STUDY FORMS

FORM 01 - Background Information

FORM 02 - Drug Use History

FORM 03 - DSM-III-R Criteria for Diagnosis of Opiate Dependence

FORM 04 - Global Rating Scale - Staff

FORM 05 - Global Rating Scale - Patient

FORM 06 - Medical History and Status

FORM 07 - Craving Scale (Screening Only)

FORM 08 - Laboratory Report

FORM 09 - Physical Exam

FORM 10 - Electrocardiogram

FORM 11 - Study Admission

FORM 12 - Coordinators Weekly Report

FORM 13 - Weekly Self-Report of Drug Use and Craving Scale

FORM 14 - Psychosocial Services Received

FORM 15 - Concomitant Medication

FORM 16 - Adverse Events

FORM 17 - Serious Adverse Event Form

FORM 18 - Termination

FORM 19 - Dose Administration Record

Locator Information

Patient Initials ☐☐☐ Center No. ☐☐☐ Patient No. ☐☐☐ Date of Visit ☐☐-☐☐-☐☐ (month - day - year)

FORM 01 - BACKGROUND INFORMATION

Current Address of Patient: _____

Zip Code of Residence: |_|_|_|_|_|

Work Phone: |_|_|_| - |_|_|_| - |_|_|_|_|

Home Phone: |_|_|_| - |_|_|_| - |_|_|_|_|

1. Date of Birth: |_|_| month |_|_| day |_|_| year

2. Race:
- 1 ☐ White, not of Hispanic origin
- 2 ☐ Black, not of Hispanic origin
- 3 ☐ American Indian
- 4 ☐ Alaskan Native
- 5 ☐ Asian or Pacific Islander
- 6 ☐ 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

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 or 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 workday)
- 4 ☐ Student
- 5 ☐ Military service
- 6 ☐ Retired/disability
- 7 ☐ Unemployed
- 8 ☐ In controlled environment

Continued

Center No. ☐☐☐ Patient No. ☐☐☐

7. Approximate Total Annual Family Income: (from all sources)

$ ☐☐☐,☐☐☐

8. Marital Status:

1 ☐ Married
2 ☐ Remarried
3 ☐ Widowed
4 ☐ Separated
5 ☐ Divorced
6 ☐ Never married

9. Usual Living Arrangements (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. Do you plan to continue living within commuting distance of the clinic during the next 6 months?

1 ☐ Yes 2 ☐ No

11. Is there Heroin or Cocaine use in the household where you live?

1 ☐ Yes
2 ☐ No
3 ☐ Don't know

12. Are you presently awaiting charges, trial or sentence that is likely to result in your going to jail during the next 6 months?

1 ☐ Yes 2 ☐ No

Comments: _____

_____

_____

_____

FORM COMPLETED BY _____

INVESTIGATOR'S SIGNATURE _____ Date _____

VA FORM 10-20923(NR)a
November 1991

Patient Initials ☐☐☐ Center No. ☐☐☐ Patient No. ☐☐☐ Date of Visit ☐☐-☐☐-☐☐ (month-day-year)

FORM 02 - DRUG USE HISTORY

1. **How many times have you been enrolled in Methadone maintenance?** ☐☐

2. **Have you been enrolled in a Methadone maintenance program in the past 30 days?** 1 ☐ Yes 2 ☐ No

3. **Have you ever been treated with Buprenorphine for your addiction?** 1 ☐ Yes 2 ☐ No

4. **DRUG USE HISTORY:**

DRUG	USED DRUG?	IF YES: Number of Years/Months Used	Primary Mode of Abuse 1=Oral 2=I.V. 3=Snorting 4=Smoking 5=Sublingual 6=Other
a. Heroin or other opiate	1 ☐ Yes 2 ☐ No	☐☐ yrs. ☐☐ mos.	☐
b. Cocaine	1 ☐ Yes 2 ☐ No	☐☐ yrs. ☐☐ mos.	☐
c. Methamphetamine	1 ☐ Yes 2 ☐ No	☐☐ yrs. ☐☐ mos.	☐
d. Alcohol	1 ☐ Yes 2 ☐ No	☐☐ yrs. ☐☐ mos.	☐
e. Tranquilizers	1 ☐ Yes 2 ☐ No	☐☐ yrs. ☐☐ mos.	☐
f. Marijuana or other forms of THC	1 ☐ Yes 2 ☐ No	☐☐ yrs. ☐☐ mos.	☐
g. PCP	1 ☐ Yes 2 ☐ No	☐☐ yrs. ☐☐ mos.	☐
h. Other, specify: _____	1 ☐ Yes 2 ☐ No	☐☐ yrs. ☐☐ mos.	☐

FORM COMPLETED BY _____

INVESTIGATOR'S SIGNATURE _____ Date _____

Patient Initials ☐☐☐ Center No. ☐☐☐ Patient No. ☐☐☐ Date of Visit ☐☐-☐☐-☐☐ (month-day-year)

FORM 03 - DSM-III-R CRITERIA FOR DIAGNOSIS OF OPIATE DEPENDENCE

Criteria: At least 3 of the conditions listed below are required. *Note: The space below each item can be used for comments or notes.*

1. Opiates are taken in larger amounts or over longer periods than the person intended.	1 ☐ YES	2 ☐ NO
2. A desire for the drug persists, or the patient has made one or more successful efforts to cut down or to control opioid use.	1 ☐ YES	2 ☐ NO
3. A great deal of time is spent in activities necessary to obtain opioids (such as theft), taking them, or recovering from their effects.	1 ☐ YES	2 ☐ NO
4. The patient is frequently intoxicated or has withdrawal symptoms when expected to fulfill major role obligations at work, school, or home: e.g., does not go to work, goes to school or work "high," is intoxicated while taking care of his or her children or when opioid use is physically hazardous (such as driving under the influence of opiates).	1 ☐ YES	2 ☐ NO
5. Important social, occupational, or recreational activities have been given up or reduced because of opioid use.	1 ☐ YES	2 ☐ NO
6. Continues opioid use despite the knowledge of having a persistent or recurrent social, psychological or physical problem that is caused or exacerbated by the use of opioids: e.g., keeps using heroin despite family arguments about it.	1 ☐ YES	2 ☐ NO
7. Marked tolerance to opioids: i.e., needs greatly increased amounts of opioids (at least a 50% increase) to achieve the desired effect, or a notably diminished effect occurs with continued use of the same amount.	1 ☐ YES	2 ☐ NO
8. Has characteristic opiate withdrawal symptoms when opioids are not taken.	1 ☐ YES	2 ☐ NO
9. Opioids are often taken to relieve or avoid withdrawal symptoms.	1 ☐ YES	2 ☐ NO
10. The above positive items have persisted for at least one month, or have recurred repeatedly over a longer period of time.	1 ☐ YES	2 ☐ NO

FORM COMPLETED BY _____

INVESTIGATOR'S SIGNATURE _____ Date _____

LAATRC/VA/NIDA STUDY 999a

A Multicenter Clinical Trial of Buprenorphine in Treatment of Opiate Dependence

Patient Initials ☐☐☐ Center No. ☐☐☐ Patient No. ☐☐☐ Date of Visit ☐☐-☐☐-☐☐ (month-day-year)

FORM 04 - GLOBAL RATING SCALE - STAFF

Rating Period: ☐ Screen ☐ 04 wk ☐ 08 wk ☐ 12 wk ☐ 16 wk

1. Considering the patient's history of drug use and its complications, how severe is the patient's problem now? Based on a scale of 1 to 100, 0 being no drug problem and 100 being the most severe problem:

SCORE: |_|_|_|

DO NOT COMPLETE QUESTIONS 2 AND 3 AT SCREENING.

