Protocol Number: NIDA-CTO-0008	Site Identification Number:	980209
Bupropion for Methamphetamine Dependence	Subject Identification Number:	0100

Study Day: UNSCHD

Form Not Done ☐

Date: ______ (mm/dd/yyyy)

ATTENTION-DEFICIT DISORDER (ADD) ASSESSMENT

Did you or do you:		If so, how old were you when this problem started?	Did/does this cause you trouble at home?	Did/does this cause you trouble at school/work?

9. Tend to be forgetful in daily activities	..as a child?	Yes / No		Yes / No	Yes / No
	..currently?	Yes / No		Yes / No	Yes / No

19) Does the subject have a diagnosis of childhood ADHD? Yes No

20) Does the subject have a diagnosis of adult ADD? Yes No

Source Completed By (Initials):

ADD v1

Protocol Number: NIDA-CTO-0008

Bupropion for Methamphetamine Dependence

Site Identification Number: 980209

Subject Identification Number: 0100

Study Day UNSCHD

ADVERSE EVENTS

Has the subject had any Adverse Events during this study? ☐ Yes ☐ No *If yes, please list all Adverse Events below:*

Severity	Study Drug Relationship	Action Taken Regarding Investigational Agent	Other Action Taken	Outcome of AE	Serious
1 = Mild 2 = Moderate 3 = Severe	1 = Definitely 2 = Probably 3 = Possibly 4 = Remotely 5 = Definitely Not 6 = Unknown	1 = None 2 = Discontinued Perm. 3 = Discontinued Temp. 4 = Reduced Dose 5 = Increased Dose 6 = Delayed Dose	1 = None 2 = Remedial Therapy-pharm 3 = Remedial Therapy-nonpharm 4 = Hospitalization	1 = Resolved, No Sequelae 2 = AE still present - no tx 3 = AE still present - being tx 4 = Residual effects present-no tx 5 = Residual effects present-tx 6 = Death 7 = Unknown	1 = Yes 2 = No (If yes, complete SAE form)

#	EVENT	Start Date	Stop Date	Cont.	Sev.	Drug Rel.	Action Taken	Other Action	Out.	Serious	Initials
				☐						☐ ☐	

AE v1

Protocol Number: NIDA-CTO-0008

Bupropion for Methamphetamine Dependence

Site Identification Number: 980209

Subject Identification Number: 0100

Study Day UNSCHD

Date: (mm/dd/yyyy)

Form Not Done ☐

ALCOHOL BREATHALYZER TEST

1) Was alcohol breathalyzer test performed? ☐ Yes ☐ No ☐ Unknown

2) Date alcohol breathalyzer test performed (mm/dd/yyyy)

3) Blood Alcohol Content (BAC): (mg/ml)

4) Provide comments for any action taken:

Source Completed By (Initials):

ALBREATH v1

Protocol Number: NIDA-CTO-0008

Bupropion for Methamphetamine Dependence

Site Identification Number: 980209

Subject Identification Number: 0100

Study Day UNSCHD

Form Not Done ☐

Date: ________ (mm/dd/yyyy)

ADDICTION SEVERITY INDEX: LITE CF VERSION (ASI) - Part 2 (Follow-Up)

LEGAL STATUS

2) Are you on probation or parole?

How many times in your life have you been arrested and charged with the following:

3) Shoplifting/vandalism
4) Parole/probation violation(s)
5) Drug charge(s)
6) Forgery
7) Weapons offense
8) Burglary, larceny, B and E
9) Robbery
10) Assault
11) Arson
12) Rape
13) Homicide, manslaughter
14) Prostitution
15) Contempt of Court
16) Other, specify:
17) How many of these charges resulted in conviction?

How many times in your life have you been charged with the following:

18) Disorderly conduct, vagrancy, public intoxication?
19) Driving while intoxicated?
20) Major driving violations (reckless driving, speeding, no license, etc.)?
21) How many months were you incarcerated in your life? (months)
22) Are you presently awaiting charges, trial or sentence?
23) What for? (if multiple charges use most severe from codes for #03 through 16 above, or use the following codes: 18=disorderly conduct, 19=driving while intoxicated, 20=major driving violation)
24) How many days in the past 30 days were you detained or incarcerated? (days)
25) How many days in the past 30 days have you engaged in illegal activities for profit? (days)

FOR QUESTIONS 26 - 27, PLEASE ASK THE SUBJECT TO USE THE SUBJECT RATING SCALE

26) How serious do you feel your present legal problems are?
27) How important to you now is counseling or referral for these legal problems?

CONFIDENCE RATINGS ***(Is the above information significantly distorted by):***

28) Subject's misrepresentation?
29) Subject's inability to understand?
30) Comments

Legal Score

FAMILY/SOCIAL RELATIONSHIPS

1) Marital status
2) Are you satisfied with this situation?
3) Usual living arrangements (past three years)
4) Are you satisfied with these living arrangements?
5) Do you live with anyone who has a current alcohol problem?
6) Do you live with anyone who uses non-prescribed drugs?
7) With whom do you spend most of your free time?
8) Are you satisfied with spending your free time this way?

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

	In the past 30 days		In the past 30 days
9) Mother		14) Other significant family	

10) Father

11) Siblings

12) Sexual partner/spouse

13) Children

15) If 14 is yes, specify:

16) Close friends

17) Neighbors

18) Co-workers

Did any of these people (#'s 9-18 above) abuse you?

19) Physically (caused you physical harm)

20) Sexually (forced sexual advances or sexual acts)

21) How many days in the past 30 days have you had serious conflicts with your family?

22) How many days in the past 30 days have you had serious conflicts with other people excluding family?

FOR QUESTIONS 23 - 26, PLEASE ASK THE SUBJECT TO USE THE SUBJECT RATING SCALE

23) How troubled or bothered have you been in the past 30 days by family problems?

24) How troubled or bothered have you been in the past 30 days by social problems?

25) How important to you now is treatment or counseling for family problems?

26) How important to you now is treatment or counseling for social problems?

CONFIDENCE RATINGS ***(Is the above information significantly distorted by):***

27) Subject's misrepresentation?

28) Subject's inability to understand?

29) Comments

Family Score

PSYCHIATRIC STATUS

1) How many times have you been treated for any psychological or emotional problem(s) in a hospital?

2) How many times have you been treated for any psychological or emotional problem(s) as an outpatient?

3) Do you receive a pension for a psychiatric disability?

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

In the past 30 days

4) Experienced serious depression?

5) Experienced serious anxiety or tension?

6) Experienced hallucinations?

7) Experienced trouble understanding, concentrating, or remembering?

8) Experienced trouble controlling violent behavior?

9) Experienced serious thoughts of suicide?

10) Attempted suicide?

11) Been prescribed medication for any psychological or emotional problem?

12) How many days in the last 30 have you experienced psychological or emotional problems?

FOR QUESTIONS 13 - 14, PLEASE ASK THE SUBJECT TO USE THE SUBJECT RATING SCALE

13) How much have you been troubled or bothered by these psychological or emotional problems in the past 30 days?

14) How important to you now is treatment for these psychological problems?

CONFIDENCE RATINGS ***(Is the above information significantly distorted by):***

15) Subject's misrepresentation?

16) Subject's inability to understand?

17) Comments

Psychiatric Score

Source Completed By (Initials):

Protocol Number: NIDA-CTO-0008

Bupropion for Methamphetamine Dependence

Site Identification Number: 980209

Subject Identification Number: 0100

Study Day UNSCHD

Form Not Done ☐

Date: ______ (mm/dd/yyyy)

ADDICTION SEVERITY INDEX: LITE CF VERSION (ASI) - Part 1 (Follow-Up)

GENERAL INFORMATION

2) Class:

3) Contact code:

5) Special:

10) Have you been in a controlled environment in the last 30 days?

11) How many days?

MEDICAL STATUS

1) How many times in your life have you been hospitalized for medical problems?

3) Are you taking any prescribed medication on a regular basis for a physical problem?

4) Do you receive a pension for a physical disability? (Exclude psychiatric disabilities)

5) If yes to #4, specify:

6) How many days have you experienced medical problems in the past 30 days?

FOR QUESTIONS 7 AND 8, PLEASE ASK THE SUBJECT TO USE THE SUBJECT RATING SCALE

7) How troubled or bothered have you been by these medical problems in the past 30 days?

8) How important to you now is treatment for these medical problems?

CONFIDENCE RATINGS ***(Is the above information significantly distorted by):***

9) Subject's misrepresentation?

10) Subject's inability to understand?

11) Comments

Medical Score

EMPLOYMENT/SUPPORT STATUS

1) Education completed (GED = 12 years): (years) (months)

2) Training or technical education completed: (months)

3) Do you have a valid driver's license?

4) Do you have an automobile available for use? (Answer NO if no valid driver's license)

6a) Usual (or last) occupation:

6b) Hollingshead occupational category:

7) Does someone contribute to your support in any way?

9) How many days were you paid for working in the past 30 days?

How much money did you receive from the following sources in the past 30 days?

10) Employment (net income) $

11) Unemployment compensation $

12) Public assistance (welfare) $

13) Pension, benefits or social security $

14) Mate, family or friends (money for personal expenses) $

15) Illegal $

16) How many people depend on you for the majority of their food, shelter, etc.?

17) How many days have you experienced employment problems in the past 30 days?

