NAME CODE ___ ___ ___ ___ **CENTER NO.** ___ ___ ___ **PATIENT NO.** ___ ___ ___ ___ **WEEK** ___ ___ **DATE COMPLETED** ___ ___/ ___ ___ /___ ___ ___ ___
Month Day Year

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 abnormal findings 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?≅)

I.	II.	III.	IV.	V.	VI.

Nature of Illness, Event, or Abnormal Lab Value	Date of Onset *(Mo Day Yr)*	I. Withdrawal Related	II. Related-ness	III. Highest Level of Severity	IV. Action Taken	V. Outcome	If Resolved, Date of Resolution *(Mo Day Yr) circle Ac≅ if a continuing event*		VI. Seriousness of Event
1.	__ __/__ __/__ __ __ __						__ __/__ __/__ __ __ __	c	
2.	__ __/__ __/__ __ __ __						__ __/__ __/__ __ __ __	c	
3.	__ __/__ __/__ __ __ __						__ __/__ __/__ __ __ __	c	
4.	__ __/__ __/__ __ __ __						__ __/__ __/__ __ __ __	c	
5.	__ __/__ __/__ __ __ __						__ __/__ __/__ __ __ __	c	
6.	__ __/__ __/__ __ __ __						__ __/__ __/__ __ __ __	c	
7.	__ __/__ __/__ __ __ __						__ __/__ __/__ __ __ __	c	

NAME CODE	CENTER NO.	PATIENT NO.	WEEK	DATE COMPLETED
___ ___ ___ ___	___ ___ ___	___ ___ ___ ___	___ ___	___ ___ / ___ ___ /___ ___ ___ ___
				Month Day Year

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.

A GENERIC NAME OF MEDICATION	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.	C PURPOSE/ INDICATION	D ROUTE 1=Oral 2=Nasal 3=Intravenous 4=Inhalation 5=Topical transdermal 6=Intramuscular 7=Sublingual 8=Subcutaneous 9=Other	E DOSE	F UNITS 01=Capsule/Tablet 02=Drop 03=Milligram 04=Milliliter 05=Puff 06=Spray/squirt 07=Tablespoon 08=Teaspoon 09=Unknown 10=Other	G FREQUENCY 1=<1/day 2=1-4 /day 3=PRN 4=>4/day	H FROM Medication Start Date *(Mo/Day/Yr)* *circle Ac≅ if continuing*		I TO Medication End Date (If ended, enter last date medication taken) *(Mo/Day/Yr)*
1.				_ _ _ _ . _ _ _	__ __	_____	_ _ / _ _ / _ _ _ _	c	_ _ /_ _ /_ _ _ _
2.				_ _ _ _ . _ _ _	__ __	_____	_ _ / _ _ / _ _ _ _	c	_ _ /_ _ /_ _ _ _
3.				_ _ _ _ . _ _ _	__ __	_____	_ _ / _ _ / _ _ _ _	c	_ _ /_ _ /_ _ _ _
4.				_ _ _ _ . _ _ _	__ __	_____	_ _ / _ _ / _ _ _ _	c	_ _ /_ _ /_ _ _ _
5.				_ _ _ _ . _ _ _	__ __	_____	_ _ / _ _ / _ _ _ _	c	_ _ /_ _ /_ _ _ _
6.				_ _ _ _ . _ _ _	__ __	_____	_ _ / _ _ / _ _ _ _	c	_ _ /_ _ /_ _ _ _
7.				_ _ _ _ . _ _ _	__ __	_____	_ _ / _ _ / _ _ _ _	c	_ _ /_ _ /_ _ _ _
8.				_ _ _ _ . _ _ _	__ __	_____	_ _ / _ _ / _ _ _ _	c	_ _ /_ _ /_ _ _ _
9.				_ _ _ _ . _ _ _	__ __	_____	_ _ / _ _ / _ _ _ _	c	_ _ /_ _ /_ _ _ _
10.				_ _ _ _ . _ _ _	__ __	_____	_ _ / _ _ / _ _ _ _	c	_ _ /_ _ /_ _ _ _

FORM COMPLETED BY _____ Date _____

PHYSICIAN=S SIGNATURE _____ Date _____

Addiction Severity Index *Lite* - CF

Clinical/Training Version

Thomas McLellan, Ph.D.
John Cacciola, Ph.D.
Deni Carise, Ph.D.
Thomas H. Coyne, MSW

Remember: This is an interview, not a test

≈Item numbers ~~circled~~ are to be asked at follow-up.≈
≈Items with an asterisk* are cumulative and should be rephrased at follow-up.≈
≈Items in a double border gray box are questions for the interviewer. Do not ask these questions of the client.≈

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 ofhis/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 personnel, managers, minor professionals, owners/proprietors 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).
6. Semi-skilled (hospital aide, painter, bartender, bus driver, cutter, cook, drill press, garage guard, checker, waiter, spot welder, machine operator).
7. Unskilled (attendant, janitor, construction helper, unspecified labor, porter, including unemployed).
8. Homemaker.
9. Student, disabled, no occupation.

LIST OF COMMONLY USED DRUGS:

Alcohol:	Beer, wine, liquor
Methadone:	Dolophine, LAAM
Opiates:	Pain killers = Morphine, Diluaudid, 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 = ChloralHydrate (Noctex), 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, Ecstacy
Inhalants:	Nitrous Oxide, Amyl Nitrate (Whippits, Poppers), Glue, Solvents, Gasoline, Toluene, Etc.

