drug Free

Inpatient Detox or Treatment

Therapeutic Community

Other, specify _____

Subject became pregnant.

Subject did not return to study/clinic.

Subject moved from area.

Subject is in a controlled environment.

Subject died.

Other **Provide comments.**

4. Comments:

I hereby certify that I have thoroughly examined this case report form and all information is correct.

Principal Investigator: _____

Signature

Date: ___ / ___ / _____