VA/NIDA STUDY 1008B

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

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

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).....$__ __ __,__ __ __**

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

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?.....___
- 1=No treatment slots available
- 2=Does not want methadone or LAAM
- 3=Not eligible
- 4=Other, Specify _____

FORM COMPLETED BY _ Date_____

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Patient Initials ☐ **Center No.** **Patient No.** **Date of Visit**

_ _
month day year

FORM 02 - NON-THERAPEUTIC DRUG USE HISTORY

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

DRUG	USED DRUG? (choose one) 1=Yes 2=No	IF YES: Number of Years/Months Used	Last Drug Use Occurred (choose one) 1=Within past week 2=Within past 30 days 3=Within past 60 days 4=Greater than 60 days	PRIMARY Mode of Use (choose one) 1=Oral 2=I.V. 3=Snorting 4=Smoking 5=Sublingual 6=Other
a. Heroin or other opiate		yrs. mos.		
b. Cocaine		yrs. mos.		
c. Methamphetamine/Amphetamine		yrs. mos.		

d. Alcohol		**yrs. mos.**		
e. Benzodiazepine		**yrs. mos.**		
f. Marijuana or other forms of THC		**yrs. mos.**		
g. PCP		**yrs. mos.**		
h. Other, specify: * _____		**yrs. mos.**		

i. Other, specify: * _____		**yrs. mos.**		

***Please list MOST FREQUENTLY USED other drugs. Leave line blank if no "OTHER" drug used.**

FORM COMPLETED BY _ Date _____

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Patient Initials	Center No.	Patient No.	Date of Visit/ Date of Scheduled Visit
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			month day year

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 <u>at any time</u> during the past 24 hours:**

NO CRAVING	**MOST INTENSE CRAVING I EVER HAD**

mm

FORM COMPLETED BY **Date** _____

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Patient Initials	Center No.	Patient No.	Date of Visit
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FORM 04 - MEDICAL HISTORY AND STATUS

A. PLEASE INDICATE WHETHER THE PATIENT HAS HAD ANY ABNORMALITIES, DISEASES, OR DISORDERS OF THE FOLLOWING:	1=YES 2=NO	IF YES, PLEASE BRIEFLY DESCRIBE ABNORMALITY, DISEASE, OR DISORDER
1. HEENT		
2. Cardiovascular System		
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 _____		

Continued

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

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:

I. Severity	II. Action Taken
1=Mild	1=None
2=Moderate	2=Outpatient Treatment
3=Severe	3=Inpatient Treatment

Nature of Problem	Date of Onset (Mo Day Yr)	I. Severity	II. Action Taken
a.	__ __/ __ __/ __ __		
b.	__ __/ __ __/ __ __		
c.	__ __/ __ __/ __ __		
d.	__ __/ __ __/ __ __		
e.	__ __/ __ __/ __ __		
f.	__ __/ __ __/ __ __		

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.

I. Severity	II. Action Taken	III. Outcome
1=Mild	1=None	1=Resolved; No sequelae
2=Moderate	2=Outpatient Treatment	2=Not yet resolved
3=Severe	3=Inpatient Treatment	3=Resulted in chronic condition, severe and/or permanent disability
		4=Unknown

Nature of Illness, Event or Abnormal Lab Value	Date of Onset	Date of Resolution	I. Severity	II. Action Taken	III. Outcome
a.	__ __/ __ __/ __ __	__ __/ __ __/ __ __			
b.	__ __/ __ __/ __ __	__ __/ __ __/ __ __			
c.	__ __/ __ __/ __ __	__ __/ __ __/ __ __			
d.	__ __/ __ __/ __ __	__ __/ __ __/ __ __			
e.	__ __/ __ __/ __ __	__ __/ __ __/ __ __			
f.	__ __/ __ __/ __ __	__ __/ __ __/ __ __			

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

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:

0: "current, severity not specified", 1: "current, mild", 2: "current, moderate", 3: "current, severe", (NOTE: no number "4"),
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_____

