FORM 01 - BACKGROUND INFORMATION

1. Date of Birth..................................................................................................................Mo__ ___ Day __ __ Yr __ __

2. Race ................................................................................................................................______
   1=White, not of Hispanic Origin
   2=Black, not of Hispanic Origin
   3=Native American
   4=Asian or Pacific Islander
   5=Hispanic

3. Gender (1=Male, 2=Female)..................................................................................................

4. Highest Level of Education Attained......................................................................................
   1=Completed graduate/professional training
   2=Standard college/university graduate
   3=Partial college training
   4=High school graduate
   5=Partial high school (10th-11th grade)
   6=Junior high school (7th-9th grade)
   7=Under 7 years schooling (kindergarten-6th grade)

5. Usual Kind of Work During the Past 3 Years........................................................................
   1=Never gainfully employed
   2=Unskilled employee
   3=Machine operator, semi-skilled employee
   4=Skilled manual employee
   5=Clerical/sales worker, technician, owner of small business
   6=Administrative personnel, owner of small independent business, minor professional
   7=Business manager of large concern, proprietor of medium-sized business, lesser professional
   8=Higher executive, proprietor of large concern, major professional

6. Usual Employment Pattern During the Past 3 Years................................................................
   1=Full time (40 hours/week)
   2=Part-time (regular hours)
   3=Part-time (irregular hours)
   4=Student
   5=Military service
   6=Retired/disability
   7=Unemployed
   8=In controlled environment

7. Approximate Total Annual Family Income (from all sources)...............................................$ __ __ __, __ __ __
8. Current Marital Status
   1=Married
   2=Widowed
   3=Separated
   4=Divorced
   5=Never married

9. Usual Living Arrangements in the Past 3 Years
   1=With sexual partner and children
   2=With sexual partner alone
   3=With parents
   4=With family
   5=With friends
   6=Alone
   7=Controlled environment
   8=No stable arrangements

10. Is There Heroin or Cocaine Use in the Household Where You Live?
    1=Yes
    2=No
    3=Don't know

11. Have You Ever Been Enrolled in a Methadone or LAAM Maintenance Program
    (not counting "detox")?
    1=Yes
    2=No
    a. If YES, How Many Times?
    b. If NO, Why Not?

FORM COMPLETED BY ___________________________ Date ___________________________
### FORM 02 - NON-THERAPEUTIC DRUG USE HISTORY

1. **DRUG USE HISTORY:** *(If NO for USED DRUG, leave rest of line blank)*

<table>
<thead>
<tr>
<th>DRUG</th>
<th>USED DRUG? (choose one)</th>
<th>IF YES: Number of Years/Months Used</th>
<th>Last Drug Use Occurred (choose one)</th>
<th>PRIMARY Mode of Use (choose one)</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Heroin or other opiate</td>
<td></td>
<td>yrs. mos.</td>
<td>1=Within past week</td>
<td>1=Oral</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2=Within past 30 days</td>
<td>2=I.V.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3=Within past 60 days</td>
<td>3=Snorting</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>4=Greater than 60 days</td>
<td>4=Smoking</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>5=Sublingual</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>6=Other</td>
</tr>
<tr>
<td>b. Cocaine</td>
<td></td>
<td>yrs. mos.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c. Methamphetamine/Amphetamine</td>
<td></td>
<td>yrs. mos.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Alcohol</td>
<td>yrs. mos.</td>
<td>yrs. mos.</td>
<td>yrs. mos.</td>
</tr>
<tr>
<td>---</td>
<td>---------</td>
<td>-----------</td>
<td>-----------</td>
<td>-----------</td>
</tr>
<tr>
<td>d.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>e.</td>
<td>Benzodiazepine</td>
<td>yrs. mos.</td>
<td>yrs. mos.</td>
<td>yrs. mos.</td>
</tr>
<tr>
<td>f.</td>
<td>Marijuana or other forms of THC</td>
<td>yrs. mos.</td>
<td>yrs. mos.</td>
<td>yrs. mos.</td>
</tr>
<tr>
<td>g.</td>
<td>PCP</td>
<td>yrs. mos.</td>
<td>yrs. mos.</td>
<td>yrs. mos.</td>
</tr>
<tr>
<td>h.</td>
<td>Other, specify: *</td>
<td>yrs. mos.</td>
<td>yrs. mos.</td>
<td>yrs. mos.</td>
</tr>
</tbody>
</table>
*Please list MOST FREQUENTLY USED other drugs. Leave line blank if no "OTHER" drug used.

FORM COMPLETED BY  Date _______________________
# FORM 03 - CRAVING SCALE

RATING PERIOD:  WEEK #  (00 [Screen], 01, 02, 03, 04)
DAY (1=MON, 2=TUE, 3=WED, 4=THUR, 5=FRI)

1. DID PATIENT COMPLETE CRAVING SCALE? (1=YES, 2=NO)
   (If YES, continue:)

2. HEROIN (OR OTHER OPIATE) CRAVING: Mark on the line below, the most craving for heroin
   (or other opiate) that occurred at any time during the past 24 hours:

<table>
<thead>
<tr>
<th>NO</th>
<th>MOST INTENSE CRAWING</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CRAVING</td>
</tr>
<tr>
<td></td>
<td>CRAVING I EVER HAD</td>
</tr>
</tbody>
</table>

   mm

FORM COMPLETED BY:  Date ________________________

VA FORM 10-21004(NR)c
June 1996
### Form 04 - Medical History and Status

**A. Please indicate whether the patient has had any abnormalities, diseases, or disorders of the following:**

| 1. HEENT                                  | 1=YES | IF YES, please briefly describe abnormality, disease, or disorder |
| 2. Cardiovascular System                  | 2=NO  |                                                                      |
| 3. Respiratory System                     |       |                                                                      |
| 4. Gastrointestinal System                |       |                                                                      |
| 5. Genitourinary System                   |       |                                                                      |
| 6. Musculoskeletal System                 |       |                                                                      |
| 7. Neurological System                    |       |                                                                      |
| 8. Endocrinological System                |       |                                                                      |
| 9. Skin or Appendages                     |       |                                                                      |
| 10. Hematopoietic System                  |       |                                                                      |
| 11. Allergies                             |       |                                                                      |

**B. If there are any others, please specify below - otherwise leave blank**

| 12. Other, specify ______________________ |       |                                                                      |
| 13. Other, specify ______________________ |       |                                                                      |
| 14. Other, specify ______________________ |       |                                                                      |
| 15. Other, specify ______________________ |       |                                                                      |
16. Does the patient have any current/ongoing medical problems other than his/her addiction? (1=Yes, 2=No)

If Yes, list these problems below:

<table>
<thead>
<tr>
<th>Nature of Problem</th>
<th>Date of Onset (Mo Day Yr)</th>
<th>I. Severity</th>
<th>II. Action Taken</th>
</tr>
</thead>
<tbody>
<tr>
<td>a.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>d.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>e.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>f.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

17. Has the patient had any problems in the past 7 days? (1=Yes, 2=No)

If YES, please describe each adverse event, intercurrent illness or clinically significant abnormal lab value and associated information below.

<table>
<thead>
<tr>
<th>Nature of Illness, Event or Abnormal Lab Value</th>
<th>Date of Onset</th>
<th>Date of Resolution</th>
<th>I. Severity</th>
<th>II. Action Taken</th>
<th>III. Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>a.</td>
<td>__ __/ __ __/ __ __</td>
<td>__ __/ __ __/ __ __</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b.</td>
<td>__ __/ __ __/ __ __</td>
<td>__ __/ __ __/ __ __</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c.</td>
<td>__ __/ __ __/ __ __</td>
<td>__ __/ __ __/ __ __</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>d.</td>
<td>__ __/ __ __/ __ __</td>
<td>__ __/ __ __/ __ __</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>e.</td>
<td>__ __/ __ __/ __ __</td>
<td>__ __/ __ __/ __ __</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>f.</td>
<td>__ __/ __ __/ __ __</td>
<td>__ __/ __ __/ __ __</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
C. 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 “/”, use the sixth digit to indicate the following specifiers:

5: “in partial remission”, 6: “in 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) ___ ___ ___. ___ ___/ ___

D. Addiction Severity Index Interviewer Severity Rating. For each of the problem areas listed, indicate the corresponding interviewer severity rating.