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

ALCOHOL/DRUG USE INSTRUCTIONS:

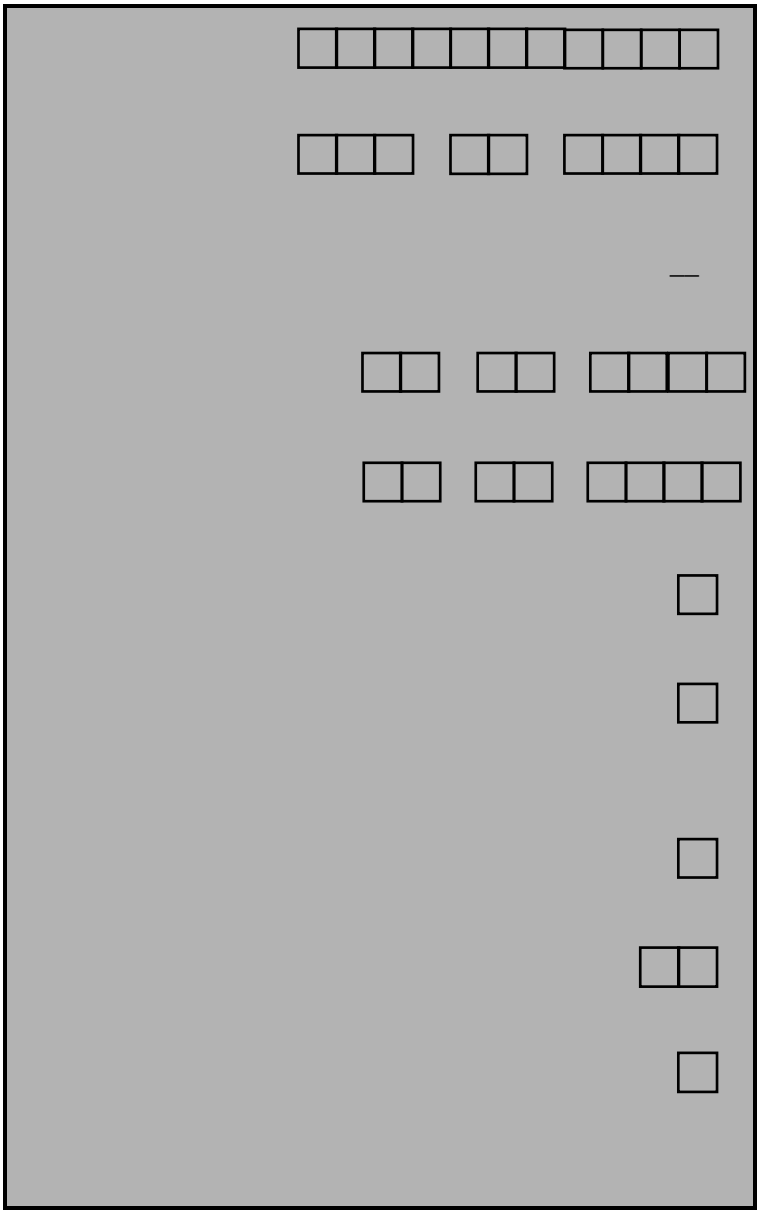
The following questions look at two time periods: the past 30 days and lifetime. Lifetime refers to the time prior to the last 30 days. However if the client has been incarcerated for more than 1 year, you would only gather lifetime information, unless the client admits to significant alcohol /drug use 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

This is a source document for CS #1021.

Addiction Severity Index *Lite* - Training Version
GENERAL INFORMATION



DO NOT COMPLETE THIS SECTION. ↑

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? ☐☐ Years ☐☐ Months

G16. Date of birth: ☐☐/☐☐/☐☐☐☐
(Month/Day/Year)

G17. Of what race do you consider yourself? ☐
1. White (not Hisp)
2. Black (not Hisp)
3. American Indian
4. Alaskan Native
5. Asian/Pacific
6. Hispanic-Mexican
7. Hispanic-Puerto Rican
8. Hispanic-Cuban
9. Other Hispanic

G18. Do you have a religious preference? ☐
1. Protestant
2. Catholic
3. Jewish
4. Islamic
5. Other
6. None

G19. Have you been in a controlled environment in the past 30 days? ☐
1. No
2. Jail
3. Alcohol/Drug Treat.
4. Medical Treatment
5. Psychiatric Treatment
6. Other: _____
•A place, theoretically, without access to drugs/alcohol.

G20. How many days? ☐☐
•"NN" if Question G19 is No. Refers to total number of days detained in the past 30 days.

(Clinical/Training Version)

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)

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**". 0 - No 1 - Yes ☐
  Does not require ownership, only requires availability on a regular basis.

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)
2. Part time (regular hours)
3. Part time (irregular hours)
4. Student
5. Service
6. Retired/Disability
7. Unemployed
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 COMMENTS
(Include question number with your notes)

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

Route of Administration Types:
1. Oral 2. Nasal 3. Smoking 4. Non-IV injection 5. IV

• *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.*

		Past 30 Days	Lifetime (years)	Route of Admin
D1	Alcohol (any use at all)	☐☐	☐☐	■
		☐☐	☐☐	■
D3	Heroin	☐☐	☐☐	☐
		☐☐	☐☐	☐
D5	Other Opiates/Analgesics	☐☐	☐☐	☐
		☐☐	☐☐	☐
D7	Sedatives/Hypnotics/ Tranquilizers	☐☐	☐☐	☐
		☐☐	☐☐	☐
D9	Amphetamines	☐☐	☐☐	☐
		☐☐	☐☐	☐
D11	Hallucinogens	☐☐	☐☐	☐
		☐☐	☐☐	☐
D13	More than 1 substance per day (including alcohol)	☐☐	☐☐	■

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.

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

ALCOHOL/DRUGS (cont.)