FOR QUESTIONS 18 AND 19, PLEASE ASK THE SUBJECT TO USE THE SUBJECT RATING SCALE

18) How troubled or bothered have you been by these employment problems in the past 30 days?

19) How important to you now is counseling for these employment problems?

CONFIDENCE RATINGS ***(Is the above information significantly distorted by):***

20) Subject's misrepresentation?

21) Subject's inability to understand?

22) Comments

Employment Score

DRUG/ALCOHOL USE

15) How many times in your life have you been treated for Alcohol abuse?

16) How many times in your life have you been treated for Drug abuse?

17) How many of these were detox only (Alcohol)?

18) How many of these were detox only (Drugs)?

19) How much money have you spent during the past 30 days on Alcohol? $

20) How much money have you spent during the past 30 days on Drugs? $

21) How many days have you been treated in an outpatient setting for alcohol or drugs in the past 30 days? (Include NA, AA)

22) How many days in the past 30 days have you experienced Alcohol problems?

23) How many days in the past 30 days have you experienced Drug problems?

FOR QUESTIONS 24 - 27, PLEASE ASK THE SUBJECT TO USE THE SUBJECT RATING SCALE

24) How troubled or bothered have you been in the past 30 days by these Alcohol problems?

25) How troubled or bothered have you been in the past 30 days by these Drug problems?

26) How important to you now is treatment for these Alcohol problems?

27) How important to you now is treatment for these Drug problems?

CONFIDENCE RATINGS ***(Is the above information significantly distorted by):***

28) Subject's misrepresentation?

29) Subject's inability to understand?

30) Comments

Alcohol Score

Drug Score

Source Completed By (Initials):

Protocol Number: NIDA-CTO-0008

Bupropion for Methamphetamine Dependence

Site Identification Number: 980209

Subject Identification Number: 0100

Study Day: UNSCHD

Date: (mm/dd/yyyy)

Form Not Done ☐

ADDICTION SEVERITY INDEX: LITE CF VERSION (ASI) - Part 2

LEGAL STATUS

1) Was this admission prompted or suggested by the criminal justice system (judge, probation/parole officer, etc.)?
2) Are you on probation or parole?

How many times in your life have you been arrested and charged with the following:

3) Shoplifting/vandalism
4) Parole/probation violation(s)
5) Drug charge(s)
6) Forgery
7) Weapons offense
8) Burglary, larceny, B and E
9) Robbery
10) Assault
11) Arson
12) Rape
13) Homicide, manslaughter
14) Prostitution
15) Contempt of Court
16) Other, specify:
17) How many of these charges resulted in conviction?

How many times in your life have you been charged with the following:

18) Disorderly conduct, vagrancy, public intoxication?
19) Driving while intoxicated?
20) Major driving violations (reckless driving, speeding, no license, etc.)?
21) How many months were you incarcerated in your life? (months)
22) Are you presently awaiting charges, trial or sentence?
23) What for? (if multiple charges use most severe from codes for #03 through 16 above, or use the following codes: 18=disorderly conduct, 19=driving while intoxicated, 20=major driving violation)
24) How many days in the past 30 days were you detained or incarcerated? (days)
25) How many days in the past 30 days have you engaged in illegal activities for profit? (days)

FOR QUESTIONS 26 - 27, PLEASE ASK THE SUBJECT TO USE THE SUBJECT RATING SCALE

26) How serious do you feel your present legal problems are?
27) How important to you now is counseling or referral for these legal problems?

CONFIDENCE RATINGS ***(Is the above information significantly distorted by):***

28) Subject's misrepresentation?
29) Subject's inability to understand?
30) Comments

Legal Score

FAMILY/SOCIAL RELATIONSHIPS

1) Marital status
2) Are you satisfied with this situation?
3) Usual living arrangements (past three years)
4) Are you satisfied with these living arrangements?
5) Do you live with anyone who has a current alcohol problem?
6) Do you live with anyone who uses non-prescribed drugs?
7) With whom do you spend most of your free time?
8) Are you satisfied with spending your free time this way?

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

	In the past 30 days	Lifetime
9) Mother		

10) Father
11) Siblings
12) Sexual partner/spouse
13) Children
14) Other significant family
15) If 14 is yes, specify:
16) Close friends
17) Neighbors
18) Co-workers

Did any of these people (#'s 9-18 above) abuse you?

19) Physically (caused you physical harm)
20) Sexually (forced sexual advances or sexual acts)
21) How many days in the past 30 days have you had serious conflicts with your family?
22) How many days in the past 30 days have you had serious conflicts with other people excluding family?

FOR QUESTIONS 23 - 26, PLEASE ASK THE SUBJECT TO USE THE SUBJECT RATING SCALE

23) How troubled or bothered have you been in the past 30 days by family problems?
24) How troubled or bothered have you been in the past 30 days by social problems?
25) How important to you now is treatment or counseling for family problems?
26) How important to you now is treatment or counseling for social problems?

CONFIDENCE RATINGS ***(Is the above information significantly distorted by):***

27) Subject's misrepresentation?
28) Subject's inability to understand?
29) Comments

Family Score

PSYCHIATRIC STATUS

1) How many times have you been treated for any psychological or emotional problem(s) in a hospital?
2) How many times have you been treated for any psychological or emotional problem(s) as an outpatient?
3) Do you receive a pension for a psychiatric disability?

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

In the past 30 days **Lifetime**

4) Experienced serious depression?
5) Experienced serious anxiety or tension?
6) Experienced hallucinations?
7) Experienced trouble understanding, concentrating, or remembering?
8) Experienced trouble controlling violent behavior?
9) Experienced serious thoughts of suicide?
10) Attempted suicide?
11) Been prescribed medication for any psychological or emotional problem?
12) How many days in the last 30 have you experienced psychological or emotional problems?

FOR QUESTIONS 13 - 14, PLEASE ASK THE SUBJECT TO USE THE SUBJECT RATING SCALE

13) How much have you been troubled or bothered by these psychological or emotional problems in the past 30 days?
14) How important to you now is treatment for these psychological problems?

CONFIDENCE RATINGS ***(Is the above information significantly distorted by):***

15) Subject's misrepresentation?
16) Subject's inability to understand?
17) Comments

Psychiatric Score

Source Completed By (Initials):

Protocol Number: NIDA-CTO-0008	Site Identification Number: 980209
Bupropion for Methamphetamine Dependence	Subject Identification Number: 0100

Study Day UNSCHD

Date: (mm/dd/yyyy)

Form Not Done ☐

ADDICTION SEVERITY INDEX: LITE CF VERSION (ASI) - Part 1

GENERAL INFORMATION

1) Date of Admission: (mm/dd/yyyy)
2) Class:
3) Contact code:
4) Gender;
5) Special:
6) How long have you lived at your current address? (years) (months)
7) Date of Birth:
8) Of what race do you consider yourself?
9) Do you have a religious preference?
10) Have you been in a controlled environment in the last 30 days?
11) How many days?

MEDICAL STATUS

1) How many times in your life have you been hospitalized for medical problems?
2) Do you have any chronic medical problem(s) which continue to interfere with your life?

   If yes to #2, specify:
3) Are you taking any prescribed medication on a regular basis for a physical problem?
4) Do you receive a pension for a physical disability? (Exclude psychiatric disabilities)
5) If yes to #4, specify:
6) How many days have you experienced medical problems in the past 30 days?

FOR QUESTIONS 7 AND 8, PLEASE ASK THE SUBJECT TO USE THE SUBJECT RATING SCALE

7) How troubled or bothered have you been by these medical problems in the past 30 days?
8) How important to you now is treatment for these medical problems?

CONFIDENCE RATINGS **(Is the above information significantly distorted by):**

9) Subject's misrepresentation?
10) Subject's inability to understand?
11) Comments

Medical Score

EMPLOYMENT/SUPPORT STATUS

1) Education completed (GED = 12 years): (years) (months)
2) Training or technical education completed: (months)
3) Do you have a valid driver's license?
4) Do you have an automobile available for use? (Answer NO if no valid driver's license)
5) How long was your longest full-time job? (years) (months)

6a) Usual (or last) occupation:

6b) Hollingshead occupational category:

7) Does someone contribute to your support in any way?
8) Usual employment pattern, past 3 years.
9) How many days were you paid for working in the past 30 days?

How much money did you receive from the following sources in the past 30 days?

10) Employment (net income) $
11) Unemployment compensation $
12) Public assistance (welfare) $
13) Pension, benefits or social security $
14) Mate, family or friends (money for personal expenses) $
15) Illegal $

16) How many people depend on you for the majority of their food, shelter, etc.?

17) How many days have you experienced employment problems in the past 30 days?

FOR QUESTIONS 18 AND 19, PLEASE ASK THE SUBJECT TO USE THE SUBJECT RATING SCALE

18) How troubled or bothered have you been by these employment problems in the past 30 days?

19) How important to you now is counseling for these employment problems?

CONFIDENCE RATINGS ***(Is the above information significantly distorted by):***

20) Subject's misrepresentation?

21) Subject's inability to understand?

22) Comments

Employment Score

DRUG/ALCOHOL USE

14) How many times have you had alcohol DTs?

15) How many times in your life have you been treated for Alcohol abuse?

16) How many times in your life have you been treated for Drug abuse?

17) How many of these were detox only (Alcohol)?

