**FORM 10 - ADVERSE EVENTS/CONCOMITANT MEDICATIONS**

**INSTRUCTIONS:** For each study week, assess and record adverse events at each clinic visit and at the first visit of the following week to capture any additional adverse events that may have occurred in the study week being assessed. (See Operations Manual/Data Management Handbook for instructions for coding of study week number).

**Definition of Adverse Event:** An adverse event is any reaction, side effect, or untoward event that occurs during the course of the study, whether or not the event is considered related to the study agent or clinically significant. For this study, events reported by the patient, as well as clinically significant abnormalities on physical examination or laboratory evaluation will be recorded on the AE CRF. A new illness, symptom, sign or clinically significant clinical laboratory abnormality or worsening of a pre-existing condition or abnormality is considered an AE. Stable chronic conditions, such as arthritis, which are present prior to study entry and do not worsen are not considered AEs. The AE CRF is also used to record follow-up information for unresolved events reported on previous visits.

A. Has the patient experienced any adverse events since last adverse event assessment?  
   0 ___ No, go to Section C, page 2  
   1 ___ Yes, give details below:  

   (Interview patient regarding adverse events by asking a non-leading question such as AHave you felt differently in any way since your last clinic visit?)

<table>
<thead>
<tr>
<th>I. Nature of Illness, Event, or Abnormal Lab Value</th>
<th>Date of Onset (Mo Day Yr)</th>
<th>I. Withdrawal Related</th>
<th>II. Relatedness</th>
<th>III. Highest Level of Severity</th>
<th>IV. Action Taken</th>
<th>V. Outcome</th>
<th>If Resolved, Date of Resolution (Mo Day Yr) circle Ac if a continuing event</th>
<th>VI. Seriousness of Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>__ / __ / __ __ __ __</td>
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</tbody>
</table>

VA Form 10-21039(NR) – Version 2 (04/20/04)
B. Has the patient taken any concomitant medications since last medication assessment?  0__ No  1__ Yes

If YES, enter all prescription and over-the-counter drugs taken therapeutically during the study including herbal preparations. Make a new entry when a dosage and/or frequency change occurs.

<table>
<thead>
<tr>
<th>A. GENERIC NAME OF MEDICATION</th>
<th>B. If medication taken as a result of an adverse event, list number of event from previous page. If NOT, please list indication in next column.</th>
<th>C. PURPOSE/INDICATION</th>
<th>D. ROUTE</th>
<th>E. DOSE</th>
<th>F. UNITS</th>
<th>G. FREQUENCY</th>
<th>H. FROM</th>
<th>I. TO</th>
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<tbody>
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</table>
Addiction Severity Index Lite - CF
Clinical/Training Version

INTRODUCING THE ASI: Seven potential problem areas: Medical, Employment/Support Status, Alcohol, Drug, Legal, Family/Social, and Psychological. All clients receive this same standard interview. All information gathered is confidential.

There are two time periods we will discuss:
1. The past 30 days
2. Lifetime Data

Patient Rating Scale: Patient input is important. For each area, I will ask you to use this scale to let me know how bothered you have been by any problems in each section. I will also ask you how important treatment is for you for the area being discussed.

The scale is:
0 - Not at all
1 - Slightly
2 - Moderately
3 - Considerably
4 - Extremely

If you are uncomfortable giving an answer, then don't answer.

Please do not give inaccurate information!

INTERVIEWER INSTRUCTIONS:
1. Leave no blanks.
2. Make plenty of Comments (if another person reads this ASI, they should have a relatively complete picture of the client’s perceptions of this/her problems).
3. X = Question not answered.
   N = Question not applicable.
4. Terminate interview if client misrepresents two or more sections.
5. When noting comments, please write the question number.
6. Tutorial/clarification notes are preceded with “•”.

HALF TIME RULE: If a question asks the number of months, round up periods of 14 days or more to 1 month. Round up 6 months or more to 1 year.

CONFIDENCE RATINGS:
• Last two items in each section.
• Do not over interpret.
• Denial does not warrant misrepresentation.
• Misrepresentation = overt contradiction in information.

Probe and make plenty of comments!

HOLLINGSHEAD CATEGORIES:
1. Higher execs, major professionals, owners of large businesses.
2. Business managers if medium sized businesses, lesser professions, i.e., nurses, opticians, pharmacists, social workers, teachers.
3. Administrative personal, managers, minor professionals, owners/proprieters of small businesses, i.e., bakery, car dealership, engraving business, plumbing business, florist, decorator, actor, reporter, travel agent.
4. Clerical and sales, technicians, small businesses (bank teller, bookkeeper, clerk, draftsman, timekeeper, secretary).
5. Skilled manual - usually having had training (baker, barber, brakeman, chef, electrician, fireman, lineman, machinist, mechanic, paperhanger, painter, repairman, tailor, welder, policeman, plumber).
7. Unskilled (attendant, janitor, construction helper, unspecified labor, porter, including unemployed).
8. Homemaker.

LIST OF COMMONLY USED DRUGS:
Alcohol: Beer, wine, liquor

Methadone: Dolophine, LAAM

Opiates: Pain killers = Morphine, Diluauaid, Demerol, Percocet, Darvon, Talwin, Codeine, Tylenol 2,3,4, Syrups = Robitussin, Fentanyl

Barbiturates: Nembutal, Seconal, Tuinol, Amytal, Pentobarbital, Secobarbital, Phenobarbital, Fiorinol

Sed/Hyp/Tranq: Benzodiazepines = Valium, Librium, Ativan, Serax, Tranxene, Dalmane, Halcion, Xanax, Miltown, Other = Chloral Hydrate (Nocotex), Quaaludes

Cocaine: Cocaine Crystal, Free Base Cocaine or "Crack", and "Rock Cocaine"

Amphetamines: Monster, Crank, Benzedrine, Dexedrine, Ritalin, Preludin, Methamphetamine, Speed, Ice, Crystal

Cannabis: Marijuana, Hashish

Hallucinogens: LSD (Acid), Mescaline, Mushrooms (Psilocybin), Peyote, Green, PCP (Phencyclidine), Angel Dust, Ecstasy

Inhalants: Nitrous Oxide, Amyl Nitrate (Whippits, Poppers), Glue, Solvents, Gasoline, Toluene, Etc.

Just note if these are used: Antidepressants, Ulcer Meds = Zantac, Tagamet
Asma Meds = Ventoline Inhaler, Theodur
Other Meds = Antipsychotics, Lithium

ALCOHOL/DRUG USE INSTRUCTIONS:
The following questions look at two time periods: the past 30 days and lifetime. Lifetime refers to the time prior to the last 30 days. However if the client has been incarcerated for more than 1 year, you would only gather lifetime information, unless the client admits to significant alcohol /drug use during incarceration. This guideline only applies to the Alcohol/Drug Section.

• 30 day questions only require the number of days used.
• Lifetime use is asked to determine extended periods of use.
• Regular use = 3+ times per week, binges, or problematic irregular use in which normal activities are compromised.
• Alcohol to intoxication does not necessarily mean "drunk", use the words felt the effects", "got a buzz", "high", etc. instead of intoxication.
• As a rule of thumb, 5+ drinks in one setting, or within a brief period of time defines "intoxication".
• "How to ask these questions:
   • "How many days in the past 30 have you used....?"
   • "How many years in your life have you regularly used....?"

Revised- 06/02/99 DC/TRJ
Addiction Severity Index Lite - Training Version

GENERAL INFORMATION

NIDA-VA-1021 – Baclofen for Cocaine Dependence

FORM 13 – ASI LITE

NAME CODE __ __ __ __ CENTER NO. __ __ __

PATIENT NO. __ __ __ __ WEEK __ __

DATE OF ASSESSMENT __ __ / __ __ / __ __ __ __

Mo   Day   Year

G14. How long have you lived at this address? __ __  __  __

G15. Date of birth: __ __ / __ __ / __ __ __ __

G16. Date of birth: __ __ / __ __ / __ __ __ __

(Month/Day/Year)

G17. Of what race do you consider yourself? __ __

1. White (not Hisp) __ 5. Asian/Pacific __ 9. Other Hispanic
2. Black (not Hisp) __ 6. Hispanic-Mexican
3. American Indian __ 7. Hispanic-Puerto Rican
4. Alaskan Native __ 8. Hispanic-Cuban

G18. Do you have a religious preference? __ __

1. Protestant __ 3. Jewish __ 5. Other
2. Catholic __ 4. Islamic __ 6. None

G19. Have you been in a controlled environment in the past 30 days? __ __

1. No __ 4. Medical Treatment
2. Jail __ 5. Psychiatric Treatment
3. Alcohol/Drug Treat. __ 6. Other: __________

A place, theoretically, without access to drugs/alcohol.

G20. How many days? __ __

*“N N” if Question G19 is No. Refers to total number of days detained in the past 30 days.
MEDICAL STATUS

M1. How many times in your life have you been hospitalized for medical problems?
- Include O.D.'s and D.T.'s. Exclude detox, alcohol/drug, psychiatric treatment and childbirth (if no complications). Enter the number of overnight hospitalizations for medical problems.

M3. Do you have any chronic medical problems which continue to interfere with your life?
- 0 - No
- 1 - Yes
- If "Yes", specify in comments.
- A chronic medical condition is a serious physical condition that requires regular care, (i.e., medication, dietary restriction) preventing full advantage of their abilities.

M4. Are you taking any prescribed medication on a regular basis for a physical problem?
- 0 - No
- 1 - Yes
- If Yes, specify in comments.
- Medication prescribed by a MD for medical conditions; not psychiatric medicines. Include medicines prescribed whether or not the patient is currently taking them. The intent is to verify chronic medical problems.

M5. Do you receive a pension for a physical disability?
- 0 - No
- 1 - Yes
- If Yes, specify in comments.
- Include Workers' compensation, exclude psychiatric disability.

M6. How many days have you experienced medical problems in the past 30 days?
- Do not include ailments directly caused by drugs/alcohol.
- Include flu, colds, etc. Include serious ailments related to drugs/alcohol, which would continue even if the patient were abstinent (e.g., cirrhosis of liver, abscesses from needles, etc.).