2. Since the last evaluation, is the patient (place an "x" in the appropriate box below):

5☐ Much Better 4☐ A Little Better 3☐ No Change 2☐ Slightly Worse 1☐ Much Worse

3. Since the patient entered the study, is the patient:

5☐ Much Better 4☐ A Little Better 3☐ No Change 2☐ Slightly Worse 1☐ Much Worse

FORM COMPLETED BY _____

INVESTIGATOR'S SIGNATURE _____ Date _____

VA Form 10-20923(NR)d
November 1991

Patient Initials ☐☐☐ Center No. ☐☐☐ Patient No. ☐☐☐ Date of Visit ☐☐-☐☐-☐☐ (month - day - year)

FORM 05 - GLOBAL RATING SCALE - PATIENT

Rating Period: ☐ Screen ☐ 04 wk ☐ 08 wk ☐ 12 wk ☐ 16 wk

1. Considering your history of drug use and the problems it has caused you, how severe is your drug problem now? Based on a scale of 1 to 100, 0 being no drug problem and 100 being the most severe problem:

SCORE: ☐☐☐

DO NOT COMPLETE QUESTIONS 2 AND 3 AT SCREENING.

2. Since the last time you completed this scale, are you (place an "x" in the appropriate box below):

5☐ Much Better 4☐ A Little Better 3☐ No Change 2☐ Slightly Worse 1☐ Much Worse

3. Since you entered the study, are you:

5☐ Much Better 4☐ A Little Better 3☐ No Change 2☐ Slightly Worse 1☐ Much Worse

FORM COMPLETED BY _____

INVESTIGATOR'S SIGNATURE _____ Date _____

VA Form 10-20923(NR)e
November 1991

Patient Initials ☐☐☐ Center No. ☐☐☐ Patient No. ☐☐☐ Date of Visit ☐☐-☐☐-☐☐ (month-day-year)

FORM 06 - MEDICAL HISTORY AND STATUS

MEDICAL HISTORY

1. Please indicate whether the patient has had any abnormalities, diseases or disorders of the following:	1=YES	2=NO	IF YES, please describe briefly
a. Head, eyes, ears, nose, throat	1 ☐	2 ☐	
b. Cardiovascular	1 ☐	2 ☐	
c. Respiratory	1 ☐	2 ☐	
d. Gastrointestinal	1 ☐	2 ☐	
e. Genitourinary	1 ☐	2 ☐	
f. Musculoskeletal	1 ☐	2 ☐	
g. Neurological	1 ☐	2 ☐	
h. Endocrinological	1 ☐	2 ☐	
i. Dermatological	1 ☐	2 ☐	
j. Hematopoietic	1 ☐	2 ☐	
k. Allergies	1 ☐	2 ☐	
l. Alcoholism or drug dependency other than opiate	1 ☐	2 ☐	
m. Other, specify _____	1 ☐	2 ☐	
n. Other, specify _____	1 ☐	2 ☐	
o. Other, specify _____	1 ☐	2 ☐	
p. Other, specify _____	1 ☐	2 ☐	

Continued

Center No. ☐☐☐ Patient No. ☐☐☐

MEDICAL STATUS

2. Do you have any current/ongoing medical problems other than your addiction? 1 ☐ Yes 2 ☐ No

If YES, list and code these problems below. (See Medical Event Code Directory to code problems.)

I. Severity	II. Action Taken
1=Mild 2=Moderate 3=Severe	1=None 2=Prescription drug therapy required 3=Inpatient hospitalization required or prolonged 4=Prescription drug therapy and hospitalization required

Nature of Problem	Medical Event Code	Date of Onset Mo Day Yr	I. Severity	II. Action Taken
a.	☐☐☐☐	☐☐ ☐☐ ☐☐		
b.	☐☐☐☐	☐☐ ☐☐ ☐☐		
c.	☐☐☐☐	☐☐ ☐☐ ☐☐		
d.	☐☐☐☐	☐☐ ☐☐ ☐☐		
e.	☐☐☐☐	☐☐ ☐☐ ☐☐		
f.	☐☐☐☐	☐☐ ☐☐ ☐☐		

3. How have you been feeling in the past 7 days? _____

_____

4. Have you had any problems in the past 7 days? 1 ☐ Yes 2 ☐ No

If YES, please describe, in the investigator's own words, each Adverse Event, Intercurrent Illness or Clinically Significant Abnormal Lab Value and associated information below. (See Medical Event Code Directory for Medical Event Code).

I. Severity	II. Action Taken	III. Outcome
1=Mild 2=Moderate 3=Severe	1=None 2=Prescription drug therapy required 3=Inpatient hospitalization required or prolonged 4=Prescription drug therapy and hospitalization required 5=Medical specialty consultation	1=Resolved; No sequelae 2=Not yet resolved 3=Resulted in chronic condition, severe and/or permanent disability 4=Unknown

Nature of Illness, Event or Abnormal Lab Value	Medical Event Code	Date of Onset Mo Day Yr	Date of Resolution Mo Day Yr	I. Severity	II. Action Taken	III. Outcome
a.	____	__ __ __	__ __ __	☐	☐	☐
b.	____	__ __ __	__ __ __	☐	☐	☐
c.	____	__ __ __	__ __ __	☐	☐	☐
d.	____	__ __ __	__ __ __	☐	☐	☐
e.	____	__ __ __	__ __ __	☐	☐	☐
f.	____	__ __ __	__ __ __	☐	☐	☐

Continued

Center No. ☐☐☐ Patient No. ☐☐☐

5. Have you taken any medications in the past 7 days? 1 ☐ **Yes** 2 ☐ **No**

If YES, list and code these medications below.
(See Drug Code Directory to code drug and Medical Event Code Directory to code indications.)

Drug Name (Generic Preferred)	**Code Drug**	**Strength** (mg)	**Doses /Day**	**Code Indication**	**Start Date** Mo Day Yr	**Stop Date** Mo Day Yr	**Check** (✓) if continuing
a.	_ _ _	_ _ _ _	_ _	_ _ _ _	_ _ _ _ _ _	_ _ _ _ _ _	
b.	_ _ _	_ _ _ _	_ _	_ _ _ _	_ _ _ _ _ _	_ _ _ _ _ _	
c.	_ _ _	_ _ _ _	_ _	_ _ _ _	_ _ _ _ _ _	_ _ _ _ _ _	
d.	_ _ _	_ _ _ _	_ _	_ _ _ _	_ _ _ _ _ _	_ _ _ _ _ _	
e.	_ _ _	_ _ _ _	_ _	_ _ _ _	_ _ _ _ _ _	_ _ _ _ _ _	

FORM COMPLETED BY _____

INVESTIGATOR'S SIGNATURE _____ Date _____

Patient Initials ☐☐☐ Center No. ☐☐☐ Patient No. ☐☐☐ Date of Visit ☐☐-☐☐-☐☐ (month - day - year)

FORM 07 - CRAVING SCALE (SCREENING ONLY)

1. HEROIN CRAVING: Mark on the line below, the estimate of your most intense craving for heroin that occurred at any time during the past 7 days.

NO CRAVING — MOST INTENSE CRAVING I EVER HAD

☐☐☐

2. COCAINE CRAVING: Mark on the line below, the estimate of your most intense craving for cocaine that occurred at any time during the past 7 days.

NO CRAVING — MOST INTENSE CRAVING I EVER HAD

☐☐☐

3. ALCOHOL CRAVING: Mark on the line below, the estimate of your most intense craving for alcohol that occurred at any time during the past 7 days.

