VA/NIDA STUDY 1018

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

Name Code	Center No.	Patient No.	Date of Visit
☐☐☐☐	☐☐☐-☐☐	☐☐☐☐	☐☐ - ☐☐ - ☐☐☐☐
			Month Day Year

FORM 01 - SCREENING

1. Gender: 1 Male 2 Female

2. Date of Birth: Mo __ __ Day __ __ Yr __ __ __ __

3. Of Hispanic Origin: 0 No 1 Yes

4. Race: 1 White
2 African-American/Black
3 Asian/Pacific Islander
4 Native American
5 Other; specify _____

NOTE: A *NO* response to *QUESTIONS 5-10*, or a *YES* response to *QUESTIONS 11-24*, makes patient *INELIGIBLE*.

A. INCLUSION CRITERIA

0 = NO
1 = YES
2 = NOT SCREENED/ SCREENING STOPPED

5. Age is 15 years or older. _____
6. Seeking opiate substitution pharmacotherapy _____
7. Expected to remain available to attend clinic for duration of study _____
8. If current medical condition exists, patient is being treated by physician willing to work with study physician _____
   If Question 8 is not applicable, enter "3" as the response to this question.
9. Able to give informed consent and willing to comply with all study procedures _____
10. DSM-IV diagnosis of current **opiate dependence** _____

B. EXCLUSION CRITERIA

11. Participated in an investigational drug or device study within 30 days of enrolling in the present study _____
12. Discontinued participation in an opiate-substitution (i.e., methadone, LAAM) treatment program within 30 days of enrolling in present study. _____
13. Has currently taken (licitly or illicitly) LAAM, methadone, or naltrexone for more than 30 days before enrolling in this study _____
14. Pregnant or nursing female _____
15. Female who refuses to use a medically acceptable form of birth control _____
16. Current dependence (by DSM-IV criteria) on alcohol requiring immediate medical attention (Form 6) _____
17. Current dependence (by DSM-IV criteria) any psychoactive substance other than opiates, caffeine, or nicotine, requiring immediate medical attention (Form 6) _____
18. Current, primary, Axis I psychiatric diagnosis other than opiate, caffeine, or nicotine dependence _____
19. Have known hypersensitivity to buprenorphine or naloxone. _____
20. Have pending legal action that could prohibit continued participation _____
21. Expected to leave the clinic's geographic area prior to study completion _____
22. Refuses to participate in study _____
    Please explain

NOTE: Please review Forms 2, 3, and 4 to determine the answers to the following two questions. Also, it is mandatory that the informed consent must be signed before the following tests can be done.

23. Aspartate or alanine aminotransferase (AST, ALT) levels greater than eight times the upper limit of normal and does not have concurrence of medical specialist to participate in study _____
24. 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) _____

Name Code | Center No. | Patient No. | Date of Visit

☐☐☐☐ ☐☐☐-☐☐ ☐☐☐☐ ☐☐-☐☐-☐☐☐☐

Month Day Year

C. INFORMED CONSENT

25. Did individual sign consent form for participation in the study? (0 = N0, 1 = YES) ..... _____

D. ENROLLMENT STATUS

26. Individual's enrollment status ..... _____

1 = INELIGIBLE, assign patient a 5000 number and record as Patient No. on both pages of this form - do not complete questions Q.27-29
2 = ELIGIBLE, DECLINES ENROLLMENT, assign patient a 5000 number and record as Patient No. on both pages of this form - do not complete questions Q.27-29
3 = ELIGIBLE, ENROLLED IN STUDY (complete Q. 27-29)

IF ENROLLED IN STUDY **(FAX Treatment Initiation Form):**

27. Date eligible ..... Mo __ __ Day __ __ Yr __ __ __ __
28. Patient's enrollment number (Patient Number) ..... ___ ___ ___ ___
29. Date of first dose . .Mo __ __ Day __ __ Yr __ __ __ __

FORM COMPLETED BY Date

SITE PHYSICIAN'S SIGNATURE Date

VA/NIDA STUDY 1018

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

Name Code ☐☐☐☐ Center No. ☐☐☐-☐☐ Patient No. ☐☐☐☐ Date of Visit ☐☐-☐☐-☐☐☐☐ Month Day Year