1) Need for medical treatment: _____
2) Need for employment counseling: _____
3) Need for alcohol abuse treatment: _____
4) Need for drug abuse treatment: _____
5) Need for legal services or counseling: _____
6) Need for family and/or social counseling: _____
7) Need for psychiatric/psychological treatment: _____

FORM COMPLETED BY Date______________________________
FORM 05A - PHYSICAL EXAM

RATING PERIOD: WEEK NUMBER
(00 [Screen], 52)

1. WAS PHYSICAL EXAM DONE? (1= YES, 2=NO) (If YES, continue:)

VITAL SIGNS AND OTHER MEASURES

<table>
<thead>
<tr>
<th>2. Height (ins.)*</th>
<th>5. Blood Pressure - sitting (mmHg) /</th>
<th>6. Pulse Rate (beats/minute resting)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>systolic</td>
<td>diastolic</td>
</tr>
<tr>
<td>3. Weight (lbs.)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Temperature (°F)</td>
<td></td>
<td>7. Respiration (/minute resting)</td>
</tr>
</tbody>
</table>

PHYSICAL EXAM

<table>
<thead>
<tr>
<th>8. HEENT</th>
<th>1=Normal 2=Abnormal 3=Not Done If ABNORMAL, Describe Abnormality</th>
</tr>
</thead>
<tbody>
<tr>
<td>9. Sublingual Mucosa</td>
<td></td>
</tr>
<tr>
<td>10. Pupil Size</td>
<td></td>
</tr>
<tr>
<td>11. Heart</td>
<td></td>
</tr>
<tr>
<td>12. Lungs</td>
<td></td>
</tr>
<tr>
<td>13. Abdomen</td>
<td></td>
</tr>
<tr>
<td>14. Extremities</td>
<td></td>
</tr>
<tr>
<td>15. Skin</td>
<td></td>
</tr>
<tr>
<td>16. Lymph Nodes</td>
<td></td>
</tr>
<tr>
<td>17. Musculoskeletal</td>
<td></td>
</tr>
<tr>
<td>18. General Appearance</td>
<td></td>
</tr>
</tbody>
</table>

Other physical findings: .

*Collect at Screening Only

FORM COMPLETED BY ______________ Date ________________________
FORM 05B - MEDICAL EVALUATION

RATING PERIOD:  WEEK NUMBER  
(04, 08, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48, 99 [Unscheduled])

1. WAS MEDICAL EVALUATION DONE?  (1= YES, 2=NO)  
   (If YES, continue:)

VITAL SIGNS AND OTHER MEASURES

2. Weight (lbs.)  •  4. Blood Pressure - sitting (mmHg)  /  
   systolic       diastolic

3. Temperature (°F)  •  5. Pulse Rate (beats/minute resting)

6. Respiration (/minute resting)

PHYSICAL EXAM

| 7. Sublingual Mucosa | 1=Normal  
|                      | 2=Abnormal  
|                      | 3=Not Done | If ABNORMAL, Describe Abnormality |

8. General Appearance

Other Physical Findings:  

FORM COMPLETED BY  
Date _________________________

INVESTIGATOR'S SIGNATURE  
Date _________________________
FORM 06A - PREGNANCY TEST/BIRTH CONTROL ASSESSMENT (Women Only) 
(SCREEnING ONLY)

1. Is patient of child bearing potential? 1=YES, 2=NO
   (If YES, go to Question 2; if NO, complete a & b below and go to Question 3)
   a. Give reason: ___
      1=Hysterectomy
      2=Tubal Ligation
      3=Post-menopausal
      4=Other, Specify ____________
   b. Date of procedure or occurrence: Mo ___ Yr ___
      (Note: for Post-Menopausal, use date of last menstrual period)

2. What method of birth control has the patient agreed to use?
   1=Oral Contraceptive
   2=Barrier (diaphragm or condom) Plus Spermicide or Condom Only
   3=Levonorgestrel Implant (Norplant)
   4=Intrauterine Progesterone Contraceptive System (IUD)
   5=Medroxyprogesterone Acetate Contraceptive Injection (Depo-provera)
   6=Complete Abstinence
   7=None, Specify Reason ______________________
   8=Other, Specify ____________________

3. Urine pregnancy test: 1=Positive, 2=Negative ___
FORM 06B - PREGNANCY TEST/BIRTH CONTROL ASSESSMENT (Women Only) (MONTHLY FOLLOW-UP)

RATING PERIOD: WEEK NUMBER
(04, 08, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48, 52, 99 [Unscheduled])

1. Was urine sample taken? 1=YES, 2=NO, 3=Not of Child Bearing Potential
   (If YES, continue)

2. Urine pregnancy test: 1=Positive, 2=Negative

3. Has reported method of birth control changed since screening? 1=YES, 2=NO

4. What method of birth control is patient reportedly using?
   1=Oral Contraceptive
   2=Barrier (diaphragm or condom) Plus Spermicide or Condom Only
   3=Levonorgestrel Implant (Norplant)
   4=Intrauterine Progesterone Contraceptive System (IUD)
   5=Medroxyprogesterone Acetate Contraceptive Injection (Depo-provera)
   6=Complete Abstinence
   7=none, Specify Reason ______________________
   8=Other, Specify ______________________

FORM COMPLETED BY ___________________  Date ___________________
**VA/NIDA STUDY 1008B**

A Multicenter Safety Trial of Buprenorphine/Naloxone for The Treatment of Opiate Dependence

---

### FORM 07 - CLINICAL LABORATORY EVALUATION

**RATING PERIOD:**

WEEK NUMBER: ___ ___

(00 [Screen], 04, 08, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48, 52, 99 [Unscheduled])

---

**A. WAS SAMPLE TAKEN?**

1=YES, 2=NO

(If YES, continue:)

---

**HEMATOLOGY**

| 1. Total WBC (thousand per mm$^3$) | 6. Neutrophils (%) |
| 2. Total RBC (million per mm$^3$) | 7. Lymphocytes (%) |
| 3. Platelet count (thousand per mm$^3$) | 8. Monocytes (%) |
| 4. Hemoglobin (gm/dL) | 9. Eosinophils (%) |
| 5. Hematocrit (%) | 10. Basophils (%) |

---

**BLOOD CHEMISTRY**

| 11. Sodium (mEq/L) | 19. Creatinine (mg/dL) |
| 12. Potassium (mEq/L) | 20. SGOT/(AST) (U/L) |
| 13. Chloride (mEq/L) | 21. SGPT/(ALT) (U/L) |
| 14. Uric Acid (mg/dL) | 22. GGT (U/L) |
| 15. Glucose (mg/dL) | 23. LDH (U/L) |
| 17. Albumin (gm/dL) | 25. Total bilirubin (mg/dL) |
| 18. BUN (mg/dL) |

---

**ANSWER THE FOLLOWING QUESTIONS EXCEPT AT SCREENING**

If values from Questions 20 or 21 are 8 times or greater than normal, complete Questions 26 and 27.

1=YES

2=NO

26. Were Forms 09 and 17 completed? ___

27. Were the Sponsor and the IRB notified? ___
<table>
<thead>
<tr>
<th>Date Sample Collected/</th>
<th>Patient Initials</th>
<th>Center No.</th>
<th>Patient No.</th>
<th>Scheduled to be Collected</th>
</tr>
</thead>
</table>

**URINALYSIS**

<table>
<thead>
<tr>
<th>No.</th>
<th>Test</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>28.</td>
<td>Specific gravity</td>
<td>•</td>
</tr>
<tr>
<td>29.</td>
<td>Reaction (record actual pH value)</td>
<td>•</td>
</tr>
<tr>
<td>30.</td>
<td>Protein (0=Absent, 1=Trace, 2=1+, 3=2+, 4=3+, 5=4+)</td>
<td></td>
</tr>
<tr>
<td>31.</td>
<td>Glucose (0=Negative, 1=Trace, 2=Present)</td>
<td></td>
</tr>
<tr>
<td>32.</td>
<td>Ketones (0=Absent, 1=Trace, 2=Present)</td>
<td></td>
</tr>
<tr>
<td>33.</td>
<td>WBCs/HPF (0=None, 1=Few, 2=Moderate, 3=Heavy)</td>
<td></td>
</tr>
<tr>
<td>34.</td>
<td>RBCs/HPF (0=None, 1=Few, 2=Moderate, 3=Heavy)</td>
<td></td>
</tr>
<tr>
<td>35.</td>
<td>Epithelial Cells (0=None, 1=Few, 2=Moderate, 3=Heavy)</td>
<td></td>
</tr>
<tr>
<td>36.</td>
<td>Occult Blood (0=Absent, 1=Present)</td>
<td></td>
</tr>
</tbody>
</table>

**(TO BE DONE AT SCREENING AND WEEK 28 ONLY)**

<table>
<thead>
<tr>
<th>No.</th>
<th>Test</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>37.</td>
<td>PPD SKIN TEST DONE? 1=YES, 2=NO</td>
<td></td>
</tr>
<tr>
<td></td>
<td>a. If YES, result: 1=Positive, 2=Negative, 3=Inconclusive</td>
<td></td>
</tr>
<tr>
<td></td>
<td>b. If NO, reason: 1=Already Positive, 2=Has TB, 3=Other, Specify ___________</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Date of Last Test: Mo ___ Day ___ Yr ___</td>
<td></td>
</tr>
</tbody>
</table>