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

D19* Alcohol abuse? ☐☐

D20* Drug abuse? ☐☐

- 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:

D21. Alcohol? ☐☐

D22. Drugs? ☐☐

- 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:

D23. Alcohol? ☐☐☐☐☐

D24. Drugs? ☐☐☐☐☐

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

D25. How many days have you been treated as an outpatient for alcohol or drugs in the past 30 days? ☐☐
- Include AA/NA

How many days in the past 30 have you experienced:

D26. Alcohol problems? ☐☐

○ ☐

○ ☐

How many days in the past 30 have you experienced:

D27. Drug problems? ☐☐
- 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)

LEGAL STATUS

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

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:

L3 * Shoplift/Vandal	☐☐	L10* Assault	☐☐
L4* Parole/Probation	☐☐	L11* Arson	☐☐
L5 Drug Charges	☐☐	L12* Rape	☐☐
L6* Forgery	☐☐	L13* Homicide/Mansl.	☐☐
L7* Weapons Offense	☐☐	L14* Prostitution	☐☐
L8* Burglary/Larceny/B&	☐☐	L15* Contempt of Court	☐☐
L9 * Robbery	☐☐	L16* Other: _____	☐☐

- 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:

L18* Disorderly conduct, vagrancy, public intoxication? ☐☐

L19* Driving while intoxicated? ☐☐

L20* Major driving violations? ☐☐
- 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)

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

F1. Marital Status:
1-Married 3-Widowed 5-Divorced
2-Remarried 4-Separated 6-Never Married
• Common-law marriage = 1. Specify in comments. ☐

F3. Are you satisfied with this situation? ☐
0-No 1-Indifferent 2-Yes
• Satisfied = generally liking the situation. - Refers to Questions F1 & F2.

F4.* Usual living arrangements (past 3 years): ☐
1-With sexual partner & 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
• 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.

F6. Are you satisfied with these arrangements? ☐
0-No 1-Indifferent 2-Yes

Do you live with anyone who:

F7. Has a current alcohol problem? 0-No 1-Yes ☐

F8 Uses non-prescribed drugs? 0-No 1-Yes ☐

F9. With whom do you spend most of your free time? ☐
1-Family 2-Friends 3-Alone
• If a girlfriend/boyfriend is considered as family by patient, then they must refer to them as family throughout this section, not a friend.

F10. Are you satisfied with spending your free time this way? 0-No 1-Indifferent 2-Yes ☐
• A satisfied response must indicate that the person generally likes the situation. Referring to Question F9.

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

	0 - No 1 - Yes Past 30 days	In Your Life
F18. Mother	☐	☐
F19. Father	☐	☐
	☐	☐
F21. Sexual Partner/Spouse	☐	☐
	☐	☐
F23. Other Significant Family (specify)_____	☐	☐
	☐	☐
F25. Neighbors	☐	☐
	☐	☐

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

Did anyone abuse you? 0- No 1-Yes

	Past 30 days	In Your Life
F28. Physically? • Caused you physical harm.	☐	☐
F29. Sexually? • Forced sexual advances/acts.	☐	☐

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? ☐☐

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

F31. With other people (excluding family)? ☐☐

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

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? ☐
0-No 1-Yes

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

0-No 1-Yes

	Past 30 Days	Lifetime
P4. Experienced serious depression-sadness, hopelessness, loss of interest, difficulty with daily function?	☐	☐
	☐	☐
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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NIDA-CSP-1021 - Baclofen for Cocaine Dependence

NAME CODE	CENTER NO.	PATIENT NO.	WEEK	DATE COMPLETED
___ ___ ___ ___	___ ___ ___	___ ___ ___ ___	___ ___	___ ___ / ___ ___ / ___ ___ ___ ___
				Month Day Year

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 ..... Mo ___ ___ Day ___ ___ Yr ___ ___ ___ ___ ___ ___ ___ (min)

B. Date and length ..... Mo ___ ___ Day ___ ___ Yr ___ ___ ___ ___ ___ ___ ___ (min)

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 ..... Mo ___ ___ Day ___ ___ Yr ___ ___ ___ ___ ___ ___ ___ (min)

B. Date and length ..... Mo ___ ___ Day ___ ___ Yr ___ ___ ___ ___ ___ ___ ___ (min)

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 Mo __ __ Day __ __ Yr __ __ __ __ ___ ___ ___ (min)

B. 1___AA 2___NA/CA 3___Other Mo __ __ Day __ __ Yr __ __ __ __ ___ ___ ___ (min)

C. 1___AA 2___NA/CA 3___Other Mo __ __ Day __ __ Yr __ __ __ __ ___ ___ ___ (min)

D. 1___AA 2___NA/CA 3___Other Mo __ __ Day __ __ Yr __ __ __ __ ___ ___ ___ (min)

E. 1___AA 2___NA/CA 3___Other Mo __ __ Day __ __ Yr __ __ __ __ ___ ___ ___ (min)

F. 1___AA 2___NA/CA 3___Other Mo __ __ Day __ __ Yr __ __ __ __ ___ ___ ___ (min)

G. 1___AA 2___NA/CA 3___Other Mo __ __ Day __ __ Yr __ __ __ __ ___ ___ ___ (min)

FORM COMPLETED BY _____ Date _____

This is a source document for CS #1021.