18) How many of these were detox only (Drugs)?

19) How much money have you spent during the past 30 days on Alcohol? $

20) How much money have you spent during the past 30 days on Drugs? $

21) How many days have you been treated in an outpatient setting for alcohol or drugs in the past 30 days? (Include NA, AA)

22) How many days in the past 30 days have you experienced Alcohol problems?

23) How many days in the past 30 days have you experienced Drug problems?

FOR QUESTIONS 24 - 27, PLEASE ASK THE SUBJECT TO USE THE SUBJECT RATING SCALE

24) How troubled or bothered have you been in the past 30 days by these Alcohol problems?

25) How troubled or bothered have you been in the past 30 days by these Drug problems?

26) How important to you now is treatment for these Alcohol problems?

27) How important to you now is treatment for these Drug problems?

CONFIDENCE RATINGS ***(Is the above information significantly distorted by):***

28) Subject's misrepresentation?

29) Subject's inability to understand?

30) Comments

Alcohol Score

Drug Score

Source Completed By (Initials):

Protocol Number: NIDA-CTO-0008

Bupropion for Methamphetamine Dependence

Site Identification Number: 980209

Subject Identification Number: 0100

Study Day UNSCHD

Date: ____ (mm/dd/yyyy)

Form Not Done ☐

BRIEF SUBSTANCE CRAVING SCALE (BSCS)

1) The INTENSITY of my craving, that is, how much I desired methamphetamine in the past 24 hrs was: ____

2) The FREQUENCY of my craving, that is, how often I desired methamphetamine in the past 24 hrs was: ____

3) The LENGTH of time I spent in craving for methamphetamine during the past 24 hrs was: ____

4) Write in the NUMBER of times you think you had craving for methamphetamine during the past 24 hours: ____

5) Write in the total TIME spent craving methamphetamine during the past 24 hours: ____ HOURS ____ MINUTES

6) WORST day: During the past week my most intense craving occurred on the following day: ____

7) The date for that day was: ____ (mm/dd/yyyy)

(If "All days the same, then skip to Question #8)

8) The INTENSITY of my craving, that is, how much I desired methamphetamine on that WORST day was: ____

---

9) A 2nd craved drug during the past 24 hours was: ____

____ Other (specify)

10) The INTENSITY of my craving, that is, how much I desired this second drug in the past 24 hrs was: ____

11) The FREQUENCY of my craving, that is, how often I desired this second drug in the past 24 hrs was: ____

12) The LENGTH of time I spent in craving for this second drug during the past 24 hrs was: ____

---

13) A 3rd craved drug during the past 24 hours was: ____

____ Other (specify)

14) The INTENSITY of my craving, that is, how much I desired this third drug in the past 24 hrs was: ____

15) The FREQUENCY of my craving, that is, how often I desired this third drug in the past 24 hrs was: ____

16) The LENGTH of time I spent in craving for this third drug during the past 24 hrs was: ____

Source Completed By (Initials): ____

BSCS v1

Protocol Number: NIDA-CTO-0008

Bupropion for Methamphetamine Dependence

Site Identification Number: 980209

Subject Identification Number: 0100

Study Day UNSCHD

Date: ______ (mm/dd/yyyy)

Form Not Done ☐

COGNITIVE FUNCTION TEST (Part 1)

1. Digit-symbol score: ______
2. Trail making - Part A: ______ (seconds)
3. Trail making - Part B: ______ (seconds)
4. Stroop
   a. Word score (W) ______
   b. Color score (C) ______
   c. Color-word score ______
5. D2 Test of Attention

Source Completed By (Initials): ______

CFT1 v1

Protocol Number: NIDA-CTO-0008

Bupropion for Methamphetamine Dependence

Site Identification Number: 980209

Subject Identification Number: 0100

Study Day: SCRNBASE

Date: ______ (mm/dd/yyyy)

Form Not Done ☐

COGNITIVE FUNCTION TEST (Part 2)

Word	A. Recall	B. Recognition
	☐	☐
	☐	☐
	☐	☐
	☐	☐
	☐	☐
	☐	☐
	☐	☐
	☐	☐
	☐	☐
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	☐	☐
	☐	☐
	☐	☐
	☐	☐
	☐	☐
	☐	☐
	☐	☐

Intrusions:

26. Recall ______
27. Recognition ______

Source confusion:

28. Recall ______

Source Completed By (Initials): ______

Protocol Number: NIDA-CTO-0008	Site Identification Number: 980209
Bupropion for Methamphetamine Dependence	Subject Identification Number: 0100

Study Day SCRNBASE

Date: (mm/dd/yyyy)

Form Not Done ☐

COGNITIVE FUNCTION TEST (Part 3)

Pictures	A. Recall	B. Recognition
	☐	☐
	☐	☐
	☐	☐
	☐	☐
	☐	☐
	☐	☐
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	☐	☐
	☐	☐
	☐	☐
	☐	☐
	☐	☐
	☐	☐
	☐	☐

Intrusions:

26. Recall

27. Recognition

Source confusion:

28. Recall

Source Completed By (Initials):

Protocol Number: NIDA-CTO-0008	Site Identification Number:	980209
Bupropion for Methamphetamine Dependence	Subject Identification Number:	0100

Study Day SCRNBASE

Date: (mm/dd/yyyy)

Form Not Done ☐

COGNITIVE FUNCTION TEST (Part 4)

Word	A. Recall	B. Recognition
	☐	☐
	☐	☐
	☐	☐
	☐	☐
	☐	☐
	☐	☐
	☐	☐
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	☐	☐
	☐	☐
	☐	☐
	☐	☐
	☐	☐

Intrusions:

26. Recall
27. Recognition

Source confusion:

28. Recall

Source Completed By (Initials):

CFT4 v1

Protocol Number: NIDA-CTO-0008

Bupropion for Methamphetamine Dependence

Site Identification Number: 980209

Subject Identification Number: 0100

Study Day: SCRNBASE

Date: ____ (mm/dd/yyyy)

Form Not Done ☐

COGNITIVE FUNCTION TEST (Part 5)

Pictures	A. Recall	B. Recognition
	☐	☐
	☐	☐
	☐	☐
	☐	☐
	☐	☐
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	☐	☐
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	☐	☐
	☐	☐
	☐	☐
	☐	☐
	☐	☐

Intrusions:

26. Recall ____
27. Recognition ____

Source confusion:

28. Recall ____

Source Completed By (Initials): ____

Protocol Number: NIDA-CTO-0008

Bupropion for Methamphetamine Dependence

Site Identification Number: 980209

Subject Identification Number: 0100

Study Day UNSCHD

Date: ______ (mm/dd/yyyy)

Form Not Done ☐

CHEMISTRIES

Analyte	Std. Quantity	Standard Unit	Other Specify	Normal	Abnormal	Abnormal Significant	Not Done
1) Sodium				○	○	○	○
2) Potassium				○	○	○	○
3) Chloride				○	○	○	○
4) CO2				○	○	○	○
5) Glucose				○	○	○	○
6) Creatinine				○	○	○	○
7) Albumin				○	○	○	○
8) Total Protein				○	○	○	○
9) Calcium				○	○	○	○
10) Cholesterol				○	○	○	○
11) Triglycerides				○	○	○	○
12) Phosphorus				○	○	○	○
13) SGOT/AST				○	○	○	○
14) SGPT/ALT				○	○	○	○
15) GGT				○	○	○	○
16) Total Bilirubin				○	○	○	○
17) LDH				○	○	○	○
18) CPK				○	○	○	○
19) AlkPhos				○	○	○	○
20) BUN				○	○	○	○
21) Uric Acid				○	○	○	○
22 Iron				○	○	○	○

Provide comments for any abormal value(s) ______

Source Completed By (Initials): ______

Protocol Number: NIDA-CTO-0008

Bupropion for Methamphetamine Dependence

Site Identification Number: 980209

Subject Identification Number: 0100

Study Day UNSCHD

Date: ____ (mm/dd/yyyy)

Form Not Done ☐

TREATMENT COMPLIANCE - THERAPY

1) **Did subject receive standardized, manual-guided group CBT?**

○ Yes ○ No ○ Unknown

2) **If yes, length of CBT session attended** ____ (minutes)

3) **Was CBT session audiotaped?**

○ Yes ○ No ○ Unknown

Additional Comments

____

Source Completed By (Initials): ____

COMPTHER v1

Protocol Number: NIDA-CTO-0008	Site Identification Number:	980209
Bupropion for Methamphetamine Dependence	Subject Identification Number:	0100

Study Day UNSCHD

DEATH REPORT

Subject Date of Death ____ (mm/dd/yyyy)

Was autopsy performed? ☐ Yes ☐ No ☐ Unknown

If yes, is autopsy report available? ☐ Yes ☐ No

Is cause of death known? ☐ Yes ☐ No

If yes, in the investigator's clinical judgement, what was the primary cause of death?

____

Narrative description of death (include information about why cause of death is unknown, if applicable.)