**(TO BE DONE AT SCREENING ONLY)**

<table>
<thead>
<tr>
<th>No.</th>
<th>Test</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>38.</td>
<td>HEPATITIS</td>
<td></td>
</tr>
<tr>
<td></td>
<td>a. Hepatitis B Surface Antigen (HBs Ag)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>b. Hepatitis B Surface Antibody (Anti-HBs)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>c. Hepatitis B Core Antibody (Anti-HBc)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>d. Hepatitis C immunoassay antibody screen (anti-HCV)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>e. Hepatitis C recombinant immunoblot or dot immunoassay</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(Performed only if hepatitis C immunoassay antibody screen is positive. If immunoblot assay is not required because immunoassay is negative, code as “0”)</td>
<td></td>
</tr>
</tbody>
</table>

**COMMENTS:** *(If there are clinically significant abnormal results observed, please describe below and complete Form 09)*

- 
- 

FORM COMPLETED BY ___________________________  
Date ________________

VA Form 10-21004(NR)ee  
June 1996
VA/NIDA STUDY 1008B
A Multicenter Safety Trial of Buprenorphine/Naloxone for The Treatment of Opiate Dependence

FORM 08 - ELECTROCARDIOGRAM

RATING PERIOD: WEEK NUMBER
(00 [Screen], 04, 12, 24, 36, 52/Termination)

1. WAS ELECTROCARDIOGRAM DONE? (1=YES, 2=NO)
   (If YES, continue:)

2. ECG OVERALL RESULTS WERE: 1=Normal, 2=Abnormal

Circle ALL appropriate codes:

3. Left Atrial Hypertrophy
4. Right Atrial Hypertrophy
5. Left Ventricular Hypertrophy
6. Right Ventricular Hypertrophy
7. Acute Infarction
8. Subacute Infarction
9. Old Infarction
10. Myocardial Ischemia
11. Digitalis Effect
12. Symmetrical T-Wave Inversions
13. Poor R-Wave Progression
14. Other Nonspecific ST/T
15. Sinus Tachycardia
16. Sinus Bradycardia
17. Supraventricular Premature Beat
18. Ventricular Premature Beat
19. Supraventricular Tachycardia
20. Ventricular Tachycardia
21. Atrial Fibrillation
22. Atrial Flutter
23. Other Rhythm Abnormalities
24. Implanted Pacemaker
25. 1st Degree A-V Block
26. 2nd Degree A-V Block
27. 3rd Degree A-V Block
28. LBB Block
29. RBB Block
30. Pre-excitation Syndrome
31. Other Intraventricular Cond. Block
32. Other (specify).

FORM COMPLETED BY __________________________ Date

INVESTIGATOR'S SIGNATURE __________________________ Date

FORM 09 - ADVERSE EVENTS/CONCOMITANT MEDICATIONS

RATING PERIOD: WEEK NUMBER 01-52

A. Was patient evaluated?  
   (If YES, Continue:)

B. Did patient have any adverse medical events in past rating period?  (include those unresolved at end of last rating period)
   (NOTE: An adverse event is any untoward medical occurrence experienced by a patient after study enrollment.
   An adverse event includes an onset of disease, a set of related symptoms or signs, a single symptom or sign, or a clinically
   significant laboratory test change from baseline.)

   If YES, give details below:

   I. Type of Report
   1=Anticipated  
   2=Unanticipated  
   3=Intercurrent Illness  
   4=Withdrawal

   II. Relatedness**
   1=Definitely Study Drug Related
   2=Probably Study Drug Related
   3=Possibly Study Drug Related
   4=Unrelated to Study Drug

   III. Severity**
   1=Mild
   2=Moderate
   3=Severe

   IV. Action Taken
   1=None
   2=Outpatient Treatment
   3=Inpatient Treatment

   V. Outcome
   1=Resolved; No sequelae
   2=Not Yet Resolved
   3=Resulted in Chronic Condition, Severe and/or Permanent Disability
   4=Deceased
   5=Unknown

C. Is a Serious/Unexpected Adverse Event Form (Form 17) required?

---

*Requires completion of Form 17 - Serious/Unexpected Adverse Event Form

**See Operations Manual (Section IX) for guidelines.
D. Was it necessary to break randomization code for this patient? 

Comments: 

Continued
E. Did the patient take any medications during this reporting period?  1=YES, 2=NO  

If YES, list these medications below and the reason. Record the dates the medications were taken, and CHECK (√) if continuing the medication.

<table>
<thead>
<tr>
<th>1 GENERIC NAME OF MEDICATION (if possible)</th>
<th>2 If medication taken as a result of an adverse event listed on Page 1 of this form, list number of event. If NOT, please list indication in next column.</th>
<th>3 INDICATION</th>
<th>4 FROM Medication Start Date Mo Day Yr</th>
<th>5 CHECK (√) if continuing</th>
<th>6 TO Medication End Date (If ended, enter last date medication taken) Mo Day Yr</th>
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</table>

FORM COMPLETED BY ___________________________________________________  Date ___________________

INVESTIGATOR’S SIGNATURE ____________________________________________  Date ___________________
FORM 10 - RISK ASSESSMENT BATTERY

RATING PERIOD: WEEK NUMBER ___ ___
(00 [Screen])

WAS RISK ASSESSMENT BATTERY COMPLETED? 1=YES, 2=NO ___
(If YES, continue:)

___ Check if asked by interviewer

Interviewer's Name ________________________________ Date ____________

Please read each of the following questions very carefully. As you will see, many of
these questions are very personal. We understand this and have taken great care to
protect the privacy of your answers.

It is very important that you answer EVERY question honestly. In fact, it's better
not to answer a question at all than to tell us something that is not accurate or true.
Some questions may not seem to have an answer that is true for you. When this
happens, you should simply choose the answer that is most right. Don't spend too
much time on any one question. Remember, always ask for help if you're unsure
about what to do.

Thank you for your time and cooperation.
A. PAST MONTH DRUG AND ALCOHOL USE:

Please CIRCLE the most correct response.

1. In the past month, how often have you injected cocaine and heroin together (Speedball)?
   - 0. Not at all
   - 1. A few times
   - 2. A few times each week
   - 3. Everyday

2. In the past month, how often have you injected heroin (not mixed)?
   - 0. Not at all
   - 1. A few times
   - 2. A few times each week
   - 3. Everyday

3. In the past month, how often have you snorted heroin (not mixed)?
   - 0. Not at all
   - 1. A few times
   - 2. A few times each week
   - 3. Everyday

4. In the past month, how often have you smoked heroin?
   - 0. Not at all
   - 1. A few times
   - 2. A few times each week
   - 3. Everyday
5. In the past month, how often have you injected cocaine (not mixed)?
   0. Not at all
   1. A few times
   2. A few times each week
   3. Everyday

6. In the past month, how often have you snorted cocaine (not mixed)?
   0. Not at all
   1. A few times
   2. A few times each week
   3. Everyday

7. In the past month, how often have you smoked crack, rock, or freebase cocaine?
   0. Not at all
   1. A few times
   2. A few times each week
   3. Everyday

8. In the past month, how often have you injected amphetamines, meth, speed, crank or crystal?
   0. Not at all
   1. A few times
   2. A few times each week
   3. Everyday
9. In the past month, how often have you snorted amphetamines, meth, speed, crank or crystal?
   0. Not at all
   1. A few times
   2. A few times each week
   3. Everyday

10. In the past month, how often have you smoked amphetamines, meth, speed, crank or crystal?
    0. Not at all
    1. A few times
    2. A few times each week
    3. Everyday

11. In the past month, how often have you used benzodiazepines (benzos, benzies) such as Xanax, Valium, Klonipin or Ativan?
    0. Not at all
    1. A few times
    2. A few times each week
    3. Everyday

12. In the past month, how often have you taken painkillers - pills such as Percodan, Percocet, Vicodin, Demerol, Dilaudid, Darvon, Darvocet or syrup (Codeine)?
    0. Not at all
    1. A few times
    2. A few times each week
    3. Everyday

    a. Which types of painkillers did you use? ______________________________
<table>
<thead>
<tr>
<th>Patient Initials</th>
<th>Center No.</th>
<th>Patient No.</th>
<th>Date of Visit/</th>
</tr>
</thead>
</table>

Date of Scheduled Visit

- - month
day
year

VA Form 10-21004(NR)hh
June 1996
13. In the past month, how often have you inject Dilaudid?
   0. Not at all
   1. A few times
   2. A few times each week
   3. Everyday

14. In the past month, how often have you used acid, LSD, or other hallucinogens?
   0. Not at all
   1. A few times
   2. A few times each week
   3. Everyday

