Form 1 - INFORMED CONSENT

1. Did the subject sign the initial informed consent?
   O Yes
   O No

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

Completed by (initials): ___________        Date completed: __ __/ ____/ __ __ __

Completed by (initials): ___________        Date completed: __ __/ ____/ __ __ __
Form 2 - DEMOGRAPHICS

General

1. Gender: O Male O Female

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

Race/Ethnicity

3. Indicate which single major race/ethnicity applies:
   O White, not of Hispanic Origin
   O Hispanic or Latino
   O African American, Black, not of Hispanic Origin
   O Asian or Pacific Islander
   O American Indian or Alaska Native
   O Other, specify __________________________
   O 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)
       O Mexican, Mexican-American, or Chicano
       O Puerto Rican
       O Cuban
       O Other, specify __________________________
   Yes  No  Asian (check all that apply)
       O Asian Indian
       O Chinese
       O Filipino
       O Japanese
       O Korean
       O Vietnamese
       O Other, specify __________________________
   Yes  No  Native Hawaiian or Pacific Islander (check all that apply)
       O Native Hawaiian
       O Guamanian or Chamorro
       O Samoan
       O Other, specify __________________________
   Yes  No  Other, specify __________________________

O 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)

- O Full Time (35+ hrs/wk)
- O Part time (regular hrs)
- O Part time (irregular hrs, day work)
- O Student
- O Military Service
- O Retired/Disabled
- O Homemaker
- O Unemployed
- O In Controlled Environment

2. Past Employment Pattern (Past 3 Years)

- O Full Time (35+ hrs/wk)
- O Part time (regular hrs)
- O Part time (irregular hrs, day work)
- O Student
- O Military Service
- O Retired/Disabled
- O Homemaker
- O Unemployed
- O In Controlled Environment

**Marital Status**

- O Legally Married
- O Living with Partner/ Cohabiting
- O Widowed
- O Separated
- O Divorced
- O Never Married
### Drug/Alcohol Use

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

*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.

- O No problem
- O Heroin
- O Opiates/analgesics
- O Cocaine
- O Hallucinogens
- O Alcohol and Drug Addiction
- O Alcohol (any)
- O Methadone/LAAM prescribed
- O Methadone/LAAM illicit
- O Barbiturates
- O Sedatives/Hypnotics/Tranquilizers/Benzodiazepines
- O Amph./Methamph.
- O Cannabis
- O Inhalants
- O Nicotine
- O Polydrug addiction

Completed by (Initials):__________ Date completed: __ __ / __ __ / __ __ __ __
**Form 3 - SCID WORKSHEET**

**Axis I Diagnosis**

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

<table>
<thead>
<tr>
<th>Code</th>
<th>Diagnosis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Code</th>
<th>Diagnosis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Code</th>
<th>Diagnosis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Code</th>
<th>Diagnosis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

Completed by (Initials): ____________  Date completed: __ __ / __ __ / __ __ __ __
<table>
<thead>
<tr>
<th>Form 4 - MEDICAL HISTORY</th>
<th>A. Yes</th>
<th>B. Yes, Excludes</th>
<th>C. No History</th>
<th>D. Did Not Evaluate</th>
<th>E. Specify or Describe</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Allergies, drug (specify)</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td></td>
</tr>
<tr>
<td>2. Allergies, other (specify)</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td></td>
</tr>
<tr>
<td>3. Sensitivity to study medication or related compounds</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td></td>
</tr>
<tr>
<td>4. History of asthma</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td></td>
</tr>
<tr>
<td>5. HEENT Disorder</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td></td>
</tr>
<tr>
<td>6. Cardiovascular Disorder</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td></td>
</tr>
<tr>
<td>7. Renal Disorder</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td></td>
</tr>
<tr>
<td>8. Hepatic Disorder</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td></td>
</tr>
<tr>
<td>9. Pulmonary Disorder</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td></td>
</tr>
<tr>
<td>10. Gastrointestinal Disorder</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td></td>
</tr>
<tr>
<td>11. Musculoskeletal Disorder</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td></td>
</tr>
<tr>
<td>12. Neurologic Disorder:</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td></td>
</tr>
<tr>
<td>13. Psychiatric Disorder</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td></td>
</tr>
<tr>
<td>14. Dermatologic Disorder</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td></td>
</tr>
<tr>
<td>15. Metabolic Disorder</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td></td>
</tr>
<tr>
<td>16. Hematologic Disorder</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td></td>
</tr>
<tr>
<td>17. Endocrine Disorder</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td></td>
</tr>
<tr>
<td>18. Genitourinary Disorder</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td></td>
</tr>
<tr>
<td>19. Reproductive System</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td></td>
</tr>
<tr>
<td>20. Seizure</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td></td>
</tr>
<tr>
<td>21. Infectious Disease</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td></td>
</tr>
<tr>
<td>22. Other 1 (specify)</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td></td>
</tr>
<tr>
<td>23. Other 2 (specify)</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td></td>
</tr>
</tbody>
</table>
Surgical History

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

If ‘Yes’, list major surgeries below.

<table>
<thead>
<tr>
<th>Type of Surgery</th>
<th>Date of Surgery (mm/dd/yyyy)</th>
<th>Is Surgery Relevant to Study Participation?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Yes, Excludes Yes, Does Not Exclude No</td>
</tr>
<tr>
<td>25._____________</td>
<td>__ / __ / ______</td>
<td>O</td>
</tr>
<tr>
<td>26._____________</td>
<td>__ / __ / ______</td>
<td>O</td>
</tr>
<tr>
<td>27._____________</td>
<td>__ / __ / ______</td>
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</tr>
<tr>
<td>28._____________</td>
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</tr>
<tr>
<td>29._____________</td>
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<tr>
<td>30._____________</td>
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</tr>
<tr>
<td>31._____________</td>
<td>__ / __ / ______</td>
<td>O</td>
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</tbody>
</table>

Tobacco History

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

O Yes O 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: __ __ / __ __ / __ __ __ __
Has the subject taken any medications in the PAST 30 DAYS? ___ Yes ___ No

(If yes, please complete table)

<table>
<thead>
<tr>
<th>Medication</th>
<th>Unit of Medication</th>
<th>Frequency</th>
<th>Route of Administration</th>
<th>Start Date</th>
<th>Stop Date</th>
<th>Continuing? (check if yes)</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
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</tbody>
</table>

Physician Signature: ________________________    Date completed: ____ / ____ / ______
**Form 6 - INFECTIOUS DISEASE ASSESSMENT**

### Hepatitis

<table>
<thead>
<tr>
<th>Test</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hepatitis B surface antigen</td>
<td>O Negative, Positive, significant, Indeterminate, Not assessed</td>
</tr>
<tr>
<td>Hepatitis B surface antibody</td>
<td>O Negative, Positive, significant, Indeterminate, Not assessed</td>
</tr>
<tr>
<td>Hepatitis B core antibody</td>
<td>O Negative, Positive, significant, Indeterminate, Not assessed</td>
</tr>
<tr>
<td>Hepatitis C virus antibody</td>
<td>O Negative, Positive, significant, Indeterminate, Not assessed</td>
</tr>
</tbody>
</table>

Provide comments for any positive value.