FORM 02 - PHYSICAL EXAM

VITAL SIGNS AND OTHER MEASURES

1. Height (ins.)* •
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. HEENT		
8. Sublingual Mucosa		
9. Pupil Size		
10. Heart		
11. Lungs		
12. Abdomen		
13. Extremities		
14. Skin		
15. Lymph Nodes		
16. Musculoskeletal		
17. General Appearance		
Other physical findings: _		

*Collect at Screening Only

FORM COMPLETED BY Date _____

SITE PHYSICIAN'S SIGNATURE Date

VA/NIDA STUDY 1018

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

Name Code	Center No.	Patient No.	Date Sample Collected
☐☐☐☐	☐☐☐-☐☐	☐☐☐☐	☐☐ - ☐☐ - ☐☐☐☐
			Month Day Year

FORM 03 - CLINICAL LABORATORY EVALUATION

HEMATOLOGY *Circle One*

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

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 Question 26 and 27.

0=NO
1=YES

26. Were the Adverse Event Form (Form 16) and/or Termination Form (Form 11) completed? ___

27. Was the Sponsor's Medical Monitor notified for concurrence? ___

Name Code	Center No.	Patient No.	Date Sample 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)

COMMENTS: (*If there are clinically significant abnormal results observed, please describe below and complete Form 16*)

(PLEASE PRINT CLEARLY)

FORM COMPLETED BY _____ Date _____

SITE PHYSICIAN'S SIGNATURE _____ Date _____

VA/NIDA STUDY 1018

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

Name Code Center No. Patient No. Date of EKG

☐☐☐☐ ☐☐☐-☐☐ ☐☐☐☐ ☐☐-☐☐-☐☐☐☐

Month Day Year

FORM 04 - ELECTROCARDIOGRAM

(For all patients over 40 and for patients under 40 with a history of cardiovascular disease.)

1. ECG OVERALL RESULTS WERE: 1 Normal 2 Abnormal

A. <u>Circle ALL</u> appropriate codes (including borderline)

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

<u>COMPLETE THIS QUESTION AT BASELINE ONLY</u>

2. Do any of these codes exclude subject from participation in the study? 0 No 1 Yes

FORM COMPLETED BY _____ Date _____

SITE PHYSICIAN'S SIGNATURE Date _____

VA/NIDA STUDY 1018
A Multicenter Safety Trial of Buprenorphine/Naloxone for the Treatment of Opiate Dependence

Name Code ☐☐☐☐ Center No. ☐☐☐-☐☐ Patient No. ☐☐☐☐ Date of Visit ☐☐-☐☐-☐☐☐☐
Month Day Year

FORM 05 - BASELINE CONCOMITANT MEDICATION

(Complete this form when completing the baseline Physical Exam Form 02. PLEASE PRINT CLEARLY.)

A. Has the patient taken any medications (prescription or over-the-counter) in the past 2 weeks? 0 No 1 Yes

If YES, list these medications below, the dose and frequency, the reason medications are taken and record the medication start date (circle "c" if continuing on medication).

1 **GENERIC NAME OF MEDICATION**	**2** **DOSE AND FREQUENCY** **(example: 50 mg, twice a day)**	**3** **INDICATION** **List indication for which medication is taken.**	**4** **FROM** **Medication Start Date** ***(Mo/Day/Yr)*** ***circle "c" if continuing***	
1.			__ __ / __ __ / __ __ __ __	c
2.			__ __ / __ __ / __ __ __ __	c
3.			__ __ / __ __ / __ __ __ __	c
4.			__ __ / __ __ / __ __ __ __	c
5.			__ __ / __ __ / __ __ __ __	c
6.			__ __ / __ __ / __ __ __ __	c
7.			__ __ / __ __ / __ __ __ __	c
8.			__ __ / __ __ / __ __ __ __	c

FORM COMPLETED BY _____ Date _____

SITE PHYSICIAN'S SIGNATURE _____ Date _____

VA/NIDA STUDY 1018

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

Name Code ☐☐☐☐ Center No. ☐☐☐-☐☐ Patient No. ☐☐☐☐ Date of Visit ☐☐-☐☐-☐☐☐☐ (Month Day Year)