15. In the past month, how often have you used marijuana?
   0. Not at all
   1. A few times
   2. A few times each week
   3. Everyday

16. In the past month, how often have you used beer, wine, or liquor?
   0. Not at all
   1. A few times
   2. A few times each week
   3. Everyday

B. NEEDLE USE:

17. In the past six months, have you injected drugs?
   1. YES
   2. NO

18. In the past six months, have you shared needles or works?
1. Yes
2. No or I have not shot up in the past six months

19. With how many different people did you share needles in the past six months?
   0. 0 or I have not shot up in the past six months
   1. 1 other person
   2. 2 or 3 different people
   3. 4 or more different people

20. In the past six months, how often have you used a needle after someone (with or without cleaning)?
   0. Never or I have not shot up or shared in the past 6 months
   1. A few times or less
   2. A few times each month
   3. Once or more each week

21. In the past six months, how often have others used after you (with or without cleaning)?
   0. Never or I have not shot up or shared in the past 6 months
   1. A few times or less
   2. A few times each month
   3. Once or more each week
22. In the past six months, how often have you shared needles with someone you knew (or later found out) had AIDS or was positive for HIV, the AIDS virus?
   0. Never or I have not shot up or shared in the past 6 months
   1. A few times or less
   2. A few times each month
   3. Once or more each week

23. Where did you get your needles during the past six months?
   (Circle all that apply)
   0. I have not shot up in the past six months
   1. From a diabetic
   2. On the street
   3. Drugstore
   4. Shooting gallery or other place where users go to shoot up
   5. Needle Exchange Program
   6. Other, specify__________________________

24. In the past six months, how often have you been to a shooting gallery/house or other place where users go to shoot-up?
   0. Never
   1. A few times or less
   2. A few times each month
   3. Once or more each week
25. In the past six months, how often have you been to a Crack House or other place where people go to smoke crack?
   0. Never
   1. A few times or less
   2. A few times each month
   3. Once or more each week

26. Which statement best describes the way you cleaned your needles during the past six months? (Please choose one)
   0. I have not shot up in the past six months
   1. I always use new needles
   2. I always clean my needle just before I shoot up
   3. After I shoot up, I always clean my needle
   4. Sometimes I clean my needle, sometimes I don't
   5. I never clean my needle

27. If you have cleaned your needles and works in the past six months, how did you clean them?
   0. I have not shot up in the past six months
   1. Soap and water or water only
   2. Alcohol
   3. Bleach
   4. Boiling water
   5. Other, specify____________________________
   6. I did not clean my needles in the past six months
   7. I ALWAYS used new needles in the past six months
28. In the past six months, how often have you shared rinse water?
   0. Never or I have not shot up in the past 6 months
   1. A few times or less
   2. A few times each month
   3. Once or more each week

29. In the past six months, how often have you shared a cooker?
   0. Never or I have not shot up in the past 6 months
   1. A few times or less
   2. A few times each month
   3. Once or more each week

30. In the past six months, how often have you shared a cotton?
   0. Never or I have not shot up in the past 6 months
   1. A few times or less
   2. A few times each month
   3. Once or more each week

31. In the past six months, how often have you divided or shared drugs with others by using one syringe (yours or someone else’s) to squirt or load the drugs into the other syringe(s) (backloading, for example)?
   0. Never or I have not shot up in the past 6 months
   1. A few times or less
   2. A few times each month
   3. Once or more each week
C. SEXUAL PRACTICES

32. How would you describe yourself?
   1. Straight
   2. Gay or Homosexual
   3. Bisexual

*Please note: For the following questions, sex means any vaginal intercourse, anal intercourse (in the butt) or oral sex (blowjobs, for example).*

33. With how many men have you had sex in the past 6 months?
   0. 0 men
   1. 1 man
   2. 2 or 3 men
   3. 4 or more men

34. With how many women have you had sex in the past 6 months?
   0. 0 women
   1. 1 woman
   2. 2 or 3 women
   3. 4 or more women

35. In the past six months, how often have you had sex so you could get drugs?
   0. Never
   1. A few times or less
   2. A few times each month
   3. Once or more each week
36. In the past six months, how often have you given drugs to someone so you could have sex with them?
   0. Never
   1. A few times or less
   2. A few times each month
   3. Once or more each week

37. In the past six months, how often were you paid money to have sex with someone?
   0. Never
   1. A few times or less
   2. A few times each month
   3. Once or more each week

38. In the past six months, how often did you give money to someone so you could have sex with them?
   0. Never
   1. A few times or less
   2. A few times each month
   3. Once or more each week

39. In the past six months, how often have you had sex with someone you knew (or later found out) had AIDS or was positive for HIV, the AIDS virus?
   0. Never
   1. A few times or less
   2. A few times each month
   3. Once or more each week

VA Form 10-21004(NR)hh
June 1996
40. In the past six months, how often did you use condoms when you had sex?
   0. I have not had sex in the past 6 months
   1. All the time
   2. Most of the time
   3. Some of the time
   4. None of the time

D. CONCERNS ABOUT HIV AND TESTING

If you know that you are HIV positive, skip to question 44.

41. How worried are you about getting HIV or AIDS?
   0. Not at all
   1. Slightly
   2. Moderately
   3. Considerably
   4. Extremely

42. How worried are you that you may have already been exposed to the HIV or AIDS virus?
   0. Not at all
   1. Slightly
   2. Moderately
   3. Considerably
   4. Extremely

43. How many times have you had a blood test for the AIDS virus (HIV)? (circle)
   0  1  2  3  4  5  6  7  8  9  10 or more times
44. When were you last tested for HIV? On the lines below, please write the month and year of your most recent test.

Month ___ ___ /Year 19 ___ ___

45. Were you ever told that you had the HIV, the AIDS virus?
   1. Yes
   2. No
   3. I never got the results

Thank You. Please let the staff person know that you have finished.
Please read each of the following questions very carefully. As you will see, many of these questions are very personal. We understand this and have taken great care to protect the privacy of your answers.

It is very important that you answer EVERY question honestly. In fact, it's better not to answer a question at all than to tell us something that is not accurate or true. Some questions may not seem to have an answer that is true for you. When this happens, you should simply choose the answer that is most right. Don't spend too much time on any one question. Remember, always ask for help if you're unsure about what to do.

Thank you for your time and cooperation.
A. PAST MONTH DRUG AND ALCOHOL USE:

Please CIRCLE the most correct response.

1. In the past month, how often have you injected cocaine and heroin together (Speedball)?
   0. Not at all
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2. In the past month, how often have you injected heroin (not mixed)?
   0. Not at all
   1. A few times
   2. A few times each week
   3. Everyday

3. In the past month, how often have you snorted heroin (not mixed)?
   0. Not at all
   1. A few times
   2. A few times each week
   3. Everyday

4. In the past month, how often have you smoked heroin?
   0. Not at all
   1. A few times
   2. A few times each week
   3. Everyday
5. In the past month, how often have you injected cocaine (not mixed)?
   0. Not at all
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10. In the past month, how often have you smoked amphetamines, meth, speed, crank or crystal?
    0. Not at all
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12. In the past month, how often have you taken painkillers - pills such as Percodan, Percocet, Vicodin, Demerol, Dilaudid, Darvon, Darvocet or syrup (Codeine)?
    0. Not at all
    1. A few times
    2. A few times each week
    3. Everyday

   a. Which types of painkillers did you use? _______________________________
<table>
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VA Form 10-21004(NR)hh
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B. NEEDLE USE:

17. In the past month, have you injected drugs?
   1. YES
   2. NO

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19. With how many different people did you share needles in the past month?
   0. 0 or I have not shot up in the past month
   1. 1 other person
   2. 2 or 3 different people
   3. 4 or more different people

20. In the past month, how often have **you** used a needle after someone (with or without cleaning)?
   0. Never or I have not shot up or shared in the past month
   1. A few times (1 or 2 times)
   2. About once a week (3 or 4 times)
   3. More than once a week (5 or more times)

21. In the past month, how often have **others** used after you (with or without cleaning)?
   0. Never or I have not shot up or shared in the past month
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23. Where did you get your needles during the past month?
   (Circle all that apply)
   0. I have not shot up in the past month
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   4. Shooting gallery or other place where users go to shoot up
   5. Needle Exchange Program
   6. Other, specify__________________________

24. In the past month, how often have you been to a shooting gallery/house or other place where users go to shoot-up?
   0. Never
   1. A few times (1 or 2 times)
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25. In the past month, how often have you been to a Crack House or other place where people go to smoke crack?
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   4. Sometimes I clean my needle, sometimes I don't
   5. I never clean my needle