NO CRAVING — MOST INTENSE CRAVING I EVER HAD

☐☐☐

Comments: _____

_____

_____

_____

_____

FORM COMPLETED BY _____

INVESTIGATOR'S SIGNATURE _____ Date _____

Patient Initials ☐☐☐ Center No. ☐☐☐ Patient No. ☐☐☐ Date of Visit ☐☐-☐☐-☐☐ (month - day - year)

FORM 08 - LABORATORY REPORT

RATING PERIOD: ☐ Screen ☐ 02 wk ☐ 04 wk ☐ 08 wk ☐ 12 wk ☐ 16 wk

DATE SAMPLE DRAWN: ☐☐ ☐☐ ☐☐ (month day year) TIME SAMPLE DRAWN: ☐☐:☐☐ (24 hour clock)

HEMATOLOGY

1. Total WBC (x 10^3 cu mm)	☐☐•☐	6. Neutrophils (%)	☐☐
2. Total RBC (x 10^3 cu mm)	☐☐•☐	7. Lymphocytes (%)	☐☐
3. Platelet count (/cu mm)	☐☐☐☐	8. Monocytes (%)	☐☐
4. Hemoglobin (gm/dl)	☐☐•☐	9. Eosinophils (%)	☐☐
5. Hematocrit (gm/dl)	☐☐•☐	10. Basophils (%)	☐☐

BLOOD CHEMISTRY

11. Glucose (mg/dl)	☐☐☐	*16. SGOT (U/L)	☐☐☐
12. Total protein (gm/dl)	☐•☐	*17. SGPT (U/L)	☐☐☐
13. Albumin (gm/dl)	☐•☐	*18. GGT (U/L)	☐☐☐
14. BUN (mg/dl)	☐☐	*19. Alk. phosphatase (U/L)	☐☐☐
15. Creatinine (mg/dl)	☐•☐	*20. Total bilirubin (mg/dl)	☐•☐

21. If any liver function test values (*) are greater than 8 times normal, were Forms 16 and 17 completed and the Sponsor and the IRB notified? 1 ☐ Yes 2 ☐ No 3 ☐ No abnormal values

URINALYSIS

22. Specific gravity	☐•☐☐☐
23. Reaction (record actual pH value)	☐•☐
24. Albumin (0=Absent, 1=Trace, 2=Neutral)	☐
25. Glucose (enter 0, 1, 2, 3, or 4)	☐
26. Acetone (0=Absent, 1=Trace, 2=Present)	☐
27. WBCS/HPF (1=None, 2=Few, 3=Moderate, 4=Heavy)	☐
28. RBCS/HPF (1=None, 2=Few, 3=Moderate, 4=Heavy)	☐
29. Epithelial Cells (1=None, 2=Few, 3=Moderate, 4=Heavy)	☐

Continued

Center No. ☐☐☐ Patient No. ☐☐☐

30. Were any clinically significant abnormal results observed? 1☐ Yes 2☐ No
If yes, please give details: _____

_____

_____

_____

PREGNANCY TEST (To be done only on women of childbearing potential.)

31. Serum Pregnancy Test: 1☐ Positive 2☐ Negative 3☐ Not Applicable

BUPRENORPHINE BLOOD LEVELS (To be done at Week 02 and Week 08 ONLY.)

32. Was blood drawn? 1☐ Yes 2☐ No

33. Date sent to Utah? |__|__| |__|__| |__|__|
month day year

COMMENTS: _____

_____

_____

_____

FORM COMPLETED BY _____

INVESTIGATOR'S SIGNATURE _____ Date _____

VA Form 10-20923(NR)h
November 1991

LAATRC/VA/NIDA STUDY 999a

A Multicenter Clinical Trial of Buprenorphine in Treatment of Opiate Dependence

Patient Initials ☐☐☐ Center No. ☐☐☐ Patient No. ☐☐☐ Date of Visit ☐☐-☐☐-☐☐ (month-day-year)

FORM 09 - PHYSICAL EXAM

Rating Period: ☐ Screen ☐ 04 wk ☐ 08 wk ☐ 12 wk ☐ 16 wk

VITAL SIGNS

1. Height (ins.) ☐☐
2. Weight (lbs.) ☐☐☐
3. Temperature (°C) ☐☐.☐
4. Blood Pressure - sitting (mmHg) ☐☐☐ / ☐☐☐
5. Pulse Rate (/minute resting) ☐☐☐
6. Respiration (/minute resting) ☐☐

PHYSICAL EXAMINATION	Normal (1)	Abnormal (2)	Not Done (3)	Describe Abnormality
7. HEENT	☐	☐	☐	
8. Sublingual Mucosa	☐	☐	☐	
9. Pupil Size	☐	☐	☐	
10. Heart	☐	☐	☐	
11. Lungs	☐	☐	☐	
12. Abdomen	☐	☐	☐	
13. Extremities	☐	☐	☐	
a. Fresh Needle Marks	1 ☐ Yes	2 ☐ No		
b. Available Veins	1 ☐ Yes	2 ☐ No		
14. Skin	☐	☐	☐	
15. Lymph Nodes	☐	☐	☐	
16. Other _____	☐	☐	☐	

Other physical findings: _____

FOR WOMEN ONLY (To be completed at Screening only.)

17. Is patient of childbearing potential? 1 ☐ Yes 2 ☐ No
    a. If NO, specify reason: 1 ☐ Hysterectomy 2 ☐ Tubal ligation 3 ☐ Post-menopausal
    b. If patient specified any of the above reasons, give date: ☐☐ (month) ☐☐ (day) ☐☐ (year)
18. Is patient nursing an infant? 1 ☐ Yes 2 ☐ No
19. What method of birth control is patient using?
    1 ☐ Pill 2 ☐ IUD 3 ☐ Diaphragm 4 ☐ Condom 5 ☐ Other, specify _____ 6 ☐ None, refuses

FORM COMPLETED BY _____

INVESTIGATOR'S SIGNATURE _____ Date _____

VA Form 10-20923(NR)i
November 1991

LAATRC/VA/NIDA STUDY 999a
A Multicenter Clinical Trial of Buprenorphine in Treatment of Opiate Dependence

Patient Initials ☐☐☐ Center No. ☐☐☐ Patient No. ☐☐☐ Date of EKG ☐☐-☐☐-☐☐ (month - day - year)

FORM 10 - ELECTROCARDIOGRAM

RATING PERIOD: ☐ Screen ☐ 04 wk ☐ 16 wk

Please answer <u>each</u> question by placing an "X" in the appropriate box.

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

30. EKG OVERALL RESULTS: 1☐ Normal 2☐ Abnormal

<u>TO BE DONE AT SCREENING ONLY</u>.

31. Do any items listed as "present" exclude the patient from the study? 1☐ Yes 2☐ No

READ BY: _____ Date _____

INVESTIGATOR'S SIGNATURE _____ Date _____

VA Form 10-20923(NR)j
November 1991

Patient Initials ☐☐☐ Center No. ☐☐☐ Patient No. ☐☐☐ Date of Visit ☐☐-☐☐-☐☐ (month - day - year)

FORM 11 - STUDY ADMISSION

1. DSM-III-R diagnosis of current **opiate dependence**	1☐ Yes	2☐ No
2. Expected to remain available to attend clinic for duration of study (e.g., those with criminal charges)	1☐ Yes	2☐ No
3. Mentally competent to give informed consent	1☐ Yes	2☐ No
4. Permanent residence within commuting distance of clinic	1☐ Yes	2☐ No
5. Patient 18 years of age or older	1☐ Yes	2☐ No

IF ANY NO RESPONSE IN QUESTIONS 1-5, PATIENT IS INELIGIBLE FOR THE STUDY.

6. Pregnant or nursing female	1☐ Yes	2☐ No
7. Female of childbearing potential who refuses birth control	1☐ Yes	2☐ No
8. Acute hepatitis or any other acute medical condition that would make participation in the study medically hazardous for the patient (e.g., active tuberculosis, unstable cardiovascular or liver disease, or unstable diabetes, or AIDS)	1☐ Yes	2☐ No
9. DSM-III-R diagnosis of current **alcohol dependence or sedative-hypnotics dependence**	1☐ Yes	2☐ No
10. Current daily use of anticonvulsants, Antabuse, or neuroleptics	1☐ Yes	2☐ No
11. Enrolled in a methadone maintenance program in past 30 days	1☐ Yes	2☐ No
12. Positive urine for methadone	1☐ Yes	2☐ No
13. Has been a subject in a prior buprenorphine trial for drug addiction	1☐ Yes	2☐ No
14. Currently participating in another research project	1☐ Yes	2☐ No
15. Refuses to participate in study	1☐ Yes	2☐ No
16. Other, specify _____	1☐ Yes	2☐ No

IF ANY YES RESPONSE IN QUESTIONS 6-16, PATIENT IS INELIGIBLE FOR THE STUDY.

17. IS PATIENT ELIGIBLE TO PARTICIPATE IN THE STUDY? 1☐ Yes 2☐ No

Patient is **INELIGIBLE** if any **NO** to Questions 1-5 or any **YES** to Questions 6-16.