MEDICAL COMMENTS
(Include question number with your notes)

[Blank lines for comments]
EMPLOYMENT/SUPPORT STATUS

E1. Education completed:
   • GED = 12 years, note in comments.
   • Include formal education only.
   [ ] Years [ ] Months

E2. Training or Technical education completed:
   • Formal/organized training only. For military training,
     only include training that can be used in civilian life,
     i.e., electronics or computers.
   [ ] Months

E4. Do you have a valid driver's license?
   • Valid license; not suspended/revoked.
   [ ] 0 - No  [ ] 1 - Yes

E5. Do you have an automobile available?
   • If answer to E4 is "No", then E5 must be "No".
   Does not require ownership, only requires
   availability on a regular basis.
   [ ] 0 - No  [ ] 1 - Yes

E6. How long was your longest full time job?
   • Full time = 35+ hours weekly;
     does not necessarily mean most
     recent job.
   [ ] Yrs [ ] Mos

E7. Usual (or last) occupation?
   (specify) __________________________
   (use Hollingshead Categories Reference Sheet)

E9. Does someone contribute the majority of
    your support?
   [ ] 0 - No  [ ] 1 - Yes

E10. Usual employment pattern, past three years?
    1. Full time (35+ hours)  5. Service
    2. Part time (regular hours)  6. Retired/Disability
    3. Part time (irregular hours)  7. Unemployed
    4. Student  8. In controlled environment
       • Answer should represent the majority of the last 3 years, not just
         the most recent selection. If there are equal times for more than one
         category, select that which best represents more current situation.

E11. How many days were you paid for working
     in the past 30 days?
     • Include "under the table" work, paid sick days and vacation.
     [ ]
EMPLOYMENT/SUPPORT (cont.)

For questions E12-17: How much money did you receive from the following sources in the past 30 days?

E12. Employment?
   • Net or “take home” pay, include any "under the table" money.

E13. Unemployment Compensation?

E14. Welfare?
   • Include food stamps, transportation money provided by an agency to go to and from treatment.

E15. Pensions, benefits or Social Security?
   • Include disability, pensions, retirement, veteran's benefits, SSI & workers' compensation.

E16. Mate, family, or friends?
   • Money for personal expenses, i.e. clothing, include unreliable sources of income (e.g. gambling). Record cash payments only, include windfalls (unexpected), money from loans, gambling, inheritance, tax returns, etc.

E17. Illegal?
   • Cash obtained from drug dealing, stealing, fencing stolen goods, gambling, prostitution, etc. *Do not* attempt to convert drugs exchanged to a dollar value.

E18. How many people depend on you for the majority of their food, shelter, etc.?
   • Must be regularly depending on patient, do include alimony/child support, do not include the patient or self-supporting spouse, etc.

E19. How many days have you experienced employment problems in the past 30?
   • Include inability to find work, if they are actively looking for work, or problems with present job in which that job is jeopardized.

EMPLOYMENT/SUPPORT COMMENTS
(Include question number with your notes)
ALCOHOL/DRUGS

<table>
<thead>
<tr>
<th>Route of Administration</th>
<th>Past 30 Days</th>
<th>Lifetime (years)</th>
<th>Route of Admin</th>
</tr>
</thead>
<tbody>
<tr>
<td>D1 Alcohol (any use at all)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>D2 Alcohol (to intoxication)</td>
<td></td>
<td></td>
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<tr>
<td>D3 Heroin</td>
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<td></td>
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</tr>
<tr>
<td>D4 Methadone</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>D5 Other Opiates/Analgesics</td>
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<td></td>
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</tr>
<tr>
<td>D6 Barbiturates</td>
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<td></td>
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<tr>
<td>D7 Sedatives/Hypnotics/ Tranquilizers</td>
<td></td>
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</tr>
<tr>
<td>D8 Cocaine</td>
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<tr>
<td>D9 Amphetamines</td>
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<td>D10 Cannabis</td>
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<td>D11 Hallucinogens</td>
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<tr>
<td>D12 Inhalants</td>
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<tr>
<td>D13 More than 1 substance per day (including alcohol)</td>
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</tbody>
</table>

- **Note the usual or most recent route. For more than one route, choose the most severe. The routes are listed from least severe to most severe.**

**ALCOHOL/DRUGS COMMENTS**

Include question number with your notes

---

D17. How many times have you had Alcohol DT's?

*Delirium Tremens (DT's): Occur 24-48 hours after last drink, or significant decrease in alcohol intake, shaking, severe disorientation, fever, hallucinations, they usually require medical attention.*

---

Page 5
**ALCOHOL/DRUGS (cont.)**

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

<table>
<thead>
<tr>
<th>Question</th>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>D19</td>
<td>Alcohol abuse?</td>
</tr>
<tr>
<td>D20</td>
<td>Drug abuse?</td>
</tr>
</tbody>
</table>

- Include detoxification, halfway houses, in/outpatient counseling, and AA or NA (if 3+ meetings within one month period).

How many of these were detox only:

<table>
<thead>
<tr>
<th>Question</th>
<th>Detox only</th>
</tr>
</thead>
<tbody>
<tr>
<td>D21</td>
<td>Alcohol?</td>
</tr>
<tr>
<td>D22</td>
<td>Drugs?</td>
</tr>
</tbody>
</table>

If D19 = "00", then question D21 is "NN"
If D20 = '00', then question D22 is “NN”

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

<table>
<thead>
<tr>
<th>Question</th>
<th>Spent</th>
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</thead>
<tbody>
<tr>
<td>D23</td>
<td>Alcohol?</td>
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<tr>
<td>D24</td>
<td>Drugs?</td>
</tr>
</tbody>
</table>

- Only count actual **money** spent. What is the financial burden caused by drugs/alcohol?

<table>
<thead>
<tr>
<th>Question</th>
<th>Number of days</th>
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<tbody>
<tr>
<td>D25</td>
<td>Outpatient for alcohol or drugs</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Question</th>
<th>Problems</th>
</tr>
</thead>
<tbody>
<tr>
<td>D26</td>
<td>Alcohol problems?</td>
</tr>
<tr>
<td>D27</td>
<td>Drug problems?</td>
</tr>
</tbody>
</table>

- Include only: Craving, withdrawal symptoms, disturbing effects of use, or wanting to stop and being unable to.

---

**ALCOHOL/DRUGS COMMENTS**

(Include question number with your notes)

---

Page 6
**LEGAL STATUS**

L1. Was this admission prompted or suggested by the criminal justice system?  
   - Judge, probation/parole officer, etc.  
   - 0 - No  1 - Yes [ ]

L2. Are you on parole or probation?  
   - Note duration and level in comments.  
   - 0 - No  1 - Yes [ ]

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

<table>
<thead>
<tr>
<th>L3</th>
<th>L10</th>
<th>Shoplift/Vandal</th>
<th>Assault</th>
</tr>
</thead>
<tbody>
<tr>
<td>L4</td>
<td>L11</td>
<td>Parole/Probation</td>
<td>Arson</td>
</tr>
<tr>
<td>L5</td>
<td>L12</td>
<td>Drug Charges</td>
<td>Rape</td>
</tr>
<tr>
<td>L6</td>
<td>L13</td>
<td>Forgery</td>
<td>Homicide/Mansl.</td>
</tr>
<tr>
<td>L7</td>
<td>L14</td>
<td>Weapons Offense</td>
<td>Prostitution</td>
</tr>
<tr>
<td>L8</td>
<td>L15</td>
<td>Burglary/Larceny/B&amp;</td>
<td>Contempt of Court</td>
</tr>
<tr>
<td>L9</td>
<td>L16</td>
<td>Robbery</td>
<td>Other: _________</td>
</tr>
</tbody>
</table>

- Include total number of counts, not just convictions. Do not include juvenile (pre-age 18) crimes, unless they were charged as an adult.
- Include formal charges only.

L17. How many of these charges resulted in convictions? [ ]

- If L03-16 = 00, then question L17 = "NN".
- Do not include misdemeanor offenses from questions L18-20 below.
- Convictions include fines, probation, incarcerations, suspended sentences, and guilty pleas.

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

<table>
<thead>
<tr>
<th>L18</th>
<th>Disorderly conduct, vagrancy, public intoxication?</th>
</tr>
</thead>
<tbody>
<tr>
<td>L19</td>
<td>Driving while intoxicated?</td>
</tr>
<tr>
<td>L20</td>
<td>Major driving violations?</td>
</tr>
</tbody>
</table>

- Moving violations: speeding, reckless driving, no license, etc.

L21. How many months were you incarcerated in your life? [ ]

- If incarcerated 2 weeks or more, round this up to 1 month. List total number of months incarcerated.

L24. Are you presently awaiting charges, trial, or sentence?  
   - 0 - No  1 - Yes [ ]

L25. What for?  

- Use the number of the type of crime committed: 03-16 and 18-20
- Refers to Q. L24. If more than one, choose most severe.
- Don't include civil cases, unless a criminal offense is involved.

L26. How many days in the past 30, were you detained or incarcerated?  

- Include being arrested and released on the same day.

LEGAL COMMENTS  
(Include question number with your notes)

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Page 7
LEGAL STATUS (cont.)

L27. How many days in the past 30 have you engaged in illegal activities for profit?  

- Exclude simple drug possession. Include drug dealing, prostitution, selling stolen goods, etc. May be cross checked with Question E17 under Employment/Family Support Section.

LEGAL COMMENTS

(Include question number with your notes)

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
**FAMILY/SOCIAL RELATIONSHIPS**

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>F3. Are you satisfied with this situation?</td>
<td>0-No 1-Indifferent 2-Yes Satisfied = generally liking the situation. - Refers to Questions F1 &amp; F2.</td>
<td></td>
</tr>
<tr>
<td>F4. Usual living arrangements (past 3 years):</td>
<td>1-With sexual partner &amp; children 2-With sexual partner alone 3-With children alone 4-With parents 5-With family 6-With friends 7-Alone 8-Controlled Environment 9-No stable arrangement</td>
<td>Choose arrangements most representative of the past 3 years. If there is an even split in time between these arrangements, choose the most recent arrangement.</td>
</tr>
<tr>
<td>F6. Are you satisfied with these arrangements?</td>
<td>0-No 1-Indifferent 2-Yes</td>
<td></td>
</tr>
<tr>
<td>Do you live with anyone who:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>F7. Has a current alcohol problem?</td>
<td>0-No 1-Yes</td>
<td></td>
</tr>
<tr>
<td>F8. Uses non-prescribed drugs?</td>
<td>0-No 1-Yes</td>
<td></td>
</tr>
<tr>
<td>F9. With whom do you spend most of your free time?</td>
<td>1-Family 2-Friends 3-Alone</td>
<td>If a girlfriend/boyfriend is considered as family by patient, then they must refer to them as family throughout this section, not a friend.</td>
</tr>
<tr>
<td>F10. Are you satisfied with spending your free time this way?</td>
<td>0-No 1-Indifferent 2-Yes A satisfied response must indicate that the person generally likes the situation. Referring to Question F9.</td>
<td></td>
</tr>
<tr>
<td>Have you had significant periods in which you have experienced serious problems getting along with:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>F18. Mother</td>
<td></td>
<td></td>
</tr>
<tr>
<td>F19. Father</td>
<td></td>
<td></td>
</tr>
<tr>
<td>F20. Brother/Sister</td>
<td></td>
<td></td>
</tr>
<tr>
<td>F21. Sexual Partner/Spouse</td>
<td></td>
<td></td>
</tr>
<tr>
<td>F22. Children</td>
<td></td>
<td></td>
</tr>
<tr>
<td>F23. Other Significant Family (specify)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>F24. Close Friends</td>
<td></td>
<td></td>
</tr>
<tr>
<td>F25. Neighbors</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*"Serious problems" mean those that endangered the relationship.  
*A "problem" requires contact of some sort, either by telephone or in person.  