FORM 06 - DSM-IV CRITERIA QUESTIONNAIRE

Have the subject answer each question with a Yes or a No. If No, score 0. If Yes, score 1. IN THE PAST TWELVE MONTHS:	Opiates	Cocaine	Sedatives	ETOH	Amphet-amines
1. Have you needed to markedly increase your (drug name) dose to achieve your desired high or have you found that the same dose has markedly diminished effect?					
2. Did you experience any withdrawal symptoms after reducing or stopping (drug name) use or did you take additional (drug name) or a similar drug to reduce or avoid withdrawal symptoms?					
3. Do you often take (drug name) in larger amounts or over a longer period of time than you intended?					
4. Have you had a persistent desire or unsuccessful efforts to cut down or control your (drug name) usage?					
5. Have you found that you spend a great deal of time obtaining, using, or recovering from (drug name) effects?					
6. Have you reduced or given up important social, occupational, or recreational activities because of (drug name) use?					
7. Have you had any persistent or recurrent physical or psychological problems which were probably caused or exacerbated by (drug name)? and have you continued to use despite these problems?					
TOTALS:					

Dependence = a sum total score greater than or equal to 3.

8. Is the subject opiate dependent? (0 = No, 1 = Yes) _____
   (IF NO, SUBJECT IS EXCLUDED FROM THE STUDY.)

9. Does the subject's dependence on any of the substances above require immediate medical attention? (0 = No, 1 = Yes) _____
   (IF YES, SUBJECT IS EXCLUDED FROM THE STUDY.)

FORM COMPLETED BY _____ Date _____

SITE PHYSICIAN'S SIGNATURE _____ Date _____

VA/NIDA STUDY 1018

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

Name Code Center No. Patient No. Date of Visit

☐☐☐☐ ☐☐☐-☐☐ ☐☐☐☐ ☐☐ - ☐☐ - ☐☐☐☐

Month Day Year

FORM 07 - RISK ASSESSMENT BATTERY

___ Check if asked by interviewer

Interviewer's Name _____ Date

_____

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

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

Thank you for your time and cooperation.

Name Code Center No. Patient No. Date of 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

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

Name Code Center No. Patient No. Date of Visit

☐☐☐☐ ☐☐☐- ☐☐ ☐☐☐☐ ☐☐ - ☐☐ - ☐☐☐☐

Month Day Year

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

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

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

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

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

Name Code Center No. Patient No. Date of Visit

☐☐☐☐ ☐☐☐-☐☐ ☐☐☐☐ ☐☐ - ☐☐ - ☐☐☐☐

Month Day Year

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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? _____

13. In the past month, how often have you injected 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

Name Code Center No. Patient No. Date of Visit

☐☐☐☐ ☐☐☐-☐☐ ☐☐☐☐ ☐☐ - ☐☐ - ☐☐☐☐

Month Day Year

---

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?
    0. NO
    1. YES

18. In the past month, have you shared needles or works?
    0. NO or I have not shot up in the past month
    1. YES

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

Name Code Center No. Patient No. Date of Visit

☐☐☐☐ ☐☐☐- ☐☐ ☐☐☐☐ ☐☐ - ☐☐ - ☐☐☐☐

Month Day Year

---

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_____

Name Code ☐☐☐☐ Center No. ☐☐☐-☐☐ Patient No. ☐☐☐☐ Date of Visit ☐☐ - ☐☐ - ☐☐☐☐
Month Day Year

---

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 always use new needles
2. I always clean my needle just before I shoot up
3. After I shoot up, I always clean my needle
4. Sometimes I clean my needle, sometimes I don't
5. I never clean my needle

Name Code Center No. Patient No. Date of Visit

☐☐☐☐ ☐☐☐- ☐☐ ☐☐☐☐ ☐☐ - ☐☐ - ☐☐☐☐

Month Day Year

--

27. If you have cleaned your needles and works in the past month, how did you clean them? (Circle all that apply)
    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)

Name Code ☐☐☐☐ Center No. ☐☐☐-☐☐ Patient No. ☐☐☐☐ Date of Visit ☐☐-☐☐-☐☐☐☐ Month Day Year

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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

Name Code	Center No.	Patient No.	Date of Visit
☐☐☐☐	☐☐☐-☐☐	☐☐☐☐	☐☐ - ☐☐ - ☐☐☐☐
			Month Day Year

---

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)

Name Code Center No. Patient No. Date of Visit

☐☐☐☐ ☐☐☐- ☐☐ ☐☐☐☐ ☐☐ - ☐☐ - ☐☐☐☐

Month Day Year

---

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

Name Code	Center No.	Patient No.	Date of Visit
☐☐☐☐	☐☐☐- ☐☐	☐☐☐☐	☐☐ - ☐☐ - ☐☐☐☐
			Month Day Year

---

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 ___ ___ ___ ___

45. Were you ever told that you had the HIV, the AIDS virus?
    O. NO
    1. YES
    2. I never got the results

Thank You. Please let the staff person know that you have finished.