IF ELIGIBLE:

a. Date randomized: ☐☐ (month) ☐☐ (day) ☐☐ (year)

b. Date of first dose: ☐☐ (month) ☐☐ (day) ☐☐ (year)

FORM COMPLETED BY _____

INVESTIGATOR'S SIGNATURE _____ Date _____

LAATRC/VA/NIDA STUDY 999a

A Multicenter Clinical Trial of Buprenorphine in Treatment of Opiate Dependence

Patient Initials ☐☐☐ Center No. ☐☐☐ Patient No. ☐☐☐ Date Completed ☐☐-☐☐-☐☐ (month - day - year)

FORM 12 - COORDINATORS WEEKLY REPORT

ENTER STUDY WEEK NUMBER: ☐☐

Day	Date (mo day yr)	Attended Clinic?	Enter Dose Code*	Is today a Monday, Wednesday or Friday?	If today is Mon., Wed., or Fri., have you collected urine samples? †	Date urine samples sent to Utah (mo day yr)	Comments
1	Enter Day: _____ Enter Date: __ __ __	1☐ Yes 2☐ No	☐	1☐ Yes 2☐ No	1☐ Yes _____ 2☐ No	__ __ __	
2	Enter Day: _____ Enter Date: __ __ __	1☐ Yes 2☐ No	☐	1☐ Yes 2☐ No	1☐ Yes _____ 2☐ No	__ __ __	
3	Enter Day: _____ Enter Date: __ __ __	1☐ Yes 2☐ No	☐	1☐ Yes 2☐ No	1☐ Yes _____ 2☐ No	__ __ __	
4	Enter Day: _____ Enter Date: __ __ __	1☐ Yes 2☐ No	☐	1☐ Yes 2☐ No	1☐ Yes _____ 2☐ No	__ __ __	
5	Enter Day: _____ Enter Date: __ __ __	1☐ Yes 2☐ No	☐	1☐ Yes 2☐ No	1☐ Yes _____ 2☐ No	__ __ __	
6	Enter Day: _____ Enter Date: __ __ __	1☐ Yes 2☐ No	☐	1☐ Yes 2☐ No	1☐ Yes _____ 2☐ No	__ __ __	
7	Enter Day: _____ Enter Date: __ __ __	1☐ Yes 2☐ No	☐	1☐ Yes 2☐ No	1☐ Yes _____ 2☐ No	__ __ __	

* Dose Code: 1 = Induction/Reinduction, 2 = Maintenance Kit, 3 = Taper Dose, 4 = Not dosed

† If urine was collected, please give the initials of the person who observed the urine collection in the space provided to the right of "Yes."

FORM COMPLETED BY _____

INVESTIGATOR'S SIGNATURE _____ Date _____

VA Form 10-20923(NR)1
November 1991

LAATRC/VA/NIDA STUDY 999a

A Multicenter Clinical Trial of Buprenorphine in Treatment of Opiate Dependence

Patient Initials ☐☐☐ Center No. ☐☐☐ Patient No. ☐☐☐ Date of Visit ☐☐-☐☐-☐☐ (month-day-year)

FORM 13 - WEEKLY SELF-REPORT OF DRUG USE AND CRAVING SCALE

ENTER STUDY WEEK NUMBER: ☐☐

THIS REPORT IS FOR THE WEEK OF ☐☐ ☐☐ ☐☐ (month day year) TO ☐☐ ☐☐ ☐☐ (month day year)

A. DRUG USE

DRUG	USED DRUG?	WHAT DAYS OF THE WEEK DID YOU USE DRUGS AND HOW MANY TIMES? Fri. Sat. Sun.	If Yes: # of Times	Mon. thru Thurs.	If Yes: # of Times	TOTAL DOLLAR AMOUNT SPENT	Primary Mode of Abuse 1=Oral 2=I.V. 3=Snorting 4=Smoking 5=Sublingual 6=Other
1. Heroin or other opiate	1☐ Yes 2☐ No	1☐ Yes 2☐ No	☐☐	1☐ Yes 2☐ No	☐☐	$ ☐☐☐☐	☐
2. Cocaine	1☐ Yes 2☐ No	1☐ Yes 2☐ No	☐☐	1☐ Yes 2☐ No	☐☐	$ ☐☐☐☐	☐
3. Methamphetamine	1☐ Yes 2☐ No	1☐ Yes 2☐ No	☐☐	1☐ Yes 2☐ No	☐☐	$ ☐☐☐☐	☐
4. Alcohol	1☐ Yes 2☐ No	1☐ Yes 2☐ No	☐☐	1☐ Yes 2☐ No	☐☐	$ ☐☐☐☐	☐
5. Tranquilizers	1☐ Yes 2☐ No	1☐ Yes 2☐ No	☐☐	1☐ Yes 2☐ No	☐☐	$ ☐☐☐☐	☐
6. Marijuana or other forms of THC	1☐ Yes 2☐ No	1☐ Yes 2☐ No	☐☐	1☐ Yes 2☐ No	☐☐	$ ☐☐☐☐	☐
7. PCP	1☐ Yes 2☐ No	1☐ Yes 2☐ No	☐☐	1☐ Yes 2☐ No	☐☐	$ ☐☐☐☐	☐
8. Other, specify: _____	1☐ Yes 2☐ No	1☐ Yes 2☐ No	☐☐	1☐ Yes 2☐ No	☐☐	$ ☐☐☐☐	☐

Continued

Center No. ☐☐☐ Patient No. ☐☐☐

B. CRAVING SCALE

9. HEROIN CRAVING: Mark on the line below, the estimate of your most intense craving for heroin that occurred at any time during the past 7 days.

0 |——————————————————————————| 100

NO CRAVING — MOST INTENSE CRAVING I EVER HAD

☐☐☐

10. COCAINE CRAVING: Mark on the line below, the estimate of your most intense craving for cocaine that occurred at any time during the past 7 days.

0 |——————————————————————————| 100

NO CRAVING — MOST INTENSE CRAVING I EVER HAD

☐☐☐

11. ALCOHOL CRAVING: Mark on the line below, the estimate of your most intense craving for alcohol that occurred at any time during the past 7 days.

0 |——————————————————————————| 100

NO CRAVING — MOST INTENSE CRAVING I EVER HAD

☐☐☐

Comments: _____

_____

_____

_____

_____

FORM COMPLETED BY _____

INVESTIGATOR'S SIGNATURE _____ Date _____

Patient Initials ☐☐☐ Center No. ☐☐☐ Patient No. ☐☐☐ Date of Visit ☐☐-☐☐-☐☐ (month-day-year)

FORM 14 - PSYCHOSOCIAL SERVICES RECEIVED

ENTER STUDY WEEK NUMBER: ☐☐

THIS REPORT IS FOR THE WEEK OF ___ ___ ___ (month day year) TO ___ ___ ___ (month day year)

Please indicate the number of sessions of psychosocial services received for the week indicated above.

Services	Number of Sessions	Total Number of Minutes
1. Individual Counseling	___	___
2. Group Sessions	___	___
3. AIDS Counseling	___	___
4. Other, specify _____ _____	___	___

Counselor Notes: _____

NAME OF COUNSELOR _____ Date _____

INVESTIGATOR'S SIGNATURE _____ Date _____

Patient Initials ☐☐☐ Center No. ☐☐☐ Patient No. ☐☐☐ Date of Visit ☐☐-☐☐-☐☐ (month-day-year)

FORM 15 - CONCOMITANT MEDICATION

ENTER STUDY WEEK NUMBER: ☐☐

THIS REPORT IS FOR THE WEEK OF ___ (month) ___ (day) ___ (year) TO ___ (month) ___ (day) ___ (year)

1. Did the patient take any prescription or over-the-counter medications in the past 7 days? 1☐ Yes 2☐ No

IF YES, list and code these medications below. Record the strength (mg) and doses per day, the dates taken **during the past 7 days**, and check (✓) if continuing the medication. (See Drug Code Directory to code drug and Medical Event Code Directory to code indications.)