____

Source Completed By (Initials): ____

DEATH v1

Protocol Number: NIDA-CTO-0008

Site Identification Number: 980209

Bupropion for Methamphetamine Dependence

Subject Identification Number: 0100

Study Day UNSCHD

Date: ______ (mm/dd/yyyy)

Form Not Done ☐

DEMOGRAPHICS

DEMOGRAPHIC DATA

1) **Gender** ☐ Male ☐ Female

2) **Date of Birth** ______ (mm/dd/yyyy)

3) **Indicate which single major race/ethnicity applies:**

- ☐ White, not of Hispanic Origin
- ☐ Hispanic or Latino
- ☐ African American, Black, not of Hispanic Origin
- ☐ Asian or Pacific Islander
- ☐ American Indian or Alaska native
- ☐ Other, (specify): ______
- ☐ Unknown

4) **Ethnicity/Race all that apply:**

For each of the following, answer Yes to all that apply and No to those that do not.

- ☐ Yes ☐ No White
- ☐ Yes ☐ No Black or African American
- ☐ Yes ☐ No American Indian or Alaskan Native
- ☐ Yes ☐ No Spanish, Hispanic, or Latino (mark all that apply)
  - ☐ Mexican, Mexican-American, or Chicano
  - ☐ Puerto Rican
  - ☐ Cuban
  - ☐ Other (specify) ______
- ☐ Yes ☐ No Asian (mark all that apply)
  - ☐ Asian Indian
  - ☐ Chinese
  - ☐ Filipino
  - ☐ Japanese
  - ☐ Korean
  - ☐ Vietnamese
  - ☐ Other (specify) ______
- ☐ Yes ☐ No Native Hawaiian or Pacific Islander (mark all that apply)
  - ☐ Native Hawaiian
  - ☐ Guamanian or Chamorro
  - ☐ Samoan
  - ☐ Other (specify) ______
- ☐ Yes ☐ No Other (specify) ______

☐ **Participant chooses not to answer**

EMPLOYMENT/SUPPORT STATUS

1) **Education completed (GED = 12 years):** ______ (years) ______ (months)

2) **Usual employment pattern, past 30 days:**

- ☐ Full time (35+ hours/week)
- ☐ Student
- ☐ Homemaker
- ☐ Part time (regular hours)
- ☐ Military Service
- ☐ Unemployed
- ☐ Part time (irregular hours, day work)
- ☐ Retired/Disabled
- ☐ In controlled environment

3) **Usual employment pattern, past 3 years:**

- ☐ Full time (35+ hours/week)
- ☐ Part time (regular hours)
- ☐ Part time (irregular hours, day work)
- ☐ Student
- ☐ Military Service
- ☐ Retired/Disabled
- ☐ Homemaker
- ☐ Unemployed
- ☐ In controlled environment

4) **Marital Status:**

- ☐ Legally married
- ☐ Living with partner/cohabitating
- ☐ Widowed
- ☐ Separated
- ☐ Divorced
- ☐ Never Married

DRUG/ALCOHOL USE

			☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐
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			☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐

According to the interviewer, which substance is the major problem? (Select only one item.)

- ☐ No problem
- ☐ Alcohol (any)
- ☐ Alcohol to intoxication
- ☐ Heroin
- ☐ Methadone/LAAM (presc.)
- ☐ Methadone/LAAM (illicit)
- ☐ Opiates/analgesics
- ☐ Barbiturates
- ☐ Sed./Hyp./Tranq./Benzos.
- ☐ Cocaine
- ☐ Amphetamines
- ☐ Methamphetamine
- ☐ Cannibis
- ☐ Hallucinogens
- ☐ Inhalants
- ☐ Nicotine
- ☐ Alcohol and Drug Addiction
- ☐ Polydrug addiction

Source Completed By (Initials): ________

DEMOG v1

Protocol Number: NIDA-CTO-0008

Bupropion for Methamphetamine Dependence

Site Identification Number: 980209

Subject Identification Number: 0100

Study Day UNSCHD

Date: (mm/dd/yyyy)

ELECTROCARDIOGRAM 12-LEAD

ECG overall results were: ☐ **Normal** ☐ **Abnormal** ☐ **Abnormal Significant** ☐ **Not Done**

Source Completed By (Initials)

ECG v1

Protocol Number: NIDA-CTO-0008	Site Identification Number:	980209
Bupropion for Methamphetamine Dependence	Subject Identification Number:	0100

Study Day UNSCHD

END OF TRIAL

1) Date of Final visit? ______ (mm/dd/yyyy)

2) Last date of study medication? ______ (mm/dd/yyyy) ☐ Unknown or ☐ N/A

3) Reason for study termination (CHECK ONLY ONE):

- ☐ A. Subject completed the study
- ☐ B. Subject was a screen failure
- ☐ C. Subject did not complete the study

If "C" is checked, please check primary reason for withdrawal below (only check one)

- ☐ Subject was determined after enrollment to be ineligible. (Provide comments)
- ☐ Subject requested to withdraw. (Provide comments)
- ☐ Subject experienced intercurrent illness, unrelated medical condition, or clinically significant adverse events, which, in the judgement of the investigator, prompted early termination. (If subject experienced adverse event(s), an Adverse Event Case Report Form(s) must be completed.) (Provide comments.)
- ☐ Subject terminated for administrative reasons. (Include protocol non-compliance in this category. Provide comments)
- ☐ Subject transferred to another treatment program (circle type)
  - ☐ Methadone ☐ LAAM ☐ Drug Free ☐ Inpatient Detox or Treatment
  - ☐ Therapeutic Community ☐ Other, specify ______
- ☐ Subject was incarcerated.
- ☐ Subject became pregnant.
- ☐ Subject developed sensitivity to study agent.
- ☐ Subject was lost to follow-up.
- ☐ Subject moved from area.
- ☐ Subject died. (Complete Death Report CRF)
- ☐ Subject can no longer attend clinic.
- ☐ Subject no longer attends clinic.
- ☐ Subject is in a controlled environment.
- ☐ Other (Provide comments)

Comments:

______

Source Completed By (Initials): ______

ENDTRIAL v1

Protocol Number: NIDA-CTO-0008

Bupropion for Methamphetamine Dependence

Site Identification Number: 980209

Subject Identification Number: 0100

Study Day UNSCHD

RANDOMIZATION AND ENROLLMENT

Is the subject eligible for the study based on Inclusion and Exclusion Criteria? ☐ Yes ☐ No

If yes:

Was the subject randomized? ☐ Yes ☐ No

If randomized:

Date randomized: ________ (mm/dd/yyyy)

Random Dose Code Number: ________

If eligible and not randomized, select/check reason:

- ☐ failed to return
- ☐ declined participation
- ☐ other, specify: ________

If randomized, was the subject enrolled (received first dose of study drug)? ☐ Yes ☐ No

If enrolled, date enrolled: ________ (mm/dd/yyyy)

If randomized and not enrolled, please select/check reason:

- ☐ failed to return
- ☐ declined participation
- ☐ other, specify: ________

Source Completed By (Initials): ________

ENROLL v1

Protocol Number: NIDA-CTO-0008	Site Identification Number:	980209
Bupropion for Methamphetamine Dependence	Subject Identification Number:	0100
Study Day: UNSCHD	Date:	(mm/dd/yyyy)

EXCLUSION CRITERIA

Participant must not:

Criterion	Response
1. Have current dependence, defined by DSM-IV criteria, on any psychoactive substance (i.e.,opioids) other than methamphetamine, nicotine, or marijuana or physiological dependence on alcohol or a sedative-hypnotic, e.g. a benzodiazepine that requires medical detoxification.	☐ Yes ☐ No
2. Have a current or past history of seizure disorder, including alcohol- or stimulant-related seizure, febrile seizure, or significant family history of idiopathic seizure disorder.	☐ Yes ☐ No
3. Currently be using drugs that lower seizure threshold.	☐ Yes ☐ No
4. Have a history of head trauma that resulted in neurological sequelae (e.g., loss of consciousness for greater than 5 minutes or that required hospitalization)	☐ Yes ☐ No
5. Have psychiatric disorders, such as major current depression, psychosis, bipolar illness, organic brain disease, or dementia as assessed by the SCID interview, which require ongoing treatment or which would make medication compliance difficult. Have had electroconvulsive therapy within the past 90 days before screening, or have a history of Bipolar I Disorder (see notes).	☐ Yes ☐ No
6. Have a current suicidal ideation/plan as assessed by the SCID interview or HAM-D question #3. Current is identified as within the past 30 days.	☐ Yes ☐ No
7. Have a current or past history of anorexia nervosa or bulimia disorder.	☐ Yes ☐ No
8. Have a serious medical illness or neurological disorders including, but not limited to, uncontrolled hypertension, significant heart disease (including myocardial infarction within one year of enrollment), angina, hepatic or renal disorders, renal insufficiency (plasma creatinine > 1.7 mg/dL), Parkinson's disease, active syphillis that has not been treated or refuse treatment for syphilis (see note), or have had therapy with any opiate-substitutes (methadone, LAAM, buprenorphine) within 2 months of enrollment, or any serious, potentially life-threatening or progressive medical illness other than addiction that may compromise subject safety or study conduct. Any ECG/cardiovascular abnormality (e.g., QTc interval prolongation > 450 milliseconds in men or 480 milliseconds in women), which in the judgement of the investigator is clincally significant.	☐ Yes ☐ No
9. Have diabetes with unstable control of blood glucose and have any incidence of hypoglycemia in the past year before screening.	☐ Yes ☐ No
10. Be mandated by the court to obtain treatment for methamphetamine-dependence where such mandate required the results of urine toxicology tests to be reported to the court.	☐ Yes ☐ No
11. In the opinion of the investigator, be expected to fail to complete the study protocol due to probable incarceration or relocation from the clinic area.	☐ Yes ☐ No
12. Be undergoing HIV treatment with antiviral and non-antiviral therapy.	☐ Yes ☐ No
13. Have AIDS according to the current CDC criteria for AIDS-MMWR 1999; 48(no, RR-13:29-31).	☐ Yes ☐ No
14. Have CD4(+) T-lymphocytes blood counts <500 cells/mm3.	☐ Yes ☐ No
15. Have known or suspected hypersensitivity to bupropion.	☐ Yes ☐ No