SITE PHYSICIAN'S SIGNATURE Date

VA/NIDA STUDY 1018

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

Name Code ☐☐☐☐ Center No. ☐☐☐-☐☐ Patient No. ☐☐☐☐ Date of Interview ☐☐-☐☐-☐☐☐☐ Month Day Year

FORM 08 - ADDICTION SEVERITY INDEX (ASI) (Fifth Edition)

INSTRUCTIONS

1. Leave No Blanks-Where appropriate code items: X = question not answered
   N = question not applicable
   Use only one character per item.

2. Item numbers circled are to be asked at last visit. Items with an asterisk are cumulative and should be rephrased at last visit (see ASI Manual in Operations Manual).

3. Space is provided after sections for additional comments.

SEVERITY RATINGS

The severity ratings are interviewer estimates of the patient's need for additional treatment in each area. The scales range from 0 (no treatment necessary) to 9 (treatment needed to intervene in life-threatening situation). Each rating is based upon the patient's history of problem symptoms, present condition and subjective asssessment of his treatment needs in a given area. For a detailed description of severity ratings' derivation procedures and conventions, see ASI Manual (in Operations Manual).
Note: These severity ratings are optional.

SUMMARY OF PATIENT'S RATING SCALE

0 = Not at all
1 = Slightly
2 = Moderately
3 = Considerably
4 = Extremely

VA Form 10-21031(NR)h
April 1999

GENERAL INFORMATION

1. How long have you lived at your current address? ☐☐ YRS. ☐☐ MOS.

2. Is this residence owned by you or your family? ☐
   0 = No 1 = Yes

3. DATE OF BIRTH (mo/day/yr) ☐☐ ☐☐ ☐☐☐☐

4. 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 - Mexican
   7=Hispanic - Puerto Rican
   8=Hispanic - Cuban
   9=Other Hispanic

5. RELIGIOUS PREFERENCE ☐
   1=Protestant 4=Islamic
   2=Catholic 5=Other
   3=Jewish 6=None

○6. Have you been in a controlled environment in the past 30 days? ☐
   1=No
   2=Jail
   3=Alcohol or Drug Treatment
   4=Medical Treatment
   5=Psychiatric
   6=Other _____

RATING PERIOD: ☐
1=Baseline
2=Last visit*

*Answer only circled item numbers at last visit.

○ 7. How many days? ☐☐

SEVERITY PROFILE

9							
8							
7							
6							
5							
4							
3							
2							
1							
0							

FORM COMPLETED BY Date _____

SITE PHYSICIAN'S SIGNATURE Date _____

VA/NIDA STUDY 1018

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

Name Code	Center No.	Patient No.	Date of Visit
☐☐☐☐	☐☐☐-☐☐	☐☐☐☐	☐☐ - ☐☐ - ☐☐☐☐
			Month Day Year

FORM 09 - PHYSICIAN'S OFFICE VISIT CHECKLIST

VITAL SIGNS AND OTHER MEASURES

1. Weight (lbs.) •
2. Temperature (°F) •
3. Blood Pressure - sitting (mmHg) / *systolic* *diastolic*
4. Pulse Rate (beats/minute resting)
5. Respiration (breaths/min resting)

PHYSICAL EXAM

1=Normal
2=Abnormal
3=Not Done

IF ABNORMAL, describe abnormality below:

6. Oral Mucosa _____ _____
7. General Appearance _____ _____

PLEASE CHECK APPROPRIATE RESPONSES BELOW:

8. **PREGNANCY TEST PERFORMED (every four weeks)**? 0 No 1 Yes 2 N/A
   If Yes: 1 Positive 2 Negative

   A. **WHAT METHOD OF BIRTH CONTROL IS PATIENT 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 Tubal Ligation
   7 Complete Abstinence
   8 None, specify reason _____
   9 Other, specify _____