Drug Name (Generic Preferred)	**Code Drug**	**Strength** (mg)	**Doses /Day**	**Code Indication**	**FROM** Mo Day Yr	**TO** Mo Day Yr	**Check (✓) if continuing**
a.	___	____	__	____	__ __ __	__ __ __	
b.	___	____	__	____	__ __ __	__ __ __	
c.	___	____	__	____	__ __ __	__ __ __	
d.	___	____	__	____	__ __ __	__ __ __	
e.	___	____	__	____	__ __ __	__ __ __	
f.	___	____	__	____	__ __ __	__ __ __	
g.	___	____	__	____	__ __ __	__ __ __	
h.	___	____	__	____	__ __ __	__ __ __	

FORM COMPLETED BY _____

INVESTIGATOR'S SIGNATURE _____ Date _____

Patient Initials ☐☐☐ Center No. ☐☐☐ Patient No. ☐☐☐ Date of Visit ☐☐-☐☐-☐☐ (month - day - year)

FORM 16 - ADVERSE EVENTS

STUDY WEEK NUMBER: ☐☐ FOR THE WEEK OF ☐☐ (month) ☐☐ (day) ☐☐ (year) TO ☐☐ (month) ☐☐ (day) ☐☐ (year)

1. **"How have you been feeling this last week?"** _____

2. **"Have you had any problems in the last week"?** (Including those present or unresolved at entry.) 1☐ Yes 2☐ No
If **YES**, give details below: ↓

I. Type of Report	II. Relatedness	III. Severity	IV. Action Taken	V. Outcome
1=Anticipated adverse event 2=Unanticipated adverse event 3=Intercurrent illness 4=Withdrawal symptom †5=Development of clinically significant abnormal lab value	1=Study drug related 2=Probably study drug related 3=Possibly study drug related 4=Unrelated to study drug	1=Mild 2=Moderate 3=Severe	1=None 2=Prescription drug therapy required *3=Inpatient hospitalization required or prolonged *4=Prescription drug therapy and hospitalization required 5=Dropped from study due to effect 6=Medical specialty consultation	1=Resolved; No sequelae 2=Not yet resolved *3=Resulted in chronic condition, severe and/or permanent disability *4=Deceased 5=Unknown

Please describe, in the investigator's own words, each Adverse Event, Intercurrent Illness or Clinically Significant Abnormal Lab Value and associated information below. (See Medical Event Code Directory for Medical Event Code).

Nature of Illness, Event or Abnormal Lab Value	Medical Event Code	Date of Onset (mo day yr)	Date of Resolution (mo day yr)	I. Type of Report	II. Relatedness	III. Severity	IV. Action Taken	V. Outcome
a.	____	__ __ __	__ __ __	☐	☐	☐	☐	☐
b.	____	__ __ __	__ __ __	☐	☐	☐	☐	☐
c.	____	__ __ __	__ __ __	☐	☐	☐	☐	☐
d.	____	__ __ __	__ __ __	☐	☐	☐	☐	☐
e.	____	__ __ __	__ __ __	☐	☐	☐	☐	☐
f.	____	__ __ __	__ __ __	☐	☐	☐	☐	☐

†May require completion of Form 17 - Serious Adverse Event Form
*Requires completion of Form 17 - Serious Adverse Event Form

3. **Is a Serious Adverse Event Form (Form 17) required?** 1☐ Yes 2☐ No

4. **Was it necessary to break randomization code for this patient?** 1☐ Yes 2☐ No

Comments: _____

FORM COMPLETED BY _____

INVESTIGATOR'S SIGNATURE _____ Date _____

FORM 17 - SERIOUS ADVERSE EVENT FORM

STUDY NO. 999a CENTER NO. ☐☐☐ PATIENT NO. ☐☐☐

I. ADVERSE EVENT

1. PATIENT INITIALS	2-4. EVENT ONSET Month: Day: Year:	5. Age: (yrs)
6. SEX	7. HEIGHT (cm/in)	8. WEIGHT

9. DESCRIBE ADVERSE EVENT:

A. MEDICAL EVENT CODE	B. EVENT DESCRIPTION	C. GREATEST SEVERITY 1 = Mild 2 = Moderate 3 = Severe	D. STUDY DRUG RELATED 0 = No 1 = Possible 2 = Probable	ACTION TAKEN E. DOSE CHANGE 0 = No Change 1 = Reduced 2 = Temp. Dc'd 3 = Perm. Dc'd	ACTION TAKEN F. TREATMENT 0 = No Treatment 1 = Outpatient Tx 2 = Hospitalization	G. OUTCOME 0 = Unknown 1 = Resolved 2 = Ongoing 3 = Died
☐☐☐☐	_____	☐	☐	☐	☐	☐

H. Provide Narrative Description of Event:

I. If Died, List Primary Cause of Death:

10. Revelant Tests/Laboratory Data:

II. SUSPECT DRUG(s) INFORMATION

11. Suspect Drug(s) (Give Trade/Generic Name(s), Manufacturer):

12. Daily Dose:	13. Route of Administration:	14. Dates of Administration: (from/to)
15. Indication(s) for Use:	16. Duration of Administration:	

III. CONCOMITANT DRUG(s) AND HISTORY

17. Concomitant Drug(s) and Date(s) of Administration (Exclude those used to treat reaction)

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

IV. INITIAL REPORTER

19-20. Name and Address of Reporter (Include Zip Code)	21. Telephone No. (Include area code)

Patient Initials ☐☐☐ Center No. ☐☐☐ Patient No. ☐☐☐ Date Terminated ☐☐-☐☐-☐☐ (month-day-year)

FORM 18 - TERMINATION

1. USING THE LIST BELOW, PLEASE INDICATE **THE PRIMARY REASON** PATIENT TERMINATED FROM THE STUDY. *(If 3, 7, 11, 13 or 14 are given as the primary reason for termination, please specify reason where indicated below.)*

☐ 1. Completed protocol

☐ 2. Toxicity or side effects related to buprenorphine

☐ 3. Medical reason unrelated to buprenorphine
IF YES, specify reason: _____

☐ 4. Missed 7 consecutive days of dosing

☐ 5. No show for 7 consecutive days

☐ 6. Required a 4th reinduction

☐ 7. Patient's request
IF YES, specify request: _____

☐ 8. Moved from area

☐ 9. Incarceration exceeding 6 days

☐ 10. Termination by clinic physician because of intercurrent illness or medical complications precluding safe administration of buprenorphine

☐ 11. Administrative discharge
IF YES, specify incident: _____

☐ 12. Pregnancy

☐ 13. Death (termination date is date of death; complete Serious Adverse Event Form (17)
IF YES, specify cause of death if known: _____

☐ 14. Other
IF YES, specify: _____

2. BRIEFLY DESCRIBE THE EVENTS WHICH LED TO TERMINATION (be specific): _____

_____

3. SINCE THE PATIENT ENTERED THE STUDY, IS HE/SHE:
5☐ Much Better 4☐ A Little Better 3☐ No Change 2☐ Slightly Worse 1☐ Much Worse

FORM COMPLETED BY _____

INVESTIGATOR'S SIGNATURE _____ Date _____

LAATRC/VA/NIDA Study #999a
"A Multicenter Clinical Trial of Buprenorphine in Treatment of Opiate Dependence"

FORM 19 - DOSE ADMINISTRATION RECORD

Patient's Initials: ___ ___ ___ Center Number: ___ ___ ___ Patient Number: ___ ___ ___

Study Drug: B-999A (Buprenorphine 1mg, 2mg, 4mg, 8mg, 12mg, or 16mg)

Study Day #	Date	**Dose Administered** (Please Check Appropriate Box)														**Missed Dose**	**Comments**
		Induction/ Reinduction Dose				Maintenance Kit				Taper Dose				X-Dose	Dosed By		
		#1	#2	#3	#4	#1	#2	#3	#4	#1	#2	#3	#4				
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LAATRC/VA/NIDA Study #999a
"A Multicenter Clinical Trial of Buprenorphine in Treatment of Opiate Dependence"