16. Be using bupropion or any medication that could interact adversely with bupropion, within the following times of beginning of administration of bupropion based on the longest time interval of A,B, and C, below or as otherwise specified:
   A. Five half lives or other medication or active metabolite(s), whichever is longer;
   B. Two weeks; or
   C. Interval recommended by other medication's product labeling.
   Medications that fall into this category include:
   a) Bupropion (Wellbutrin, Zyban) used during the past 30 days
   b) All Antidepressants
   c) Neuroleptics
   d) Systemic corticosteroids
   e) Xanthines, i.e., theophilline, theophilline sodium glycinate and aminophylline

   ☐ Yes ☐ No

17. Have participated in any experimental study within 8 weeks (the nature of excluded studies may be discussed with NIDA investigators).

   ☐ Yes ☐ No

18. Be pregnant or lactating.

   ☐ Yes ☐ No

19. Have clinically significant laboratory values (outside of normal limits), in the judgement of the investigator (Appendix I).

   ☐ Yes ☐ No

20. Have active tuberculosis (positive tuberculin test and confirmatory diagnostic chest x-ray).

   ☐ Yes ☐ No

21. Have a diagnosis of adult (i.e., 21 years or older) asthma, or chronic obstructive pulmonary disease (COPD), including those with a history of acute asthma within the past two years, and those with current or recent (past 3 months) treatment with inhaled or oral beta-agonist or steroid therapy (because of potential serious adverse interactions with methamphetamine).

   ☐ Yes ☐ No

22. For subjects suspect for asthma but without a formal diagnosis, 1) have a history of coughing and/or wheezing, 2) have history of asthma and/or asthma treatment two or more years before, 3) have history of other respiratory illness, e.g., complications of pulmonary disease (exclude if on beta agonists), 4) use of over-the-counter agonist or allergy medication for respiratory problems (e.g., Primatene Mist): a detailed history and physical exam, pulmonary consult, and pulmonary function tests should be performed prior to including or excluding from the study or 5) have an FEV1 < 70%.

   ☐ Yes ☐ No

All answers to Exclusion Criteria must be NO.

Source Completed By (Initials): ______

(EXCLUS v1)

Protocol Number: NIDA-CTO-0008

Bupropion for Methamphetamine Dependence

Site Identification Number: 980209

Subject Identification Number: 0100

Study Day UNSCHD

Date: ______ (mm/dd/yyyy)

Form Not Done ☐

FOLLOW-UP

1) Has contact been made with the subject? ○ Yes ○ No

If so, date: ______ (mm/dd/yyyy)

2) If unable to reach subject, has contact been made with someone who can verify his/her status? ○ Yes ○ No

If yes, has the subject died? ○ Yes ○ No *(If the subject died, a Death Report CRF must be completed)*

3) If contact has not been made with the subject, explain: ______

4) Does subject report use of any of the following and if so, for how many days in the last week? *(Check all that apply).*

DRUG	Days Used	DRUG	Days Used
☐ Cocaine		☐ Sedatives	
☐ Methamphetamines		☐ Nicotine	
☐ Amphetamines		☐ Opiates	
☐ Benzodiazepines		☐ Barbiturates	
☐ Alcohol		☐ None	
☐ Marijuana		☐ Other	*(specify)*

5) Does the subject report currently receiving treatment for drug or alcohol abuse/dependence? ○ Yes ○ No

6) Does the subject report that he/she would take the study drug again if it were generally available for substance abuse treatment? ○ Yes ○ No ○ Unknown

7) Have any adverse events occurred? ○ Yes ○ No

8) Have any serious adverse events occurred? ○ Yes ○ No *(If yes, a Serious Adverse Event CRF must be completed)*

9) Additional comments: ______

Source Completed By (Initials): ______

FOLLOWUP v1

Protocol Number: NIDA-CTO-0008

Bupropion for Methamphetamine Dependence

Site Identification Number: 980209

Subject Identification Number: 0100

Study Day UNSCHD

Date: ______ (mm/dd/yyyy)

Form Not Done ☐

Check if HAMD for Randomization ☐

HAMILTON DEPRESSION RATING SCALE

Item	Score
1) Depressed Mood	
2) Feelings of Guilt	
3) Suicide	
4) Insomnia Early	
5) Insomnia Middle	
6) Insomnia Late	
7) Work and Activities	
8) Retardation	
9) Agitation	
10) Anxiety Psychic	
11) Anxiety Somatic	
12) Somatic Symptoms Gastrointestinal	
13) Somatic Symptoms General	
14) Genital Symptoms	
15) Hypochondriasis	
16) Loss of Weight	
17) Insight	
18) Diurnal Variation	

If answer is 1 or 2, note whether the symptoms are worse in:

○ a.m. ○ p.m.

Item	Score
19) Depersonalization	
20) Paranoid Symptoms	
21) Obsessive and Compulsive Symptoms	
22) Helplessness	
23) Hopelessness	
24) Worthlessness	

Hamilton Depression Score: ______

Source Completed By (Initials): ______

HDRS v1

Protocol Number: NIDA-CTO-0008

Burpropion for Methamphetamine Dependence

Site Identification Number: 980209

Subject Identification Number: 0100

Study Day UNSCHD

Date: (mm/dd/yyyy)

Form Not Done ☐

HEMATOLOGY

Complete Blood Count	Std. Quantity	Standard Unit	Other Specify	Normal	Abnormal	Abnormal Significant	Not Done
1) Hemoglobin				☐	☐	☐	☐
2) Hematocrit				☐	☐	☐	☐
3) RBC				☐	☐	☐	☐
4) Platelet Count				☐	☐	☐	☐
5) WBC				☐	☐	☐	☐
6) Neutrophils				☐	☐	☐	☐
7) Lymphocytes				☐	☐	☐	☐
8) Monocytes				☐	☐	☐	☐
9) Eosinophils				☐	☐	☐	☐
10) Basophils				☐	☐	☐	☐
11) CD4 Positive				☐	☐	☐	☐

Provide comments for any abnormal value(s)

Source Completed By (Initials):

HEMA v1

Protocol Number: NIDA-CTO-0008

Bupropion for Methamphetamine Dependence

Site Identification Number: 980209

Subject Identification Number: 0100

Study Day UNSCHD

Date: ________ (mm/dd/yyyy)

Form Not Done ☐

HIV RISK-TAKING BEHAVIOR SCALE (HRBS)

DRUG USE

1) How many times have you hit up (i.e. injected any drugs) in the last month? ________

If you have not injected drugs in the last month, go to Question 7.

2) How many times in the last month have you used a needle after someone else had already used it? ________
3) How many different people have used a needle before you in the past month? ________
4) How many times in the last month has someone used a needle after you? ________
5) How often, in the last month, have you cleaned needles before re-using them? ________
6) Before using needles again, how often in the past month did you use bleach to clean them? ________

Drug Score ________

SEXUAL BEHAVIOR

7) How many people, including clients, have you had sex with in the last month? ________

If no sex in the last month, skip to question #12

8) How often have you used condoms when having sex with your regular partner(s) in the last month? ________
9) How often have you used condoms when you had sex with casual partners? ________
10) How often have you used condoms when you have been paid for sex in the last month? ________
11) How many times have you had anal sex in the last month? ________
12) Have you had an HIV test come back positive? ○ Yes ○ No ○ Unknown

Sex Score ________

Source Completed By (Initials): ________

HRBS Score ________

HRBS v1

Protocol Number: NIDA-CTO-0008

Bupropion for Methamphetamine Dependence

Study Day UNSCHD

Site Identification Number: 980209

Subject Identification Number: 0100

Date: ____ (mm/dd/yyyy)

INCLUSION CRITERIA

Participant must:

	Criterion	Response
1.	Be males and/or females, between 18 and 65 years of age.	☐ Yes ☐ No
2.	Have a DSM-IV diagnosis of methamphetamine dependence as determined by SCID.	☐ Yes ☐ No
3.	Have at least 1 amphetamine or methamphetamine positive urine specifmen (> 1000 ng/mL) within the two-week baseline period prior to randomization with a minimum of 4 samples tested.	☐ Yes ☐ No
4.	Be willing and able to comply with study procedures.	☐ Yes ☐ No
5.	Be able to verbalize understanding of consent form, able to provide written informed consent, and verbalize willingness to complete study procedures.	☐ Yes ☐ No
6.	Be seeking treatment for methamphetamine dependence.	☐ Yes ☐ No
7.	If female, have a negative pregnancy test and agree to use one of the following methods of birth control. a) oral contraceptives b) patch c) barrier (diaphragm or condom) with spermicide or condom only d) intrauterine progesterone or non-hormonal contraceptive system e) levonorgestrel implant f) medroxyprogesterone acetate contraceptive injection g) surgical sterilization h) complete abstinence from sexual intercourse	☐ Yes ☐ No ☐ NA

All answers to Inclusion Criteria must be YES

Source Completed By (Initials): ____

(INCLUS V1)

Protocol Number: NIDA-CTO-0008

Bupropion for Methamphetamine Dependence

Site Identification Number: 980209

Subject Identification Number: 0100

Study Day UNSCHD

Form Not Done ☐

INFORMED CONSENT DATES

Date Step One of Informed Consent was signed: ____ Completed by (initials): ____

Date Step Two of Informed Consent was signed: ____ Completed by (initials): ____

INCONSNT v1

Protocol Number: NIDA-CTO-0008

Bupropion for Methamphetamine Dependence

Site Identification Number: 980209

Subject Identification Number: 0100

Study Day UNSCHD

Date: ______ (mm/dd/yyyy)

Form Not Done ☐

INFECTIOUS DISEASE ASSESSMENT

Indicate whether the laboratory value is NEGATIVE: negative test result, POSITIVE: but DOES NOT EXCLUDE subject from participation or continued study participation, POSITIVE SIGNIFICANT: significant during screening means subject is ineligible for study; significant while on study means consider reporting result as adverse event if unexpected and at least possibly related to investigational agent or early termination of the subject from study, INDETERMINANT: result was not interpretable.