27. If you have cleaned your needles and works in the past month, how did you clean them?
   0. I have not shot up in the past month
   1. Soap and water or water only
   2. Alcohol
   3. Bleach
   4. Boiling water
   5. Other, specify____________________________
   6. I did not clean my needles in the past month
   7. I ALWAYS used new needles in the past month
28. In the past month, how often have you shared rinse water?
   0. Never or I have not shot up in the past month
   1. A few times (1 or 2 times)
   2. About once a week (3 or 4 times)
   3. More than once a week (5 or more times)

29. In the past month, how often have you shared a cooker?
   0. Never or I have not shot up in the past month
   1. A few times (1 or 2 times)
   2. About once a week (3 or 4 times)
   3. More than once a week (5 or more times)

30. In the past month, how often have you shared a cotton?
   0. Never or I have not shot up in the past month
   1. A few times (1 or 2 times)
   2. About once a week (3 or 4 times)
   3. More than once a week (5 or more times)

31. In the past month, how often have you divided or shared drugs with others by using one syringe (yours or someone else’s) to squirt or load the drugs into the other syringe(s) (backloading, for example)?
   0. Never or I have not shot up in the past month
   1. A few times (1 or 2 times)
   2. About once a week (3 or 4 times)
   3. More than once a week (5 or more times)
C. SEXUAL PRACTICES

32. How would you describe yourself?
   1. Straight
   2. Gay or Homosexual
   3. Bisexual

_Please note: For the following questions, sex means any vaginal intercourse, anal intercourse (in the butt) or oral sex (blowjobs, for example)._

33. With how many men have you had sex in the past month?
   0. 0 men
   1. 1 man
   2. 2 or 3 men
   3. 4 or more men

34. With how many women have you had sex in the past month?
   0. 0 women
   1. 1 woman
   2. 2 or 3 women
   3. 4 or more women

35. In the past month, how often have you had sex so you could get drugs?
   0. Never
   1. A few times (1 or 2 times)
   2. About once a week (3 or 4 times)
   3. More than once a week (5 or more times)
36. In the past month, how often have you given drugs to someone so you could have sex with them?
   0. Never
   1. A few times (1 or 2 times)
   2. About once a week (3 or 4 times)
   3. More than once a week (5 or more times)

37. In the past month, how often were you paid money to have sex with someone?
   0. Never
   1. A few times (1 or 2 times)
   2. About once a week (3 or 4 times)
   3. More than once a week (5 or more times)

38. In the past month, how often did you give money to someone so you could have sex with them?
   0. Never
   1. A few times (1 or 2 times)
   2. About once a week (3 or 4 times)
   3. More than once a week (5 or more times)

39. In the past month, how often have you had sex with someone you knew (or later found out) had AIDS or was positive for HIV, the AIDS virus?
   0. Never
   1. A few times (1 or 2 times)
   2. About once a week (3 or 4 times)
   3. More than once a week (5 or more times)
40. In the past month, how often did you use condoms when you had sex?
   0. I have not had sex in the past month
   1. All the time
   2. Most of the time
   3. Some of the time
   4. None of the time

D. CONCERNS ABOUT HIV AND TESTING

If you know that you are HIV positive, skip to question 44.

41. How worried are you about getting HIV or AIDS?
   0. Not at all
   1. Slightly
   2. Moderately
   3. Considerably
   4. Extremely

42. How worried are you that you may have already been exposed to the HIV or AIDS virus?
   0. Not at all
   1. Slightly
   2. Moderately
   3. Considerably
   4. Extremely

43. How many times have you had a blood test for the AIDS virus (HIV)? (circle)
   0  1  2  3  4  5  6  7  8  9  10 or more times
44. When were you last tested for HIV? On the lines below, please write the month and year of your most recent test.

Month ___ ___ /Year 19 ___ ___

45. Were you ever told that you had the HIV, the AIDS virus?
   1. Yes
   2. No
   3. I never got the results

Thank You. Please let the staff person know that you have finished.
VA/NIDA STUDY 1008B  
A Multicenter Efficacy/Safety Trial of Buprenorphine/Naloxone for The Treatment of Opiate Dependence

<table>
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<th>Patient Initials</th>
<th>Center No.</th>
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FORM 11 - STUDY ADMISSION

NOTE: A NO response to QUESTIONS 1-5, or a YES response to QUESTIONS 6-17, makes patient INELIGIBLE.

A. INCLUSION CRITERIA

<table>
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<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td>1. Between 18-59 years of age (inclusive).</td>
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<tr>
<td>2. Seeking opiate substitution pharmacotherapy.</td>
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<tr>
<td>3. Expected to remain available to attend clinic for duration of study.</td>
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<td>4. Able to give informed consent and willing to comply with all study procedures.</td>
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<td>5. DSM-IV diagnosis of current opiate dependence.</td>
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B. EXCLUSION CRITERIA

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<th>Question</th>
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<th>Ineligible</th>
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<tbody>
<tr>
<td>6. Participated in an investigational drug or device study within 45 days of enrolling in the present study.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Enrolled in an opiate-substitution (i.e. methadone, LAAM) treatment program within 45 days of enrolling in present study.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Has taken (licitly or illicitly) LAAM, methadone, or naltrexone within 14 days of enrolling in the present study.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. Has taken buprenorphine, other than as an analgesic, within 365 days of enrolling in the present study.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. Currently taking systemic anti-retroviral or anti-fungal therapy.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. Female of childbearing potential who refuses to use a medically acceptable method of birth control.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12. Current dependence (by DSM-IV criteria) on any psychoactive substance other than opiates, caffeine, or nicotine.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>13. Current, primary, Axis I psychiatric diagnosis other than opiate, caffeine, or nicotine dependence.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>14. Pregnant or nursing female.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>15. Aspartate or alanine aminotransferase (AST, ALT) levels greater than three times the upper limit of normal.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>16. Any acute or chronic medical condition that would make participation in the study medically hazardous (e.g., acute hepatitis, unstable cardiovascular, hepatic or renal disease, unstable diabetes, symptomatic AIDS; not HIV-seropositivity alone).</td>
<td></td>
<td></td>
</tr>
<tr>
<td>17. Refuses to participate in study.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>18. Did individual sign consent form for participation in the study?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

C. INFORMED CONSENT

<table>
<thead>
<tr>
<th>Question</th>
<th>Eligible</th>
<th>Ineligible</th>
</tr>
</thead>
<tbody>
<tr>
<td>18. Did individual sign consent form for participation in the study?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

D. ENROLLMENT STATUS

<table>
<thead>
<tr>
<th>Question</th>
<th>Eligible</th>
<th>Ineligible</th>
</tr>
</thead>
<tbody>
<tr>
<td>19. Individual's enrollment status (1 = INELIGIBLE, 2 = ELIGIBLE, ENROLLED IN STUDY, 3 = ELIGIBLE, DECLINES ENROLLMENT)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

IF ENROLLED IN STUDY:

<table>
<thead>
<tr>
<th>Question</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>20. Date enrolled</td>
<td></td>
</tr>
<tr>
<td>21. Patient's enrollment number (Patient Number)</td>
<td></td>
</tr>
<tr>
<td>22. Date of first dose</td>
<td></td>
</tr>
</tbody>
</table>

FORM COMPLETED BY ____________________________  Date ____________________________

INVESTIGATOR'S SIGNATURE __________________________  Date ____________________________
FORM 12 - CLINICIAN GLOBAL IMPRESSION

RATING PERIOD: WEEK # (01, 02, 03, 04) ___ ___
                DAY (1=MON, 2=WED, 3=FRI) ___

1. Was patient evaluated? (1=YES, 2=NO) ___
   (If YES, continue:)

2. Considering all aspects related to the patient's overall health and well being, rate the patient's overall status since the previous observation:

   |           |           |           |
   | MUCH     | NO        | MUCH     |
   | WORSE    | CHANGE    | BETTER   |

   mm

3. Considering all aspects related to the patient's overall health and well being, rate the patient's overall status since entering the study:

   |           |           |           |
   | MUCH     | NO        | MUCH     |
   | WORSE    | CHANGE    | BETTER   |

   mm

FORM COMPLETED BY __________ Date ____________________
FORM 13 - PATIENT GLOBAL IMPRESSION

RATING PERIOD: WEEK # (01, 02, 03, 04) ___ ___  
DAY (1=MON, 2=WED, 3=FRI) ___

1. Did patient complete evaluation? (1=YES, 2=NO) ___  
(If YES, continue):

2. Considering all aspects related to your overall health and well being, rate your overall status since the previous observation:

   | MUCH | NO | MUCH |
   | WORSE | CHANGE | BETTER |

   mm

3. Considering all aspects related to your overall health and well being, rate your overall status since entering the study:

   | MUCH | NO | MUCH |
   | WORSE | CHANGE | BETTER |

   mm

FORM COMPLETED BY _ Date ________________
FORM 14A - WEEKLY DOSING RECORD (EFFICACY)