FORM 19 - DOSE ADMINISTRATION RECORD

Patient's Initials: ___ ___ ___ Center Number: ___ ___ ___ Patient Number: ___ ___ ___

Study Drug: B-999A (Buprenorphine 1mg, 2mg, 4mg, 8mg, 12mg, or 16mg)

Study Day #	Date	**Dose Administered** (Please Check Appropriate Box)														**Missed Dose**	**Comments**
		Induction/ Reinduction Dose				Maintenance Kit				Taper Dose				X-Dose	Dosed By		
		#1	#2	#3	#4	#1	#2	#3	#4	#1	#2	#3	#4				
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Continued

LAATRC/VA/NIDA Study #999a
"A Multicenter Clinical Trial of Buprenorphine in Treatment of Opiate Dependence"

FORM 19 - DOSE ADMINISTRATION RECORD

Patient's Initials: ___ ___ ___ Center Number: ___ ___ ___ Patient Number: ___ ___ ___

Study Drug: B-999A (Buprenorphine 1mg, 2mg, 4mg, 8mg, 12mg, or 16mg)

Study Day #	Date	Dose Administered (Please Check Appropriate Box)														Missed Dose	Comments
		Induction/ Reinduction Dose				Maintenance Kit				Taper Dose				X-Dose	Dosed By		
		#1	#2	#3	#4	#1	#2	#3	#4	#1	#2	#3	#4				
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112																	

Signature of Person(s) Administering Dose:

Initials	Name	Initials	Name
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

LAATRC/VA/NIDA Study #999a - A Multicenter Clinical Trial of Buprenorphine in Treatment of Opiate Dependence

LOCATOR INFORMATION

Patient Name _____ Patient No. _ _ _ Date Completed _ _ _ _ _ _
Mo Day Yr

We would like to ask you some questions that will help us contact you now and in the future. The information that you give will be used only to help us locate you.

1. What is your full name? (Print response verbatim)

_____ _____ _____
First Name Middle Name(s) Last Name

2. Do you have any street names, nicknames, aliases or other names you're known by? (1=Yes, 2=No) . . . . . ____

   If Yes, what are they? (Print response verbatim)

   a. _____

   b. _____

   c. _____

3. What is the address of your present place of residence or place you live now? (Print response verbatim)

   Street Number and Name: _____

   Apartment No., Box No., etc.: _____

   City, State, Zip Code: _____

4. Do you receive your mail at that address? (1=Yes, 2=No) . . . . . ____

   If No, what is your mailing address or where do you get your mail? (Print response verbatim)

   In care of (name of person, institution, etc.): _____

   Street Number and Name: _____

   Apartment No., Box No., etc.: _____

   City, State, Zip Code: _____

5. Do you have a phone number or numbers which can be used to contact you? (1=Yes, 2=No) . . . . . ____

   If Yes:

   a. What telephone number or numbers should be used to contact you?

      Area Code: _ _ _ Number: _ _ _ - _ _ _ _

      Area Code: _ _ _ Number: _ _ _ - _ _ _ _

   b. Is (are) the telephone(s) located at your residence or somewhere else? . . . . . ____
      1=Subject's
      2=Other, specify _____

   c. Whose name is (are) the telephone(s) listed under? . . . . . ____
      1=Subject's
      2=Other, specify _____

6. Where do you expect to be living a year from now? . . . . . ___
   1=Same address
   2=Different address in same city
   3=With friends or relatives
   4=Different city
   5=Other, specify _____

We'd like to know some people we could contact who usually know where you are. These people will only be contacted to help locate you if you miss an appointment and we can't reach you by phone or mail. We will not interview these people about you.

7. Do you have a spouse or girlfriend/boyfriend? (1=Yes, 2=No) . . . . . ___

   If Yes:

   a. What is that person's name: (First) _____ (Last) _____

   b. Is he/she now living with you? (1=Yes, 2=No) . . . . . ___

   c. If he/she is not living with you, what is his/her present address?

      Street Number and Name: _____

      Apartment No., Box No., etc.: _____

      City, State, Zip Code: _____

   d. What telephone number should we use to contact him/her?

      Area Code _ _ _ Number _ _ _ - _ _ _ _

8. What are the names, addresses and telephone numbers of relatives or friends who usually know where you will be? (Print response verbatim)

   a. (First Name) _____ (Last Name) _____

      Street Number and Name: _____

      Apartment No., Box No., etc.: _____

      City, State, Zip Code: _____

      Telephone Number: Area Code _ _ _ Number _ _ _ - _ _ _ _

   b. (First Name) _____ (Last Name) _____

      Street Number and Name: _____

      Apartment No., Box No., etc.: _____

      City, State, Zip Code: _____

      Telephone Number: Area Code _ _ _ Number _ _ _ - _ _ _ _

9. Do you have a probation or parole officer? (1=Yes, 2=No) . . . . . ___

   If Yes:

   a. What is his/her name and address? (Print response vertabim)

      (First Name) _____ (Last Name) _____

      Street Number and Name: _____

      Apartment No., Box No., etc.: _____

      City, State, Zip Code: _____

   b. What telephone number should we use to contact him/her?

      Telephone Number: Area Code _ _ _ Number _ _ _ - _ _ _ _

VA/NIDA STUDY 999a EXT

A Long Term Multicenter Clinical Trial of Buprenorphine in Treatment of Opiate Dependence

Patient Initials	Center No.	Patient No.
☐☐☐	☐☐☐	☐☐☐

SUMMARY OF LENGTH OF TIME IN 999a PROTOCOL:

PARENT: _____ *weeks*

CONTINUATION: _____ *weeks*

EXTENSION: _____ *weeks*

STUDY FORMS FOR 999a EXT

FORM 01 - Laboratory Report

FORM 02 - Physical Exam

FORM 03 - Electrocardiogram

FORM 04 - Weekly Self-Report of Drug Use

FORM 05 - Concomitant Medication

FORM 06 - Adverse Events

FORM 07 - Serious Adverse Event Form

FORM 08 - Termination

FORM 09 - Dose Administration Record

VA/NIDA STUDY 999a EXT

A Long Term Multicenter Clinical Trial of Buprenorphine in Treatment of Opiate Dependence

Patient Initials ☐☐☐ Center No. ☐☐☐ Patient No. ☐☐☐ Date of Visit ☐☐-☐☐-☐☐ (month-day-year)

FORM 01 - LABORATORY REPORT

RATING PERIOD: ☐ 12 wk ☐ 24 wk ☐ 36 wk/termination ☐ other _____

DATE SAMPLE DRAWN: ☐☐ ☐☐ ☐☐ (month day year) TIME SAMPLE DRAWN: ☐☐:☐☐ (24 hour clock)

HEMATOLOGY

1. Total WBC (x 10^3 cu mm)	☐☐•☐	6. Neutrophils (%)	☐☐•☐
2. Total RBC (x 10^6 cu mm)	☐☐•☐	7. Lymphocytes (%)	☐☐•☐
3. Platelet count (/cu mm)	☐☐☐☐	8. Monocytes (%)	☐☐•☐
4. Hemoglobin (gm/dl)	☐☐•☐	9. Eosinophils (%)	☐☐•☐
5. Hematocrit (gm/dl)	☐☐•☐	10. Basophils (%)	☐☐•☐

BLOOD CHEMISTRY

11. Glucose (mg/dl)	☐☐☐	*16. SGOT or AST (U/L)	☐☐☐
12. Total protein (gm/dl)	☐•☐	*17. SGPT or ALT (U/L)	☐☐☐
13. Albumin (gm/dl)	☐•☐	*18. GGT (U/L)	☐☐☐
14. BUN (mg/dl)	☐☐	*19. Alk. phosphatase (U/L)	☐☐☐
15. Creatinine (mg/dl)	☐•☐	*20. Total bilirubin (mg/dl)	☐•☐

21. If any liver function test values (*) are 8 times or greater than normal, were Forms 06 and 07 completed and the Sponsor and the IRB notified? 1☐ Yes 2☐ No

URINALYSIS

22. Specific gravity	☐•☐☐☐
23. Reaction (record actual Ph value)	☐•☐
24. Albumin (0=Negative, 1=Present)	☐
25. Glucose (0=Negative, 1=Trace, 2=1+, 3=2+, 4=3+, 5=4+)	☐
26. Acetone (0=Negative, 1=Present)	☐
27. WBCS/HPF (1=None, 2=Few, 3=Moderate, 4=Heavy)	☐
28. RBCS/HPF (1=None, 2=Few, 3=Moderate, 4=Heavy)	☐
29. Epithelial Cells (1=None, 2=Few, 3=Moderate, 4=Heavy)	☐

 Center No. ☐☐☐ Patient No. ☐☐☐

RATING PERIOD: ☐ 12 wk ☐ 24 wk ☐ 36 wk/termination ☐ other _____

30. Were any clinically significant abnormal results observed? 1☐ Yes 2☐ No
If yes, please give details: _____

_____

_____

_____

PREGNANCY TEST (To be done only on women of childbearing potential.)