Infectious Disease	Result	Provide comments for any abnormal value
Hepatitis B surface antigen result		
Hepatitis B surface antibody result		
Hepatitis B core antibody result		
Hepatitis C virus antibody result		

Date PPD test administered ______ (mm/dd/yyyy)

Time PPD test administered ______ (00:00 - 23:59)

Date PPD test read ______ (mm/dd/yyyy)

Time PPD test read ______ (00:00 - 23:59)

☐ **PPD Previously Positive**
*(Test not done, chest X-ray required)

PPD test result ______ *If positive, chest X-ray required.

If test not done, state reason. ______

Provide comments for any positive value. ______

Date chest X-ray performed ______ (mm/dd/yyyy)

Results of chest X-ray ______

If chest X-ray not done, state reason. ______

Provide comments for any abnormal finding. ______

Source Completed By (Initials): ______

INFECDIS v1

Protocol Number: NIDA-CTO-0008

Bupropion for Methamphetamine Dependence

Site Identification Number: 980209

Subject Identification Number: 0100

Study Day: UNSCHD

Form Not Done ☐

LAB TEST TRACKING FORM

Visit	Date:	Tests:	Completed By
		☐ ☐ ☐ ☐	
		☐ ☐ ☐ ☐	
		☐ ☐ ☐ ☐	
		☐ ☐ ☐ ☐	
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		☐ ☐ ☐ ☐	

13. Week 1 Visit 1	(mm/dd/yyyy)	☐ UrineMeth/Creatinine **or** ☐ N/A ☐ Urine Toxicology - NWT **or** ☐ N/A	(Initials)
		☐ ☐ ☐ ☐	
		☐ ☐ ☐ ☐	
		☐ ☐ ☐ ☐	
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		☐ ☐ ☐ ☐	

28. Week 6 Visit 1	(mm/dd/yyyy)	☐ UrineMeth/Creatinine **or** ☐ N/A ☐ Urine Toxicology - NWT **or** ☐ N/A	(Initials)
		☐ __ ☐ ☐ __ ☐	
		☐ __ ☐ ☐ __ ☐	
		☐ __ ☐ ☐ __ ☐	
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		☐ __ ☐ ☐ __ ☐	
		☐ __ ☐ ☐ __ ☐	

43. Week 11 Visit 1	(mm/dd/yyyy)	☐ UrineMeth/Creatinine **or** ☐ N/A ☐ Urine Toxicology - NWT **or** ☐ N/A	(Initials)
		☐ _ ☐ ☐ _ ☐	
		☐ _ ☐ ☐ _ ☐	
		☐ _ ☐ ☐ _ ☐	
		☐ _ ☐ ☐ _ ☐	
		☐ _ ☐ ☐ _ ☐	
		☐ _ ☐ ☐ _ ☐	
		☐ _ ☐ ☐ _ ☐	

Protocol Number: NIDA-CTO-0008

Bupropion for Methamphetamine Dependence

Site Identification Number: 980209

Subject Identification Number: 0100

Study Day: UNSCHD

Date: (mm/dd/yyyy)

Form Not Done ☐

MCTG METHAMPHETAMINE WITHDRAWAL QUESTIONNAIRE (MAWQ) - Part I

Date of Participant's Last Methamphetamine Use: (mm/dd/yyyy)

Source Completed By (Initials):

MAWQPT1 v1

Protocol Number: NIDA-CTO-0008

Bupropion for Methamphetamine Dependence

Site Identification Number: 980209

Subject Identification Number: 0100

Study Day UNSCHD

Form Not Done ☐

Date: (mm/dd/yyyy)

MCTG METHAMPHETAMINE WITHDRAWAL QUESTIONNAIRE (MAWQ) - Part 2

Please tell me if you agree with each statement below on how you have felt in the LAST 24 HOURS

	○	○	○	○	○
	○	○	○	○	○
	○	○	○	○	○
	○	○	○	○	○
	○	○	○	○	○
	○	○	○	○	○
	○	○	○	○	○
	○	○	○	○	○

VITAL SIGNS/PATELLAR REFLEX *(to be assessed after participant has been seated for five minutes)*

VITAL SIGNS

Temperature (F)

Blood Pressure (mm Hg) (sys) / (dias)

Pulse (BPM)

Respirations (1 MIN)

Weight (LB)

PATELLAR REFLEX (choose one)

○ No Response

○ Hyperreflexia

○ Hyporeflexia

○ Marked Hyperreflexia

○ Normal

Source Completed By (Initials):

MAWQPT2 v1

Protocol Number: NIDA-CTO-0008

Bupropion for Methamphetamine Dependence

Site Identification Number: 980209

Subject Identification Number: 0100

Study Day UNSCHD

Date: (mm/dd/yyyy)

Form Not Done ☐

METHAMPHETAMINE CLINICAL GLOBAL IMPRESSION - OBSERVER (MCGI-O)

1) Global Severity of Methamphetamine Dependence

Considering your total clinical experience with the methamphetamine dependent population, how severe are his/her methamphetamine dependence symptoms at this time?

- ○ Normal, no symptoms
- ○ Borderline symptoms
- ○ Mild symptoms
- ○ Moderate symptoms
- ○ Marked symptoms
- ○ Severe symptoms
- ○ Among the most extreme symptoms

2) Global Improvement of Methamphetamine Dependence

Rate the total improvement in the participant's methamphetamine dependence symptoms whether or not in your judgement, it is due entirely to drug treatment. Compared to his/her admission to the project how much has she/he changed?

- ○ Not assessed, first rating
- ○ Very much improved
- ○ Much improved
- ○ Minimally improved
- ○ Unchanged
- ○ Minimally worse
- ○ Much worse
- ○ Very much worse

3) Please rate the subject's current severity in the eight specific problem areas below:

	○	○	○	○	○	○	○
	○	○	○	○	○	○	○
	○	○	○	○	○	○	○
	○	○	○	○	○	○	○
	○	○	○	○	○	○	○
	○	○	○	○	○	○	○
	○	○	○	○	○	○	○
	○	○	○	○	○	○	○

Source Completed By (Initials):

MCGIOBS v1

Protocol Number: NIDA-CTO-0008

Bupropion for Methamphetamine Dependence

Site Identification Number: 980209

Subject Identification Number: 0100

Study Day UNSCHD

Date: (mm/dd/yyyy)

Form Not Done ☐

METHAMPHETAMINE CLINICAL GLOBAL IMPRESSION - SELF (MCGI-S)

1) Methamphetamine Global Severity

At this time, how would you have rate yourself for Methamphetamine use and Methamphetamine related problems?

- ○ No problems
- ○ Borderline problems
- ○ Mild problems
- ○ Moderate problems
- ○ Marked problems
- ○ Severe problems
- ○ Most extreme problems possible

2) Methamphetamine Global Improvement

How would you rate yourself for changes in Methamphetamine use and Methamphetamine related problems since the beginning of this study?