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Patient Initials	Center No.	Patient No.	Date of Visit/ Date of Scheduled Visit
			- -
			month day year

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

2. Height (ins.)* •

3. Weight (lbs.) •

4. Temperature (°F) •

5. Blood Pressure - sitting (mmHg) /
systolic *diastolic*

6. Pulse Rate (beats/minute resting)

7. Respiration (/minute resting)

PHYSICAL EXAM

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

Other physical findings:

***Collect at Screening Only**

FORM COMPLETED BY **Date** _____

INVESTIGATOR'S SIGNATURE _ **Date** _

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Patient Initials	Center No.	Patient No.	Date of Visit/ Date of Scheduled Visit
☐			- -
			month day year

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.) •

3. Temperature (°F) •

4. Blood Pressure - sitting (mmHg) / *systolic* *diastolic*

5. Pulse Rate (beats/minute resting)

6. Respiration (/minute resting)

PHYSICAL EXAM

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

Other Physical Findings:

FORM COMPLETED BY **Date** _____

INVESTIGATOR'S SIGNATURE **Date**

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

Patient Initials	Center No.	Patient No.	Date Urine Collected
☐			- -
			month day year

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 COMPLETED BY _ Date _____

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

Patient Initials	Center No.	Patient No.	Date Urine Collected/ Scheduled to be Collected
☐			- -
			month day year

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

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Patient Initials	Center No.	Patient No.	Date Sample Collected/ Scheduled to be Collected
			- -
			month day year

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)	
16.	Total protein (gm/dL)	•	24.	Alk. phosphatase (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? ___

Patient Initials	Center No.	Patient No.	Date Sample Collected/ Scheduled to be Collected
			- -
			month day year

URINALYSIS

28. Specific gravity •
29. Reaction (record actual pH value) •
30. Protein (0=Absent, 1=Trace, 2=1+, 3=2+, 4=3+, 5=4+)
31. Glucose (0=Negative, 1=Trace, 2=Present)
32. Ketones (0=Absent, 1=Trace, 2=Present)
33. WBCs/HPF (0=None, 1=Few, 2=Moderate, 3=Heavy)
34. RBCs/HPF (0=None, 1=Few, 2=Moderate, 3=Heavy)
35. Epithelial Cells (0=None, 1=Few, 2=Moderate, 3=Heavy)
36. Occult Blood (0=Absent, 1=Present)

(TO BE DONE AT SCREENING AND WEEK 28 ONLY)

37. PPD SKIN TEST DONE? 1=YES, 2=NO ___

a. If YES, result: 1=Positive, 2=Negative, 3=Inconclusive ___

b. If NO, reason: 1=Already Positive, 2=Has TB, 3=Other, Specify _____ ___

Date of Last Test: Mo __ __ Day __ __ Yr __ __

(TO BE DONE AT SCREENING ONLY)

38. HEPATITIS

		1=POS 2=NEG
a.	Hepatitis B Surface Antigen (HBs Ag)	___
b.	Hepatitis B Surface Antibody (Anti-HBs)	___
c.	Hepatitis B Core Antibody (Anti-HBc)	___
d.	Hepatitis C immunoassay antibody screen (anti-HCV)	__
e.	Hepatitis C recombinant immunoblot or dot immunoassay (Performed only if hepatitis C immunoassay antibody screen is positive. If immunoblot assay is not required because immunoassay is negative, code as "0")	___

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

FORM COMPLETED BY _ **Date** _____

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Patient Initials	Center No.	Patient No.	Date of EKG/ Date of Scheduled EKG
☐			- -
			month day year

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

FORM COMPLETED BY_____ **Date** _____

INVESTIGATOR'S SIGNATURE _ **Date** _____

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Patient Initials	Center No.	Patient No.	First Day of Study - - month day year	Week Evaluated

FORM 09 - ADVERSE EVENTS/CONCOMITANT MEDICATIONS

RATING PERIOD: WEEK NUMBER 01-52 ___ ___

1=YES
2=NO

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 signfiicant laboratory test change from baseline.)