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>F28. Physically?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>F29. Sexually?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>F28. Physically?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>F29. Sexually?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

FAMILY/SOCIAL COMMENTS  
(Include question number with your notes)
FAMILY/SOCIAL (cont.)

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

F30. With your family?

F31. With other people (excluding family)?

FAMILY/SOCIAL COMMENTS

(Include question number with your notes)

_____________________________________________________________________________________

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Page 10
PSYCHIATRIC STATUS

How many times have you been treated for any psychological or emotional problems:

P1. In a hospital or inpatient setting? [ ] [ ]

P2. Outpatient/private patient?
- Do not include substance abuse, employment, or family counseling.
- Treatment episode = a series of more or less continuous visits or treatment days, not the number of visits or treatment days.
- Enter diagnosis in comments if known.

P3. Do you receive a pension for a psychiatric disability? [ ] [ ]

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

P4. Experienced serious depression-sadness, hopelessness, loss of interest, difficulty with daily function? [ ] [ ]

P5. Experienced serious anxiety/tension, uptight, unreasonably worried, inability to feel relaxed? [ ] [ ]

P6. Experienced hallucinations-saw things or heard voices that were not there? [ ] [ ]

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

P8. Experienced trouble controlling violent behavior including episodes of rage, or violence? [ ] [ ]

P10. Attempted suicide?
- Include actual suicidal gestures or attempts.

P12. How many days in the past 30 have you experienced these psychological or emotional problems?
- This refers to problems noted in Questions P4-P10.

PSYCHIATRIC STATUS COMMENTS

(Include question number with your comments)

__________________________________________________
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Page 11

This is a source document for CS #1021.
# FORM 22 - BEHAVIORAL TREATMENT

1. **Did patient attend behavioral therapy with the study therapist?**
   - 0 __ No (go to Q.2)
   - 1 __ Yes (go to Q.1A)

   If Yes, enter date and length of each session:
   - A. Date and length
   - B. Date and length

2. **Did patient have an emergency crisis management session with the study therapist?**
   - 0 __ No (go to Q.3)
   - 1 __ Yes (go to Q.2A)

   If Yes, enter date and length of each session:
   - A. Date and length
   - B. Date and length

3. **Did patient receive behavioral treatment from someone other than the study therapist?**
   - 0 __ No (stop)
   - 1 __ Yes (go to Q.3A)

   If Yes, enter source of therapy, date, and length of session and record total minutes of therapy for each day:
   - A. 1__AA 2__NA/CA 3__Other
   - B. 1__AA 2__NA/CA 3__Other
   - C. 1__AA 2__NA/CA 3__Other
   - D. 1__AA 2__NA/CA 3__Other
   - E. 1__AA 2__NA/CA 3__Other
   - F. 1__AA 2__NA/CA 3__Other
   - G. 1__AA 2__NA/CA 3__Other
### FORM 17 - BRIEF SUBSTANCE CRAVING SCALE

**INSTRUCTIONS:** To be completed by the study patient once a week during screening, at the 1st visit of each week during weeks 1 thru 8, and at the week 9 visit.

Please answer the following questions with regard to craving for cocaine.

1. **The INTENSITY** of my craving, that is, how much I desired cocaine in the past 24 hours was:

   

2. **The FREQUENCY** of my craving, that is, how often I desired cocaine in the past 24 hours was:

   

3. **The LENGTH** of time I spent craving cocaine during the past 24 hours was:

   

4. Write in the **NUMBER** of times you think you had craving for cocaine during the past 24 hours:

   

5. Write in the total **TIME** spent craving cocaine during the past 24 hours:

   

---

This is a source document for CS #1021.
6. **WORST** day: During the past week my most intense craving occurred on the following day:


7. The date for that day was:  


8. The **INTENSITY** of my craving, that is, how much I desired cocaine on that worst day was:


9. **A 2nd craved drug during the past 24 hours was:** (mark ONLY ONE of the following)  
   (If no 2nd craved drug, mark 0=None and leave questions 10-16 blank.)


10. The **INTENSITY** of my craving, that is, how much I desired this second drug in the past 24 hours was:
11. The **FREQUENCY** of my craving, that is, how often I desired this second drug in the past 24 hours was:

12. The **LENGTH** of time I spent craving this second drug during the past 24 hours was:

13. **A 3rd craved drug during the past 24 hours was:** (mark ONLY ONE of the following) 
   (If no 3rd craved drug, mark 0=None and leave questions 14-16 blank.)

14. The **INTENSITY** of my craving, that is, how much I desired this third drug in the past 24 hours was:
15. The **FREQUENCY** of my craving, that is, how often I desired this third drug in the past 24 hours was:

[Blank]

16. The **LENGTH** of time I spent craving this third drug during the past 24 hours was:

[Blank]

FORM COMPLETED BY ................................................................. 1 Patient 2 Interviewer
### FORM 19 - COCAINE CLINICAL GLOBAL IMPRESSION SCALE

**OBSERVER (CGI-O)**

Complete this form once a week during the baseline and treatment phases of the study, at the first visit of each study week.

**PART A.** Please rate the Current Severity of the eight specific problem areas below. See a table of descriptive anchors for specific Cocaine Dependence Problems in the instructions. Indicate one answer for each question.

1. Reported Cocaine Use:
   (frequency and amount of cocaine use) 
   ........................................................................... 1 ___ 2 ___ 3 ___ 4 ___ 5 ___ 6 ___ 7 ___

2. Cocaine Seeking:
   (craving for cocaine, effort to stop, and drug-seeking behavior) 
   ........................................................................... 1 ___ 2 ___ 3 ___ 4 ___ 5 ___ 6 ___ 7 ___

3. Reported Use of Other Drugs:
   (frequency and amount of non-cocaine drug/alcohol use) 
   ........................................................................... 1 ___ 2 ___ 3 ___ 4 ___ 5 ___ 6 ___ 7 ___

4. Observable Psychiatric Symptoms:
   (orientation, memory, comprehension, disorganized thinking, rapid/retarded speech, agitation, grooming, hostility, irritability, affective disturbance, paranoia, suspiciousness) 
   ........................................................................... 1 ___ 2 ___ 3 ___ 4 ___ 5 ___ 6 ___ 7 ___

5. Reported Psychiatric Symptoms:
   (mood disturbance, depression, anxiety, inner restlessness, covert anger, somatic symptoms, energy level, motivation, sleep, appetite, libido, anhedonia, paranoia, suspiciousness) 
   ....................................................... 1 ___ 2 ___ 3 ___ 4 ___ 5 ___ 6 ___ 7 ___

6. Physical/Medical Problems:
   (those that have emerged or gotten worse after drug use) 
   ........................................................................... 1 ___ 2 ___ 3 ___ 4 ___ 5 ___ 6 ___ 7 ___

7. Maladaptive Coping in the Family/Social area:
   (movement away from healthy relationship) 
   ....................................................... 1 ___ 2 ___ 3 ___ 4 ___ 5 ___ 6 ___ 7 ___

8. 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 ___
PART B.

9. Global Severity of Cocaine Dependence .................................................................

Considering your total clinical experience with the cocaine population, how severe are his/her cocaine dependence symptoms at this time?

1 = Normal no symptoms  5 = Marked symptoms
2 = Borderline symptoms  6 = Severe symptoms
3 = Mild symptoms        7 = Among the most extreme symptoms
4 = Moderate symptoms

If this is a baseline visit, STOP here.

10. 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 his/her status at randomization, how much has s/he changed?

1 = Very much improved  5 = Minimally worse
2 = Much improved        6 = Much worse
3 = Minimally improved   7 = Very much worse
4 = No change

FORM COMPLETED BY _______________________________      Date ________________

PHYSICIAN=S SIGNATURE ______________________________     Date ________________
FORM 18 - COCAINE CLINICAL GLOBAL IMPRESSION SCALE
SELF REPORT (CGI-S)
Complete this form once a week during the baseline and treatment phases of the study, at the first visit of each study week.

1. Cocaine Global Severity

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

1 = No problems
2 = Borderline problems
3 = Mild problems
4 = Moderate problems
5 = Marked problems
6 = Severe symptoms
7 = Among the most extreme symptoms

If this is a baseline visit, STOP here. Do not answer Question 2.

2. 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? .....................................................