NIDA-CSP-1021 - Baclofen for Cocaine Dependence

NAME CODE	CENTER NO.	PATIENT NO.	WEEK	DATE OF ASSESSMENT
___ ___ ___ ___	___ ___ ___	___ ___ ___ ___	___ ___	___ ___ / ___ ___ /___ ___ ___ ___
				Month Day Year

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:

NAME CODE	CENTER NO.	PATIENT NO.	WEEK	DATE OF ASSESSMENT
___ ___ ___ ___	___ ___ ___	___ ___ ___ ___	___ ___	___ ___ / ___ ___ / ___ ___ ___ ___
				Month Day Year

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. **<u>A 2nd craved drug during the past 24 hours was</u>:** (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:

NAME CODE	CENTER NO.	PATIENT NO.	WEEK	DATE OF ASSESSMENT
___ ___ ___ ___	___ ___ ___	___ ___ ___ ___	___ ___	___ ___ / ___ ___ / ___ ___ ___ ___
				Month Day Year

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:

NAME CODE	CENTER NO.	PATIENT NO.	WEEK	DATE OF ASSESSMENT
___ ___ ___ ___	___ ___ ___	___ ___ ___ ___	___ ___	___ ___ / ___ ___ / ___ ___ ___ ___
				Month Day Year

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

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

FORM COMPLETED BY ..... 1___Patient 2___Interviewer

VA/NIDA STUDY 1021
Baclofen for Cocaine Dependence

NAME CODE	CENTER NO.	PATIENT NO.	WEEK	DATE OF ASSESSMENT
___ ___ ___ ___	___ ___ ___	___ ___ ___ ___	___ ___	___ ___/ ___ ___ /___ ___ ___ ___
				Month Day Year

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 Atable 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___

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

___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___/ ___ ___ /___ ___ ___ ___
Month **Day** **Year**

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
2 = Borderline symptoms
3 = Mild symptoms
4 = Moderate symptoms
5 = Marked symptoms
6 = Severe symptoms
7 = Among the most extreme 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
2 = Much improved
3 = Minimally improved
4 = No change
5 = Minimally worse
6 = Much worse
7 = Very much worse

FORM COMPLETED BY _____ Date _____

PHYSICIAN=S SIGNATURE _____ Date _____

VA/NIDA STUDY 1021
Baclofen for Cocaine Dependence

NAME CODE	CENTER NO.	PATIENT NO.	WEEK	DATE OF ASSESSMENT
___ ___ ___ ___	___ ___ ___	___ ___ ___ ___	___ ___	___ ___/ ___ ___ /___ ___ ___ ___
				Month Day Year

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 COMPLETED BY _____ Date _____

VA/NIDA STUDY 1021
Baclofen for Cocaine Dependence

NAME CODE	CENTER NO.	PATIENT NO.	WEEK	DATE OF ASSESSMENT
___ ___ ___ ___	___ ___ ___	___ ___ ___ ___	___ ___	___ ___/ ___ ___ /___ ___ ___ ___
				Month Day Year

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:....._____

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

NAME CODE	CENTER NO.	PATIENT NO.	WEEK	DATE OF ASSESSMENT
___ ___ ___ ___	___ ___ ___	___ ___ ___ ___	___ ___	___ ___/ ___ ___ /___ ___ ___ ___
				Month Day Year

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

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

___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___

Month **Day** **Year**

Interviewer Initials:_____ **Total**:_____

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

NIDA-CSP-1021 - Baclofen for Cocaine Dependence

NAME CODE	CENTER NO.	PATIENT NO.	WEEK	DATE COMPLETED
___ ___ ___ ___	___ ___ ___	___ ___ ___ ___	___ ___	___ ___ / ___ ___ / ___ ___ ___ ___
				Month Day Year

FORM 21 – WEEKLY DOSING RECORD

A. DOSING RECORD:

DAY	Date (mo/day/yr)	Attended Clinic? 0=No 1=Yes	Dose Code 1=Induction 2=Maintenance 3=Taper 4=Not applicable*	Total number of tablets taken on this day	Comments
1	__ __ __ __ __	____	____	____	
2	__ __ __ __ __	____	____	____	
3	__ __ __ __ __	____	____	____	
4	__ __ __ __ __	____	____	____	
5	__ __ __ __ __	____	____	____	
6	__ __ __ __ __	____	____	____	
7	__ __ __ __ __	____	____	____	

***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 _____

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NAME CODE	CENTER NO.	PATIENT NO.	WEEK	DATE OF ECG
___ ___ ___ ___	___ ___ ___	___ ___ ___ ___	___ ___	___ ___/ ___ ___ /___ ___ ___ ___
				Month Day Year

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:

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

3. Ventricular rate (bpm) ..... ___ ___ ___

4. PR (ms) ..... ___ ___ ___

5. QRS (ms) ..... ___ ___ ___

6. QT_c (ms) ..... ___ ___ ___

7. Read By: _____Date Read: Mo ___ ___ Day ___ ___ Yr ___ ___ ___ ___

FORM COMPLETED BY_____ Date _____

PHYSICIAN'S SIGNATURE_____ Date _____

NIDA-CSP-1021 - Baclofen for Cocaine Dependence

NAME CODE **CENTER NO.** **PATIENT NO.** **DATE COMPLETED**

___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ / ___ ___ / ___ ___ ___ ___

Month **Day** **Year**

FORM 25 - FOLLOW-UP

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

0 = NO
1 = YES

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 _____

NIDA-CSP-1021
Baclofen for Cocaine Dependence

NAME CODE ___ ___ ___ ___ **CENTER NO.** ___ ___ ___ **PATIENT NO.** ___ ___ ___ ___ **DATE OF MONITORING VISIT** ___ ___/ ___ ___ /___ ___ ___ ___
Month **Day** **Year**

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.

Date of Noncompliance	Noncompliance Code	Event No.	Reason for Noncompliance
1. __ __ / __ __ / __ __ __ __ Mo Day Year	_____	_____	_____
2. __ __ / __ __ / __ __ __ __ Mo Day Year	_____	_____	_____
3. __ __ / __ __ / __ __ __ __ Mo Day Year	_____	_____	_____

Signature of Study Monitor _____ PAGE __ __ OF __ __

Signature of Site Investigator _____ Date _____

This is a source document for CS #1021.