If YES, give details below: ↓

I. Type of Report	II. Relatedness**	III. Severity**	IV. Action Taken	V. Outcome
1=Anticipated 2=Unanticipated 3=Intercurrent Illness 4=Withdrawal	1=Definitely 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=Outpatient Treatment *3=Inpatient Treatment	1=Resolved; No sequelae 2=Not Yet Resolved *3=Resulted in Chronic Condition, Severe and/or Permanent Disability *4=Deceased 5=Unknown

Nature of Illness, Event, or Abnormal Lab Value	Date of Onset *(Mo Day Yr)*	I. Type of Report	II. Related-ness**	III. Highest Level of Severity**	IV. Action Taken	V. Outcome	If Resolved, Date of Resolution *(Mo Day Yr)*
1.	__ __/__ __/__ __						__ __/__ __/__ __
2.	__ __/__ __/__ __						__ __/__ __/__ __
3.	__ __/__ __/__ __						__ __/__ __/__ __
4.	__ __/__ __/__ __						__ __/__ __/__ __
5.	__ __/__ __/__ __						__ __/__ __/__ __
6.	__ __/__ __/__ __						__ __/__ __/__ __
7.	__ __/__ __/__ __						__ __/__ __/__ __
8.	__ __/__ __/__ __						__ __/__ __/__ __
9.	__ __/__ __/__ __						__ __/__ __/__ __

***Requires completion of Form 17 - Serious/Unexpected Adverse Event Form**
****See Operations Manual (Section IX) for guidelines.**

1=YES
2=NO

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

D. Was it necessary to break randomization code for this patient? ___

Comments:

Patient Initials _ _ **Center No.** _ _ _ **Patient No.** _ _ _ _ **First Day of Study Week Evaluated** month day year

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.

1 GENERIC NAME OF MEDICATION (if possible)	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.	3 INDICATION List indication, if not related to an Adverse Event listed on the previous page.	4 FROM Medication Start Date *Mo Day Yr*	5 CHECK (√) if continuing	6 TO Medication End Date (If ended, enter last date medication taken) *Mo Day Yr*
1.	____		__ __ / __ __ / __ __		__ __ / __ __ / __ __
2.	____		__ __ / __ __ / __ __		__ __ / __ __ / __ __
3.	____		__ __ / __ __ / __ __		__ __ / __ __ / __ __
4.	____		__ __ / __ __ / __ __		__ __ / __ __ / __ __
5.	____		__ __ / __ __ / __ __		__ __ / __ __ / __ __
6.	____		__ __ / __ __ / __ __		__ __ / __ __ / __ __
7.	____		__ __ / __ __ / __ __		__ __ / __ __ / __ __
8.	____		__ __ / __ __ / __ __		__ __ / __ __ / __ __
9.	____		__ __ / __ __ / __ __		__ __ / __ __ / __ __
10.	____		__ __ / __ __ / __ __		__ __ / __ __ / __ __

FORM COMPLETED BY _____ Date_____

INVESTIGATOR'S SIGNATURE _____ Date _____

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☐			- -
			month day year

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 <u>EVERY</u> 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.

Patient Initials	Center No.	Patient No.	Date of Visit/ Date of Scheduled Visit
☐			- -
			month day year

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**

Patient Initials	Center No.	Patient No.	Date of Visit/ Date of Scheduled Visit
☐			- -
			month day year

5. In the past month, how often have you <u>injected</u> 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 <u>snorted</u> 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 <u>smoked</u> 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**

Patient Initials	Center No.	Patient No.	Date of Visit/ Date of Scheduled Visit
☐			- -
			month day year

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? _____

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Patient Initials	Center No.	Patient No.	Date of Visit/ Date of Scheduled Visit
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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?

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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 <u>you</u> 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 <u>others</u> 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 <u>always</u> use new needles**
2. **I <u>always</u> clean my needle just <u>before</u> I shoot up**
3. **<u>After</u> I shoot up, I <u>always</u> clean my needle**
4. **<u>Sometimes</u> I clean my needle, sometimes I don't**
5. **I <u>never</u> 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

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.