1 = Very much improved
2 = Much improved
3 = Minimally improved
4 = No change
5 = Minimally worse
6 = Much worse
7 = Very much worse
FORM-14 COCAINE SELECTIVE SEVERITY ASSESSMENT

1. HYPERPHAGIA: ........................................................................................................____
   0= normal appetite
   3-4= eats a lot more than usual
   7= eats more than twice my usual amount of food

2. HYPOPHAGIA: ........................................................................................................____
   0= normal appetite
   3-4= eats less than half of normal amount
   7= no appetite at all

3. CARBOHYDRATE CRAVING: ................................................................................____
   0= no craving
   3-4= strong craving for sweets, half the time
   7= strong craving for sweets, all the time

4. COCAINE CRAVING: (please have subject rate intensity on pg.3) 0-7 .........................____

5. CRAVING FREQUENCY: (please have subject rate intensity on pg.3) 0-7 .....................____

6. BRADYCARDIA: ........................................................................................................____

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

7. SLEEP I: ..................................................................................................................____
   0= normal amount of sleep
   3-4= half of normal amount
   7= no sleep at all

8. SLEEP II: ..................................................................................................................____
   0= normal amount of sleep
   3-4= could sleep or do 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
<table>
<thead>
<tr>
<th>NAME CODE</th>
<th>CENTER NO.</th>
<th>PATIENT NO.</th>
<th>WEEK</th>
<th>DATE OF ASSESSMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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 irritation
- 7 = feels that mostly everything is irritating and upsetting

Version: (DRAFT 1 - 5/19/03)
### CSSA VISUAL ANALOG SCALE

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

```
|_____|_____|_____|_____|_____|_____|_____|
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:

```
|_____|_____|_____|_____|_____|_____|_____|
never            all the time
```
FORM 21 – WEEKLY DOSING RECORD

A. DOSING RECORD:

<table>
<thead>
<tr>
<th>DAY</th>
<th>Date (mo/day/yr)</th>
<th>Attended Clinic? 0=No 1=Yes</th>
<th>Dose Code 1=Induction 2=Maintenance 3=Taper 4=Not applicable*</th>
<th>Total number of tablets taken on this day</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>___ ___ ___ ___</td>
<td>___</td>
<td>___</td>
<td>___</td>
<td>___</td>
</tr>
<tr>
<td>2</td>
<td>___ ___ ___ ___</td>
<td>___</td>
<td>___</td>
<td>___</td>
<td>___</td>
</tr>
<tr>
<td>3</td>
<td>___ ___ ___ ___</td>
<td>___</td>
<td>___</td>
<td>___</td>
<td>___</td>
</tr>
<tr>
<td>4</td>
<td>___ ___ ___ ___</td>
<td>___</td>
<td>___</td>
<td>___</td>
<td>___</td>
</tr>
<tr>
<td>5</td>
<td>___ ___ ___ ___</td>
<td>___</td>
<td>___</td>
<td>___</td>
<td>___</td>
</tr>
<tr>
<td>6</td>
<td>___ ___ ___ ___</td>
<td>___</td>
<td>___</td>
<td>___</td>
<td>___</td>
</tr>
<tr>
<td>7</td>
<td>___ ___ ___ ___</td>
<td>___</td>
<td>___</td>
<td>___</td>
<td>___</td>
</tr>
</tbody>
</table>

*If Dose Code = Not applicable, comments must be provided.

B. Total number of tablets dispensed during this 7-day period ................................................................. ........................................... ___ ___ ___

If an in-clinic emergency dose or an emergency replacement card was dispensed during this 7-day period, comments must be provided:

____________________________________________________________________________________________________________________
____________________________________________________________________________________________________________________

C. Total number of tablets returned during this 7-day period (assess on 1st visit of next study week) ............................................ ___ ___ ___

FORM COMPLETED BY ________________________________________________ Date _____________________

PHYSICIAN=S SIGNATURE ______________________________________________ Date _____________________
### FORM 09 - ELECTROCARDIOGRAM RESULTS (ECG)

(To be completed at Screening, Week 4, Week 8 or Termination Visit)

1. **ECG overall results were:** 1=Normal, 2=Abnormal

2. If ECG is abnormal, CHECK ALL that apply below:

<p>| | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Increased QRS Voltage</td>
<td>L</td>
<td>Sinus tachycardia</td>
</tr>
<tr>
<td>B</td>
<td>Qtc prolongation</td>
<td>M</td>
<td>Sinus bradycardia</td>
</tr>
<tr>
<td>C</td>
<td>Left ventricular hypertrophy</td>
<td>N</td>
<td>Supraventricular premature beat</td>
</tr>
<tr>
<td>D</td>
<td>Right ventricular hypertrophy</td>
<td>O</td>
<td>Ventricular premature beat</td>
</tr>
<tr>
<td>E</td>
<td>Acute infarction</td>
<td>P</td>
<td>Supraventricular tachycardia</td>
</tr>
<tr>
<td>F</td>
<td>Subacute infarction</td>
<td>Q</td>
<td>Ventricular tachycardia</td>
</tr>
<tr>
<td>G</td>
<td>Old infarction</td>
<td>R</td>
<td>1st degree A-V block</td>
</tr>
<tr>
<td>H</td>
<td>Myocardial ischemia</td>
<td>S</td>
<td>2nd degree A-V Block</td>
</tr>
<tr>
<td>I</td>
<td>Symmetrical t-wave inversions</td>
<td>T</td>
<td>3rd degree A-V block</td>
</tr>
<tr>
<td>J</td>
<td>Poor R-wave progression</td>
<td>U</td>
<td>Other, specify _____________</td>
</tr>
<tr>
<td>K</td>
<td>Other nonspecific ST/T</td>
<td>V</td>
<td>Other, specify _____________</td>
</tr>
</tbody>
</table>

3. Ventricular rate (bpm) .............................................................................................................................................. __ __

4. PR (ms) ........................................................................................................................................ __ __

5. QRS (ms) .................................................................................................................................... __ __

6. QTc (ms) ...................................................................................................................................... __ __

7. Read By: ________________________________ Date Read: Mo ___ ___ Day ___ ___ Yr ___ ___

---

**FORM COMPLETED BY** ________________________________ Date _____________

**PHYSICIAN’S SIGNATURE** ________________________________ Date _____________

VA Form 10-21039(NR) Version: (DRAFT 1– 5/19/03)
FORM 25 - FOLLOW-UP

INSTRUCTIONS: Complete this form for all patients approximately one month after the last dose of study medication was dispensed.

1. Has contact been made with the patient? .................................................................
   (If Yes, complete a thru e and Question 5. If No, go to Question 2.)
   A. If Yes, date of contact ...........................................Mo  ____  Day  ____  Yr  ____  ____  ____
   B. Does the patient report currently using cocaine illicitly? ........................................
   C. Does the patient report currently using other drugs illicitly? .................................
   D. Does the patient report currently receiving treatment for drug or alcohol abuse/dependence? ..........
   E. Does the patient report that he/she would take the study medication again if it were generally available for cocaine-dependence treatment? .................................................................
   F. Indicate whether the patient thinks that he/she had received placebo or the active drug during the treatment phase of the study? 0  ____ Placebo  _1_ Active drug

2. If contact has not been made with the patient, code reason ..........................................  
   1 = Unable to contact ...........................................Mo  ____  Day  ____  Yr  ____  ____  ____
   2 = Other reason, specify .................................................................................................

3. If unable to reach patient, has contact been made with someone who can verify his/her status? ............
   A. If Yes, date of contact ...........................................Mo  ____  Day  ____  Yr  ____  ____  ____
      (If Yes, go to Question 4)
   B. If No, explain .................................................................................................

4. Has the patient died? (enter “2” if unknown) .................................................................
   If Yes:
   A. Date of Death .........................................................Mo  ____  Day  ____  Yr  ____  ____  ____
   B. Cause of Death ...........................................................
   C. Information verified by site staff (e.g., coroner's office, death certificate).........................

5. Additional Comments: ..............................................................................................

FORM COMPLETED BY ____________________________________________  Date ________________

SITE INVESTIGATOR’S SIGNATURE ____________________________________________  Date ________________
**FORM 26 - GCP/Protocol Noncompliance Form** (To be completed by Study Monitor)

For multiple events of noncompliance occurring on the same date, assign a sequential number to each event. For single events, assign the event number a value of 1.

<table>
<thead>
<tr>
<th>Date of Noncompliance</th>
<th>Noncompliance Code</th>
<th>Event No.</th>
<th>Reason for Noncompliance</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. __ __ / __ __ / __ __</td>
<td>___</td>
<td>___</td>
<td>____________________________________________________________________</td>
</tr>
<tr>
<td></td>
<td>Mo     Day     Year</td>
<td></td>
<td>____________________________________________________________________</td>
</tr>
<tr>
<td>2. __ __ / __ __ / __ __</td>
<td>___</td>
<td>___</td>
<td>____________________________________________________________________</td>
</tr>
<tr>
<td></td>
<td>Mo     Day     Year</td>
<td></td>
<td>____________________________________________________________________</td>
</tr>
<tr>
<td>3. __ __ / __ __ / __ __</td>
<td>___</td>
<td>___</td>
<td>____________________________________________________________________</td>
</tr>
<tr>
<td></td>
<td>Mo     Day     Year</td>
<td></td>
<td>____________________________________________________________________</td>
</tr>
</tbody>
</table>

Signature of Study Monitor ____________________________

PAGE ___ OF ___

Signature of Site Investigator ____________________________

Date _______________________

VA Form 10-21039(NR)z – Version 2 (04/20/04)
FORM 16 - HAMILTON DEPRESSION RATING SCALE


This form is to be completed once during screening, at the last visit of Week 4 and the last visit of Week 8 or the Termination Visit.

1. DEPRESSED MOOD (sadness, 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 = Patient 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 2 hour
   2 = Complains of nightly difficulty falling asleep

5. INSOMNIA MIDDLE .................................................................................................................. ____
   0 = No difficulty
   1 = Patient 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)
<table>
<thead>
<tr>
<th>NAME CODE</th>
<th>CENTER NO.</th>
<th>PATIENT NO.</th>
<th>WEEK</th>
<th>DATE OF ASSESSMENT</th>
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</thead>
<tbody>
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</table>

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. (In hospital, rate 3 if patient does not spend at least three hours a day in activities exclusive of ward chores.)  
4 = Stopped working because of present illness. (In hospital, rate 4 if patient engages in no activities except ward chores, or if patient fails to perform ward chores unassisted.)

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 = APlaying with hands, hair, etc.  
3 = Moving about, cannot sit still  
4 = Hand-wringing, nail-biting, hair-pulling, biting of lips

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

11. **ANXIETY SOMATIC**  
0 = Absent  
1 = Mild  
2 = Moderate  
3 = Severe  
4 = Incapacitating  

*Physiological concomitants of anxiety, such as:*

- Gastrointestinal - dry mouth, wind, indigestion, diarrhea, cramps, belching
- Cardiovascular - palpitations, headaches
- Respiratory - hyperventilation, sighing
- Urinary frequency, sweating
<table>
<thead>
<tr>
<th>NAME CODE</th>
<th>CENTER NO.</th>
<th>PATIENT NO.</th>
<th>WEEK</th>
<th>DATE OF ASSESSMENT</th>
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</thead>
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</table>

12. SOMATIC SYMPTOMS GASTROINTESTINAL ................................................................. ___

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

13. SOMATIC SYMPTOMS GENERAL ................................................................. ___

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

14. GENITAL SYMPTOMS ................................................................. ___

0 = Absent
1 = Mild
2 = Severe

Symptoms such as: Loss of libido, Menstrual disturbances

15. HYPOCHONDRIASIS ................................................................. ___

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

16. LOSS OF WEIGHT ................................................................. ___

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

17. INSIGHT ................................................................. ___

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

18. DIURNAL VARIATION (If no variation, mark 0°. If variation exists, note whether symptoms are worse in the morning or evening.) .................................................. ___

0 = No variation (go to Question 19)
1 = Mild
2 = Severe

___ Worse in A.M.

___ Worse in P.M.
19. DEPERSONALIZATION AND DEREALIZATION .................................................................
   0 = Absent
   1 = Mild  
   2 = Moderate
   3 = Severe
   4 = Incapacitating
   Such as: Feelings of unreality, Nihilistic ideas

20. PARANOID SYMPTOMS ..............................................................................................
   0 = None
   1 = Suspicious
   2 = Ideas of reference
   3 = Delusions of reference and persecution
   4 = Incapacitating

21. OBSESSIONAL AND COMPULSIVE SYMPTOMS .....................................................
   0 = Absent
   1 = Mild
   2 = Severe

22. HELPLESSNESS ...........................................................................................................
   0 = Not present
   1 = Subjective feelings which are elicited only by inquiry
   2 = Patient volunteers his helpless feelings
   3 = Requires urging, guidance and reassurance to accomplish ward chores or personal hygiene
   4 = Requires physical assistance for dress, grooming, eating, bedside tasks 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 esteem, feelings of inferiority, self-deprecation to delusional 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: patient volunteers that (s)he is no good, inferior, etc.
   4 = Delusional notions of worthless - e.g., I am a heap of garbage or its equivalent

Ranges from mild loss of esteem, feelings of inferiority, self-deprecation (loss of self-esteem) to delusional notions of worthlessness.

FORM COMPLETED BY ___________________________  Date ___________________________
### VA/NIDA STUDY 1021
Baclofen for Cocaine Dependence

<table>
<thead>
<tr>
<th>NAME CODE</th>
<th>CENTER NO.</th>
<th>PATIENT NO.</th>
<th>WEEK</th>
<th>DATE OF ASSESSMENT</th>
</tr>
</thead>
<tbody>
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</tr>
</tbody>
</table>

**FORM 15 – HIV RISK-TAKING BEHAVIOR SCALE (HRBS)**  
(To Be Completed at Baseline and Week 8 or Termination Visit)

**DRUG USE**

1. How many times have you hit up (i.e. injected any drugs) in the last month? ..........................................................  
   - 0. I haven’t hit up  
   - 1. Once a week or less  
   - 2. More than once a week but less than once a day  
   - 3. Once a day  
   - 4. 2-3 times a day  