### Purified Protein Derivative (PPD) Test

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is the subject abusing any drugs intravenously?</td>
<td>O Yes, O No</td>
</tr>
<tr>
<td>Has the subject ever had a positive PPD test?</td>
<td>O Yes, O No</td>
</tr>
</tbody>
</table>

**If “Yes”, a PPD test is required. If “No”, skip to the HIV Section of this form.**

<table>
<thead>
<tr>
<th>PPD test administered:</th>
<th>Date</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date</td>
<td><strong><strong>/</strong>__<strong>/</strong></strong>__</td>
<td>___ : ___</td>
</tr>
<tr>
<td>Time (24-hour clock)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**If “Yes”, do not perform PPD and leave the rest of the PPD section blank, however a chest X-ray is required.**

<table>
<thead>
<tr>
<th>PPD test read:</th>
<th>Date</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date</td>
<td><strong><strong>/</strong>__<strong>/</strong></strong>__</td>
<td>___ : ___</td>
</tr>
<tr>
<td>Time (24-hour clock)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PPD test result:</th>
<th>O Negative, O Positive, O Unknown, O Test not done</th>
</tr>
</thead>
</table>

**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

Was a chest X-ray performed?  O Yes  O No

Date chest x-ray performed:   ___/___/______

(mmm/dd/yyyy)

Results of chest X-ray:
O Normal
O Abnormal, not significant
O Abnormal, significant
O Indeterminate
O Not assessed

Provide comments for any abnormal finding:

HIV

Was a consent to perform an HIV test signed by the subject?  O Yes  O No

Was an HIV test performed?  O Yes  O No

What was the result of the HIV test?  O Positive     O Negative     O Indeterminate

Physician Signature:___________________  Date: ___/___/______
Form 7 - SYPHILIS TEST

Rapid plasma reagin (RPR) test result:  
- O negative
- O positive
- O indeterminant
- O 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:  
- O negative
- O positive
- O indeterminant
- O 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?
- O Yes
- O 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: __ __ / __ __ / __ __ __ __
**Form 8 - PHYSICAL EXAM**

1. Height ___ ___ . ___ inches
2. Weight ___ ___ ___ pounds

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

Physician Signature:________________________ Date: _ _ / _ _ / _ _ _ _
Form 9 - VITAL SIGNS

First Study Visit of Week

O Vital signs not assessed at this visit

Date __ __ / __ __ / __ __ __ __ 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

O Vital signs not assessed at this visit

Date __ __ / __ __ / __ __ __ __ 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

O Vital signs not assessed at this visit

Date __ __ / __ __ / __ __ __ __ 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):__________
Form 10 - HEMATOLOGY

<table>
<thead>
<tr>
<th>Value</th>
<th>Normal</th>
<th>Abnormal*</th>
<th>Abnormal*</th>
<th>Not Significant</th>
<th>Done</th>
<th>Comments (required for abnormal values)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Hemoglobin</td>
<td>_     · _ g/dL</td>
<td>___</td>
<td>___</td>
<td>___</td>
<td>___</td>
<td>______________________________</td>
</tr>
<tr>
<td>2. Hematocrit</td>
<td>_ _ · _ %</td>
<td>___</td>
<td>___</td>
<td>___</td>
<td>___</td>
<td>______________________________</td>
</tr>
<tr>
<td>3. RBC</td>
<td>_ _ · _ M/μL</td>
<td>___</td>
<td>___</td>
<td>___</td>
<td>___</td>
<td>______________________________</td>
</tr>
<tr>
<td>4. Platelet count</td>
<td>_ _ K/μL</td>
<td>___</td>
<td>___</td>
<td>___</td>
<td>___</td>
<td>______________________________</td>
</tr>
<tr>
<td>5. WBC</td>
<td>_ _ K/μL</td>
<td>___</td>
<td>___</td>
<td>___</td>
<td>___</td>
<td>______________________________</td>
</tr>
<tr>
<td>6. Neutrophils</td>
<td>_ _ · _ %</td>
<td>___</td>
<td>___</td>
<td>___</td>
<td>___</td>
<td>______________________________</td>
</tr>
<tr>
<td>7. Lymphocytes</td>
<td>_ _ · _ %</td>
<td>___</td>
<td>___</td>
<td>___</td>
<td>___</td>
<td>______________________________</td>
</tr>
<tr>
<td>8. Monocytes</td>
<td>_ _ · _ %</td>
<td>___</td>
<td>___</td>
<td>___</td>
<td>___</td>
<td>______________________________</td>
</tr>
<tr>
<td>9. Eosinophils</td>
<td>_ _ · _ %</td>
<td>___</td>
<td>___</td>
<td>___</td>
<td>___</td>
<td>______________________________</td>
</tr>
<tr>
<td>10. Basophils</td>
<td>_ _ · _ %</td>
<td>___</td>
<td>___</td>
<td>___</td>
<td>___</td>
<td>______________________________</td>
</tr>
</tbody>
</table>

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

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

\[
\text{million/μL} = \text{mil/cumm} = \text{mill/mcl} = M/cmm = x10^6/\text{cumm} \\
x 10^3/\text{μL} = \text{thou/cumm} = \text{thou/mcl} = K/cmm = 1000/\text{μL} = x10^3/\text{cumm}
\]
## Form 11 - BLOOD CHEMISTRY