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FORM 10A - RISK ASSESSMENT BATTERY

RATING PERIOD: WEEK NUMBER ___ ___

(04, 08, 12, 16, 20, 24, 28, 32, 36, 40, 44, 48, 52)

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 <u>EVERY</u> 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.

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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**

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5. In the past month, how often have you <u>injected</u> 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 <u>snorted</u> 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 <u>smoked</u> 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**

Patient Initials	Center No.	Patient No.	Date of Visit/ Date of Scheduled Visit
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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? _____

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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 month, have you injected drugs?

1. YES
2. NO

18. In the past month, have you shared needles or works?

Patient Initials	Center No.	Patient No.	Date of Visit/ Date of Scheduled Visit
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1. **Yes**
2. **No or I have not shot up in the past month**

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 <u>you</u> 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 <u>others</u> used after you (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)**

22. In the past month, 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 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)**

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**
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 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)**
2. **About once a week (3 or 4 times)**
3. **More than once a week (5 or more times)**

25. In the past month, how often have you been to a Crack House or other place where people go to smoke crack?

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)**

26. Which statement best describes the way you cleaned your needles during the past month? (Please choose one)

0. **I have not shot up in the past month**
1. **I <u>always</u> use new needles**
2. **I <u>always</u> clean my needle just <u>before</u> I shoot up**
3. **<u>After</u> I shoot up, I <u>always</u> clean my needle**
4. **<u>Sometimes</u> I clean my needle, sometimes I don't**
5. **I <u>never</u> 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

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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

1 = YES
2 = NO
3 = NOT SCREENED/ SCREENING

STOPPED

1. **Between 18-59 years of age (inclusive)**.....
2. **Seeking opiate substitution pharmacotherapy**.....
3. **Expected to remain available to attend clinic for duration of study**.....
4. **Able to give informed consent and willing to comply with all study procedures**.....
5. **DSM-IV diagnosis of current opiate dependence**.....

B. EXCLUSION CRITERIA

6. **Participated in an investigational drug or device study within 45 days of enrolling in the present study**.....
7. **Enrolled in an opiate-substitution (i.e. methadone, LAAM) treatment program within 45 days of enrolling in present study**.....
8. **Has taken (licitly or illicitly) LAAM, methadone, or naltrexone within 14 days of enrolling in the present study**.....
9. **Has taken buprenorphine, other than as an analgesic, within 365 days of enrolling in the present study**.....
10. **Currently taking systemic anti-retroviral or anti-fungal therapy**.....
11. **Female of childbearing potential who refuses to use a medically acceptable method of birth control**.....
12. **Current dependence (by DSM-IV criteria) on any psychoactive substance other than opiates, caffeine, or nicotine** .....
13. **Current, primary, Axis I psychiatric diagnosis other than opiate, caffeine, or nicotine dependence**.....
14. **Pregnant or nursing female**.....
15. **Aspartate or alanine aminotransferase (AST, ALT) levels greater than three times the upper limit of normal**.....
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)**.....
17. **Refuses to participate in study**.....

Please explain _

C. INFORMED CONSENT

18. **Did individual sign consent form for participation in the study?**.....

D. ENROLLMENT STATUS

19. **Individual's enrollment status**.....

(1 = INELIGIBLE, 2 = ELIGIBLE, ENROLLED IN STUDY, 3 = ELIGIBLE, DECLINES ENROLLMENT)

***IF ENROLLED IN STUDY*:**

20. **Date enrolled**.....**Mo __ __ Day __ __ Yr __ __**
21. **Patient's enrollment number (Patient Number)**..... **___ ___ ___ ___**
22. **Date of first dose:**.....**Mo __ __ Day __ __ Yr __ __**

FORM COMPLETED BY _ **Date** _____

INVESTIGATOR'S SIGNATURE _ **Date** _

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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 WORSE	NO CHANGE	MUCH 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 WORSE	NO CHANGE	MUCH BETTER

mm

FORM COMPLETED BY **Date** _____

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Patient Initials	Center No.	Patient No.	Date of Visit/ Date of Scheduled Visit
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			month day year