   - 5. 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? ......................................................................................  
   - 0. No times  
   - 1. One time  
   - 2. Two times  
   - 3. 3-5 times  
   - 4. 6-10 times  
   - 5. More than 10 times  

3. How many different people have used a needle before you in the past month? ..........................................................  
   - 0. No times  
   - 1. One time  
   - 2. Two times  
   - 3. 3-5 times  
   - 4. 6-10 times  
   - 5. More than 10 times  

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

File: NIDA_HIV_RISK Version: (DRAFT 1– 5/19/03)
<table>
<thead>
<tr>
<th>NAME CODE</th>
<th>CENTER NO.</th>
<th>PATIENT NO.</th>
<th>WEEK</th>
<th>DATE OF ASSESSMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>

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

6. Before using needles again, now often in the past month did you use bleach to clean them?............
   
   0. I do not re-use
   1. Every time
   2. Sometimes
   3. Rarely
   4. Never

**SEXUAL BEHAVIOR**

7. How many people, including clients, have you had sex with in the last month? ..........................
   
   0. None
   1. One
   2. Two
   3. 3-5 people
   4. 6-10 people
   5. More than 10 people

*If no 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? ..........................
   
   0. No regular partner/no penetrative sex
   1. Every time
   2. Often
   3. Sometimes
   4. Rarely
   5. Never
9. How often have you used condoms when you had sex with casual partners? ................................................... 
   0. No casual partner/no penetrative sex 
   1. Every time 
   2. Often 
   3. Sometimes 
   4. Rarely 
   5. Never 

10. How often have you used condoms when you have been paid for sex in the last month? ............................. 
    0. No paid sex/no penetrative sex 
    1. Every time 
    2. Often 
    3. Sometimes 
    4. Rarely 
    5. Never 

11. How many times have you had anal sex this month? .......................................................................... ........... 
    0. No time 
    1. One time 
    2. Two times 
    3. 3-5 times 
    4. 6-10 times 
    5. More than 10 times 

12. Have you had an HIV test come back positive? ......................................................................................... 
    0. Yes 
    1. No 
    2. Don’t Know 

13. Date of most recent HIV test .............................................. ___ ___ / ___ ___ ___ ___    Never tested ___ ___ / ___ ___ ___ ___ 
    Month         Year

Form Completed By: ___________________________________________ Date: ____/____/________
Administrated by (initials): ______ ______

(Source: Darke S et. Al., The reliability and validity of a scale to measure HIV risk-taking behavior among intravenous drug users. AIDS, Feb 1991)
### FORM 02 - INFECTIOUS DISEASE (Screening Only)

<table>
<thead>
<tr>
<th>VALUE</th>
<th>EVALUATION</th>
<th>COMMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1=Positive</td>
<td>1=Excludes</td>
<td>Provide comments for any assessment that is positive, for an indeterminate PPD, or if an evaluation is not done.</td>
</tr>
<tr>
<td>2=Negative</td>
<td>2=Does not exclude</td>
<td></td>
</tr>
<tr>
<td>3=Indeterminate PPD</td>
<td>9=Not done</td>
<td></td>
</tr>
<tr>
<td>9=Not done</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1. Hepatitis B Surface Antigen (Hbs Ag)  
2. Hepatitis B Surface Antibody (Anti-HBs)  
3. Hepatitis B Core Antibody (Anti-HBc)  
4. Hepatitis C Virus Antibody (HCV Ab)  
5. PPD  

A. Date PPD Read: Mo ___ ___ Day ___ ___ Yr ___ ___ ___ ___  

   **If PPD is positive, or indeterminate, or not done, a chest x-ray is required.**

B. Date of chest x-ray: Mo ___ ___ Day ___ ___ Yr ___ ___ ___ ___  

C. Chest x-ray result: 1 ____ Normal 2 ____ Abnormal, study entry OK 3 ____ Abnormal, excludes from study entry  

6. RPR: 1 ____ Reactive 2 ____ Nonreactive  

   **If reactive, patient must be referred for appropriate follow-up and/or treatment, if required.**  
   **If treatment is required, it must be completed within the 14-day screening window.**  
   **Documentation of appropriate follow-up and/or treatment is required prior to randomization.**
**FORM 07 – CLINICAL LABORATORY REPORT**

INSTRUCTIONS: To be completed at screening, the 1st visit of Week 4 and the 1st visit Week 8 or Termination. You may contact the Medical Monitor at NIDA as needed if any lab value is clinically significantly abnormal. Examples of lab values that could be considered clinically significantly abnormal can be found in Appendix I of the protocol.

Please indicate if the lab values reported on this form are for: 1___ Scheduled labs 2___ Repeat labs

<table>
<thead>
<tr>
<th>BLOOD CHEMISTRY</th>
<th>Value</th>
<th>Evaluation</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>1=Normal</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>2=Abnormal, not clinically significant, does not exclude</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>3=Abnormal, clinically significant, does not exclude</td>
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</tr>
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<td></td>
<td></td>
<td>4=Abnormal, clinically significant, excludes</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>9=Not done</td>
<td></td>
</tr>
<tr>
<td>1. Sodium (mEq/L)</td>
<td>___</td>
<td>____</td>
<td></td>
</tr>
<tr>
<td>2. Potassium (mEq/L)</td>
<td>___</td>
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<tr>
<td>3. Chloride (mEq/L)</td>
<td>___</td>
<td>____</td>
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<tr>
<td>4. CO2 (mEq/L)</td>
<td>___</td>
<td>____</td>
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</tr>
<tr>
<td>5. Glucose (mg/dL)</td>
<td>___</td>
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<tr>
<td>6. Creatinine (mg/dL)</td>
<td>___</td>
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<tr>
<td>7. Albumin (g/dL)</td>
<td>___</td>
<td>____</td>
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<tr>
<td>8. Total protein (g/dL)</td>
<td>___</td>
<td>____</td>
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<tr>
<td>9. Calcium (mg/dL)</td>
<td>___</td>
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<tr>
<td>10. Cholesterol (mg/dL)</td>
<td>___</td>
<td>____</td>
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</tr>
<tr>
<td>11. Triglycerides (mg/dL)</td>
<td>___</td>
<td>____</td>
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</tr>
<tr>
<td>12. SGOT/AST (U/L)</td>
<td>___</td>
<td>____</td>
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<tr>
<td>13. SGPT/ALT (U/L)</td>
<td>___</td>
<td>____</td>
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<tr>
<td>14. GGT (U/L)</td>
<td>___</td>
<td>____</td>
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<tr>
<td>15. Total bilirubin (mg/dL)</td>
<td>___</td>
<td>____</td>
<td></td>
</tr>
<tr>
<td>16. LDH (U/L)</td>
<td>___</td>
<td>____</td>
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<tr>
<td>17. Alkaline Phos. (U/L)</td>
<td>___</td>
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<tr>
<td>18. BUN (mg/dL)</td>
<td>___</td>
<td>____</td>
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<tr>
<td>19. Uric acid (mg/dL)</td>
<td>___</td>
<td>____</td>
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<tr>
<td>20. Phosphorus (mg/dL)</td>
<td>___</td>
<td>____</td>
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</tr>
<tr>
<td>21. Creatine phosphokinase (CPK) (U/L)</td>
<td>___</td>
<td>____</td>
<td></td>
</tr>
<tr>
<td>CBC</td>
<td>Value</td>
<td>Evaluation</td>
<td>Comments</td>
</tr>
<tr>
<td>-----</td>
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</tr>
<tr>
<td>22. Hemoglobin (g/dL)</td>
<td>____ · ____</td>
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</tr>
<tr>
<td>23. Hematocrit (%)</td>
<td>____ · ____</td>
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</tr>
<tr>
<td>24. RBC (M/mm³)</td>
<td>____ · ____</td>
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</tr>
<tr>
<td>25. Platelet count (K/mm³)</td>
<td>____</td>
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</tr>
<tr>
<td>26. WBC (K/mm³)</td>
<td>____ · ____</td>
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</table>

**URINALYSIS**

<p>| | | | |</p>
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<thead>
<tr>
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<tbody>
<tr>
<td>32. Specific gravity</td>
<td>____ · ____</td>
<td></td>
<td></td>
</tr>
<tr>
<td>33. pH</td>
<td>____ · ____</td>
<td></td>
<td></td>
</tr>
<tr>
<td>34. Glucose</td>
<td>1__Neg 2__Trace 3__Present</td>
<td></td>
<td></td>
</tr>
<tr>
<td>35. Protein</td>
<td>1__Neg 2__Trace 3__Present</td>
<td></td>
<td></td>
</tr>
<tr>
<td>36. Ketones</td>
<td>1__Neg 2__Trace 3__Present</td>
<td></td>
<td></td>
</tr>
<tr>
<td>37. Blood</td>
<td>1__Neg 2__Present</td>
<td></td>
<td></td>
</tr>
<tr>
<td>38. Nitrite</td>
<td>1__Neg 2__Present</td>
<td></td>
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</tr>
</tbody>
</table>

**CODING FOR Q. 39-40:**

| 39. WBC | 1__None 2__Few 3__Mod 4__Heavy | |
| 40. RBC | 1__None 2__Few 3__Mod 4__Heavy | |

**FORM COMPLETED BY** ___________________________ **Date** __________

**PHYSICIAN’S SIGNATURE** ___________________________ **Date** __________
NIDA-CSP-1021 - Baclofen for Cocaine Dependence

FORM 03 - MEDICAL HISTORY (Screening Only)

HISTORY
0=No History
1=Yes, Does Not Exclude
2=Yes, Excludes
9=Not Evaluated

EXPLAIN If a “1”, “2” or “9” is recorded under History.
(Please Print Clearly)

Medical Conditions:

1. Allergies, drug
2. Allergies, other
3. Sensitivity to study med
4. HEENT Disorder
5. Cardiovascular Disorder
6. Renal Disorder
7. Hepatic Disorder
8. Pulmonary Disorder, Asthma
9. Pulmonary Disorder, other
10. Gastrointestinal Disorder
11. Musculoskeletal Disorder
12. Neurologic Disorder:
   b. Other
13. Psychiatric Disorder
14. Dermatologic Disorder
15. Metabolic Disorder
16. Hematologic Disorder
17. Endocrine Disorder
18. Genitourinary Disorder
19. Reproductive System Disorder
20. Infectious Disease Disorder
21. Other ________________
22. Other ________________
23. Has the patient had any major surgeries? ................................................................. 0__ No  1___ Yes
   If Yes, list MAJOR SURGERIES below.  If No, skip to Q. 24.
   TYPE OF SURGERY  DATE OF SURGERY  IS SURGERY RELEVANT TO STUDY?
   (Month/Year)  0=No  1=Yes, Does Not Exclude  
   2=Yes, Excludes
   a. ____________________________________  __ __ / __ __ __ __         ____
   b. ____________________________________  __ __ / __ __ __ __         ____
   c. ____________________________________  __ __ / __ __ __ __         ____
   d. ____________________________________  __ __ / __ __ __ __         ____
   e. ____________________________________  __ __ / __ __ __ __         ____

SMOKING HISTORY

24. Has the patient ever smoked cigarettes? ................................................................. 0__ No, skip to Q. 25  1___ Yes
   If Yes:
   a. Currently using? ................................................................................................. 0 ___ No  1 ___ Yes
   b. Number of YEARS smoked (if < 6 months, record “00”; if > 6 months but < one year, record “01”)
      .................................................................  ___ ___
   c. Average NUMBER of cigarettes/day .........................................................................................  ___ ___

25. Has the patient ever used other tobacco products? ...................................................... 0___ No  1___ Yes
   If Yes:
   CIGAR  CHEW  SNUFF  PIPE
   a. Currently using?  0__ no  1__ yes  0__ no  1__ yes  0__ no  1__ yes  0__ no  1__ yes
   b. Number of years used:  
   c. Average number of times used/day:

FORM COMPLETED BY _________________________________________  Date _____________
PHYSICIAN’S SIGNATURE_______________________________________  Date _____________
FORM 05 - PHYSICAL EXAM/SCID
(To be completed at Screening and Week 8 or Termination Visit)

1. Height (complete at Screening Only)........................................................................... ___ ___ . ___ inches

A. RESULTS OF EXAM
0=Normal
1=Abnormal, does not exclude
2=Abnormal, excludes
9=Not done

B. PROVIDE DETAILS ON EACH ABNORMALITY BELOW

2. HEENT (incl. thyroid/neck) ..........____
3. Cardiovascular ................................____
4. Lungs ............................................____
5. Abdomen (incl. liver, spleen).........____
6. Extremities ......................................____
7. Skin ..............................................____
8. Neuropsychiatric:
   A. Mental Status .........................____
   B. Sensory/Motor ..............................____
9. Lymph Nodes ...............................____
10. Musculoskeletal ............................____
11. General Appearance .....................____
12. Other, specify ________________________
13. Other, specify __________________________
14. Other, specify ____________________________
15. Other, specify _____________________________
16. SCID - Summary of Axis I Diagnoses. Indicate the three, four, or five-digit DSM-IV diagnostic code for all Axis I diagnoses, followed by the diagnostic description. After the A/±, use the sixth digit to indicate the following specifiers: 0: Acurrent, severity not specified,± 1: Acurrent, mild,± 2: Acurrent, moderate,± 3: Acurrent, severe,± (NOTE: no number A4±), 5: Ain partial remission,± 6: Ain full remission.± When the specifier information is already included in the fifth digit of the code, repeat this information as the sixth digit.

1) _______ . ____ / __ ______________________________________________________
2) _______ . ____ / __ ______________________________________________________
3) _______ . ____ / __ ______________________________________________________