9. **URINE DRUG SCREEN:** 1 All Negative
   Positive For: 2 Amphetamines 3 Cocaine 4 Barbiturates 5 Opiates 6 Benzodiazepines

10. **REPORT OF SELF USE SINCE LAST VISIT(if Baseline, record for the past 4 weeks):** 1 No Use
    Use of: 2 Opiates 3 Cocaine 4 Benzodiazepines 5 Amphetamines 6 Barbiturates

11. **PHYSICIAN ASSESSMENT OF PATIENT'S OVERALL CONDITION (compared to baseline):**
    1 Much worse 2 Slightly worse 3 No change 4 Slightly improved 5 Much improved 6 Baseline

12. **PATIENT ASSESSMENT OF PATIENT'S OVERALL CONDITION (compared to baseline):**
    1 Much worse 2 Slightly worse 3 No change 4 Slightly improved 5 Much improved 6 Baseline

Name Code ☐☐☐☐ Center No. ☐☐☐-☐☐ Patient No. ☐☐☐☐ Date of Visit ☐☐-☐☐-☐☐☐☐ Month Day Year

13. **NO. OF TABLETS PATIENT HAS ON HAND:** __ __ __ 8 MG __ __ __ 2 MG Not available Baseline

14. **OPIATE SYMPTOM CHECKLIST:** 1 No symptoms present
If symptoms present, check all that apply:

2 Nausea/vomiting 5 Excessive sweating 8 Miosis 11 Gooseflesh

3 Diarrhea 6 Runny nose/tearing 9 Tremor 12 Insomnia

4 Bone/Joint Pain 7 Anxiety/Irritability 10 Constipation 13 Sedation

DOSING INFORMATION

15. **TREATMENT PRESCRIBED**: 1 Induction 2 Maintenance 3 Dose Taper 4 Reinduction

16. **DOSE PRESCRIBED**: 1 First dose __ __ mg buprenorphine (enter TOTAL mg given on Day 1)
2 No change from __ __ mg buprenorphine
3 Dose increase to __ __ mg buprenorphine, reason _____
4 Dose decrease to __ __ mg buprenorphine, reason _____
5 Dose taper
a. Daily dose __ __ mg buprenorphine for __ __ days
b. Daily dose __ __ mg buprenorphine for __ __ days
c. Daily dose __ __ mg buprenorphine for __ __ days
d. Daily dose __ __ mg buprenorphine for __ __ days
e. Daily dose __ __ mg buprenorphine for __ __ days
f. Daily dose __ __ mg buprenorphine for __ __ days
g. Daily dose __ __ mg buprenorphine for __ __ days

17. **DOSE FREQUENCY PRESCRIBED**:
1 Once daily 3 Every other day 5 Other; specify _____
2 BID 4 Every 3 days

18. **NO. OF TABLETS PRESCRIBED:** __ __ __ 8 MG __ __ __ 2 MG

19. **ATTENDING PSYCHOSOCIAL COUNSELING**? 0 No 1 Yes 2 Baseline
A. If Yes, how many times since last visit? ___ ___

20. **ADVERSE DRUG REACTION**: 0 No 1 Yes, complete Form 16, Adverse Events 2 Baseline

21. **PATIENT'S LAST VISIT**? 0 No 1 Yes, complete Form 11, Termination 2 Baseline

PROGRESS NOTES:

_____

_____

_____

_____

_____

FORM COMPLETED BY Date _____

SITE PHYSICIAN'S SIGNATURE Date _____

VA/NIDA STUDY 1018

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

Name Code	Center No.	Patient No.	Date Form Completed
☐☐☐☐	☐☐☐-☐☐	☐☐☐☐	☐☐ - ☐☐ - ☐☐☐☐
			Month Day Year

FORM 10 - PSYCHOSOCIAL SERVICES RENDERED

1. Did patient attend any psychosocial services in the last four weeks? (0=No, 1=Yes) _____

   IF YES:

   A. Enter the beginning date and ending date of the four-week period:

      FROM: Mo __ __ Day __ __ Year __ __ __ __ TO: Mo __ __ Day __ __ Year __ __ __ __

   B. Indicate the number of sessions of psychosocial services received in last four weeks.

Services	Number of Sessions	Total Number of Minutes
1. Individual Counseling		
2. Group Sessions (e.g., NA, AA)		
3. AIDS Counseling		
4. Other, specify_____ _____		

How many of the sessions listed on this form should you be reimbursed for?