31. Serum Pregnancy Test: 1☐ Positive 2☐ Negative 3☐ Not Applicable

BUPRENORPHINE BLOOD LEVELS (To be done just prior to and 2 weeks after dose change and when a Serious Adverse Event occurs.)

32. Was blood drawn? 1☐ Yes 2☐ No

33. Date: |__|__| |__|__| |__|__|
month day year

COMMENTS: _____

_____

_____

_____

FORM COMPLETED BY _____

INVESTIGATOR'S SIGNATURE _____ Date _____

VA/NIDA STUDY 999a EXT

A Long Term Multicenter Clinical Trial of Buprenorphine in Treatment of Opiate Dependence

Patient Initials ☐☐☐ Center No. ☐☐☐ Patient No. ☐☐☐ Date of Visit ☐☐-☐☐-☐☐ (month - day - year)

FORM 02 - PHYSICAL EXAM

Rating Period: ☐ 12 wk ☐ 24 wk ☐ 36 wk/termination ☐ other _____

VITAL SIGNS

1. Height (ins.) |__|__|
2. Weight (lbs.) |__|__|__|
3. Temperature (°C) |__|__|.|__|
4. Blood Pressure - sitting (mmHg) |__|__|__| / |__|__|__|
5. Pulse Rate (/minute resting) |__|__|__|
6. Respiration (/minute resting) |__|__|

PHYSICAL EXAMINATION	Normal (1)	Abnormal (2)	Not Done (3)	Describe Abnormality
7. HEENT	☐	☐	☐	
8. Sublingual Mucosa	☐	☐	☐	
9. Pupil Size	☐	☐	☐	
10. Heart	☐	☐	☐	
11. Lungs	☐	☐	☐	
12. Abdomen	☐	☐	☐	
13. Extremities	☐	☐	☐	
a. Fresh Needle Marks	1 ☐ Yes	2 ☐ No		
b. Available Veins	1 ☐ Yes	2 ☐ No		
14. Skin	☐	☐	☐	
15. Lymph Nodes	☐	☐	☐	
16. Other _____	☐	☐	☐	

Other physical findings: _____

_____

FORM COMPLETED BY _____

INVESTIGATOR'S SIGNATURE _____ Date _____

VA Form 10-20923(NR)i
November 1991

VA/NIDA STUDY 999a EXT

A Long Term Multicenter Clinical Trial of Buprenorphine in Treatment of Opiate Dependence

Patient Initials ☐☐☐ Center No. ☐☐☐ Patient No. ☐☐☐ Date of EKG ☐☐-☐☐-☐☐ (month - day - year)

FORM 03 - ELECTROCARDIOGRAM

Electrocardiogram to be performed 24 weeks after Parent Protocol is completed and at termination.

ENTER STUDY WEEK NUMBER: ☐☐

Please answer <u>each</u> question by placing an "X" in the appropriate box.

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

30. EKG OVERALL RESULTS: 1☐ Normal 2☐ Abnormal

31. Do any items listed as "present" exclude the patient from continuing with the study? 1☐ Yes 2☐ No

READ BY: _____ Date _____

INVESTIGATOR'S SIGNATURE _____ Date _____

VA Form 10-20923(NR)j
November 1991

VA/NIDA STUDY 999a EXT

A Long Term Multicenter Clinical Trial of Buprenorphine in Treatment of Opiate Dependence

Patient Initials ☐☐☐ Center No. ☐☐☐ Patient No. ☐☐☐ Date of Visit ☐☐-☐☐-☐☐ (month-day-year)

FORM 04 - WEEKLY SELF-REPORT OF DRUG USE

ENTER STUDY WEEK NUMBER: ☐☐

THIS REPORT IS FOR THE WEEK OF ☐☐ (month) ☐☐ (day) ☐☐ (year) TO ☐☐ (month) ☐☐ (day) ☐☐ (year)

DRUG	USED DRUG?	WHAT DAYS OF THE WEEK DID YOU USE DRUGS AND HOW MANY TIMES? Fri. Sat. Sun.	If Yes: # of Times	Mon. thru Thurs.	If Yes: # of Times	TOTAL DOLLAR AMOUNT SPENT	Primary Mode of Abuse 1=Oral 2=I.V. 3=Snorting 4=Smoking 5=Sublingual 6=Other
1. Heroin or other opiate	1☐ Yes 2☐ No	1☐ Yes 2☐ No	☐☐	1☐ Yes 2☐ No	☐☐	$☐☐☐☐	☐
2. Cocaine	1☐ Yes 2☐ No	1☐ Yes 2☐ No	☐☐	1☐ Yes 2☐ No	☐☐	$☐☐☐☐	☐
3. Methamphetamine	1☐ Yes 2☐ No	1☐ Yes 2☐ No	☐☐	1☐ Yes 2☐ No	☐☐	$☐☐☐☐	☐
4. Alcohol	1☐ Yes 2☐ No	1☐ Yes 2☐ No	☐☐	1☐ Yes 2☐ No	☐☐	$☐☐☐☐	☐
5. Tranquilizers	1☐ Yes 2☐ No	1☐ Yes 2☐ No	☐☐	1☐ Yes 2☐ No	☐☐	$☐☐☐☐	☐
6. Marijuana or other forms of THC	1☐ Yes 2☐ No	1☐ Yes 2☐ No	☐☐	1☐ Yes 2☐ No	☐☐	$☐☐☐☐	☐
7. PCP	1☐ Yes 2☐ No	1☐ Yes 2☐ No	☐☐	1☐ Yes 2☐ No	☐☐	$☐☐☐☐	☐
8. Other, specify: _____	1☐ Yes 2☐ No	1☐ Yes 2☐ No	☐☐	1☐ Yes 2☐ No	☐☐	$☐☐☐☐	☐

FORM COMPLETED BY _____

INVESTIGATOR'S SIGNATURE _____ Date _____

VA/NIDA STUDY 999a EXT

A Long Term Multicenter Clinical Trial of Buprenorphine in Treatment of Opiate Dependence

Patient Initials ☐☐☐ Center No. ☐☐☐ Patient No. ☐☐☐ Date of Visit ☐☐-☐☐-☐☐ (month - day - year)

FORM 05 - CONCOMITANT MEDICATION

ENTER STUDY WEEK NUMBER: ☐☐

1. Did the patient take any prescription or over-the-counter medications in the past month? 1 ☐ Yes 2 ☐ No

IF YES, list drug(s) and give indication(s) below. Record the strength (mg) and doses per day, the dates the drug(s) were taken, and check (✓) if continuing the medication.