STUDY WEEK NUMBER:

1. DOSING RECORD

<table>
<thead>
<tr>
<th>Day</th>
<th>1. Date (mo  day  yr)</th>
<th>2. Attended Clinic? (1=YES  2=NO)</th>
<th>3. Enter Dose Code (Choose One:)</th>
<th>4. If Dosed, Time of Dosing</th>
<th>5. Check (√) if Urine Sample Collected</th>
<th>6. Take-Home Doses Given to Patient?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>___ ___ ___ ___</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1 Yes</td>
</tr>
<tr>
<td>2</td>
<td>___ ___ ___ ___</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2 No (Number of Doses)</td>
</tr>
<tr>
<td>3</td>
<td>___ ___ ___ ___</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1 Yes</td>
</tr>
<tr>
<td>4</td>
<td>___ ___ ___ ___</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2 No (Number of Doses)</td>
</tr>
</tbody>
</table>
2. WERE THERE ANY TAKE-HOME DOSES RETURNED?  
   1 YES  
   2 NO

   If YES, record Date Returned and Number of Tablets:

   a. Mo ___ Day ___ Yr ___ Number of Tablets: ___ ___
   b. Mo ___ Day ___ Yr ___ Number of Tablets: ___ ___
### VA/NIDA STUDY 1008B
A Multicenter Efficacy/Safety Trial of Buprenorphine/Naloxone for The Treatment of Opiate Dependence

**Patient Initials**

**Center No.**

**Patient No.**

**First Day of Study Week**

-  
  -  
  -  
  -  
  -  
  -  
  -  

**FORM 14A - WEEKLY DOSING RECORD (EFFICACY)**

**STUDY WEEK NUMBER:**

1. **DOISING RECORD**

| Day | 1. Date (mo day yr) | 2. Attended Clinic? | 3. Enter Dose Code (Choose One:)
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>1=YES 2=NO</td>
<td>1=Induction</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2=Maintenance</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3=Re-induction</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>4=Emergency Dose</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>5=Not Dosed</td>
</tr>
<tr>
<td>8</td>
<td></td>
<td></td>
<td>(24 hour clock)</td>
</tr>
<tr>
<td>9</td>
<td></td>
<td></td>
<td>(24 hour clock)</td>
</tr>
<tr>
<td>10</td>
<td></td>
<td></td>
<td>(24 hour clock)</td>
</tr>
<tr>
<td>11</td>
<td></td>
<td></td>
<td>(24 hour clock)</td>
</tr>
</tbody>
</table>

4. If Dosed, Time of Dosing

5. Check (√) if Urine Sample Collected

6. Take-Home Doses Given to Patient?

1 Yes

2 No (Number of Doses)

1 Yes

2 No (Number of Doses)

1 Yes

2 No (Number of Doses)

1 Yes
2. WERE THERE ANY TAKE-HOME DOSES RETURNED?  1 YES  2 NO

If YES, record Date Returned and Number of Tablets:

a. Mo ___ Day ___ Yr ___  Number of Tablets: ___ ___

b. Mo ___ Day ___ Yr ___  Number of Tablets: ___ ___

FORM COMPLETED BY Date ___
### FORM 14A - WEEKLY DOSING RECORD (EFFICACY)

#### STUDY WEEK NUMBER:

1. **DOISING RECORD**

| Day | 1. Date (mo  day  yr) | 2. Attended Clinic? (1=YES  2=NO) | 3. Enter Dose Code (Choose One:)
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>1=Induction  2=Maintenance  3=Re-induction  4=Emergency Dose  5=Not Dosed</td>
</tr>
<tr>
<td>15</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>16</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>17</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>1. If Dosed, Time of Dosing</th>
<th>5. Check (√) if Urine Sample Collected</th>
<th>6. Take-Home Doses Given to Patient?</th>
</tr>
</thead>
<tbody>
<tr>
<td>(24 hour clock)</td>
<td></td>
<td>1 Yes</td>
</tr>
<tr>
<td>(24 hour clock)</td>
<td></td>
<td>2 No (Number of Doses)</td>
</tr>
<tr>
<td>(24 hour clock)</td>
<td></td>
<td>1 Yes</td>
</tr>
<tr>
<td>(24 hour clock)</td>
<td></td>
<td>2 No (Number of Doses)</td>
</tr>
</tbody>
</table>

1. Yes

2. No

(Number of Doses)

1. Yes

(Number of Doses)

1. Yes

(Number of Doses)

1. Yes
2. WERE THERE ANY TAKE-HOME DOSES RETURNED?  1 YES  2 NO

If YES, record Date Returned and Number of Tablets:

a. Mo ___ Day ___ Yr ___  Number of Tablets: ___ ___

b. Mo ___ Day ___ Yr ___  Number of Tablets: ___ ___
**FORM 14A - WEEKLY DOSING RECORD (EFFICACY)**

**STUDY WEEK NUMBER:**

### 1. DOSING RECORD

<table>
<thead>
<tr>
<th>Study Week</th>
<th>1. Date (mo  day  yr)</th>
<th>2. Attended Clinic? (1=YES, 2=NO)</th>
<th>3. Enter Dose Code (Choose One:)</th>
<th>4. If Dosed, Time of Dosing (24 hour clock)</th>
<th>5. Check (✓) if Urine Sample Collected</th>
<th>6. Take-Home Doses Given to Patient?</th>
</tr>
</thead>
<tbody>
<tr>
<td>22</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1 Yes</td>
</tr>
<tr>
<td>23</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1 Yes</td>
</tr>
<tr>
<td>24</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2 No (Number of Doses)</td>
</tr>
<tr>
<td>25</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1 Yes</td>
</tr>
</tbody>
</table>
2: WERE THERE ANY TAKE-HOME DOSES RETURNED?  1 YES  2 NO

If YES, record Date Returned and Number of Tablets:

a. Mo ___ Day ___ Yr ___  Number of Tablets: ___ ___

b. Mo ___ Day ___ Yr ___  Number of Tablets: ___ ___

FORM COMPLETED BY ______________________ Date __________
14B - WEEKLY DOSING RECORD (SAFETY)

**ENTER STUDY WEEK NUMBER:** (05-52)  
*(NOTE: Complete a new form each week)*

1. **DOsing RECORD**

<table>
<thead>
<tr>
<th>Day</th>
<th>1. Date (mo  day  yr)</th>
<th>2. Attended Clinic? 1=YES 2=NO</th>
<th>3. Dose Given In Clinic 1=Bup Mono 2=Bup Combo 3= None</th>
<th>4. Enter Dose Code (Choose One): 1=Induction 2=Maintenance 3=Re-induction 4=Taper Dose</th>
<th>5. If Dosed, Time of Dosing (24 hour clock)</th>
<th>6. Check (√) if Urine Taken</th>
<th>7. Take-Home Doses Patient has on Hand</th>
<th>8. Take-Home Doses Given to Patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
<td>1=Induction</td>
<td>(24 hour clock)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
<td>1=Maintenance</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
<td>1=Re-induction</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td></td>
<td></td>
<td>1=Taper Dose</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td></td>
<td></td>
<td>1=Induction</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
2. Were there any Take-Home Doses returned to clinic and retained by clinic staff? 1 YES 2 NO

If YES, record Date Returned and Number of Tablets:

a. Mo ___ Day ___ Yr ___ Number of Tablets: ___2mg/0.5mg ___8mg/2mg

b. Mo ___ Day ___ Yr ___ Number of Tablets: ___2mg/0.5mg ___8mg/2mg

*If Re-Induction, enter the target dose*
CSP #1008B - FORM 14B

3. A. WAS PATIENT INSTRUCTED TO CHANGE HOW DRUG IS TAKEN? (1=YES, 2=NO)  
   If yes, was drug: (Please check (√ one)  
   1 Changed to two times/day  
   2 Changed to three times/day  
   3 Changed back to one time/day  
   4 Changed to every other day

B. WAS DOSE CHANGED DURING WEEK? (1=YES, 2=NO)  

C. If either question 3A or 3B above is answered YES, choose Main Reason For Change: (Please check (√ one)  
   1 Induction/Re-Induction Period  
   2 Taper Period  
   3 Study Medication Side Effects: (Please check (√ one)  
      a Drowsiness/Sedation  
      b Feeling High  
      c Constipation  
      d Other (Specify)  
   4 Dose not Holding  
   5 Heroin/Opiate Craving  
   6 Withdrawal Symptoms  
   7 Dirty Urines  
   8 Other (Specify)  

4. WAS PATIENT SCHEDULED FOR RANDOM DRUG COUNT THIS WEEK? (1=YES, 2=NO)  
   (If YES, please answer question 5: If NO, form is complete)  