NIDA-CSP-1021 - Baclofen for Cocaine Dependence

NAME CODE	CENTER NO.	PATIENT NO.	WEEK	DATE OF ASSESSMENT
___ ___ ___ ___	___ ___ ___	___ ___ ___ ___	___ ___	___ ___ / ___ ___ /___ ___ ___ ___
				Month Day Year

FORM 16 - HAMILTON DEPRESSION RATING SCALE

INSTRUCTIONS: *FOR EACH ITEM, WRITE THE NUMBER IN THE SPACE CORRESPONDING WITH THE ACUE≅ WHICH BEST CHARACTERIZES THE PARTICIPANT (see Guide for The Hamilton Depression Rating Scale in the Data Management Handbook section of the Operations Manual). 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)*

NAME CODE	CENTER NO.	PATIENT NO.	WEEK	DATE OF ASSESSMENT
___ ___ ___ ___	___ ___ ___	___ ___ ___ ___	___ ___	___ ___ / ___ ___ /___ ___ ___ ___
				Month Day Year

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	*Physiological concomitants of anxiety, such as:*
1 = Mild	*Gastrointestinal - dry mouth, wind, indigestion, diarrhea, cramps, belching*
2 = Moderate	*Cardiovascular - palpitations, headaches*
3 = Severe	*Respiratory - hyperventilation, sighing*
4 = Incapacitating	*Urinary frequency, sweating*

NAME CODE	CENTER NO.	PATIENT NO.	WEEK	DATE OF ASSESSMENT
___ ___ ___ ___	___ ___ ___	___ ___ ___ ___	___ ___	___ ___ / ___ ___ /___ ___ ___ ___
				Month Day Year

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 A0". 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.

NAME CODE	CENTER NO.	PATIENT NO.	WEEK	DATE OF ASSESSMENT
___ ___ ___ ___	___ ___ ___	___ ___ ___ ___	___ ___	___ ___ / ___ ___ /___ ___ ___ ___
				Month Day Year

19. DEPERSONALIZATION AND DEREALIZATION ..... _____
    0 = Absent
    1 = Mild *Such as: Feelings of unreality, Nihilistic ideas*
    2 = Moderate
    3 = Severe
    4 = Incapacitating

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 Athings will improve≅ but can be reassured
    2 = Consistently feels Ahopeless≅ but accepts reassurances
    3 = Expresses feelings of discouragement, despair, pessimism about future, which cannot be dispelled
    4 = Spontaneously and inappropriately perseverates, AI=ll never get well≅ or its equivalent

24. WORTHLESSNESS (ranges from mild loss of esteem, feelings of inferiority, self-depreciation 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 Ano good,≅ Ainferior,≅ etc.
    4 = Delusional notions of worthless - e.g., AI 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

NAME CODE	CENTER NO.	PATIENT NO.	WEEK	DATE OF ASSESSMENT
___ ___ ___ ___	___ ___ ___	___ ___ ___ ___	___ ___	___ ___/ ___ ___ /___ ___ ___ ___
				Month Day Year

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

NAME CODE	CENTER NO.	PATIENT NO.	WEEK	DATE OF ASSESSMENT
___ ___ ___ ___	___ ___ ___	___ ___ ___ ___	___ ___	___ ___/ ___ ___ /___ ___ ___ ___
				Month Day Year

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

NAME CODE	CENTER NO.	PATIENT NO.	WEEK	DATE OF ASSESSMENT
___ ___ ___ ___	___ ___ ___	___ ___ ___ ___	___ ___	___ ___/ ___ ___ /___ ___ ___ ___
				Month Day Year

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: ____/____/_____

Administered by (initials): _____ _____

(Source: Darke S et. Al., The reliability and validity of a scale to measure HIV risk-taking behavior amoung intravenous drug users. *AIDS,* Feb 1991)

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NAME CODE	CENTER NO.	PATIENT NO.	DATE COMPLETED
___ ___ ___ ___	___ ___ ___	___ ___ ___ ___	___ ___ / ___ ___ / ___ ___ ___ ___
			Month Day Year

FORM 02 - INFECTIOUS DISEASE (Screening Only)

	VALUE 1=Positive 2=Negative 3=Indeterminate PPD 9=Not done	EVALUATION 1=Excludes 2=Does not exclude 9=Not done	COMMENTS Provide comments for any assessment that is positive, for an indeterminate PPD, or if an evaluation is not done.
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 COMPLETED BY _____ Date _____

PHYSICIAN'S SIGNATURE_____ Date_____

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

___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___/ ___ ___ /___ ___ ___ ___

Month **Day** **Year**

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**

BLOOD CHEMISTRY	**Value**	**Evaluation** 1=Normal 2=Abnormal, not clinically significant, does not exclude 3=Abnormal, clinically significant, does not exclude 4=Abnormal, clinically significant, excludes 9=Not done	**Comments** – MUST provide comments if a 3, 4 or 9 is recorded under Evaluation.
1. Sodium (mEq/L)	___ ___ ___	_____	
2. Potassium (mEq/L)	___ . ___	_____	
3. Chloride (mEq/L)	___ ___ ___	_____	
4. CO_2 (mEq/L)	___ ___	_____	
5. Glucose (mg/dL)	___ ___ ___	_____	
6. Creatinine (mg/dL)	___ . ___	_____	
7. Albumin (g/dL)	___ ___ . ___	_____	
8. Total protein (g/dL)	___ ___ . ___	_____	
9. Calcium (mg/dL)	___ ___ . ___	_____	
10. Cholesterol (mg/dL)	___ ___ ___	_____	
11. Triglycerides (mg/dL)	___ ___ ___	_____	
12. SGOT/AST (U/L)	___ ___ ___ ___	_____	
13. SGPT/ALT (U/L)	___ ___ ___ ___	_____	
14. GGT (U/L)	___ ___ ___ ___	_____	
15. Total bilirubin (mg/dL)	___ ___ . ___	_____	
16. LDH (U/L)	___ ___ ___	_____	
17. Alkaline Phos. (U/L)	___ ___ ___	_____	
18. BUN (mg/dL)	___ ___ ___	_____	
19. Uric acid (mg/dL)	___ ___ . ___	_____	
20. Phosphorus (mg/dL)	___ ___ . ___	_____	
21. Creatine phospho-kinase (CPK) (U/L)	___ ___ ___ ___ ___	_____	