<table>
<thead>
<tr>
<th></th>
<th>Value</th>
<th>Normal</th>
<th>Abnormal*</th>
<th>Abnormal*</th>
<th>Not Done</th>
<th>Comments (Required for Abnormal values)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Sodium</td>
<td>_ _ _  mmol/L</td>
<td>___ ___ ___ ___</td>
<td>___ ___ ___ ___</td>
<td>___ ___ ___ ___</td>
<td>___________________</td>
</tr>
<tr>
<td>2</td>
<td>Potassium</td>
<td>_ _ _ mmol/L</td>
<td>___ ___ ___ ___</td>
<td>___ ___ ___ ___</td>
<td>___ ___ ___ ___</td>
<td>___________________</td>
</tr>
<tr>
<td>3</td>
<td>Chloride</td>
<td>_ _ _ mmol/L</td>
<td>___ ___ ___ ___</td>
<td>___ ___ ___ ___</td>
<td>___ ___ ___ ___</td>
<td>___________________</td>
</tr>
<tr>
<td>4</td>
<td>CO2</td>
<td>_ _ _ mmol/L</td>
<td>___ ___ ___ ___</td>
<td>___ ___ ___ ___</td>
<td>___ ___ ___ ___</td>
<td>___________________</td>
</tr>
<tr>
<td>5</td>
<td>Glucose</td>
<td>_ _ _ mg/dL</td>
<td>___ ___ ___ ___</td>
<td>___ ___ ___ ___</td>
<td>___ ___ ___ ___</td>
<td>___________________</td>
</tr>
<tr>
<td>6</td>
<td>Creatinine</td>
<td>_ _ _ mg/dL</td>
<td>___ ___ ___ ___</td>
<td>___ ___ ___ ___</td>
<td>___ ___ ___ ___</td>
<td>___________________</td>
</tr>
<tr>
<td>7</td>
<td>Albumin</td>
<td>_ _ _ g/dL</td>
<td>___ ___ ___ ___</td>
<td>___ ___ ___ ___</td>
<td>___ ___ ___ ___</td>
<td>___________________</td>
</tr>
<tr>
<td>8</td>
<td>Total protein</td>
<td>_ _ _ g/dL</td>
<td>___ ___ ___ ___</td>
<td>___ ___ ___ ___</td>
<td>___ ___ ___ ___</td>
<td>___________________</td>
</tr>
<tr>
<td>9</td>
<td>SGOT/AST</td>
<td>_ _ _ U/L</td>
<td>___ ___ ___ ___</td>
<td>___ ___ ___ ___</td>
<td>___ ___ ___ ___</td>
<td>___________________</td>
</tr>
<tr>
<td>10</td>
<td>SGPT/ALT</td>
<td>_ _ _ U/L</td>
<td>___ ___ ___ ___</td>
<td>___ ___ ___ ___</td>
<td>___ ___ ___ ___</td>
<td>___________________</td>
</tr>
<tr>
<td>11</td>
<td>GGT</td>
<td>_ _ _ U/L</td>
<td>___ ___ ___ ___</td>
<td>___ ___ ___ ___</td>
<td>___ ___ ___ ___</td>
<td>___________________</td>
</tr>
<tr>
<td>12</td>
<td>Bilirubin</td>
<td>_ _ _ mg/dL</td>
<td>___ ___ ___ ___</td>
<td>___ ___ ___ ___</td>
<td>___ ___ ___ ___</td>
<td>___________________</td>
</tr>
<tr>
<td>13</td>
<td>BUN</td>
<td>_ _ _ mg/dL</td>
<td>___ ___ ___ ___</td>
<td>___ ___ ___ ___</td>
<td>___ ___ ___ ___</td>
<td>___________________</td>
</tr>
</tbody>
</table>

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

* “Abnormal” is any value outside the normal laboratory range.

\[ \text{mmol/L} = \text{mEq/L} \]

Physician Signature:______________________ Date: __ __ / __ __ / __ __ __ __
### Form 12 - URINALYSIS

<table>
<thead>
<tr>
<th>Value</th>
<th>Normal Abnormal* Abnormal* Not Significant Done</th>
<th>Comments (required for abnormal values)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Specific gravity</td>
<td>_ _ _ _</td>
<td></td>
</tr>
<tr>
<td>2. pH</td>
<td>_ _ _ _</td>
<td></td>
</tr>
<tr>
<td>3. Glucose</td>
<td>_ _ _ _</td>
<td></td>
</tr>
<tr>
<td>4. Protein</td>
<td>_ _ _ _</td>
<td></td>
</tr>
<tr>
<td>5. Ketones</td>
<td>_ _ _ _</td>
<td></td>
</tr>
<tr>
<td>6. Occult Blood</td>
<td>_ _ _ _</td>
<td></td>
</tr>
<tr>
<td>7. WBC</td>
<td>_ _ _ _</td>
<td></td>
</tr>
<tr>
<td>8. RBC</td>
<td>_ _ _ _</td>
<td></td>
</tr>
<tr>
<td>9. Epithelial Cells</td>
<td>_ _ _ _</td>
<td></td>
</tr>
</tbody>
</table>

**“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)
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.

<table>
<thead>
<tr>
<th>Abnormality</th>
<th>Abnormal</th>
<th>Significant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increased QRS voltage</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>QTc prolongation</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Left atrial hypertrophy</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Right atrial hypertrophy</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Left ventricular hypertrophy</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Right ventricular hypertrophy</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Acute infarction</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Subacute infarction</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Old infarction</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Myocardial ischemia</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Digitalis effect</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Symmetrical T-wave inversions</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Poor R-wave progression</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Other nonspecific ST/T</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Sinus tachycardia</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Sinus bradycardia</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Supraventricular premature beat</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Ventricular premature beat</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Supraventricular tachycardia</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Ventricular premature beat</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Supraventricular tachycardia</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Ventricular tachycardia</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Atrial flutter</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Other rhythm abnormalities</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Implanted pacemaker</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>1st degree A-V block</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>2nd degree A-V block</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>3rd degree A-V block</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>LBB block</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>RBB block</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Pre-excitation syndrome</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Other intraventricular condition</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Other, specify _________________________</td>
<td>O</td>
<td>O</td>
</tr>
</tbody>
</table>

C. Ventricular rate (bpm)      ________
D. PR (ms)                    ________
E. QRS (ms)                   ________
F. QT (ms)                    ________

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

Physician Signature: _________________________  Date: ___ / ___ / ___ ___
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?  O Yes  O No

What method of birth control is the participant currently using?

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

If ‘Yes’, circle one.

Was a pregnancy test performed?  O Yes  O No

If yes, what was the result?  O Positive  O Negative  O Unknown

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

If no, specify reason.

Is the subject lactating?  O Yes  O No

Comments:

Completed by (Initials):___________  Date completed: __ __ / __ __ / __ __ __ __
**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-wrangling, 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
   O 0 = None
   O 1 = Heaviness in limbs, back or head. Backaches, headache, muscle aches. Loss of energy and fatigability.
   O 2 = Any clear-cut symptom rates 2.