4) _______ . ____ / __ ______________________________________________________
5) _______ . ____ / __ ______________________________________________________
6) _______ . ____ / __ ______________________________________________________
7) _______ . ____ / __ ______________________________________________________
8) _______ . ____ / __ ______________________________________________________
9) _______ . ____ / __ ______________________________________________________
10) _______ . ____ / __ _____________________________________________________

FORM COMPLETED BY ___________________________________________ Date __________

PHYSICIAN=S SIGNATURE _________________________________________ Date __________
**FORM 04 - PRIOR MEDICATION FORM**

Complete this form on the day patient signs the Informed Consent. List all medications taken by the patient for the PAST 30 DAYS.

<table>
<thead>
<tr>
<th>A GENERIC NAME OF MEDICATION</th>
<th>B PURPOSE/INDICATION</th>
<th>C - ROUTE</th>
<th>D DOSE</th>
<th>E - UNITS</th>
<th>F FREQUENCY</th>
<th>G MEDICATION START DATE (Mo/Day/Yr)</th>
<th>H MEDICATION STOP DATE (Mo/Day/Yr)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>1=Oral</td>
<td></td>
<td>1=Capsule/Tablet</td>
<td>1=&lt;1/DAY</td>
<td>c</td>
<td>c</td>
</tr>
<tr>
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<td>2=Nasal</td>
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<td>3=Intravenous</td>
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<td></td>
<td></td>
<td>5=Topical-transdermal</td>
<td></td>
<td>5=Puff</td>
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<td>c</td>
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<td>6=Intramuscular</td>
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<td>6=Spray/squirt</td>
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<td>7=Sublingual</td>
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<td>7=Tablespoon</td>
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<td></td>
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<td>8=Subcutaneous</td>
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<td>8=Teaspoon</td>
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<td>c</td>
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<td></td>
<td>9=Other</td>
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<td>9=Unknown</td>
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## VA/NIDA STUDY 1021
Baclofen for Cocaine Dependence

<table>
<thead>
<tr>
<th>NAME CODE</th>
<th>CENTER NO.</th>
<th>PATIENT NO.</th>
<th>DATE OF ASSESSMENT</th>
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<tbody>
<tr>
<td>___ ___ ___ ___ ___ ___ ___</td>
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</table>

### A GENERIC NAME OF MEDICATION

<table>
<thead>
<tr>
<th>B PURPOSE/INDICATION</th>
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<tbody>
<tr>
<td>1=Oral</td>
</tr>
<tr>
<td>2=Nasal</td>
</tr>
<tr>
<td>3=Intravenous</td>
</tr>
<tr>
<td>4=Inhalation</td>
</tr>
<tr>
<td>5=Topical</td>
</tr>
<tr>
<td>6=Transdermal</td>
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<tr>
<td>7=Intramuscular</td>
</tr>
<tr>
<td>8=Sublingual</td>
</tr>
<tr>
<td>9=Subcutaneous</td>
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<td>10=Other</td>
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### C - ROUTE

<table>
<thead>
<tr>
<th>1=Oral</th>
<th>2=Nasal</th>
<th>3=Intravenous</th>
<th>4=Inhalation</th>
<th>5=Topical</th>
<th>6=Transdermal</th>
<th>7=Intramuscular</th>
<th>8=Sublingual</th>
<th>9=Subcutaneous</th>
<th>10=Other</th>
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</table>

### D DOSE

<table>
<thead>
<tr>
<th>E - UNITS</th>
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<tbody>
<tr>
<td>1=Cap/Pill</td>
</tr>
<tr>
<td>2=Drop</td>
</tr>
<tr>
<td>3=Milligram</td>
</tr>
<tr>
<td>4=Milliter</td>
</tr>
<tr>
<td>5=Puff</td>
</tr>
<tr>
<td>6=Spray/squirt</td>
</tr>
<tr>
<td>7=Tablespoon</td>
</tr>
<tr>
<td>8=Teaspoon</td>
</tr>
<tr>
<td>9=Unknown</td>
</tr>
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<td>10=Other</td>
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### F FREQUENCY

<table>
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<tr>
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<th>2=1-4 /DAY</th>
<th>3=PRN</th>
<th>4=&gt;4/DAY</th>
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</table>

### G MEDICATION START DATE

(Mo/Day/Yr) circle Ac Days if continuing

### H MEDICATION STOP DATE

(Mo/Day/Yr)

<table>
<thead>
<tr>
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</tbody>
</table>

**FORM COMPLETED BY** ___________________________________________  **Date** __________

**PHYSICIAN’S SIGNATURE** ___________________________________________  **Date** __________

VA Form 10-21039(NR)h - Version: (DRAFT 1– 5/19/03)
INSTRUCTIONS: Submit this form for the pregnancy assessments that occur at screening (WITHIN 2 DAYS PRIOR TO RANDOMIZATION), at the 1st visit of Week 4 and Week 8 or Termination.

1. What method of birth control is participant currently using? .............................................................. ___
   01 = Oral contraceptive
   02 = Contraceptive skin patch (Ortho Evra®)
   03 = Barrier (diaphragm or condom)
   04 = Intrauterine Progesterone Contraceptive system (IUD)
   05 = Levonorgestrel implant (Norplant®)
   06 = Medroxyprogesterone Acetate Contraceptive injection (Depo-Provera®)
   07 = Complete abstinence
   08 = Hormonal vaginal contraceptive ring (NuvaRing®)
   09 = Hysterectomy, record date of procedure: Mo __ ___ Yr __ __ __ __
   10 = Tubal ligation, record date of procedure: Mo __ ___ Yr __ __ __ __
   11 = Post-menopausal, record date of last menstrual period: Mo __ ___ Yr __ __ __ __
   12 = Other, specify __________________________________________

2. Was a pregnancy test performed? .............................................................. 0 ___ No     1 ___ Yes
   If Yes:
   a. Result of pregnancy test .............................................................. 1 ___ Positive   2 ___ Negative
   b. Date specimen collected .............................................................. Mo __ ___ Day __ ___ Yr __ __ __ __
   c. Type of specimen .............................................................. 1 ___ Urine   2 ___ Serum

FORM COMPLETED BY _____________________________ Date ___________________

PHYSICIAN=S SIGNATURE _____________________________ Date ___________________

VA Form 10-21039(NR)h – Version 2 (04/20/04)
FORM 01 – ENTRY CRITERIA & RANDOMIZATION

INSTRUCTIONS: Please complete the entire form regardless of whether the patient is enrolled in the study. If the patient fails screening, record the appropriate patient screening number above and submit form to Perry Point CSPCC. If the patient is enrolled, record the appropriate patient randomization number above and submit form to CSPCC.

1. Did patient sign the Informed Consent? ................................................................. 0 ____ No  1 ____ Yes
2. Gender (1=Male, 2=Female) ................................................................................... _______
3. Date of Birth .................................................................................................Month ___ ___  Day ___ ___   Year ___ ___ ___ ___

INCLUSION CRITERIA - TO RANDOMIZE PATIENT, QUESTIONS 4 THRU 11 MUST ALL BE “YES”.
(NS = Not Screened)

4. Age is 18 or greater ................................................................................................. 0 ____ No  1 ____ Yes  2 ____NS
5. DSM-IV diagnosis of cocaine dependence as determined by SCID ......................................................................................... 0 ____ No  1 ____ Yes  2 ____NS
6. Seeking treatment for cocaine dependence ........................................................................... 0 ____ No  1 ____ Yes  2 ____NS
7. At least 3 positive urine BE specimens during the 14-day screening period .......... 0 ____ No  1 ____ Yes  2 ____NS
8. Provided at least 4 urine samples during the 14-day screening period ...................... 0 ____ No  1 ____ Yes  2 ____NS
9. Ability to understand and provide written informed consent ........................................ 0 ____ No  1 ____ Yes  2 ____NS
10. Completed all other psychological assessments (e.g., ASI-Lite, HRBS, CSSA, CGI-S, CGI-O, BSCS, HAM-D) during the 14-day screening period ............................................................................................. 0 ____ No  1 ____ Yes  2 ____NS
11. Use of an acceptable method of birth control (as defined in protocol) (for males, mark “NS”) ............................................................................................................. 0 ____ No  1 ____ Yes  2 ____NS

EXCLUSION CRITERIA - TO RANDOMIZE PATIENT, QUESTIONS 12 THRU 30 MUST ALL BE “NO”.

12. Current dependence, defined by DSM-IV criteria, on any psychoactive substance other than cocaine, alcohol, nicotine or marijuana, physiological dependence on alcohol requiring medical detoxification ......................................................................................... 0 ____ No  1 ____ Yes  2 ____NS
13. Mandated by the court to obtain treatment for cocaine dependence ......................... 0 ____ No  1 ____ Yes  2 ____NS
14. In the opinion of the investigator, subject is not expected to complete the protocol; for example, due to probable incarceration, vacation or relocation from the clinic area ............................................................................................................. 0 ____ No  1 ____ Yes  2 ____NS
15. Psychiatric or neurological disorder which requires ongoing treatment would make study participation unsafe or treatment compliance difficult ........................................................................... 0 ____ No  1 ____ Yes  2 ____NS
16. Electroconvulsive therapy within the past 3 months preceding screening .................. 0 ____ No  1 ____ Yes  2 ____NS

CS# 1021- Form 01 (Page 2 of 2)
<table>
<thead>
<tr>
<th></th>
<th>NAME CODE</th>
<th>CENTER NO.</th>
<th>PATIENT NO.</th>
<th>DATE COMPLETED</th>
</tr>
</thead>
<tbody>
<tr>
<td>17.</td>
<td>Current suicidal ideation or plan (within the past 30 days)</td>
<td>0 No 1 Yes 2 NS</td>
<td></td>
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</tr>
<tr>
<td>18.</td>
<td>Pregnant or lactating (pregnancy test must be completed within two days prior to study drug administration)</td>
<td>0 No 1 Yes 2 NS</td>
<td></td>
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</tr>
<tr>
<td>19.</td>
<td>Serious medical illnesses or any potentially life-threatening or progressive medical illness other than addiction that may compromise subject safety or study conduct (as listed in the protocol)</td>
<td>0 No 1 Yes 2 NS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>20.</td>
<td>Clinically significant abnormal laboratory values (see Appendix I of protocol)</td>
<td>0 No 1 Yes 2 NS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>21.</td>
<td>AIDS (according to the current CDC criteria for AIDS)</td>
<td>0 No 1 Yes 2 NS</td>
<td></td>
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<tr>
<td>22.</td>
<td>Active syphilis that has not been treated or patient refused treatment</td>
<td>0 No 1 Yes 2 NS</td>
<td></td>
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</tr>
<tr>
<td>23.</td>
<td>Active tuberculosis (positive tuberculin test and confirmatory diagnostic chest x-ray)</td>
<td>0 No 1 Yes 2 NS</td>
<td></td>
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</tr>
<tr>
<td>24.</td>
<td>Diagnosis of adult onset asthma, or chronic obstructive pulmonary disease (COPD)</td>
<td>0 No 1 Yes 2 NS</td>
<td></td>
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</tr>
<tr>
<td>25.</td>
<td>Actively using albuterol or other beta agonist medications, regardless of formal diagnosis of asthma</td>
<td>0 No 1 Yes 2 NS</td>
<td></td>
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</tr>
<tr>
<td>26.</td>
<td>Received medication that could interact adversely with baclofen (see protocol, for medications that fall into that category)</td>
<td>0 No 1 Yes 2 NS</td>
<td></td>
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</tr>
<tr>
<td>27.</td>
<td>Participated in any pharmacological or behavioral intervention study within 2 months preceding screening</td>
<td>0 No 1 Yes 2 NS</td>
<td></td>
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</tr>
<tr>
<td>28.</td>
<td>Known or suspected hypersensitivity to baclofen</td>
<td>0 No 1 Yes 2 NS</td>
<td></td>
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<tr>
<td>29.</td>
<td>Taken baclofen for any reason currently or during the past year</td>
<td>0 No 1 Yes 2 NS</td>
<td></td>
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</tr>
<tr>
<td>30.</td>
<td>Had 2 benzodiazepine positive urines samples during screening</td>
<td>0 No 1 Yes 2 NS</td>
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<tr>
<td>31.</td>
<td>Is the patient eligible for randomization?</td>
<td>0 No 1 Yes 2 Yes, but declined randomization</td>
<td></td>
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</table>

If patient is eligible and willing to be randomized, call the CSPCC to randomize the patient. The CSPCC will provide the following information:

<table>
<thead>
<tr>
<th></th>
<th>Date of randomization</th>
<th>Randomization Number</th>
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<tbody>
<tr>
<td>32.</td>
<td>Mo ___ Day ___ Year ___ ___ ___ ___</td>
<td>(Center-Patient) ___ ___ ___ ___ - ___ ___ ___ ___</td>
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FORM COMPLETED BY ________________________________ DATE _______________________

SITE INVESTIGATOR’S SIGNATURE ________________________________ DATE _______________________
NIDA-CSP-1021 - Baclofen for Cocaine Dependence

NAME CODE CENTER NO. PATIENT NO. WEEK DATE OF REPORT

FORM 23 - SERIOUS ADVERSE EVENT FORM