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 WORSE	**NO CHANGE**	**MUCH BETTER**

mm

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

MUCH WORSE	**NO CHANGE**	**MUCH BETTER**

mm

FORM COMPLETED BY _ Date _____

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** - - (month day year)

FORM 14A - WEEKLY DOSING RECORD (EFFICACY)

STUDY WEEK NUMBER: ●

1. DOSING RECORD

Day	1. Date (mo day yr)	2. Attended Clinic? 1=YES 2=NO	3. Enter Dose Code *(Choose One:)* 1=Induction 2=Maintenance 3=Re-induction 4=Emergency Dose 5=Not Dosed	4. If Dosed, Time of Dosing	5. Check (√) if Urine Sample Collected	6. Take-Home Doses Given to Patient?
1	__ __ __ __ __ __			(24 hour clock)		1 Yes 2 No (Number of Doses)
2	__ __ __ __ __ __			(24 hour clock)		1 Yes 2 No (Number of Doses)
3	__ __ __ __ __ __			(24 hour clock)		1 Yes 2 No (Number of Doses)
4	__ __ __ __ __ __					1 Yes

						2 No (Number of Doses)
				(24 hour clock)		
						1 Yes
						2 No (Number of Doses)
				(24 hour clock)		
5	__ __ __ __ __ __					1 Yes
						2 No (Number of Doses)
				(24 hour clock)		
6	__ __ __ __ __ __					1 Yes
						2 No (Number of Doses)
				(24 hour clock)		
7	__ __ __ __ __ __					

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 _

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** - - (month day year)

FORM 14A - WEEKLY DOSING RECORD (EFFICACY)

STUDY WEEK NUMBER: 1

1. DOSING RECORD

Day	1. Date (mo day yr)	2. Attended Clinic? 1=YES 2=NO	3. Enter Dose Code *(Choose One:)* 1=Induction 2=Maintenance 3=Re-induction 4=Emergency Dose 5=Not Dosed	4. If Dosed, Time of Dosing	5. Check (√) if Urine Sample Collected	6. Take-Home Doses Given to Patient?
8	__ __ __ __ __ __			(24 hour clock)		1 Yes 2 No (Number of Doses)
9	__ __ __ __ __ __			(24 hour clock)		1 Yes 2 No (Number of Doses)
10	__ __ __ __ __ __			(24 hour clock)		1 Yes 2 No (Number of Doses)
11	__ __ __ __ __ __					1 Yes

12	__ __ __ __ __ __			(24 hour clock)		2 No (Number of Doses) 1 Yes 2 No (Number of Doses)
13	__ __ __ __ __ __			(24 hour clock)		2 No (Number of Doses) 1 Yes 2 No (Number of Doses)
14	__ __ __ __ __ __			(24 hour clock)		

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 _

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
			- -
			month day year

FORM 14A - WEEKLY DOSING RECORD (EFFICACY)

STUDY WEEK NUMBER:

1. DOSING RECORD

Day	1. Date (mo day yr)	2. Attended Clinic? 1=YES 2=NO	3. Enter Dose Code *(Choose One:)* 1=Induction 2=Maintenance 3=Re-induction 4=Emergency Dose 5=Not Dosed	4. If Dosed, Time of Dosing	5. Check (√) if Urine Sample Collected	6. Take-Home Doses Given to Patient?
15	__ __ __ __ __ __			(24 hour clock)		1 Yes 2 No (Number of Doses)
16	__ __ __ __ __ __			(24 hour clock)		1 Yes 2 No (Number of Doses)
17	__ __ __ __ __ __			(24 hour clock)		1 Yes 2 No (Number of Doses)
18	__ __ __ __ __ __					1 Yes

				(24 hour clock)		2 No (Number of Doses)
19	__ __ __ __ __ __			(24 hour clock)		1 Yes 2 No (Number of Doses)
20	__ __ __ __ __ __			(24 hour clock)		1 Yes 2 No (Number of Doses)
21	__ __ __ __ __ __			(24 hour clock)		1 Yes 2 No (Number of Doses)