14. Genital Symptoms
   *(such as loss of libido and menstrual disturbances)*
   O 0 = Absent
   O 1 = Mild
   O 2 = Severe

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

16. Loss of Weight
   O 0 = No weight loss
   O 1 = Probable weight loss associated with present illness.
   O 2 = Definite weight loss (according to subject)

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

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

19. Depersonalization and Derealization
   *(symptoms such as feelings of unreality and nihilistic ideas)*
   O 0 = Absent
   O 1 = Mild
   O 2 = Moderate
   O 3 = Severe
   O 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-deprecation (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: __ __ / __ __ / __ __ __
### Form 16 - ADVERSE EVENTS

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

<table>
<thead>
<tr>
<th>A</th>
<th>Adverse Event</th>
<th>B</th>
<th>Start Date</th>
<th>C</th>
<th>Stop Date</th>
<th>D</th>
<th>Severity</th>
<th>E</th>
<th>Related</th>
<th>F</th>
<th>Action</th>
<th>G</th>
<th>Other Act.</th>
<th>H</th>
<th>Outcome</th>
<th>I</th>
<th>Serious?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

Physician Signature: ________________________________  __ / __ / ___
Form 17 - SERIOUS ADVERSE EVENTS

Demographic Information

Date of Consent: __ / __ / __ (mm/dd/yyyy)  Gender: O Male  O Female

Date of Birth: __ / __ / __ (mm/dd/yyyy)  Height: __ . __ in  Weight: __ __ __ lb

Race:
O White, not of Hispanic Origin
O American Indian or Alaska Native
O Male or Latino
O Other, specify_____________________
O African American, Black, not of Hispanic Origin
O Unknown
O Asian or Pacific Islander

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: O Mild  O Moderate  O Severe

Was the SAE related to the investigational agent?
O Definitely  O Probably  O Possibly  O Remotely  O Definitely Not  O Unknown

Action Taken regarding investigational agent:
O None  O Discontinued temporarily  O Increased dose
O Discontinued permanently  O Reduced dose  O Delayed dose

Other actions taken:
O None  O Remedial therapy – pharmacologic  O Remedial therapy – nonpharmacologic
O 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:
- allergies, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.

______________________________________________________________________________________

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

Investigational Agent Administration

Is the investigational agent information known?  O Yes  O No

If yes, investigational agent name _______________________ Lot number: _________________

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

Quantity: _____ Units: ____ Frequency: ____ Route of Administration: _____

Codes listed below.

<table>
<thead>
<tr>
<th>Unit of Medication</th>
<th>Frequency</th>
<th>Route of Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAP = capsule</td>
<td>ONCE = one dose</td>
<td>PO = oral</td>
</tr>
<tr>
<td>g = gram</td>
<td>QD = once daily</td>
<td>SL = sublingual</td>
</tr>
<tr>
<td>GR = grain</td>
<td>BID = twice daily</td>
<td>AUR = auricular</td>
</tr>
<tr>
<td>GTT = drop</td>
<td>TID = 3 times/day</td>
<td>NAS = nasal</td>
</tr>
<tr>
<td>ug = microgram</td>
<td>QID = 4 times/day</td>
<td>IM = intramuscular</td>
</tr>
<tr>
<td>uL = microliter</td>
<td>QOD = every other day</td>
<td>IV = intravenous</td>
</tr>
<tr>
<td>mg = milligram</td>
<td>PRN = as needed</td>
<td>REC = rectal</td>
</tr>
<tr>
<td>mL = milliliter</td>
<td>QID = every other day</td>
<td>UNK = unknown</td>
</tr>
<tr>
<td>OTH = other (specify)</td>
<td>OTH = other (specify)</td>
<td>SQ = subcutaneous</td>
</tr>
</tbody>
</table>

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

Comments: ____________________________________________________________________

Physician Signature: _______________________ Date signed: __/__/____
Form 18 - CONCOMITANT MEDICATIONS

Has the subject taken any concomitant medications during this study?  ___ Yes  ___ No  
(If yes, please complete table)

<table>
<thead>
<tr>
<th>Medication</th>
<th>Dose</th>
<th>Units</th>
<th>Other</th>
<th>Frequency</th>
<th>Other</th>
<th>Route of Administration</th>
<th>Start Date</th>
<th>Stop Date</th>
<th>Continuing? (check if yes)</th>
<th>Indication</th>
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</table>

Physician Signature: ________________________________  __ __ / __ __ / __ __
Form 19 - ENTRY CRITERIA

**Inclusion Criteria**

1. Subject is at least 18 years-of-age.
2. Subject has a DSM-IV diagnosis of cocaine dependence as determined by SCID.
3. Subject is seeking treatment for cocaine dependence.
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.
5. Subject has the ability to understand, and having understood, has provided written informed consent.
6. If female, the subject agrees to use one of the following methods of birth control:
   - oral contraceptives
   - barrier (diaphragm or condom)
   - intrauterine contraceptive system
   - levonorgestrel implant
   - medroxyprogesterone acetate contraceptive injection
   - surgical sterilization
   - 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**

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.
2. Subject is mandated by the court to obtain treatment for cocaine-dependence.
3. Subject has been enrolled in an opiate-substitution program (methadone, LAAM, buprenorphine) within 2 months of screening.
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.
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.

6. Subject has had electroconvulsive therapy within the past 3 months preceding screening.

7. Subject has a current suicidal ideation or plan (within the past 30 days) as assessed by the SCID.

8. Subject is pregnant or lactating.

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.

10. Subject has clinically significant abnormal laboratory values, per protocol (Appendix I).

11. Subject has AIDS according to the current CDC criteria for AIDS MMWR 1999; 48 (No.RR-13:29-31).

12. Subject has active syphilis that has not been treated or refuses treatment for syphilis (see note below).

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).

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.
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).

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.

17. Subject has participated in any experimental study within 2 months preceding screening.

18. Subject has a known or suspected hypersensitivity to tiagabine.

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 (FTP-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.

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.

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: __ __ / __ __ / __ __ __ __
Form 20 - RANDOMIZATION

Personal Information

1. At the time the informed consent to screen (Part I) was signed, indicate the number of self-reported days of cocaine use in the past 30 days. __ __

2. Gender O Male O Female

Screening

3. Is the subject eligible for randomization? O Yes O No

   If “Yes”, call Stephanie Chang at BRCI 734-426-2820 ext. 29 or, if she is not available, Joan Shen at ext. 44.

Randomization

4. Date of randomization __ __ / __ __ / __ __ __ __ (mm/dd/yyyy)

5. Treatment kit number assigned __ __ __ __

It is assumed that the first dose will be received on the same day as randomization. Therefore, Day of Randomization = Study Day 1.