Counselor Notes:_____

_____

_____

_____

_____

NAME OF COUNSELOR _____ Date _____

SITE PHYSICIAN'S SIGNATURE _____ Date _____

VA Form 10-21031(NR)j
April 1999 (Revised 10/20/99)

VA/NIDA STUDY 1018

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

Name Code	Center No.	Patient No.	Date of Last Clinic Visit
☐☐☐☐	☐☐☐-☐☐	☐☐☐☐	☐☐ - ☐☐ - ☐☐☐☐
			Month Day Year

FORM 11 - TERMINATION

1. PLEASE INDICATE PATIENT'S TERMINATION STATUS:

1. Completed protocol
2. Did not complete protocol (*CIRCLE **PRIMARY REASON** PATIENT TERMINATED BELOW.*)

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 (please check one): 1 Patient became pregnant
2 Patient stopped using birth control

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

11 Other, Specify:

2. PATIENT REFERRED TO: 1 Methadone 2 LAAM 3 Drug Free 4 Naltrexone 5 Not Referred

FORM COMPLETED BY Date _____

SITE PHYSICIAN'S SIGNATURE Date

VA Form 10-21031(NR)k
April 1999

VA/NIDA STUDY 1018

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

Name Code	Center No.	Patient No.	Date Completed
☐☐☐☐	☐☐☐- ☐☐	☐☐☐☐	☐☐ - ☐☐ - ☐☐☐☐
			Month Day Year

FORM 12 - FOLLOW-UP

COMPLETE THIS FORM <u>FOR ALL PATIENTS</u> APPROXIMATELY 30 DAYS AFTER PATIENT TERMINATES OR COMPLETES PROTOCOL.

0 = NO
1 = YES

1. Has contact been made with the patient?..... _____
(If YES, complete a-e, and Q.5. 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, code reason ..... _____
1 = Unable to contact
2 = Other reason, specify _____

3. If unable to reach patient, has contact been made with someone who can verify his/her status?..... _____

a. If **YES**, date of contact ..... Mo __ __ Day __ __ Yr __ __ __ __
(If YES, go to **Question 4**)

b. If **NO**, explain _____

4. Has the patient died?..... _____

If **YES**:

a. Date of Death ..... Mo __ __ Day __ __ Yr __ __ __ __

b. Cause of Death _____

c. Information verified by site staff (e.g., coroner's office, death certificate)..... _____

5. Additional Comments:

FORM COMPLETED BY Date _____

SITE PHYSICIAN'S SIGNATURE _____ Date _____

VA/NIDA STUDY 1018

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

Center No. ☐☐☐-☐☐

Date Completed ☐☐ - ☐☐ - ☐☐☐☐
Month Day Year

FORM 14 - PHYSICIAN/STAFF GLOBAL ASSESSMENT OF THE OFFICE-BASED TREATMENT SETTING

1. What treatment setting did you use to deliver office-based treatment? (check all that apply)

   1 Private office 2 University Clinic 3 Hospital Clinic 4 HMO/PPO 5 Other, specify_____

2. Did you find the office-based treatment setting to be an acceptable way to deliver opiate dependence treatment?
   0 No 1 Yes

3. Were there any special accommodations you found necessary to make in order to deliver office-based treatment?
   0 No 1 Yes
   If Yes, describe: _____
   (Please print) _____
   _____
   _____

4. What was your preferred prescribing practices regarding: (Please print clearly)
   Induction: _____
   _____
   Dose Adjustment: _____
   _____
   Maintenance: _____
   _____
   Take-home Dosing: _____
   _____

5. Do you consider buprenorphine/naloxone treatment safe to extend to a younger population (ages 15-18)?
   0 No 1 Yes Why? (Please Print)_____
   _____

6. Do you consider buprenorphine/naloxone treatment efficacious to extend to a younger population (ages 15-18)?
   0 No 1 Yes Why? (Please Print)_____
   _____

7. Do you consider buprenorphine/naloxone treatment feasible to extend to a younger population (ages 15-18)?
   0 No 1 Yes Why? (Please Print)_____
   _____