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

___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ / ___ ___ / ___ ___ ___ ___

Month **Day** **Year**

CBC	**Value**	**Evaluation** 1=Normal 2=Abnormal, not clinically significant, does not exclude 3=Abnormal, clinically significant, does not exclude 4=Abnormal, clinically significant, excludes 9=Not done	**Comments** – MUST provide comments if a 3, 4 or 9 is recorded under Evaluation.
22. Hemoglobin (g/dL)	___ ___ . ___	_____	
23. Hematocrit (%)	___ ___ . ___	_____	
24. RBC (M/mm^3)	___ ___ . ___	_____	
25. Platelet count (K/mm^3)	___ ___ ___	_____	
26. WBC (K/mm^3)	___ ___ . ___	_____	
27. Neutrophils (%)	___ ___ . ___	_____	
28. Lymphocytes (%)	___ ___ . ___	_____	
29. Monocytes (%)	___ ___ . ___	_____	
30. Eosinophils (%)	___ ___ . ___	_____	
31. Basophils (%)	___ ___ . ___	_____	
URINALYSIS			
32. Specific gravity	___ . ___ ___ ___	_____	
33. pH	___ ___ . ___	_____	
34. Glucose	**1___Neg 2___Trace 3___Present**	_____	
35. Protein	**1___Neg 2___Trace 3___Present**	_____	
36. Ketones	**1___Neg 2___Trace 3___Present**	_____	
37. Blood	**1___Neg 2___Present**	_____	
38. Nitrite	**1___Neg 2___Present**	_____	
CODING FOR Q. 39-40: **1=None 2=Few (1-5) 3=Mod (6-10) 4=Heavy (>10)**			
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 _____

This is a source document for CS #1021.

NIDA-CSP-1021 - Baclofen for Cocaine Dependence

NAME CODE	CENTER NO.	PATIENT NO.	DATE OF ASSESSMENT
___ ___ ___ ___	___ ___ ___	___ ___ ___ ___	___ ___ / ___ ___ / ___ ___ ___ ___
			Month Day Year

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:		
a. Neuroleptic Malignant Syn.	____	_____
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 _____	____	_____

NAME CODE	CENTER NO.	PATIENT NO.	DATE OF ASSESSMENT
___ ___ ___ ___	___ ___ ___	___ ___ ___ ___	___ ___/ ___ ___ /___ ___ ___ ___
			Month Day Year

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 (Month/Year)	IS SURGERY RELEVANT TO STUDY? 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 _____

VA/NIDA STUDY 1021
Baclofen for Cocaine Dependence

NAME CODE	CENTER NO.	PATIENT NO.	WEEK	DATE OF ASSESSMENT
___ ___ ___ ___	___ ___ ___	___ ___ ___ ___	___ ___	___ ___/ ___ ___ /___ ___ ___ ___
				Month Day Year

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 _____	_____	_____

NAME CODE	CENTER NO.	PATIENT NO.	WEEK	DATE OF ASSESSMENT
___ ___ ___ ___	___ ___ ___	___ ___ ___ ___	___ ___	___ ___/ ___ ___ /___ ___ ___ ___
				Month Day Year

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 _____

VA/NIDA STUDY 1021
Baclofen for Cocaine Dependence

NAME CODE ___ ___ ___ ___

CENTER NO. ___ ___ ___

PATIENT NO. ___ ___ ___ ___

DATE OF ASSESSMENT ___ ___/ ___ ___ /___ ___ ___ ___
Month Day Year

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.

A GENERIC NAME OF MEDICATION	B PURPOSE/INDICATION	C - ROUTE 1=Oral 2=Nasal 3=Intravenous 4=Inhalation 5=Topical transdermal 6=Intramuscular 7=Sublingual 8=Subcutaneous 9=Other	D DOSE	E - UNITS 01=Capsule/Tablet 02=Drop 03=Milligram 04=Milliliter 05=Puff 06=Spray/squirt 07=Tablespoon 08=Teaspoon 09=Unknown 10=Other	F FREQUENCY 1=<1/DAY 2=1-4 /DAY 3=PRN 4=>4/DAY	G MEDICATION START DATE (Mo/Day/Yr) *circle Ac≅ if continuing*		H MEDICATION STOP DATE (Mo/Day/Yr)
1.		_____	__ __ __ __ . __ __ __	__ __	_____	__ __/__ __/__ __ __ __	c	__ __/ __ __/ __ __ __ __
2.		_____	__ __ __ __ . __ __ __	__ __	_____	__ __/__ __/__ __ __ __	c	__ __/ __ __/ __ __ __ __
3.		_____	__ __ __ __ . __ __ __	__ __	_____	__ __/__ __/__ __ __ __	c	__ __/ __ __/ __ __ __ __
4.		_____	__ __ __ __ . __ __ __	__ __	_____	__ __/__ __/__ __ __ __	c	__ __/ __ __/ __ __ __ __
5.		_____	__ __ __ __ . __ __ __	__ __	_____	__ __/__ __/__ __ __ __	c	__ __/ __ __/ __ __ __ __
6.		_____	__ __ __ __ . __ __ __	__ __	_____	__ __/__ __/__ __ __ __	c	__ __/ __ __/ __ __ __ __
7.		_____	__ __ __ __ . __ __ __	__ __	_____	__ __/__ __/__ __ __ __	c	__ __/ __ __/ __ __ __ __
8.		_____	__ __ __ __ . __ __ __	__ __	_____	__ __/__ __/__ __ __ __	c	__ __/ __ __/ __ __ __ __
9.		_____	__ __ __ __ . __ __ __	__ __	_____	__ __/__ __/__ __ __ __	c	__ __/ __ __/ __ __ __ __
10.		_____	__ __ __ __ . __ __ __	__ __	_____	__ __/__ __/__ __ __ __	c	__ __/ __ __/ __ __ __ __