5. IF SCHEDULED, DID PATIENT COME IN FOR RANDOM DRUG COUNT THIS WEEK? (1=YES, 2=NO)  
   (If YES, please answer the following questions: If NO, please explain in the comments section below)  
   a. Date Called  
      Mo __ __ Day __ __ Yr __ __  
   b. Date Scheduled to Come to Clinic  
      Mo __ __ Day __ __ Yr __ __  
   c. Date Came to Clinic  
      Mo __ __ Day __ __ Yr __ __  
   d. Doses Expected  
      ___ ___  
   e. Verified Doses on Hand  
      ___ ___  

Comments:  

FORM COMPLETED BY  
Date  
VA Form 10-21004(NR)q  
June 1996
## 14C - WEEKLY DOSING RECORD (SAFETY)

**ENTER STUDY WEEK NUMBER:** (01-52)  
( NOTE: Complete a new form each week)

### 1. DOSING RECORD

| Day | 1. Date (mo day yr) | 2. Attended Clinic? (1=YES 2=NO) | 3. Dose Given In Clinic (Choose One):  
1=Bup Mono  
2=Bup Combo  
3=None  

4. Enter Dose Code (Choose One):  
1=Induction  
2=Maintenance  
3=Re-induction  
4=Taper Dose  

5. If Dosed, Time of Dosing  

6. Check (✓) if Urine Taken  

7. Take-Home Doses Patient has on Hand  

8. Take-Home Doses Given to Patient |
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
<td>___ mg (BUP) (24 hour clock)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
<td>___ mg (BUP) (24 hour clock)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
<td>___ mg (BUP) (24 hour clock)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td></td>
<td></td>
<td>___ mg (BUP) (24 hour clock)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
*If Re-Induction, enter the target dose

2. Were there any Take-Home Doses returned to clinic and retained by clinic staff? 1 YES  2 NO

If YES, record Date Returned and Number of Tablets:

a. Mo  __ __ Day  __ __ Yr __ __  Number of Tablets:  __ __2mg/0.5mg  __ __8mg/2mg

b. Mo  __ __ Day  __ __ Yr __ __  Number of Tablets:  __ __2mg/0.5mg  __ __8mg/2mg

Continued

VA Form 10-21004(NR)jj
June 1996
3. A. WAS PATIENT INSTRUCTED TO CHANGE HOW DRUG IS TAKEN?  (1=YES, 2=NO) __
   If yes, was drug: (Please check (✓) one)
   1 Changed to two times/day
   2 Changed to three times/day
   3 Changed back to one time/day
   4 Changed to every other day

B. WAS DOSE CHANGED DURING WEEK?  (1=YES, 2=NO) __

C. If either question 3A or 3B above is answered YES, choose Main Reason For Change: (Please check (✓) one)
   1 Induction/Re-Induction Period
   2 Taper Period
   3 Study Medication Side Effects: (Please check (✓) one)
      a Drowsiness/Sedation
      b Feeling High
      c Constipation
      d Other (Specify)
   4 Dose not Holding
   5 Heroin/Opiate Craving
   6 Withdrawal Symptoms
   7 Dirty Urines
   8 Other (Specify)

4. WAS PATIENT SCHEDULED FOR RANDOM DRUG COUNT THIS WEEK?  (1=YES, 2=NO) __
   (If YES, please answer question 5: If NO, form is complete)

5. IF SCHEDULED, DID PATIENT COME IN FOR RANDOM DRUG COUNT THIS WEEK? (1=YES, 2=NO) __
   (If YES, please answer the following questions: If NO, please explain in the comments section below)
   a. Date Called Mo ___ Day ___ Yr ___
   b. Date Scheduled to Come to Clinic Mo ___ Day ___ Yr ___
   c. Date Came to Clinic Mo ___ Day ___ Yr ___
   d. Doses Expected ___ ___
   e. Doses Verified on Hand ___ ___

Comments:

FORM COMPLETED BY Date
### FORM 15 - TREATMENT SERVICES REVIEW

**RATING PERIOD: WEEK NUMBER (01-52)**

WAS TREATMENT SERVICES REVIEW COMPLETED? (1=YES, 2=NO)

(If YES, continue:)

<table>
<thead>
<tr>
<th></th>
<th>By Study Personnel (In-program)</th>
<th>By Outside Sources (Out-program)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>B.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### A. MEDICAL PROBLEMS

How many DAYS in the past week have you:

1. Experienced significant physical medical problems?
   -

2. Been hospitalized for physical medical problems?
   -

3. Received medication for a medical problem?
   -

For questions 4 - 6 how many TIMES in the past week have you:

4. Seen a physician for medical care?
   -

5. Seen a nurse, nurse practitioner, or physician's assistant for medical care?
   -

6. Had a significant discussion pertinent to your medical problems?
   - Individual session?
   - Group session?

#### B. EMPLOYMENT AND SUPPORT PROBLEMS

How many DAYS in the past week have you:

7. Been paid for working?

-
8. Been in school or training? __  __  __

(Continued)
For questions 9 - 11, how many TIMES in the past week have you:

9. Seen someone regarding employment opportunities, training or education:
   Employment specialist? 
   Counselor/social worker? 

10. Seen someone regarding unemployment compensation, welfare, social security, housing, or other income:
    Benefits specialist? 
    Counselor/social worker? 

11. Had a significant discussion pertinent to your employment/support problem:
    Individual session? 
    Group session? 

C. ALCOHOL PROBLEMS

How many DAYS in the past week have you:

12. Drunk any alcohol? 

13. Drunk any alcohol to the point of intoxication (note definition)? 

14. Been in inpatient treatment for an alcohol problem? 

15. Received medication to help you to detoxify from alcohol? 

16. Received medication to prevent you from drinking? 

17. Received a blood alcohol test (e.g. breathalyzer)? 

For questions 18 - 21 how many TIMES in the past week have you:

18. Attended an alcohol education session? 

19. Attended an AA or 12 step meeting? 

20. Attended an alcohol relapse prevention meeting?
<table>
<thead>
<tr>
<th>Patient Initials</th>
<th>Center No.</th>
<th>Patient No.</th>
<th>First Day of Study Week Evaluated</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

21. Had a significant discussion pertinent to your alcohol problem:
   Individual session?  __ __ __ __
   Group session?      __ __ __ __

D. DRUG PROBLEMS

How many DAYS in the past week have you:

22. Used any illicit drug?  __

23. Been in inpatient treatment for a drug problem?  __ __

24. Received medication to help you detoxify/come off a drug?  __ __

25. Received medication to maintain/stabilize your drug use?  __ __

26. Received medication to block the effects of drugs?  __ __

27. Received a urinalysis, or other test for drug use?  __ __

For questions 28 - 31, how many TIMES in the past week have you:

28. Attended a drug education session?  __ __ __ __

29. Attended a session of NA or CA?  __ __ __ __

30. Attended a drug relapse prevention group or session?  __ __ __ __

31. Had a significant discussion pertinent to your drug problem:
   Individual session?  __ __ __ __
   Group session?      __ __ __ __

E. LEGAL PROBLEMS

How many DAYS in the past week have you:

32. Been incarcerated?  __

33. Engaged in illegal activities for profit?  __
For questions 34 & 35, how many TIMES in the past week have:

34. The courts, criminal justice system, probation/parole office been contacted regarding your legal problem (either by patient or program):
   __ __ __ __

35. You had a significant discussion pertinent to your legal problems:
   Individual session? __ __ __ __
   Group session?   __ __ __ __

**F. FAMILY PROBLEMS**

How many DAYS in the past week have you:

36. Experienced significant family/social problems? __

37. Experienced significant loneliness and/or boredom? __

For questions 38 & 39, how many TIMES in the past week have you:

38. Had a significant discussion pertinent to your family problems with family present:
   Family specialist? __ __ __ __
   Counselor/social worker? __ __ __ __

39. Had a significant discussion pertinent to your family problems without your family present:
   Family specialist? __ __ __ __
   Counselor/social worker? __ __ __ __

**G. PSYCHOLOGICAL/EMOTIONAL PROBLEMS**

How many DAYS in the past week have you:

40. Experienced significant emotional problems? __

41. Been hospitalized for an emotional or psychological problem? __ __

42. Received testing for psychological or emotional problems? __ __
<table>
<thead>
<tr>
<th>Patient Initials</th>
<th>Center No.</th>
<th>Patient No.</th>
<th>First Day of Study Week Evaluated</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>-  - month  - day - year</td>
</tr>
</tbody>
</table>

43. Received medication for your psychological or emotional problems? __ __ __

For questions 44 - 46, how many TIMES in the past week have you:

44. Received a session in which you **practiced** a form of relaxation training, biofeedback or meditation?
   - Psych specialist? __ __ __
   - Counselor/social worker? __ __ __