Completed by (Initials):__________ Date completed: __ __ / __ __ / __ __ __ __
Form 21 - ADDICTION SEVERITY INDEX: LITE

General Information

G4. Date of admission:  ____ / ____ / _____ (mm/dd/yyyy)

G8. Class:  O Intake  O Follow-up

G9. Contact code:  O In person  O Telephone  O Mail

G10. Gender:  O Male  O Female

G12. Special:  O Terminated  O Refused  O 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?  O White (not Hispanic)  O Hispanic - Mexican
O Black (not Hispanic)  O Hispanic – Puerto Rican
O American Indian  O Hispanic - Cuban
O Alaskan Native  O Hispanic - Other
O Asian/Pacific Islander

G18. Do you have a religious preference?  O Protestant  O Islamic
O Catholic  O Other
O Jewish  O None

G19. Have you been in a controlled environment in the last 30 days?  O No  O Medical treatment
O Jail  O Psychiatric treatment
O Alcohol/drug treatment  O 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?  O Yes  O 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?  O Yes  O No

If “Yes”, please specify in ‘Comments’.
M5  Do you receive a pension for a physical disability? (Exclude psychiatric disabilities.)

O Yes  O 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?

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

M8  How important to you now is treatment for these medical problems?

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

Confidence Ratings

Is the above information significantly distorted by:

M10  Subject's misrepresentation?  O Yes  O No

M11  Subject's inability to understand?  O Yes  O 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?  O Yes  O No

E5  Do you have an automobile available for use?  O Yes  O 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:  O 1  O 2  O 3  O 4  O 5  O 6  O 7  O 8  O 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, draftsperson, timekeeper, secretary
5 = Skilled manua – 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?  O Yes  O No
E10. Usual employment pattern, past 3 years.
- O 1 = full time (35+ hrs/week)
- O 2 = part time (regular hours)
- O 3 = part time (irregular hours)
- O 4 = student
- O 5 = military service
- O 6 = retired/disabled
- O 7 = unemployed
- O 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?
- O 0 = Not at all
- O 1 = Slightly
- O 2 = Moderately
- O 3 = Considerably
- O 4 = Extremely

E21. How important to you now is counseling for these employment problems?
- O 0 = Not at all
- O 1 = Slightly
- O 2 = Moderately
- O 3 = Considerably
- O 4 = Extremely

Confidence Ratings

Is the above information significantly distorted by:

E23. Subject’s misrepresentation? O Yes O No
E24. Subject’s inability to understand? O Yes O No

Comments: ________________________________________________________________
__________________________________________________________________________
### Drug/Alcohol Abuse

<table>
<thead>
<tr>
<th>Substance</th>
<th>Days in Past 30 Days</th>
<th>Lifetime Years</th>
<th>Route of Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcohol – any use at all</td>
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<tr>
<td>Alcohol – to intoxication</td>
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<tr>
<td>Heroin</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Methadone</td>
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<tr>
<td>Other opiates/analgesics</td>
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<td></td>
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<tr>
<td>Barbiturates</td>
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<tr>
<td>Other sedatives/hypnotics/tranquilizers</td>
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<td></td>
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<tr>
<td>Cocaine</td>
<td></td>
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<td></td>
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<tr>
<td>Amphetamines</td>
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<td></td>
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<tr>
<td>Cannabis</td>
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<tr>
<td>Hallucinogens</td>
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<td></td>
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<tr>
<td>Inhalants</td>
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<tr>
<td>More than one substance per day (including alcohol)</td>
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</tr>
</tbody>
</table>

How many times have you had alcohol DTs?  

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

- Alcohol abuse:  
- Drug abuse:  

How many times of these were detox only?

- Alcohol:  
- 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:

- Alcohol: $__________  
- Drugs: $__________

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  ____  ____

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:

D28  Alcohol problems
O 0 = Not at all  O 1 = Slightly  O 2 = Moderately  O 3 = Considerably  O 4 = Extremely
D29  Drug problems
O 0 = Not at all  O 1 = Slightly  O 2 = Moderately  O 3 = Considerably  O 4 = Extremely

How important to you now is treatment for these:

D30  Alcohol problems
O 0 = Not at all  O 1 = Slightly  O 2 = Moderately  O 3 = Considerably  O 4 = Extremely
D31  Drug problems
O 0 = Not at all  O 1 = Slightly  O 2 = Moderately  O 3 = Considerably  O 4 = Extremely

Confidence Ratings

Is the above information significantly distorted by:

D34  Subject’s misrepresentation?  O Yes  O No
D35  Subject’s inability to understand?  O Yes  O No

Comments: ________________________________________________________________

Legal Status

L1. Was this admission prompted or suggested by the criminal justice system (judge, probation/parole officer, etc.)?  O Yes  O No
L2  Are you on probation or parole?  O Yes  O No

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

L3*  Shoplifting/vandalism  ____
L4*  Parole/probation violation(s)  ____
L5*  Drug charge(s)  ____
L6*  Forgery  ____
L7*  Weapons offense  ____
L8*  Burglary, larceny, breaking and entering  ____
L9*  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? O Yes O 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?
   O 0 = Not at all   O 1 = Slightly   O 2 = Moderately   O 3 = Considerably   O 4 = Extremely

L29 How important to you now is counseling or referral for these legal problems?
   O 0 = Not at all   O 1 = Slightly   O 2 = Moderately   O 3 = Considerably   O 4 = Extremely

Confidence Ratings

Is the above information significantly distorted by:

L31 Subject’s misrepresentation? O Yes O No

L32 Subject’s inability to understand? O Yes O No

Comments: ________________________________________________________________
### Family/Social Relationships

**F1** Marital status  
- O Married  
- O Remarried  
- O Widowed  
- O Separated  
- O Divorced  
- O Never Married

**F3** Are you satisfied with this situation?  
- O Yes  
- O No  
- O Indifferent

**F4** Usual living arrangements (past three years)  
- O 1 = with sexual partner and children  
- O 2 = with sexual partner alone  
- O 3 = with children alone  
- O 4 = with parents  
- O 5 = with family  
- O 6 = with friends  
- O 7 = alone  
- O 8 = controlled environment  
- O 9 = no stable arrangements

**F6** Are you satisfied with these living arrangements?  
- O Yes  
- O No  
- O Indifferent

Do you live with anyone who:

**F7** Has a current alcohol problem?  
- O Yes  
- O No

**F8** Uses non-prescribed drugs?  
- O Yes  
- O No

**F9** With whom do you spend most of your free time?  
- O Family  
- O Friends  
- O Alone

**F10** Are you satisfied with spending your free time this way?  
- O Yes  
- O No  
- O Indifferent

Have you had any significant periods in which you have experienced serious problems getting along with:

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<th>In the past 30 days</th>
<th>Lifetime</th>
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<td>Yes</td>
<td>No</td>
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</table>

**F18** Mother  
- O Yes  
- O No  
- O N/A

**F19** Father  
- O Yes  
- O No  
- O N/A

**F20** Siblings  
- O Yes  
- O No  
- O N/A

**F21** Sexual partner/spouse  
- O Yes  
- O No  
- O N/A

**F22** Children  
- O Yes  
- O No  
- O N/A

**F23** Other significant family  
- O Yes  
- O No  
- O N/A

Please specify if “Yes”:

**F24** Close friends  
- O Yes  
- O No  
- O N/A

**F25** Neighbors  
- O Yes  
- O No  
- O N/A

**F26** Co-workers  
- O Yes  
- O No  
- O N/A
Did anyone abuse you?

F28 Physically (caused you physical harm)
   In the past 30 days   O Yes  O No   Lifetime   O Yes  O No

F29 Sexually (forced sexual advances or sexual acts)
   In the past 30 days   O Yes  O No   Lifetime   O Yes  O No

How many days in the past 30 have you had serious conflicts?

F30 With your family:  __ __

F31 With other people excluding family:  __ __

For Questions F32-35 please ask the subject to use the subject rating scale.

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

F32 Family problems
   O 0 = Not at all  O 1 = Slightly  O 2 = Moderately  O 3 = Considerably  O 4 = Extremely

F33 Social problems
   O 0 = Not at all  O 1 = Slightly  O 2 = Moderately  O 3 = Considerably  O 4 = Extremely

How important to you now is treatment or counseling for these:

F34 Family problems
   O 0 = Not at all  O 1 = Slightly  O 2 = Moderately  O 3 = Considerably  O 4 = Extremely

F35 Social problems
   O 0 = Not at all  O 1 = Slightly  O 2 = Moderately  O 3 = Considerably  O 4 = Extremely

Confidence Ratings

Is the above information significantly distorted by:

F37 Subject’s misrepresentation?   O Yes  O No

F38 Subject’s inability to understand?   O Yes  O 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?   O Yes  O No
Have you had a significant period (that was not a direct result of drug/alcohol use) in which you have:

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<th>Question</th>
<th>In the past 30 days</th>
<th>Lifetime</th>
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<tr>
<td>P4</td>
<td>Experienced serious depression (sadness, hopelessness, loss of interest, difficulty with daily functioning)?</td>
<td>O Yes O No</td>
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<tr>
<td>P5</td>
<td>Experienced serious anxiety/tension (uptight, unreasonably worried, inability to feel relaxed)?</td>
<td>O Yes O No</td>
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<tr>
<td>P6</td>
<td>Experienced hallucinations (saw things or heard voices that were not there)?</td>
<td>O Yes O No</td>
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<tr>
<td>P7</td>
<td>Experienced trouble understanding, concentrating, or remembering?</td>
<td>O Yes O No</td>
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</table>

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

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<tr>
<th>Question</th>
<th>In the past 30 days</th>
<th>Lifetime</th>
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<tr>
<td>P8</td>
<td>Experienced trouble controlling violent behavior?</td>
<td>O Yes O No</td>
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<td>P9</td>
<td>Experienced serious thoughts of suicide?</td>
<td>O Yes O No</td>
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<tr>
<td>P10</td>
<td>Attempted suicide?</td>
<td>O Yes O No</td>
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<tr>
<td>P11</td>
<td>Been prescribed medication for any psychological or emotional problem?</td>
<td>O Yes O No</td>
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<tr>
<td>P12</td>
<td>How many days in the past 30 have you experienced these psychological or emotional problems?</td>
<td>___</td>
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</table>

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

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<th>Question</th>
<th>In the past 30 days</th>
<th>Rating</th>
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<tr>
<td>P13</td>
<td>How much have you been troubled or bothered by these psychological or emotional problems in the past 30 days?</td>
<td>O 0 = Not at all O 1 = Slightly O 2 = Moderately O 3 = Considerably O 4 = Extremely</td>
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<tr>
<td>P14</td>
<td>How important to you now is treatment for these psychological problems?</td>
<td>O 0 = Not at all O 1 = Slightly O 2 = Moderately O 3 = Considerably O 4 = Extremely</td>
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*Confidence Ratings*

Is the above information significantly distorted by:

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<th>Question</th>
<th>In the past 30 days</th>
<th>Rating</th>
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<tr>
<td>P22</td>
<td>Subject's misrepresentation?</td>
<td>O Yes O No</td>
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<tr>
<td>P23</td>
<td>Subject's inability to understand?</td>
<td>O Yes O No</td>
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</tbody>
</table>

Comments: ________________________________________________________________

Completed by (Initials):__________ Date completed: __ __ / __ __ / __ __ __
Form 22 - URINE BE SPECIMEN COLLECTION FORM

**First Study Visit of Week**

Date urine collected __ __ / __ __ / __ __ __ __ Urine not collected O

Was urine temperature within expected range? O Yes O No

*The temperature must be higher than 96.3 °F and lower than 100.5 °F*

Result (Recorded at Screening/Baseline Only):

O Cocaine Positive O Cocaine Negative O Not Recorded

Completed by (Initials):__________

**Second Study Visit of Week**

Date urine collected __ __ / __ __ / __ __ __ __ Urine not collected O

Was urine temperature within expected range? O Yes O No

*The temperature must be higher than 96.3 °F and lower than 100.5 °F*

Result (Recorded at Screening/Baseline Only):

O Cocaine Positive O Cocaine Negative O Not Recorded

Completed by (Initials):__________

**Third Study Visit of Week**

Date urine collected __ __ / __ __ / __ __ __ __ Urine not collected O

Was urine temperature within expected range? O Yes O No

*The temperature must be higher than 96.3 °F and lower than 100.5 °F*

Result (Recorded at Screening/Baseline Only):

O Cocaine Positive O Cocaine Negative O Not Recorded

Completed by (Initials):__________
## 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)

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

Completed by (Initials):__________       Date completed: ___/___/_____
Drug Use

1. How many times have you hit up (i.e. injected any drugs) in the last month?
   - O I haven’t hit up
   - O Once a week or less
   - O More than once a week but less than once a day
   - O Once a day
   - O 2–3 times a day
   - O More than three times a day