Additional Comments: (Please Print)_____
_____
_____

FORM COMPLETED BY _____ Date _____

SITE PHYSICIAN'S SIGNATURE _____ Date _____

VA/NIDA STUDY 1018

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

Name Code ☐☐☐☐ Center No. ☐☐☐-☐☐ Patient No. ☐☐☐☐ Date Completed ☐☐-☐☐-☐☐☐☐

Month Day Year

FORM 15 - PATIENT GLOBAL ASSESSMENT OF THE OFFICE-BASED TREATMENT SETTING

1. Did you find the office-based treatment setting to be an acceptable way to receive opiate dependence treatment?
   0 No 1 Yes

2. Have you ever received opiate dependence treatment before at a narcotic treatment program?
   0 No 1 Yes (Skip to Question 4)

3. If No, why not:
   1 Not available
   2 On waiting list
   3 Don't like going to a narcotic treatment clinic
   4 Don't like methadone or LAAM
   5 Other; specify: _____

4. Would you prefer to receive your opiate dependence treatment in the office-based setting?
   0 No 1 Yes
   Why? _____
   (Please Print) _____

5. Were there any special accommodations you found necessary to make in order to receive office-based treatment?
   0 No 1 Yes
   If yes, describe: _____
   (Please Print) _____
   _____
   _____

6. Do you consider buprenorphine/naloxone treatment a valuable addition to the medications currently available (for example: LAAM, methadone) for opiate dependence treatment?
   0 No 1 Yes

Additional Comments: (Please Print) _____
_____
_____

FORM COMPLETED BY _____ Date_____

SITE PHYSICIAN'S SIGNATURE_____Date_____

Name Code ☐☐☐☐ Center No. ☐☐☐-☐☐ Patient No. ☐☐☐☐ Date of Report ☐☐-☐☐-☐☐☐☐ (Month Day Year)

FORM 16 - ADVERSE EVENTS/CONCOMITANT MEDICATIONS

COMPLETE THIS FORM AT **EACH** VISIT. (Definition of adverse event: An adverse event is any untoward medical occurrence experienced by a patient after study enrollment. An adverse event includes an onset of disease, a set of related symptoms or signs, a single symptom or sign, or a clinically significant laboratory test change from baseline.)

A. Has the patient experienced an adverse event since last visit? 0 No, go to Section C, page 2 1 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, But Improving 3=Not Yet Resolved, No Change 4=Not Yet Resolved, But Worsening *5=Resulted in Chronic Condition, Severe and/or Permanent Disability *6=Deceased 7=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) circle "c" if continuing*	
1.	__ __/__ __/__ __ __ __						__ __/__ __/__ __ __ __	c
2.	__ __/__ __/__ __ __ __						__ __/__ __/__ __ __ __	c
3.	__ __/__ __/__ __ __ __						__ __/__ __/__ __ __ __	c
4.	__ __/__ __/__ __ __ __						__ __/__ __/__ __ __ __	c
5.	__ __/__ __/__ __ __ __						__ __/__ __/__ __ __ __	c
6.	__ __/__ __/__ __ __ __						__ __/__ __/__ __ __ __	c
7.	__ __/__ __/__ __ __ __						__ __/__ __/__ __ __ __	c

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

**See Operations Manual (Section VII) for guidelines. If unable to assess relatedness at this time, enter missing value code "U" (unknown).

‡If event is fatal, life-threatening, requires or prolongs hospitalization, is disabling or incapacitating, an overdose, cancer, or a congenital abnormality, complete Form 17 (see Operations Manual, Section VII, for guidelines).

B. Is a Serious/Unexpected Adverse Event Form (Form 17) required? 0 No 1 Yes

Comments (e.g., dose adjustment): _____

Name Code ☐☐☐☐ Center No. ☐☐☐-☐☐ Patient No. ☐☐☐☐ Date of Report ☐☐-☐☐-☐☐☐☐

Month Day Year

C. Has the patient taken any concomitant medications since last visit? 0 No 1 Yes

If YES, list these medications below, the dose and frequency, and reason. Record the dates the medications were taken (circle "c" if continuing).