VA/NIDA STUDY 1021

Baclofen for Cocaine Dependence

NAME CODE ___ ___ ___ ___

CENTER NO. ___ ___ ___

PATIENT NO. ___ ___ ___ ___

DATE OF ASSESSMENT ___ ___/ ___ ___ /___ ___ ___ ___

Month Day Year

A GENERIC NAME OF MEDICATION	B PURPOSE/INDICATION	C - ROUTE 1=Oral 2=Nasal 3=Intravenous 4=Inhalation 5=Topical transdermal 6=Intramuscular 7=Sublingual 8=Subcutaneous 9=Other	D DOSE	E - UNITS 01=Capsule/Tablet 02=Drop 03=Milligram 04=Milliliter 05=Puff 06=Spray/squirt 07=Tablespoon 08=Teaspoon 09=Unknown 10=Other	F FREQUENCY 1=<1/DAY 2=1-4 /DAY 3=PRN 4=>4/DAY	G MEDICATION START DATE (Mo/Day/Yr) *circle Ac≅ if continuing*		H MEDICATION STOP DATE (Mo/Day/Yr)
11.		_____	__ __ __ __ . __ __ __	__ __	_____	__ __/__ __/__ __ __ __	c	__ __/ __ __/ __ __ __ __
12.		_____	__ __ __ __ . __ __ __	__ __	_____	__ __/__ __/__ __ __ __	c	__ __/ __ __/ __ __ __ __
13.		_____	__ __ __ __ . __ __ __	__ __	_____	__ __/__ __/__ __ __ __	c	__ __/ __ __/ __ __ __ __
14.		_____	__ __ __ __ . __ __ __	__ __	_____	__ __/__ __/__ __ __ __	c	__ __/ __ __/ __ __ __ __
15.		_____	__ __ __ __ . __ __ __	__ __	_____	__ __/__ __/__ __ __ __	c	__ __/ __ __/ __ __ __ __
16.		_____	__ __ __ __ . __ __ __	__ __	_____	__ __/__ __/__ __ __ __	c	__ __/ __ __/ __ __ __ __
17.		_____	__ __ __ __ . __ __ __	__ __	_____	__ __/__ __/__ __ __ __	c	__ __/ __ __/ __ __ __ __
18.		_____	__ __ __ __ . __ __ __	__ __	_____	__ __/__ __/__ __ __ __	c	__ __/ __ __/ __ __ __ __
19.		_____	__ __ __ __ . __ __ __	__ __	_____	__ __/__ __/__ __ __ __	c	__ __/ __ __/ __ __ __ __
20.		_____	__ __ __ __ . __ __ __	__ __	_____	__ __/__ __/__ __ __ __	c	__ __/ __ __/ __ __ __ __

FORM COMPLETED BY _____ Date_____

PHYSICIAN=S SIGNATURE _____ Date _____

NIDA-CSP-1021 - Baclofen for Cocaine Dependence

NAME CODE	CENTER NO.	PATIENT NO.	WEEK	DATE OF ASSESSMENT
__ __ __ __	__ __ __	__ __ __ __	__ __	__ __/ __ __ /__ __ __ __
				Month Day Year

FORM 08 - BIRTH CONTROL/PREGNANCY ASSESSMENT (Women Only)

***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 _____

NIDA-CSP-1021 - Baclofen for Cocaine Dependence

NAME CODE	CENTER NO.	PATIENT NO.	DATE COMPLETED
___ ___ ___ ___	___ ___ ___	___ ___ ___ ___	___ ___ / ___ ___ / ___ ___ ___ ___
			Month Day Year

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

NAME CODE	CENTER NO.	PATIENT NO.	DATE COMPLETED
___ ___ ___ ___	___ ___ ___	___ ___ ___ ___	___ ___ / ___ ___ / ___ ___ ___ ___
			Month Day Year

17. Current suicidal ideation or plan (within the past 30 days) ..... 0____ No 1 ____Yes 2 ____NS

18. Pregnant or lactating (pregnancy test must be completed within two days prior to study drug administration)..... 0____ No 1 ____Yes 2 ____NS

19. 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) ..... 0____ No 1 ____Yes 2 ____NS

20. Clinically significant abnormal laboratory values (see Appendix I of protocol)..... 0____ No 1 ____Yes 2 ____NS

21. AIDS (according to the current CDC criteria for AIDS)..... 0____ No 1 ____Yes 2 ____NS

22. Active syphilis that has not been treated or patient refused treatment..... 0____ No 1 ____Yes 2 ____NS

23. Active tuberculosis (positive tuberculin test and confirmatory diagnostic chest x-ray)..... 0____ No 1 ____Yes 2 ____NS