   *If you have not injected drugs in the last month, go to Question 7.*

2. How many times in the last month have you used a needle after someone else had already used it?
   - O No times
   - O One time
   - O Two times
   - O 3-5 times
   - O 6-10 times
   - O More than 10 times

3. How many different people have used a needle before you in the past month?
   - O None
   - O One person
   - O Two people
   - O 3-5 people
   - O 6-10 people
   - O More than 10 people

4. How many times in the last month has someone used a needle after you?
   - O No times
   - O One time
   - O Two times
   - O 3-5 times
   - O 6-10 times
   - O More than 10 times

5. How often, in the last month, have you cleaned needles before re-using them?
   - O I do not re-use
   - O Every time
   - O Often
   - O Sometimes
   - O Rarely
   - O Never

6. Before using needles again, how often in the past month did you use bleach to clean them?
   - O I do not re-use
   - O Every time
   - O Often
   - O Sometimes
   - O Rarely
   - O Never
Sexual Behavior

7. How many people, including clients, have you had sex with in the last month?
   - None
   - One
   - Two
   - 3-5 people
   - 6-10 people
   - More than 10 people
   
   *If you have not had sex in the last month, skip to Question 12.*

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 completed: _ _ / _ _ / _ _ _ _
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.)
   - Alcohol
   - Heroin or other Opiates (Morphine, etc.)
   - Marijuana
   - Nicotine
   - 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.)
   - Benzos (Valium, Xanax, etc.)
   - Nicotine
   - Alcohol
   - Heroin or other Opiates (Morphine, etc.)
   - 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 Completed: __ __ / __ __ / __ __ __
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.

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

Completed by (Initials):__________  
Date completed: __ __ / __ __ / ______
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

Completed by (Initials): __________ Date completed: __ __ / __ __ / __ __ __ __
Subject ID # __________ Subject Initials: __ __ __ Date: __ __ / __ __ / __ __ __ __

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.

<table>
<thead>
<tr>
<th>None, Least Severe</th>
<th>Most Severe</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Reported Cocaine Use:** (frequency and amount of cocaine used)

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
</tr>
</thead>
</table>

**Cocaine Seeking:** (craving for cocaine, effort to stop, and drug seeking behavior)

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
</tr>
</thead>
</table>

**Reported Use of Other Drugs:** (frequency and amount of non-cocaine drug/alcohol use)

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
</tr>
</thead>
</table>

**Observable Psychiatric Symptoms:** (orientation, memory, comprehension, disorganized thinking, rapid/retarded speech, agitation, grooming, hostility, irritability, affective disturbance)

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
</tr>
</thead>
</table>

**Reported Psychiatric Symptoms:** (mood disturbance, depression, anxiety, inner restlessness, covert anger, somatic symptoms, energy level, motivation, sleep, appetite, libido, anhedonia)

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
</tr>
</thead>
</table>

**Physical/Medical Problems:** (those that have emerged or gotten worse after drug use)

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
</tr>
</thead>
</table>

**Maladaptive Coping in the Family/Social area:** (movement away from healthy relationships)

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
</tr>
</thead>
</table>

**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
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.
   Apical Pulse (BPM)
   0 1 2 3 4 5 6 7
   >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:

|____I____I____I____I____I____I____I

No Desire at all  Unable to Resist

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

|____I____I____I____I____I____I____I

Never  All the Time

Completed by (Initials):__________  Date completed: __ __ / __ __ / __ __
**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
   - O None at All
   - O Slight
   - O Moderate
   - O Considerable
   - O Extreme

2. Depression
   - O None at All
   - O Slight
   - O Moderate
   - O Considerable
   - O Extreme

3. Restlessness
   - O None at All
   - O Slight
   - O Moderate
   - O Considerable
   - O Extreme

4. Anger
   - O None at All
   - O Slight
   - O Moderate
   - O Considerable
   - O Extreme

5. Irritability
   - O None at All
   - O Slight
   - O Moderate
   - O Considerable
   - O Extreme

6. Frustration
   - O None at All
   - O Slight
   - O Moderate
   - O Considerable
   - O Extreme

7. Impatience
   - O None at All
   - O Slight
   - O Moderate
   - O Considerable
   - O Extreme

8. Difficulty Concentrating
   - O None at All
   - O Slight
   - O Moderate
   - O Considerable
   - O Extreme

Completed by (Initials):__________  Date completed: __ __ / __ __ / __ __ __ __
Form 32 - COCAINE SUBJECTIVE EFFECTS QUESTIONNAIRE

Recent Cocaine Use

1. Have you used cocaine/crack since the last assessment?  
   O Yes  O No

   If "No", please leave the rest of this form blank.

   If "Yes", please answer the following questions based on your most recent use:

2. Route of Administration:  
   O Smoked  O Intranasal (snorted)  O Intravenous (IV)

3. Amount of cocaine used: 
   _____  Unit:  O Rocks ($10)  O Grams  O Milligrams
   (# of units)

4. Carefully read the following questions and try to remember the degree to which you experienced each sensation during your last cocaine use. Rate your experience by checking the circle that best reflects what you were feeling.

<table>
<thead>
<tr>
<th>None</th>
<th>O</th>
<th>O</th>
<th>O</th>
<th>O</th>
<th>O</th>
<th>O</th>
<th>Extreme</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any drug effect?</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Rush?</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Good effects?</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Bad effects?</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Liking?</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
<tr>
<td>Desire for cocaine?</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
</tbody>
</table>

Effects of Study Drug on Cocaine Use

5. Has the study medication changed the quality of your cocaine high?  
   O Yes  O No  O N/A – Baseline Assessment

   If yes, please complete the next two questions.

6. Has the study medication increased or decreased your ability to get high?  
   O Increased  O Decreased

7. Please rate the degree to which the quality of your cocaine high has changed.

<table>
<thead>
<tr>
<th>None</th>
<th>O</th>
<th>O</th>
<th>O</th>
<th>O</th>
<th>O</th>
<th>O</th>
<th>Extreme</th>
</tr>
</thead>
<tbody>
<tr>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
<td>O</td>
</tr>
</tbody>
</table>