- ○ Not assessed, first rating
- ○ Very much improved
- ○ Much improved
- ○ Minimally improved
- ○ Unchanged
- ○ Minimally worse
- ○ Much worse
- ○ Very much worse

Source Completed By (Initials):

MCGISELF v1

Protocol Number: NIDA-CTO-0008

Bupropion for Methamphetamine Dependence

Site Identification Number: ☐

Subject Identification Number: ☐

Study Day UNSCHD

Date: ☐ (mm/dd/yyyy)

Form Not Done ☐

MEDICAL HISTORY ADDENDUM FOR FEMALES

☐ **N/A, Subject is male**

1) **Date of last menstrual cycle:** ☐ (mm/dd/yyyy)

2) **History of irregular cycle:** ☐ Yes ☐ No

3) **Please specify form of birth control used:**

- ☐ Oral Contraceptives
- ☐ Barrier (diaphragm or condom) plus spermicide or condom only
- ☐ Levonorgestrel implant (Norplant)
- ☐ Intrauterine progesterone contraceptive system (IUD)
- ☐ Medroxyprogesterone acetate contraceptive injection (Depo-provera)
- ☐ Tubal ligation Date of Tubal Ligation: ☐ (mm/dd/yyyy)
- ☐ Complete abstinence
- ☐ None (specify reason): ____
- ☐ Other (specify): ____

Source Completed By (Initials): ☐

MEDHISAD v1

Protocol Number: NIDA-CTO-0008

Bupropion for Methamphetamine Dependence

Site Identification Number: 980209

Subject Identification Number: 0100

Study Day UNSCHD

Date: ______ (mm/dd/yyyy)

Form Not Done ☐

MEDICAL HISTORY

Disorder	Yes excludes	Yes doesn't exclude	No history of disorder	Not evaluated	If yes, specify or describe
1. Allergies: drug	☐	☐	☐	☐	
2. Allergies: other, specify ______	☐	☐	☐	☐	
3. Sensitivity to Agent/Compounds	☐	☐	☐	☐	
4. History of Asthma	☐	☐	☐	☐	
5. HEENT	☐	☐	☐	☐	
6. Cardiovascular	☐	☐	☐	☐	
7. Renal	☐	☐	☐	☐	
8. Hepatic	☐	☐	☐	☐	
9. Pulmonary	☐	☐	☐	☐	
10. Gastrointestinal	☐	☐	☐	☐	
11. Musculoskeletal	☐	☐	☐	☐	
12. Neurologic	☐	☐	☐	☐	
13. Psychiatric	☐	☐	☐	☐	
14. Dermatologic	☐	☐	☐	☐	
15. Metabolic	☐	☐	☐	☐	
16. Hematologic	☐	☐	☐	☐	
17. Endocrine	☐	☐	☐	☐	
18. Genitourinary	☐	☐	☐	☐	
19. Reproductive System	☐	☐	☐	☐	
20. Seizure	☐	☐	☐	☐	
21. Infectious Disease	☐	☐	☐	☐	
22. Other 1, specify: ______	☐	☐	☐	☐	
23. Other 2, specify: ______	☐	☐	☐	☐	

24. **Was major surgery ever performed?** ☐ Yes ☐ No ***(If Yes, list surgeries:)***

	Type of Surgery	Date of Surgery (mm/dd/yyyy)	Yes excludes	Yes doesn't exclude	No
25.			☐	☐	☐
26.			☐	☐	☐
27.			☐	☐	☐
28.			☐	☐	☐
29.			☐	☐	☐
30.			☐	☐	☐
31.			☐	☐	☐

TOBACCO HISTORY

32. Has subject used any tobacco product (e.g. cigarettes, cigars, pipe, chewing tobacco) in the past week? ☐ Yes ☐ No

33. Has subject ever used any tobacco product for at least one year? ☐ Yes ☐ No

34. If yes, number of years tobacco used? ______

COMMENTS

______

Source Completed By (Initials): ______

MEDHIST v1

Protocol Number: NIDA-CTO-0008

Bupropion for Methamphetamine Dependence

Site Identification Number: 980209

Subject Identification Number: 0100

Study Day UNSCHD

Date: ______ (mm/dd/yyyy)

Form Not Done ☐

METHAMPHETAMINE TIMELINE FOLLOW BACK

Consent Date: ______ (mm/dd/yyyy)

Date 30 Days Prior to consent date: ______ (mm/dd/yyyy)

Day	Methamphetamine Use	Alcohol Use
Day 1	○ Yes ○ No	○ Yes ○ No
Day 2	○ Yes ○ No	○ Yes ○ No
Day 3	○ Yes ○ No	○ Yes ○ No
Day 4	○ Yes ○ No	○ Yes ○ No
Day 5	○ Yes ○ No	○ Yes ○ No
Day 6	○ Yes ○ No	○ Yes ○ No
Day 7	○ Yes ○ No	○ Yes ○ No
Day 8	○ Yes ○ No	○ Yes ○ No
Day 9	○ Yes ○ No	○ Yes ○ No
Day 10	○ Yes ○ No	○ Yes ○ No
Day 11	○ Yes ○ No	○ Yes ○ No
Day 12	○ Yes ○ No	○ Yes ○ No
Day 13	○ Yes ○ No	○ Yes ○ No
Day 14	○ Yes ○ No	○ Yes ○ No
Day 15	○ Yes ○ No	○ Yes ○ No
Day 16	○ Yes ○ No	○ Yes ○ No
Day 17	○ Yes ○ No	○ Yes ○ No
Day 18	○ Yes ○ No	○ Yes ○ No
Day 19	○ Yes ○ No	○ Yes ○ No
Day 20	○ Yes ○ No	○ Yes ○ No
Day 21	○ Yes ○ No	○ Yes ○ No
Day 22	○ Yes ○ No	○ Yes ○ No
Day 23	○ Yes ○ No	○ Yes ○ No
Day 24	○ Yes ○ No	○ Yes ○ No
Day 25	○ Yes ○ No	○ Yes ○ No
Day 26	○ Yes ○ No	○ Yes ○ No
Day 27	○ Yes ○ No	○ Yes ○ No
Day 28	○ Yes ○ No	○ Yes ○ No
Day 29	○ Yes ○ No	○ Yes ○ No
Day 30	○ Yes ○ No	○ Yes ○ No

Source Completed By (Initials): ______

Protocol Number: NIDA-CTO-0008	Site Identification Number:	980209
Bupropion for Methamphetamine Dependence	Subject Identification Number:	0100

Study Day UNSCHD

Date: ____ (mm/dd/yyyy)

Form Not Done ☐

PHYSICAL EXAMINATION

Height: ____ ☐ inches ☐ centimeters

Weight: ____ ☐ pounds ☐ kilograms

	General Exam	Normal	Abnormal	Abnormal Significant	Not Done	If Abnormal, explain below
1)	Oral (mouth)	☐	☐	☐	☐	
2)	Head and Neck	☐	☐	☐	☐	
3)	EENT	☐	☐	☐	☐	
4)	Cardiovascular	☐	☐	☐	☐	
5)	Chest	☐	☐	☐	☐	
6)	Lungs	☐	☐	☐	☐	
7)	Abdomen (include liver/spleen)	☐	☐	☐	☐	
8)	Extremities	☐	☐	☐	☐	
9)	Skin, Hair, Nails	☐	☐	☐	☐	
10)	Neuropsychiatric mental status	☐	☐	☐	☐	
11)	Neuropsychiatric sensory/motor	☐	☐	☐	☐	
12)	Musculoskeletal	☐	☐	☐	☐	
13)	General Appearance	☐	☐	☐	☐	
14)	Rectal	☐	☐	☐	☐	
15)	Prostate	☐	☐	☐	☐	
16)	Breast	☐	☐	☐	☐	
17)	Lymph	☐	☐	☐	☐	
18)	Genital	☐	☐	☐	☐	
19)	Pelvic	☐	☐	☐	☐	
20)	Forced Expiratory Volume (FEV1) ____ (%)	☐	☐	☐	☐	
21)	Other *(specify)* ____	☐	☐	☐	☐	
22)	Other *(specify)* ____	☐	☐	☐	☐	

Source Completed By (Initials): ____

Protocol Number: NIDA-CTO-0008

Bupropion for Methamphetamine Dependence

Site Identification Number: 980209

Subject Identification Number: 0100

Study Day UNSCHD

Date: (mm/dd/yyyy)

Form Not Done ☐

PREGNANCY

1) Was a pregnancy test performed?
   - ○ Yes
   - ○ No (If no, skip to #4)
   - ○ N/A, subject is male (if N/A, the rest of the form should be blank)

2) Pregnancy test result:
   - ○ Positive
   - ○ Negative

3) Pregnancy test comments:

4) Is the subject lactating?
   - ○ Yes ○ No ○ Not Applicable

5) Is the subject using an acceptable method of birth control?
   - ○ Yes ○ No

6) What method of birth control is the subject using?
   - ○ oral contraceptives
   - ○ patch
   - ○ barrier (diaphragm or condom) with spermicide or condom only
   - ○ intrauterine progesterone contraceptive system (IUD)
   - ○ lovenorgestrel implant (Norplant)
   - ○ medroxyprogesterone acetate contraceptive injection
   - ○ surgical sterilization
   - ○ complete abstinence from sexual intercourse

Source Completed By (Initials):

PREGNANT v1

Protocol Number: NIDA-CTO-0008

Bupropion for Methamphetamine Dependence

Site Identification Number: 980209

Subject Identification Number: 0100

Study Day UNSCHD

PRIOR AND CONCOMITANT MEDICATIONS

Has the subject taken any medications 30 days prior to or during the study? ☐ Yes ☐ No *If yes, please complete table*

Dose	Unit of Medication		Frequency	Route of Administration	
Strength of Medication	CAP = capsule	PUF = puff	ONCE = single dose	PO = oral	AUR = auricular
	g = gram	SPY = spray/squirt	QD = once daily	TD = transdermal	IA = intra-articular
	GR = grain	SUP = suppository	BID = twice daily	INH = inhaled	NAS = nasal
	GTT = drop	TSP = teaspoon	TID = three times a day	IM = intramuscular	IO = intraocular
	ug = microgram	TBS = tablespoon	QID = four times a day	IV = intravenous	TOP = topical
	uL = microliter	TAB = tablet	QOD = every other day	REC = rectal	UNK = unknown
	mg = milligram	UNK = unknown	PRN = as needed	VAG = vaginal	OTH = other, specify
	mL = milliliter	OTH = other, specify	OTH = other, specify	SQ = subcutaneous	
	OZ = ounce			SL = sublingual	