Drug Name (Generic Preferred)	Strength (mg)	Doses /Day	Indication	FROM Mo Day Yr	TO Mo Day Yr	Check (✓) if continuing
a.	----	--		-- -- --	-- -- --	
b.	----	--		-- -- --	-- -- --	
c.	----	--		-- -- --	-- -- --	
d.	----	--		-- -- --	-- -- --	
e.	----	--		-- -- --	-- -- --	
f.	----	--		-- -- --	-- -- --	
g.	----	--		-- -- --	-- -- --	
h.	----	--		-- -- --	-- -- --	

FORM COMPLETED BY _____

INVESTIGATOR'S SIGNATURE _____ Date _____

VA Form 10-20923(NR)o
November 1991

VA/NIDA STUDY 999a EXT

A Long Term Multicenter Clinical Trial of Buprenorphine in Treatment of Opiate Dependence

Patient Initials ☐☐☐ Center No. ☐☐☐ Patient No. ☐☐☐ Date of Visit ☐☐-☐☐-☐☐ (month - day - year)

FORM 06 - ADVERSE EVENTS

STUDY WEEK NUMBER: ☐☐ FOR THE WEEK OF ___ ___ ___ (month day year) TO ___ ___ ___ (month day year)

1. **"How have you been feeling this last week?"** _____

2. **"Have you had any problems in the last week such as an accident or hospitalization"?** (Including those present or unresolved at entry.) 1☐ Yes 2☐ No

3. **"Has your drug dose been holding you ok?"** 1☐ Yes 2☐ No
   If **NO**, describe: _____

I. Type of Report	II. Relatedness	III. Severity	IV. Action Taken	V. Outcome
1=Anticipated adverse event 2=Unanticipated adverse event 3=Intercurrent illness 4=Withdrawal symptom †5=Development of clinically significant abnormal lab value	1=Study drug related 2=Probably study drug related 3=Possibly study drug related 4=Unrelated to study drug	1=Mild 2=Moderate 3=Severe	1=None 2=Prescription or OTC drug therapy required *3=Inpatient hospitalization required or prolonged *4=Prescription drug therapy and hospitalization required 5=Dropped from study due to effect 6=Medical specialty consultation	1=Resolved; No sequelae 2=Not yet resolved *3=Resulted in chronic condition, severe and/or permanent disability *4=Deceased 5=Unknown

Considering the patient's responses to questions 1, 2, and 3 above and any other pertinent information (i.e., lab results, etc.), please describe, in the investigator's own words, each Adverse Event, Intercurrent Illness or Clinically Significant Abnormal Lab Value and associated information below.

Nature of Illness, Event or Abnormal Lab Value	Date of Onset (mo day yr)	Date of Resolution (mo day yr)	I. Type of Report	II. Relatedness	III. Severity	IV. Action Taken	V. Outcome
a.	__ __ __	__ __ __	☐	☐	☐	☐	☐
b.	__ __ __	__ __ __	☐	☐	☐	☐	☐
c.	__ __ __	__ __ __	☐	☐	☐	☐	☐
d.	__ __ __	__ __ __	☐	☐	☐	☐	☐
e.	__ __ __	__ __ __	☐	☐	☐	☐	☐
f.	__ __ __	__ __ __	☐	☐	☐	☐	☐

†May require completion of Form 07 - Serious Adverse Event Form
*Requires completion of Form 07 - Serious Adverse Event Form

4. **Is a Serious Adverse Event Form (Form 07) required?** 1☐ Yes 2☐ No

FORM COMPLETED BY _____

INVESTIGATOR'S SIGNATURE _____ Date _____

FORM 07 - SERIOUS ADVERSE EVENT FORM

STUDY NO. 999a EXT CENTER NO. ☐☐☐ PATIENT NO. ☐☐☐

I. ADVERSE EVENT

STUDY WEEK NO. ☐☐

PATIENT INITIALS ☐☐☐	2-4. EVENT ONSET Month: Day: Year:	5. Age: (yrs)
SEX	7. HEIGHT (in)	8. WEIGHT (lb)

A. PROVIDE A NARRATIVE DESCRIPTION OF EVENT:

B. GREATEST SEVERITY
1 = Mild
2 = Moderate
3 = Severe
☐

C. STUDY DRUG RELATED
0 = No
1 = Possible
2 = Probable
☐

ACTION TAKEN

D. DOSE CHANGE
0 = No Change
1 = Reduced
2 = Temp. Dc'd
3 = Perm. Dc'd
☐

E. TREATMENT
0 = No Treatment
1 = Outpatient Tx
2 = Hospitalization
☐

F. OUTCOME
0 = Unknown
1 = Resolved
2 = Ongoing
3 = Died
☐

G. If Died, List Primary Cause of Death:

Relevant Tests/Laboratory Data:

II. SUSPECT DRUG(s) INFORMATION

Suspect Drug(s) (Give Trade/Generic Name(s), Manufacturer):

12. Daily Dose:	13. Route of Administration:	14. Dates of Administration: (from/to)
15. Indication(s) for Use:	16. Duration of Administration:	

III. CONCOMITANT DRUG(s) AND HISTORY

17. Concomitant Drug(s) and Date(s) of Administration (Exclude those used to treat reaction)

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

IV. INITIAL REPORTER

19-20. Name, Title, and Address of Reporter (Include Zip Code)	21. Telephone No. (Include area code)
Date Completed:	

VA/NIDA STUDY 999a EXT

A Long Term Multicenter Clinical Trial of Buprenorphine in Treatment of Opiate Dependence

Patient Initials ☐☐☐ Center No. ☐☐☐ Patient No. ☐☐☐ Date Terminated ☐☐-☐☐-☐☐ (month - day - year)

FORM 08 - TERMINATION

1. USING THE LIST BELOW, PLEASE INDICATE **THE PRIMARY REASON** PATIENT TERMINATED FROM THE STUDY. *(If 3, 7, 10, or 12 are given as the primary reason for termination, please specify reason where indicated below.)*

   ☐ 1. Completed protocol

   ☐ 2. Toxicity or side effects related to buprenorphine

   ☐ 3. Medical reason unrelated to buprenorphine; or termination by clinic physician because of intercurrent illness or medical complications precluding safe administration of buprenorphine
   IF YES, specify reason: _____

   ☐ 4. Drug not "holding"

   ☐ 5. Missed 9 consecutive calendar days of dosing

   ☐ 6. Required a 6th reinduction

   ☐ 7. Patient's request
   IF YES, specify request: _____

   ☐ 8. Moved from area

   ☐ 9. Incarceration exceeding 8 days

   ☐ 10. Administrative discharge
   IF YES, specify incident: _____

   ☐ 11. Death (termination date is date of death if patient is dosed up until death, or date of last dose of buprenorphine if patient is not dosed up until death; complete Serious Adverse Event Form (07))
   IF YES, specify cause of death if known: _____

   ☐ 12. Other
   IF YES, specify: _____

2. BRIEFLY DESCRIBE THE EVENTS WHICH LED TO TERMINATION (be specific): _____

3. SINCE THE PATIENT ENTERED THE STUDY, IS HE/SHE:
   5☐ Much Better 4☐ A Little Better 3☐ No Change 2☐ Slightly Worse 1☐ Much Worse

FORM COMPLETED BY _____

INVESTIGATOR'S SIGNATURE _____ Date _____

VA Form 10-20923(NR)r
November 1991

VA/NIDA Study #999a EXTENSION

"A Long Term Multicenter Clinical Trial of Buprenorphine in Treatment of Opiate Dependence"

FORM 09 - DOSE ADMINISTRATION RECORD

Center Number: ___ ___ ___ **Patient Number:** ___ ___ ___ **Patient's Initials:** ___ ___ ___

Study Drug: B-999AE (Buprenorphine 1mg, 2mg, 4mg, 8mg, 12mg, 16mg, or 32mg)

Date FAXed (Mo/Day)	Buprenorphine Day Number	Day of Week	Date (Mo/Day/Yr)	No Dose Given		Extension Study Drug		Dose Administered (Please Check Appropriate Box)										Dosed By	Comments (Record dose changes here)
								Weekly Dose		Reinduction Regimen				Taper Regimen					
				Missed Dose	Day Off	Drawer Number	Unit ID Number	Weekday Dose	Weekend Dose	Dose #1	Dose #2	Dose #3	Dose #4	Dose #1	Dose #2	Dose #3	Dose #4		
		Su																	
		Mo																	
		Tu																	
		We																	
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		Mo																	
		Tu																	
		We																	
		Th																	
		Fr																	
		Sa																	

Signature of Person(s) Administering Dose:

Initials ______ Name ____________________ Initials ______ Name ____________________ Initials ______ Name ____________________

VA Form 10-20923(NR)s - November 1991