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 _

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** - - (month day year)

FORM 14A - WEEKLY DOSING RECORD (EFFICACY)

STUDY WEEK NUMBER:

1. DOSING RECORD

Day	1. Date (mo day yr)	2. Attended Clinic? 1=YES 2=NO	3. Enter Dose Code *(Choose One:)* 1=Induction 2=Maintenance 3=Re-induction 4=Emergency Dose 5=Not Dosed	4. If Dosed, Time of Dosing (24 hour clock)	5. Check (√) if Urine Sample Collected	6. Take-Home Doses Given to Patient? 1 Yes / 2 No (Number of Doses)
22	__ __ __ __ __ __					1 Yes / 2 No (Number of Doses)
23	__ __ __ __ __ __					1 Yes / 2 No (Number of Doses)
24	__ __ __ __ __ __					1 Yes / 2 No (Number of Doses)
25	__ __ __ __ __ __					1 Yes

				(24 hour clock)		2 No (Number of Doses)
26	__ __ __ __ __ __			(24 hour clock)		1 Yes 2 No (Number of Doses)
27	__ __ __ __ __ __			(24 hour clock)		1 Yes 2 No (Number of Doses)
28	__ __ __ __ __ __			(24 hour clock)		1 Yes 2 No (Number of Doses)

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 _

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** - - (month day year)

14B - WEEKLY DOSING RECORD (SAFETY)

ENTER STUDY WEEK NUMBER: (05-52) ***(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 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
1	__ __ __ __ __ __		__ __ mg (BUP)		(24 hour clock)		___ ___ (# of Full Doses) ___ ___ mg (BUP)/dose	1 Yes ___ ___ (# of Doses) ___ ___ mg (BUP)/dose* 2 No
2	__ __ __ __ __ __		__ __ mg (BUP)		(24 hour clock)		___ ___ (# of Full Doses) ___ ___ mg (BUP)/dose	1 Yes ___ ___ (# of Doses) ___ ___ mg (BUP)/dose* 2 No
3	__ __ __ __ __ __		__ __ mg (BUP)		(24 hour clock)		___ ___ (# of Full Doses) ___ ___ mg (BUP)/dose	1 Yes ___ ___ (# of Doses) ___ ___ mg (BUP)/dose* 2 No
4	__ __ __ __ __ __		__ __ mg (BUP)		(24 hour clock)		___ ___ (# of Full Doses) ___ ___ mg (BUP)/dose	1 Yes ___ ___ (# of Doses) ___ ___ mg (BUP)/dose* 2 No
5	__ __ __ __ __ __						___ ___ (# of Full ___ ___ mg (BUP)/dose	1 Yes ___ ___

6	__ __ __ __ __ __		__ __ mg (BUP)		(24 hour clock)		Doses)	(# of Doses) __ __ mg (BUP)/dose* 2 No 1 Yes _____ (# of Doses) __ __ mg (BUP)/dose* 2 No
			__ __ mg (BUP)		(24 hour clock)		___ ___ (# of Full Doses) ___ ___ mg (BUP)/dose	1 Yes _____ (# of Doses) __ __ mg (BUP)/dose* 2 No
7	__ __ __ __ __ __		__ __ mg (BUP)		(24 hour clock)		___ ___ (# of Full Doses) ___ ___ mg (BUP)/dose	

*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

Patient Initials ☐ **Center No.** **Patient No.** **First Day of Study Week**

_ _
month day year

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/NIDA STUDY 1008B
A Multicenter Safety Trial of Buprenorphine/Naloxone for The Treatment of Opiate Dependence

Patient Initials ☐ **Center No.** **Patient No.** **First Day of Study Week** __ __ (month) __ __ (day) __ __ (year)