24. Diagnosis of adult onset asthma, or chronic obstructive pulmonary disease (COPD)..... 0____ No 1 ____Yes 2 ____NS

25. Actively using albuterol or other beta agonist medications, regardless of formal diagnosis of asthma.. ..... 0____ No 1 ____Yes 2 ____NS

26. Received medication that could interact adversely with baclofen (see protocol, for medications that fall into that category). ..... 0____ No 1 ____Yes 2 ____NS

27. Participated in any pharmacological or behavioral intervention study within 2 months preceding screening..... 0____ No 1 ____Yes 2 ____NS

28. Known or suspected hypersensitivity to baclofen ..... 0____ No 1 ____Yes 2 ____NS

29. Taken baclofen for any reason currently or during the past year..... 0____ No 1 ____Yes 2 ____NS

30. Had 2 benzodiazepine positive urines samples during screening ..... 0____ No 1 ____Yes 2 ____NS

31. Is the patient eligible for randomization?..... 0____ No 1 ____Yes 2 ____Yes, but declined randomization

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

32. Date of randomization ..... Mo ___ ___ Day ___ ___ Year ___ ___ ___ ___

33. Randomization Number ..... (Center-Patient) ___ ___ ___ - ___ ___ ___ ___

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**

___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ / ___ ___ / ___ ___ ___ ___

Month **Day** **Year**

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) ..... ___ ___ : ___ ___

NAME CODE	CENTER NO.	PATIENT NO.	WEEK	DATE OF ASSESSMENT
___ ___ ___ ___	___ ___ ___	___ ___ ___ ___	___ ___	___ ___ / ___ ___ / ___ ___ ___ ___
				Month Day Year

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: _____

_____

B. SUSPECT DRUG(S) INFORMATION:

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) _____

NAME CODE	CENTER NO.	PATIENT NO.	WEEK	DATE OF ASSESSMENT
___ ___ ___ ___	___ ___ ___	___ ___ ___ ___	___ ___	___ ___ / ___ ___ / ___ ___ ___ ___
				Month Day Year

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 _____

This is a source document for CS #1021.

NIDA-CSP-1021 - Baclofen for Cocaine Dependence

NAME CODE ___ ___ ___ ___ **CENTER NO.** ___ ___ ___ **PATIENT NO.** ___ ___ ___ ___ **WEEK** ___ ___ **DATE COMPLETED** ___ ___ / ___ ___ / ___ ___ ___ ___
Month Day Year

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).

*Nicotine Codes (Q.7): 1=Cigarettes, 2=Sticks of gum/nicorette, 3=Patch, 4=Cigars, 5=Other HSubstance Codes (Q.8-11): 1=Other stimulants (amph, crystal meth, etc), 2=Hallucinogens (PCP, LSD, ecstacy, etc), 3=Inhalants (glue, ethyl chl, etc.), 4=Sedative hypn/anxiolytics (valium, seconal, etc.), 5=Other	A. TOTAL AMOUNT	B. ROUTE 1=Oral 2=Nasal 3=Intravenous 4=Inhalation 5=Topical Transdermal 6=Intramuscular 7=Sublingual 8=Subcutaneous 9=Other
3A. Cocaine		_____
3B. Cocaine		_____
3C. Cocaine		_____
4A. Beer (record the # of standard 12 oz beer drinks)	___ ___ ___ ___	One ≡standard drink≡ is equal to:
4B. Wine (record the # of standard 4 oz. wine drinks)	___ ___ ___ ___	
4C. Hard liquor (record the # of standard 1 oz. liquor drinks)	___ ___ ___ ___	
5. Marijuana		_____
6A. Opioids: specify _____		_____
6B. Opioids: specify _____		_____
7A. Nicotine, specify (Code ____ *) _____	___ ___ ___ ___	_____
7B. Nicotine, specify (Code ____ *) _____	___ ___ ___ ___	_____
8. Other, specify (Code ____ H) _____		_____
9. Other, specify (Code ____ H) _____		_____
10. Other, specify (Code ____ H) _____		_____
11. Other, specify (Code ____ H) _____		_____

FORM COMPLETED BY _____ Date _____

NIDA-CSP-1021 - Baclofen for Cocaine Dependence

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

___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ ___ / ___ ___ / ___ ___ ___ ___

Month **Day** **Year**

FORM 24 - STUDY COMPLETION/TERMINATION

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/NIDA STUDY 1021
Baclofen for Cocaine Dependence

NAME CODE	CENTER NO.	PATIENT NO.	WEEK	DATE COMPLETED
___ ___ ___ ___	___ ___ ___	___ ___ ___ ___	___ ___	___ ___/ ___ ___ /___ ___ ___ ___
				Month Day Year

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 _____

NIDA/VA CSP 1021 Shipping and Receiving Log

Study Number

N I D A - 1 0 2 1

Site:

T B D

Date Urine Samples Shipped

2

Total Samples in shipment

Name Code:	Patient ID:	Bar Code Label:	Sample #	Date Collected:	**NWT USE ONLY**	Data Center Verification
1.		Place Barcode Label Here		/ /		
2.		Place Barcode Label Here		/ /		
3.		Place Barcode Label Here		/ /		
4.		Place Barcode Label Here		/ /		
5.		Place Barcode Label Here		/ /		

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 #:

DRAFT

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 #.)

This is a source document for CS #1021.

NIDA-CSP-1021 - Baclofen for Cocaine Dependence

NAME CODE	CENTER NO.	PATIENT NO.	DATE SPECIMEN COLLECTED
___ ___ ___ ___	___ ___ ___	___ ___ ___ ___	___ ___ / ___ ___ /___ ___ ___ ___
			Month Day Year

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 _____

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 _____