45. Received a session in which you **practiced** a form of behavior modification (e.g. role play, rehearsal, psychodrama, etc.):
   - Psych specialist? __ __ __
   - Counselor/social worker? __ __ __

46. Had a significant discussion pertinent to your psychological or emotional problems?
   - Psych specialist? __ __ __
   - Counselor/social worker? __ __ __

---

FORM COMPLETED BY______________________________________ Date

________________________________________________________
FORM 16 - BLOOD SAMPLING FOR PHARMACOKINETIC ASSESSMENTS

1. Time first sample drawn today: (before dosing)

   - (24 hour clock)

2. Time of Dosing Today:

   - (24 hour clock)

3. Time second sample drawn today: (approximately 2 hrs. after dosing)

   - (24 hour clock)

4. Time third sample drawn: (approximately 6 hrs. after dosing)

   - (24 hour clock)

If third sample WAS NOT drawn on the same day as samples one and two, complete question 5:

5. Date and Time of Dose (complete only if third blood sample was taken on a different day)

   - Mo Day Yr (24 hour clock)

FORM COMPLETED BY . Date____________________
FORM 17 - SERIOUS/UNEXPECTED ADVERSE EVENT FORM

RATING PERIOD: WEEK NUMBER (01-52) __ __

A. ADVERSE EVENT:

1. Date of Onset.................................................................Mo __ __Day __ __Yr __ __

2. Age of Patient............................................................. __ __

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

4. Patient's Height (inches).............................................. __ __ . __

5. Patient's Weight (pounds)............................................ __ __ __ . __

6. Provide Narrative Description of Event 

   a. Greatest Severity............................................................__
      1=Mild, 2=Moderate, 3=Severe

   b. Study Drug Related?....................................................__
      1=Definitely Study Related, 2=Probably Study Related,
      3=Possibly Study Related, 4=Unrelated to Study

   c. Dose Change?..............................................................__
      0=No Change, 1=Temp. Decreased, 2=Perm. Decreased, 3=Discontinued

   d. Action Taken?............................................................__
      1=None, 2=Outpatient Treatment, 3=Inpatient Treatment

   e. Outcome?........................................................................__
      1=Resolved; no sequelae, 2=Not Yet Resolved, 3=Resulted in Chronic Condition
      4=Deceased, 5=Unknown

Continued
7. If Died, List Primary Cause of Death:

8. Relevant Tests/Laboratory Data:

B. SUSPECT DRUG(S) INFORMATION:

9. Suspect Drug(s): ....................................................................................................................................................... ___
   1=Study drug, 2=Non-study drug(s), 3=NA (not drug)

10. Daily Dose of Study Drug (even if not suspected):

11. If Non-study drug(s), continue; otherwise skip to “c”.
   a. Trade/generic name of drug(s):

   b. Dose, regimen, routes of administration:

   c. Dates of Administration: (from/to) 

   d. Indication(s) for Use:

C. CONCOMITANT DRUG(S) AND HISTORY:

15. Concomitant Drug(s) and Dates of Administration:

16. Other Relevant History (e.g. diagnoses, allergies, etc.):

FORM COMPLETED BY: Date

INVESTIGATOR’S SIGNATURE Date

VA FORM 10-21004(NR)t
June 1996
FORM 18A - PHASE 1 (EFFICACY) TERMINATION

1. USING THE LIST BELOW, PLEASE INDICATE THE PRIMARY REASON PATIENT TERMINATED FROM THE STUDY.

1. Completed Phase 1 protocol and continuing in Phase 2 protocol
   (Please call DCC to enroll patient in Phase 2 of this study. Remember to have patient sign informed consent.)

2. Completed Phase 1 protocol and continuing in Phase 2 protocol ONLY to receive taper
   (Please call DCC to enroll patient in Phase 2 of this study. Remember to have patient sign informed consent.)

   (Select one of the reasons listed below (01-11) and write in number here: ____ ____)

   3. Completed Phase 1 protocol and NOT continuing in Phase 2 protocol
      (Select one of the reasons listed below (01-11) and write in number here: ____ ____)

   4. Did not complete Phase 1 protocol
      (Select one of the reasons listed below (01-11) and write in number here: ____ ____)

01. Toxicity or side effects related to study medication
    Specify: _

02. Medical reason unrelated to study medication
    Specify reason: _

03. Failed to return to clinic
    If contacted, specify reason: _

04. Patient's request
    Specify request: _

05. Moved from area

06. Incarceration

07. Termination by clinic physician because of intercurrent illness or medical complications precluding safe administration of study medication

08. Administrative discharge
    Specify incident: _

09. Pregnancy

10. Death (Complete Serious/Unexpected Adverse Event Form - 17)
    Date of Death: Mo Day Yr
    Specify cause of death if known: _

11. Other
    Specify: _

FORM COMPLETED BY ________________________

INVESTIGATOR'S SIGNATURE ________________________

Date ________________________
FORM 18B - PHASE 2 (SAFETY) TERMINATION

1. USING THE LIST BELOW, PLEASE INDICATE THE PRIMARY REASON PATIENT TERMINATED FROM THE STUDY.

1. Completed Phase 2 protocol
2. Entered Phase 2 protocol only to receive taper
3. Did not complete Phase 2 protocol
   (Select one of the reasons listed below (01-11) and write in number here: ____ ____)

01. Toxicity or side effects related to study medication
   Specify: 

02. Medical reason unrelated to study medication
   Specify reason: 

03. Failed to return to clinic
   If contacted, specify reason: 

04. Patient's request
   Specify request: 

05. Moved from area

06. Incarceration

07. Termination by clinic physician because of intercurrent illness or medical complications precluding safe administration of study medication

08. Administrative discharge
   Specify incident: 

09. Pregnancy

10. Death (Complete Serious/Unexpected Adverse Event Form - 17)
   Date of Death: Mo ___ Day ___ Yr ___
   Specify cause of death if known: 

11. Other
   Specify: 

FORM COMPLETED BY ______________________________
Date ______________________________

INVESTIGATOR'S SIGNATURE ______________________________
Date ______________________________
### FORM 18C - TERMINATION

1. **USING THE LIST BELOW, PLEASE INDICATE THE PRIMARY REASON** PATIENT TERMINATED FROM THE STUDY.

   - 1. Completed Protocol
   - 2. Did not complete Protocol

   *(Select one of the reasons listed below (01-11) and write in number here: _____ _____ )*

<table>
<thead>
<tr>
<th>Reason</th>
<th>Specify:</th>
</tr>
</thead>
<tbody>
<tr>
<td>01. Toxicity or side effects related to study medication</td>
<td></td>
</tr>
<tr>
<td>02. Medical reason unrelated to study medication</td>
<td></td>
</tr>
<tr>
<td>03. Failed to return to clinic</td>
<td></td>
</tr>
<tr>
<td>04. Patient's request</td>
<td></td>
</tr>
<tr>
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</tr>
<tr>
<td>08. Administrative discharge</td>
<td></td>
</tr>
<tr>
<td>09. Pregnancy</td>
<td></td>
</tr>
<tr>
<td>10. Death (Complete Serious/Unexpected Adverse Event Form - 17)</td>
<td></td>
</tr>
<tr>
<td>Date of Death: Mo ____ Day ____ Yr ____</td>
<td></td>
</tr>
<tr>
<td>Specify cause of death if known:</td>
<td></td>
</tr>
<tr>
<td>11. Other</td>
<td></td>
</tr>
</tbody>
</table>

**FORM COMPLETED BY** ____________________________  Date ____________________________

INVESTIGATOR'S SIGNATURE ____________________________  Date ____________________________

VA Form 10-21004(NR)n
June 1996
**FORM 19 - FOLLOW-UP**

FORM IS TO BE COMPLETED APPROXIMATELY 30 DAYS AFTER PATIENT TERMINATES OR COMPLETES PROTOCOL

<p>| | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1 = YES</td>
<td>2 = NO</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1. Has contact been made with the patient?...........................................................
   (If Yes, complete a-e, If No, Go to Question 2)
   a. If YES, date of contact..............................................................................Mo ___ Day ___ Yr ___
   b. Does the patient report currently using opiates 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 opiate-dependence treatment?..........................................................................

2. If contact has not been made with the patient, explain .

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 ___
      (go to Question 4)
   b. If NO, explain .

4. Has the patient died?..........................................................................................
   If YES:
   a. Date of Death: ..............................................................................................Mo ___ Day ___ Yr ___
   b. Is date of death more than 30 days after patient terminated?........................
   c. Cause of Death .
   d. Information verified by site staff (e.g., coroner’s office, death certificate) ..................

5. Additional Comments: .

FORM COMPLETED BY .    Date _____________________

VA FORM 10-21004(NR)oo
June 1996