ALL SERIOUS ADVERSE EVENTS MUST ALSO BE REPORTED ON FORM 10-ADVERSE EVENTS.

1. Type of Report (check one): ................................................................. 1  ___ Initial  2  ___ Final

A. ADVERSE EVENT:

2. Serious adverse event being reported: ..............................................................

3. Date of Onset ........................................................................................................ Mo  ___ Day  ___ Yr  ___ ___ ___

4. Time of Onset (24 hour clock) ........................................................................... ___ : ___ ___ ___

5. Age of Patient ..................................................................................................... ___ ___ ___ ___

6. Sex of Patient (1= Male, 2= Female) .................................................................

7. Patient's Height (inches) ..................................................................................... ___ ___ ___ ___

8. Patient's Weight (pounds) .................................................................................. ___ ___ ___ ___

9. Provide Narrative Description of Event

_____________________________________________________________________________

_____________________________________________________________________________

_____________________________________________________________________________

A. Greatest Severity (1= Mild, 2= Moderate, 3= Severe) .................................

B. Study Drug Related? ..................................................................................
   (1= Definitely Not Related, 2= Possibly Related, 3= Probably Related, 4= Definitely Related)

C. Action Taken? (1= None, 2= Outpatient Treatment, 3= Inpatient Treatment) .......

D. Was study drug interrupted? (0= No, 1= Yes) ......................................................

E. If yes, date of last study dose .............................................................................. Mo  ___ Day  ___ Yr  ___ ___ ___

F. Time of last dose (24 hour clock) ...................................................................... ___ : ___ ___ ___

VA Form 10-21039(NR)w – Version 1 (11/12/03)
### NAME CODE CENTER NO. PATIENT NO. WEEK DATE OF ASSESSMENT

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### GPAQ (Global Patient Assessment Questionnaire)

G. Did event abate after study drug stopped? (0= No, 1= Yes, 2= NA) .................................................. ___

H. Did event reappear after study drug was reintroduced? (0= No, 1= Yes, 2= NA) .................. ___

I. Outcome to date? .......................................................... ___
   1= Resolved; no sequelae
   2= Not yet resolved, but improving
   3= Not yet resolved, no change
   4= Not yet resolved, worsening
   5= Resulted in chronic condition, severe and/or permanent disability
   6= Deceased
   7= Unknown

J. Was patient terminated? (0= No, 1= Yes, 2= NA) ................................................................. ___
   (If terminated, complete Termination Form 24.)

10. If patient died, date of death ............................................. Mo ___ Day ___ Yr ___ ___ ___

   A. Cause of Death .......................................................

11. Relevant Tests/Laboratory Data: ...............................................................

12. Suspect Drug(s): ............................................................................................................. ____
   1= Study drug,
   2= Nonstudy drug(s),
   3= Combination (study & nonstudy drug),
   4= NA (not drug)

13. If Nonstudy drug(s):
   A. Trade/generic name of drug(s):
      1) ........................................ 3) ........................................
      2) ........................................ 4) ........................................
   B. Dose, regimen, routes of administration:
      1) ........................................ 3) ........................................
      2) ........................................ 4) ........................................
### CSP #1021 - FORM 23 (Page 3 of 3)

<table>
<thead>
<tr>
<th>NAME CODE</th>
<th>CENTER NO.</th>
<th>PATIENT NO.</th>
<th>WEEK</th>
<th>DATE OF ASSESSMENT</th>
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</table>

#### C. Dates of Administration:

1) FROM: ____/____/____  TO: ____/____/____
   Mo  Day  Year          Mo  Day  Year

2) FROM: ____/____/____  TO: ____/____/____
   Mo  Day  Year          Mo  Day  Year

3) FROM: ____/____/____  TO: ____/____/____
   Mo  Day  Year          Mo  Day  Year

4) FROM: ____/____/____  TO: ____/____/____
   Mo  Day  Year          Mo  Day  Year

#### D. Indication(s) for Use:

1) ______________________________________  3) _________________________________

2) ______________________________________  4) _________________________________

---

FORM COMPLETED BY _______________________________  Date _________________

PHYSICIAN=S SIGNATURE _______________________________  Date _________________

SITE INVESTIGATOR=S SIGNATURE ________________________  Date _________________

VA Form 10-21039(NR)w – Version 1 (11/12/03)
**FORM 20 - SUBSTANCE USE REPORT (SUR)**

1. This form is being completed for date: ................................................................. Mo ___ Day ___ Yr ___ ___ ___

2. Any substance use on this date: ................................................................. 0__ No (stop, form is complete) 1__ Yes (continue)

Complete a line below for each unique route employed to use a substance (e.g., “nasal” and “inhaled” for cocaine require separate lines).

### H. Substance Codes (Q.8-11)
- 1=Other stimulants (amph, crystal meth, etc)
- 2=Hallucinogens (PCP, LSD, ecstasy, etc)
- 3=Inhalants (glue, ethyl chl, etc.)
- 4=Sedative hypn/anxiolytics (valium, seconal, etc.)
- 5=Other

<table>
<thead>
<tr>
<th>Substance</th>
<th>A. TOTAL AMOUNT</th>
<th>B. ROUTE</th>
</tr>
</thead>
<tbody>
<tr>
<td>3A. Cocaine</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3B. Cocaine</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3C. Cocaine</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4A. Beer (record the # of standard 12 oz beer drinks)</td>
<td>____ ____ ____</td>
<td></td>
</tr>
<tr>
<td>4B. Wine (record the # of standard 4 oz. wine drinks)</td>
<td>____ ____ ____</td>
<td></td>
</tr>
<tr>
<td>4C. Hard liquor (record the # of standard 1 oz. liquor drinks)</td>
<td>____ ____ ____</td>
<td></td>
</tr>
<tr>
<td>5. Marijuana</td>
<td></td>
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</tr>
<tr>
<td>6A. Opioids: specify ___________________________</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6B. Opioids: specify ___________________________</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7A. Nicotine, specify (Code ____ *)</td>
<td>____ ____ ____</td>
<td></td>
</tr>
<tr>
<td>7B. Nicotine, specify (Code ____ *)</td>
<td>____ ____ ____</td>
<td></td>
</tr>
<tr>
<td>8. Other, specify (Code ____ H )</td>
<td>___________________________</td>
<td></td>
</tr>
<tr>
<td>9. Other, specify (Code ____ H )</td>
<td>___________________________</td>
<td></td>
</tr>
<tr>
<td>10. Other, specify (Code ____ H )</td>
<td>___________________________</td>
<td></td>
</tr>
<tr>
<td>11. Other, specify (Code ____ H )</td>
<td>___________________________</td>
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</tr>
</tbody>
</table>

One standard drink is equal to:
- 12 oz. of beer (4-5% EtOH)
- 4 oz. of wine (10-12% EtOH)
- 2.5 oz. of fortified wine (16-18% EtOH)
- 1 oz. of hard liquor (86-100 proof, 43-50% EtOH)
1. Was the patient terminated from the study? ................................................................. 0 ___ No 1 ___ Yes

   *If the patient did not request to be withdrawn from the study and the patient was not terminated for any reason listed in Question 2, then the patient is a completer and Question 1 should be coded as “No”.*

   If No, go to Question 3. If Yes, go to Question 2.

2. Code PRIMARY reason for termination ................................................................. ___ ___
   01 = Toxicity or side effects suspected to be related to study medication (complete Adverse Event Form 10)
   02 = Medical reason unrelated to study medication which prevents study participation,
       specify __________________________
   03 = Termination by clinic physician because of intercurrent illness or medical complication
       which prevents safe administration of study medication (complete adverse event Form 10),
       specify __________________________
   04 = Patient missed 7 consecutive visits
   05 = Failed to return to clinic (patient missed less than 7 consecutive visits)
   06 = Patient's request, specify __________________________
   07 = Moved from area
   08 = Incarceration
   09 = Pregnancy
   10 = Death (complete Serious Adverse Event Form 23)
   11 = Other, specify: __________________________

3. Record date of last dose of study drug taken by patient ............ Mo __ __ Day __ __ Yr __ __ __ __

4. Record date of last on-study clinic visit (not including any follow-up visits) ................................................................. Mo __ __ Day __ __ Yr __ __ __ __

FORM COMPLETED BY ___________________________________ Date __________________

SITE INVESTIGATOR=S SIGNATURE ______________________________ Date __________________

VA Form 10-21039(NR)x – Version 2 (2/1/05)
FORM 12 - URINE BE COLLECTION

First Sample of Study Week
1. Date of sample ......................................................... Mo ___ ___ Day ___ ___ Yr ___ ___ ___ ___

Second Sample of Study Week
2. Date of sample ......................................................... Mo ___ ___ Day ___ ___ Yr ___ ___ ___ ___

Third Sample of Study Week
3. Date of sample ......................................................... Mo ___ ___ Day ___ ___ Yr ___ ___ ___ ___

FORM COMPLETED BY _______________________________ Date __________________

VA Form 10-21039(NR)x - Version: (DRAFT 1– 5/19/03)
NIDA/VA CSP 1021 Shipping and Receiving Log

<table>
<thead>
<tr>
<th>Study Number</th>
<th>Site:</th>
</tr>
</thead>
<tbody>
<tr>
<td>N I D A - 1 0 2 1</td>
<td>TBD</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Date Urine Samples Shipped</th>
<th>Total Samples in shipment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name Code:</th>
<th>Patient ID:</th>
<th>Bar Code Label:</th>
<th>Sample #</th>
<th>Date Collected:</th>
<th>NWT USE ONLY</th>
<th>Data Center Verification</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td></td>
<td>Place Barcode Label Here</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td></td>
<td>Place Barcode Label Here</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td></td>
<td>Place Barcode Label Here</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td></td>
<td>Place Barcode Label Here</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td></td>
<td>Place Barcode Label Here</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Site Name: Specific to each collection site
PI:
Contact: Name of person to ship supplies to and resolve problems.
Phone #:
Return Data To: Data management center
Phone #:

Sample #: First sample of the week, typically Monday, mark 1 (This gets a 4 panel drug screen.)
Mark 2 or 3 for the subsequent samples, typically Wed and Fri, for the week, as both panels will be tested for Cocaine and creatinine only.
FOR SCREENING ONLY: A 4th urine specimen can be collected in any 7-day period during the 14-day screening period only. (Record “4” in sample #.)
NIDA-CSP-1021 - Baclofen for Cocaine Dependence

<table>
<thead>
<tr>
<th>NAME CODE</th>
<th>CENTER NO.</th>
<th>PATIENT NO.</th>
<th>DATE SPECIMEN COLLECTED</th>
</tr>
</thead>
<tbody>
<tr>
<td>___ ___ ___ ___ ___ ___</td>
<td>___ ___ ___ ___ ___ ___</td>
<td>___ ___ / ___ ___ / ___ ___ ___</td>
<td></td>
</tr>
</tbody>
</table>

**FORM 11 - URINE TOXICOLOGY DURING SCREENING**

**SCREEN FOR:**

1. BENZODIAZEPINES ........................................................... 1 ____ Pos 2 ____ Neg
2. COCAINE ................................................................................................... 1 ____ Pos 2 ____ Neg
3. METHAMPHETAMINE .......................................................... 1 ____ Pos 2 ____ Neg
4. MORPHINE (OPiates).................................................. 1 ____ Pos 2 ____ Neg
5. THC......................................................................................... 1 ____ Pos 2 ____ Neg

**NOTE:** REFRIGERATE ONE-HALF URINE SAMPLE AND SHIP TO:

NWT, INC.
1141 EAST 3900 SOUTH
SALT LAKE CITY, UT 84124

FREEZE THE REMAINDER OF THE URINE SAMPLE AND RETAIN AT YOUR SITE UNTIL NOTIFIED BY CSPCC, PERRY POINT TO DISCARD.

FORM COMPLETED BY ___________________________ Date ________________

This is a source document for CS #1021.
VA/NIDA STUDY 1021
Baclofen for Cocaine Dependence

NAME CODE  CENTER NO.  PATIENT NO.  WEEK  DATE OF ASSESSMENT

MONTH  DAY  YEAR

FORM 06 - VITAL SIGNS

(Complete this form 3 times a week during the screening and baseline phases of the study. During the
treatment phase of the study, complete this form at the first visit of each study week.)

1. Weight (round to nearest lb.) .............................................................. ___ ___ ___

2. Time Vital Signs taken (use 24 hr clock) ........................................... ___ : ___ ___

3. Temperature (oral) (F1) ................................................................. ___ ___ ___ . ___

4. Blood Pressure (sitting) (mm Hg) .................................................... ___ ___ ___ / ___ ___ ___

5. Pulse Rate (sitting) (beats/min) ...................................................... ___ ___ ___

6. Respiratory Rate (sitting) (breaths/min) ......................................... ___ ___ ___

FORM COMPLETED BY ___________________________ Date ____________________

PHYSICIAN’S SIGNATURE ___________________________ Date ____________________