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 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
1	__ __ __ __ __ __	☐	__ __ mg (BUP)	☐	(24 hour clock)	☐	__ __ (# of Full Doses) __ __ __ mg (BUP)/dose	1 Yes __ __ __ (# of Doses) __ __ __ mg (BUP)/dose* 2 No ☐
2	__ __ __ __ __ __	☐	__ __ mg (BUP)	☐	(24 hour clock)	☐	__ __ (# of Full Doses) __ __ __ mg (BUP)/dose	1 Yes __ __ __ (# of Doses) __ __ __ mg (BUP)/dose* 2 No ☐
3	__ __ __ __ __ __	☐	__ __ mg (BUP)	☐	(24 hour clock)	☐	__ __ (# of Full Doses) __ __ __ mg (BUP)/dose	1 Yes __ __ __ (# of Doses) __ __ __ mg (BUP)/dose* 2 No ☐
4	__ __ __ __ __ __	☐	__ __ mg (BUP)	☐	(24 hour clock)	☐	__ __ (# of Full Doses) __ __ __ mg (BUP)/dose	1 Yes __ __ __ (# of Doses) __ __ __ mg (BUP)/dose* 2 No ☐
								1 Yes __ __

5	__ __ __ __ __ __		__ __ mg (BUP)		(24 hour clock)		___ ___ (# of Full Doses) ___ ___ mg (BUP)/dose	(# of Doses) __ __ mg (BUP)/dose* 2 No 1 Yes ____ (# of Doses) __ __ mg (BUP)/dose* 2 No
6	__ __ __ __ __ __		__ __ mg (BUP)		(24 hour clock)		___ ___ (# of Full Doses) ___ ___ mg (BUP)/dose	1 Yes ____ (# of Doses) __ __ mg (BUP)/dose* 2 No
7	__ __ __ __ __ __		__ __ mg (BUP)		(24 hour clock)		___ ___ (# of Full Doses) ___ ___ mg (BUP)/dose	

*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

Patient Initials	Center No.	Patient No.	First Day of Study Week
☐			- -
			month day year

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 _

VA/NIDA STUDY 1008B
A Multicenter Safety Trial of Buprenorphine/Naloxone for The Treatment of Opiate Dependence

Patient Initials	Center No.	Patient No.	First Day of Study Week
Evaluated ☐			- - month day year

FORM 15 - TREATMENT SERVICES REVIEW

RATING PERIOD: WEEK NUMBER (01-52) __

__

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

(If YES, continue:)

	A. By Study Personnel (In-program)	B. By Outside Sources (Out-program)
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)

Patient Initials	Center No.	Patient No.	First Day of Study Week Evaluated - - month day year
☐			

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?** __ __

Patient Initials	Center No.	Patient No.	First Day of Study Week Evaluated - - month day year
☐			

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? ___

Patient Initials	Center No.	Patient No.	First Day of Study Week Evaluated - - month day year
☐			

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? __ __

Patient Initials	Center No.	Patient No.	First Day of Study Week Evaluated - - month day year
☐			

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 <u>practiced</u> a form of relaxation training, biofeedback or meditation?

Psych specialist? __ __ __ __

Counselor/social worker? __ __ __ __

45. Received a session in which you <u>practiced</u> 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** _____

VA/NIDA STUDY 1008B

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

Patient Initials	Center No.	Patient No.	Date First Sample Drawn
☐			- -
			month day year

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 <u>WAS NOT</u> 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**_____

VA/NIDA STUDY 1008B

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

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

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

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

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/NIDA STUDY 1008B

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

Patient Initials	Center No.	Patient No.	Date of Last Clinic Visit
☐			- -
			month day year

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 _ Date _____

INVESTIGATOR'S SIGNATURE _ Date _

VA/NIDA STUDY 1008B

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

Patient Initials	Center No.	Patient No.	Date of Last Clinic Visit
☐			- -
			month day year

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 _

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Patient Initials	Center No.	Patient No.	Date of Last Clinic Visit
☐			- -
			month day year

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*: ____ ____)**

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 _

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

FORM 19 - FOLLOW-UP

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

1 = YES
2 = NO

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 _____