PRIORMED v1

Protocol Number: NIDA-CTO-0008

Bupropion for Methamphetamine Dependence

Study Day UNSCHD

Site Identification Number: 980209

Subject Identification Number: 0100

SERIOUS ADVERSE EVENT

DEMOGRAPHIC INFORMATION

Enrollment Date ____ (mm/dd/yyyy)

Gender ☐ Male ☐ Female

Date of Birth ____ (mm/dd/yyyy)

Race

- ☐ White, not of Hispanic Origin
- ☐ Hispanic or Latino
- ☐ African American, Black, not of Hispanic Origin
- ☐ Asian or Pacific Islander
- ☐ American Indian or Alaska native
- ☐ Other, (specify): ____
- ☐ Unknown

Height ____ ☐ inches ☐ centimeters

Weight ____ ☐ pounds ☐ kilograms

AE/Diagnosis: ____ ____ ____ ____

SERIOUS ADVERSE EVENT

SAE Description

____

Onset Date ____ (mm/dd/yyyy)

Reported to Coord. Center by: ____

Date Reported to Center: ____ (mm/dd/yyyy)

Reported to FDA by: ____

Initial Date reported to FDA: ____ (mm/dd/yyyy)

Reported to Sponsor by: ____

Date reported to sponsor: ____ (mm/dd/yyyy)

Reported to NIDA by: ____

Initial Date reported to NIDA: ____ (mm/dd/yyyy)

Severity grade ☐ mild ☐ moderate ☐ severe

Was SAE related to investigational agent?

☐ definitely ☐ probably ☐ possibly ☐ remotely ☐ definitely not ☐ unknown

Action taken regarding investigational agent

- ☐ none
- ☐ discontinued permanently
- ☐ discontinued temporarily
- ☐ reduced dose
- ☐ increased dose
- ☐ delayed dose

Other action(s) taken

- ☐ none
- ☐ remedial therapy - pharmacologic
- ☐ remedial therapy - nonpharmacologic
- ☐ hospitalization (new or prolonged)

Outcome If outcome was death, a Death Report Form must be completed.

- ☐ death
- ☐ disability
- ☐ life-threatening event
- ☐ congenital anomaly
- ☐ hospitalization
- ☐ other (specify) ____

Concomitant Medications

____

Relevant tests/laboratory data, including dates

____

Relevant history including pre-existing medical conditions (e.g., allergies, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

____

SAE resolution date ____ (mm/dd/yyyy) OR ☐ continuing

INVESTIGATIONAL AGENT ADMINISTRATION

Is investigational agent information known? ☐ Yes ☐ No

If yes, investigational agent name ____

Lot number ____

Expiration date ____ (mm/dd/yyyy)

Quantity ____

Unit Code ____ **Other unit** ____

Start date ____ (mm/dd/yyyy) **Stop date** ____ (mm/dd/yyyy) or ☐ continuing

Route of administration

- ☐ auricular
- ☐ inhaled
- ☐ intra-articular
- ☐ intramuscular
- ☐ intraocular
- ☐ intravenous
- ☐ nasal
- ☐ oral
- ☐ rectal
- ☐ subcutaneous
- ☐ sublingual
- ☐ transdermal
- ☐ vaginal
- ☐ unknown
- ☐ other (specify) ____

Frequency

- ☐ single dose
- ☐ once daily
- ☐ every other day
- ☐ twice daily
- ☐ three times a day
- ☐ four times a day
- ☐ as needed
- ☐ other (specify) ____

Comments

Source Completed by:

SAE v1

Protocol Number: NIDA-CTO-0008

Bupropion for Methamphetamine Dependence

Site Identification Number: 980209

Subject Identification Number: 0100

Study Day UNSCHD

Date: (mm/dd/yyyy)

Form Not Done ☐

SCID WORKSHEET

AXIS I - Diagnosis

Please list all CURRENT and PAST Substance Abuse or Dependence Diagnoses, OTHER CURRENT, AND OTHER PAST Diagnoses (Include DSM-IV code).

Source Completed By (Initials):

SCID v1

Protocol Number: NIDA-CTO-0008

Bupropion for Methamphetamine Dependence

Study Day UNSCHD

Site Identification Number: 980209

Subject Identification Number: 0100

Date: (mm/dd/yyyy)

Form Not Done ☐

SUBSTANCE USE REPORT

Date of substance use or no use reported for: (mm/dd/yyyy)

Day of substance use or no use reported for: ○ Monday ○ Tuesday ○ Wednesday ○ Thursday ○ Friday ○ Saturday ○ Sunday

			A. Total amount	B. Unit	C. Unit code	D. Route	E. Route code
1. Cocaine	☐ No use	i)					
		ii)					
2. Alcohol	☐ No use	i)					
		ii)					
3. Marijuana	☐ No use	i)					
		ii)					
4. Opioids Specify:	☐ No use						
i)							
ii)							
5. Nicotine	☐ No use	i)					
		ii)					
6. Methamphetamine	☐ No use	i)					
		ii)					
7. Other, Specify:	Code						
i)							
ii)							
iii)							

Source Completed By (Initials):

SUR v1

Protocol Number: NIDA-CTO-0008

Bupropion for Methamphetamine Dependence

Site Identification Number: 980209

Subject Identification Number: 0100

Study Day UNSCHD

Date: ______ (mm/dd/yyyy)

Form Not Done ☐

SYPHILIS TEST

Indicate whether the laboratory value is NEGATIVE: negative test result, POSITIVE: positive test result, INDETERMINANT: result is not interpretable or NOT DONE.

Rapid plasma reagin (RPR) test result ______

If RPR test is not done, state reason. ______

***If positive, fluorescent treponemal antibody absorbent (FTA-abs) confirmatory test is required.**

****If RPR test is indeterminant, it must be repeated.**

Date FTA-abs test administered ______ (mm/dd/yyyy)

FTA-abs test result ______

If test not done, state reason. ______

+If FTA-abs result is positive, is subject willing to undergo treatment for syphilis?

☐ Yes ☐ No

If treated, date of written proof of treatment: ______ (mm/dd/yyyy)

If subject is unwilling to undergo treatment for active syphilis, s/he is ineligible to participate in research study.

Comments:

______

Source Completed By (Initials): ______

SYPHILIS v1

Protocol Number: NIDA-CTO-0008	Site Identification Number: 980209
Bupropion for Methamphetamine Dependence	Subject Identification Number: 0100

Study Day: UNSCHD

Form Not Done ☐

TREATMENT COMPLIANCE - STUDY DRUG

#	Date Study Drug Dispensed (mm/dd/yyyy)	Study Week/Visit Study Drug Dispensed	Number of Tablets Dispensed	Date Unused Study Drug Returned (mm/dd/yyyy)	Study Week/Visit Study Drug Returned	Number of Tabs. Returned (per timeline follow-back)
1						

Number of Tabs. Returned (per count)	Number of Tabs. Reported Lost by Subject	Dispensed by:	Returned by:	Comments:

TRTMENT v1

Protocol Number: NIDA-CTO-0008

Bupropion for Methamphetamine Dependence

Site Identification Number: 980209

ject Identification Number: 0100

Study Day UNSCHD

Date: (mm/dd/yyyy)

Form Not Done ☐

URINALYSIS

hether the laboratory value is NORMAL: within normal limits, ABNORMAL: outside of normal limits but not ABNORMAL SIGNIFICANT: significant during screening means subject is ineligible for study; significant w r reporting result as adverse event if unexpected and at least possibly related to investigational agen early termination from study.

Dipstick Urinalysis

Specific gravity

pH

rce Completed By (Initials):

URINE v1

Protocol Number: NIDA-CTO-0008

Bupropion for Methamphetamine Dependence

Site Identification Number:

Subject Identification Number:

Study Day UNSCHD

Form Not Done ☐

Date: (mm/dd/yyyy)

URINE TOXICOLOGY

Urine temperature within expected range? ☐ Yes ☐ No ☐ Unknown (96.4 < or = T < or = 100.4 F)

	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐
	☐	☐	☐

Source Completed By (Initials):

URINETOX v1

Protocol Number: NIDA-CTO-0008

Bupropion for Methamphetamine Dependence

Site Identification Number: 980209

Subject Identification Number: 0100

Study Day UNSCHD

Date: ____ (mm/dd/yyyy)

Form Not Done ☐

VITAL SIGNS

Time: ____ (00:00-23:59)

Temp: (oral) ____ ☐ F ☐ C

SITTING:

Respiratory Rate ____ breaths/minute

Pulse Rate ____ beats/minute

Blood Pressure ____ / ____ mm/hg

Source Completed By (Initials): ____

VITALS v1

Protocol Number: NIDA-CTO-0008

Bupropion for Methamphetamine Dependence

Site Identification Number: 980209

Subject Identification Number: 0001

Study Day UNSCHD

Form Not Done ☐

TREATMENT COMPLIANCE - TIMELINE FOLLOW-BACK

Line No	Date (mm/dd/yyyy)	Morning	Evening
		☐ ☐	☐ ☐

TCTLFB v1