Completed by (Initials):__________  Date completed: __ __ / __ __ / __ __ __
<table>
<thead>
<tr>
<th>Date tablets dispensed</th>
<th>__ __ / __ __ / __ __ __ __</th>
<th>AM</th>
<th>PM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of tablets dispensed</td>
<td>__ __</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date unused tablets returned</td>
<td>__ __ / __ __ / __ __ __ __</td>
<td>(mm/dd/yyyy)</td>
<td></td>
</tr>
<tr>
<td>Number of tablets returned</td>
<td>__ __</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of tablets reported lost by subject</td>
<td>__ __</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of tablets taken:</td>
<td>Date (mm/dd/yyyy)</td>
<td>AM</td>
<td>PM</td>
</tr>
<tr>
<td>Monday</td>
<td>__ __ / __ __ / __ __ __ __</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tuesday</td>
<td>__ __ / __ __ / __ __ __ __</td>
<td></td>
<td></td>
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<tr>
<td>Wednesday</td>
<td>__ __ / __ __ / __ __ __ __</td>
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<td>Thursday</td>
<td>__ __ / __ __ / __ __ __ __</td>
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<td>Friday</td>
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<tr>
<td>Saturday</td>
<td>__ __ / __ __ / __ __ __ __</td>
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<tr>
<td>Sunday</td>
<td>__ __ / __ __ / __ __ __ __</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Comments:

Completed by (Initials): ____________ Date completed: __ __ / __ __ / __ __ __
### Form 34 - TREATMENT COMPLIANCE—PSYCHOTHERAPY

**Did subject receive standardized, manual-guided individual psychotherapy this week?**
- [ ] Yes
- [x] No
- [ ] Unknown

If yes, length of psychotherapy session

---

**Did subject require emergency crisis management sessions this week?**
- [x] Yes
- [ ] No

If yes, how many?

---

**Additional comments:**

---

Completed by (Initials): ____________

Date completed: __ __ / __ __ / __ __ __ __
Form 36 - MISSED VISIT LOG

Reasons for missed visit:
1 – child care problems 6 – using other substances
2 – transportation problems 7 – out of town
3 – illness 8 – working
4 – using cocaine 9 – recovering from substance use
5 – incarcerated 10 – other (specify)

<table>
<thead>
<tr>
<th>Date</th>
<th>Reason(s) for missed visit:</th>
<th>Initials</th>
</tr>
</thead>
<tbody>
<tr>
<td><em><strong><strong>/</strong></strong></em>/_______</td>
<td>1 2 3 4 5 6 7 8 9 10__________</td>
<td>______</td>
</tr>
<tr>
<td><em><strong><strong>/</strong></strong></em>/_______</td>
<td>1 2 3 4 5 6 7 8 9 10__________</td>
<td>______</td>
</tr>
<tr>
<td><em><strong><strong>/</strong></strong></em>/_______</td>
<td>1 2 3 4 5 6 7 8 9 10__________</td>
<td>______</td>
</tr>
<tr>
<td><em><strong><strong>/</strong></strong></em>/_______</td>
<td>1 2 3 4 5 6 7 8 9 10__________</td>
<td>______</td>
</tr>
<tr>
<td><em><strong><strong>/</strong></strong></em>/_______</td>
<td>1 2 3 4 5 6 7 8 9 10__________</td>
<td>______</td>
</tr>
<tr>
<td><em><strong><strong>/</strong></strong></em>/_______</td>
<td>1 2 3 4 5 6 7 8 9 10__________</td>
<td>______</td>
</tr>
<tr>
<td><em><strong><strong>/</strong></strong></em>/_______</td>
<td>1 2 3 4 5 6 7 8 9 10__________</td>
<td>______</td>
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<td><em><strong><strong>/</strong></strong></em>/_______</td>
<td>1 2 3 4 5 6 7 8 9 10__________</td>
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<td>1 2 3 4 5 6 7 8 9 10__________</td>
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<td><em><strong><strong>/</strong></strong></em>/_______</td>
<td>1 2 3 4 5 6 7 8 9 10__________</td>
<td>______</td>
</tr>
</tbody>
</table>
Form 37 - FOLLOW-UP

1. Has contact been made with the subject?  O Yes  O 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.)

<table>
<thead>
<tr>
<th>Drug</th>
<th>Days Used</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cocaine</td>
<td></td>
</tr>
<tr>
<td>Methamphetamines</td>
<td></td>
</tr>
<tr>
<td>Amphetamines</td>
<td></td>
</tr>
<tr>
<td>Benzodiazepines</td>
<td></td>
</tr>
<tr>
<td>Alcohol</td>
<td></td>
</tr>
<tr>
<td>Marijuana</td>
<td></td>
</tr>
<tr>
<td>Sedatives</td>
<td></td>
</tr>
<tr>
<td>Nicotine</td>
<td></td>
</tr>
<tr>
<td>Opiates</td>
<td></td>
</tr>
<tr>
<td>Barbiturates</td>
<td></td>
</tr>
<tr>
<td>None</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
</tr>
</tbody>
</table>

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

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

5. Have any adverse events occurred?  O Yes  O No

   If ‘Yes’, an Adverse Event CRF form must be completed.

6. Have any serious adverse events occurred?  O Yes  O 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?  O Yes  O No

   If yes, is the subject still alive?  O Yes  O No

   If the subject has died, a Serious Adverse Event report must be filed.

9. Additional comments:

Completed by (Initials): ___________  Date completed:  __ __ / __ __ / __ __ __ __
Form 38 - COMMENT PAGE

Date of Comment: __ __ / __ __ / __ __ __ __  This Comment Applies to ______________________

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

Comment: ____________________________________________________________

_______________________________________________________________________

_______________________________________________________________________

_______________________________________________________________________

_______________________________________________________________________

Signature

Date of Comment: __ __ / __ __ / __ __ __ __  This Comment Applies to ______________________

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

Comment: ____________________________________________________________

_______________________________________________________________________

_______________________________________________________________________

_______________________________________________________________________

_______________________________________________________________________

Signature

Date of Comment: __ __ / __ __ / __ __ __ __  This Comment Applies to ______________________

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

Comment: ____________________________________________________________

_______________________________________________________________________

_______________________________________________________________________

_______________________________________________________________________

_______________________________________________________________________

Signature
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? O Yes O 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.

O Subject completed study.
O Subject failed to meet Inclusion/Exclusion criteria. Entry Criteria form must indicate which criteria were/were not met.
O Subject declined to participate (during Screening).
O Subject requested to withdraw from study
   O Subject reports drug not working O Other Please specify below.
O 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.
O Subject terminated for administrative reasons. Include protocol non-compliance in this Category. Provide comments.
O Subject transferred to another treatment program (circle type)
   Methadone LAAM Drug Free Inpatient Detox or Treatment
   Therapeutic Community Other, specify_________________________
O Subject became pregnant. O Subject did not return to study/clinic.
O Subject moved from area. O Subject is in a controlled environment.
O Subject died. O Other Provide comments.

4. Comments:

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

Principal Investigator: ___________________________ Date: __ __ / __ __ / __ __ __ __
Signature