1 GENERIC NAME OF MEDICATION	2 DOSE AND FREQUENCY (ex.: 50 mg, twice a day)	3 If medication taken as a result of an adverse event, list number of event. If NOT, please list indication in next column.	4 INDICATION List indication, if not related to an Adverse Event listed on the previous page.	5 FROM Medication Start Date *(Mo/Day/Yr)*	6 Circle "c" if continuing medication	7 TO Medication End Date (If ended, enter last date medication taken) *(Mo/Day/Yr)*
1.				__ __/__ __/__ __ __ __	c	__ __/__ __/__ __ __ __
2.				__ __/__ __/__ __ __ __	c	__ __/__ __/__ __ __ __
3.				__ __/__ __/__ __ __ __	c	__ __/__ __/__ __ __ __
4.				__ __/__ __/__ __ __ __	c	__ __/__ __/__ __ __ __
5.				__ __/__ __/__ __ __ __	c	__ __/__ __/__ __ __ __
6.				__ __/__ __/__ __ __ __	c	__ __/__ __/__ __ __ __
7.				__ __/__ __/__ __ __ __	c	__ __/__ __/__ __ __ __
8.				__ __/__ __/__ __ __ __	c	__ __/__ __/__ __ __ __

FORM COMPLETED BY _____ Date _____

SITE PHYSICIAN'S SIGNATURE _____ Date _____

Name Code ☐☐☐☐ Center No. ☐☐☐-☐☐ Patient No. ☐☐☐☐ Date of Report ☐☐-☐☐-☐☐☐☐ (Month Day Year)

FORM 17 - SERIOUS/UNEXPECTED ADVERSE EVENT FORM

A. ADVERSE EVENT:

1. Adverse Event: _____
2. Date of Onset…Mo __ __ Day __ __ Yr __ __ __ __
3. Age of Patient. .__ __
4. Sex of Patient (**1**=Male, **2**=Female).….....____
5. Patient's Height (inches)....__ __ . __
6. Patient's Weight (pounds)..__ __ __ . __
7. 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. Was dose reduced? (**0** = No, **1** = Yes) ____
      1. If yes, specify new dose _____

   f. Was dose interrupted? (**0** = No, **1** = Yes) ____
      1. If yes, specify total number of days drug was not given __ __

   g. Did event abate after study drug stopped or dose reduced? (**0** = No, **1** = Yes, **2** = NA) ____

   h. Did event reappear after drug was reintroduced? (**0** = No, **1** = Yes, **2** = NA) ____

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

Name Code Center No. Patient No. Date of Report

☐☐☐☐ ☐☐☐-☐☐ ☐☐☐☐ ☐☐-☐☐-☐☐☐☐

Month Day Year

j. Terminated? (**0** = No, **1** = Yes) ____
(If terminated, complete Termination Form 11.)

8. If Died, List Primary Cause of Death:

9. Relevant Tests/Laboratory Data:

B. SUSPECT DRUG(S) INFORMATION:

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

11. Daily Dose of Study Drug (even if not suspected) .....(Record buprenorphine dose) __ __ mg

12. If Non-study drug(s)

a. Trade/generic name of drug(s):

1) _____ 3) _____
2) _____ 4) _____

b. Dose, regimen, routes of administration:

1) _____ 3) _____
2) _____ 4) _____

c. Dates of Administration:

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

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

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

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

d. Indication(s) for Use:

1) _____ 3) _____
2) _____ 4) _____

FORM COMPLETED BY: Date

SITE INVESTIGATOR'S SIGNATURE Date

VA/NIDA STUDY 1018

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

Name Code	Center No.	Patient No.	Date of Report
□□□□	□□□-□□	□□□□	□□-□□-□□□□
			Month Day Year

FORM 18 - UNANNOUNCED MEDICATION CALL BACK

1. DID PATIENT COME IN FOR UNANNOUNCED MEDICATION CALL BACK? (0=No, 1=Yes) ..... ____

   If NO, please explain in comments below. If YES, please answer the questions below.

   A. Date called . . Mo __ __ Day __ __ Yr __ __ __ __

   B. Date patient scheduled to come to clinic ..... Mo __ __ Day __ __ Yr __ __ __ __

   C. Date patient came to clinic ..... Mo __ __ Day __ __ Yr __ __ __ __

   D. Doses expected . . __ __

   E. Verified doses on hand ..... __ __

   Comments: _____

   _____

   _____

   _____

FORM COMPLETED BY _____. Date _____

SITE PHYSICIAN'S SIGNATURE _____ Date _____