Protocol Number: NIDA-CTO-0010

Bupropion for Methamphetamine Dependence

Site Identification Number: 980202

Subject Identification Number: 0001

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):

Protocol Number: NIDA-CTO-0010

Bupropion for Methamphetamine Dependence

Site Identification Number: 980202

Subject Identification Number: 0001

Study Day UNSCHD

Form Not Done ☐

Date: ________ (mm/dd/yyyy)

ADJECTIVE SCALE

Actual Time ________ (00:00 - 23:59)

For each item presented, indicate HOW YOU FEEL RIGHT NOW.

	☐	☐	☐	☐	☐
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Source Completed By (Initials): ________

ADJSCALE v1

Protocol Number: NIDA-CTO-0010

Bupropion for Methamphetamine Dependence

Study Day UNSCHD

Site Identification Number: 980202

Subject Identification Number: 0001

ADVERSE EVENTS

Has the subject had any Adverse Experiences during this study? ☐ Ye ☐ No *If yes, please list all Adverse Experiences 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 Sequela 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	Yes No (If yes, complete SAE form)

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

AE v1

Protocol Number: NIDA-CTO-0010

Bupropion for Methamphetamine Dependence

Site Identification Number: 980202

Subject Identification Number: 0001

Study Day UNSCHD

Form Not Done ☐

Date: (mm/dd/yyyy)

ARCI SHORT FORM

These 49 items may or may not describe how you feel right now. Mark T (for true) next to each item that does describe how you feel, and F (for false) for each item that does not describe how you feel.

Actual Time (00:00 - 23:59)

Feelings

	True	False
27. Less discouraged	◯	◯

Source Completed By (Initials):

Protocol Number: NIDA-CTO-0010	Site Identification Number: 980202
Bupropion for Methamphetamine Dependence	Subject Identification Number: 0001

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 hospit
2) How many times have you been treated for any psychological or emotional problem(s) as an out
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-0010

Bupropion for Methamphetamine Dependence

Site Identification Number: 980202

Subject Identification Number: 0001

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?

Alcohol Score

30) Comments

Drug Score

Source Completed By (Initials):

ASILITE v1

Protocol Number: NIDA-CTO-0010

Bupropion for Methamphetamine Dependence

Site Identification Number: 980202

Subject Identification Number: 0001

Study Day UNSCHD

Form Not Done ☐

Date: ____ (mm/dd/yyyy)

BECK DEPRESSION INVENTORY (BDI)

Which statement best describes the way you have been feeling the PAST WEEK, (INCLUDING TODAY).

1)	8)	15)
2)	9)	16)
3)	10)	17)
4)	11)	18)
5)	12)	19)
6)	13)	20)
7)	14)	21)

Source Completed By (Initials): ____

BECK v1

Protocol Number: NIDA-CTO-0010

Bupropion for Methamphetamine Dependence

Site Identification Number: 980202

Subject Identification Number: 0001

Study Day UNSCHD

Form Not Done ☐

Date: ______ (mm/dd/yyyy)

BRIEF PSYCHIATRIC RATING SCALE

Actual Time: ______ (00:00 - 23:59)

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Source Completed By (Initials): ______

Protocol Number: NIDA-CTO-0010	Site Identification Number:	980202
Bupropion for Methamphetamine Dependence	Subject Identification Number:	0001

Study Day UNSCHD   **Form Not Done** ☐   **Date:** ____ (mm/dd/yyyy)

BRIEF SYMPTOM INVENTORY

For the past week, how much were you distressed by:

#	Item		#	Item	
1)	Nervousness or shakiness inside		28)	Feeling afraid to travel on buses, subways, or trains.	
2)	Faintness or dizziness		29)	Trouble getting your breath	
3)	The idea that someone else can control your thoughts		30)	Hot or cold spells	
4)	Feeling others are to blame for most of your problems		31)	Having to avoid certain things, places or activities..	
5)	Trouble remembering things		32)	Your mind going blank	
6)	Feeling easily annoyed or irritated		33)	Numbness or tingling in parts of your body	
7)	Pains in heart or chest		34)	The idea that you should be punished for your sins	
8)	Feeling afraid in open spaces or on the streets		35)	Feeling hopeless about the future	
9)	Thoughts of ending your life		36)	Trouble concentrating	
10)	Feeling that most people cannot be trusted		37)	Feeling weak in parts of your body	
11)	Poor Appetite		38)	Feeling tense or keyed up	
12)	Suddenly scared for no reason		39)	Thoughts of death or dying	
13)	Temper outbursts that you could not control		40)	Having urges to beat, injure or harm someone	
14)	Feeling lonely even when you are with people		41)	Having urges to break or smash things	
15)	Feeling blocked in getting things done		42)	Feeling very self-conscious with others	
16)	Feeling lonely		43)	Feeling very uneasy in crowds (shopping, movie)	
17)	Feeling blue		44)	Never feeling close to another person	
18)	Feeling no interest in things		45)	Spells of terror or panic	
19)	Feeling fearful		46)	Getting into frequent arguments	
20)	Your feelings being easily hurt		47)	Feeling nervous when you are left alone	
21)	Feeling that people are unfriendly and dislike you		48)	Others not giving you proper credit for achievements	
22)	Feeling inferior to others		49)	Feeling so restless you couldn't sit still	
23)	Nausea or upset stomach		50)	Feelings of worthlessness	
24)	Feeling that you are watched or talked about by others		51)	Feeling that people will take advantage of you...	
25)	Trouble falling asleep		52)	Feelings of guilt	
26)	Having to check and double-check what you do		53)	The idea that something is wrong with your mind	
27)	Difficulty making decisions			Source Completed By	

BRFSYMP v1

Protocol Number: NIDA-CTO-0010

Bupropion for Methamphetamine Dependence

Site Identification Number: 980202

Subject Identification Number: 0001

Study Day UNSCHD

Form Not Done ☐

Date: ______ (mm/dd/yyyy)

CHEMISTRIES

Analyte	Std. Quantity	Standard Unit	Other Unit	Normal	Abnormal	Abnormal Significant	Not Done
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Provide comments for any abnormal value(s)

Source Completed By (Initials):

CHEM v1

Protocol Number: NIDA-CTO-0010

Bupropion for Methamphetamine Dependence

Site Identification Number: 980202

Subject Identification Number: 0001

Study Day UNSCHD

Form Not Done ☐

Date: ______ (mm/dd/yyyy)

COGNITIVE BATTERY SUMMARY SCORE SHEET (CBS)

Am-NART SCORE ______

Rey O'Complex Figure

Copy Score: ______ Percentile: ______ Intrusions: ______

30 Min Delay: ______ Percentile: ______ Intrusions: ______

Wechsler Memory Scale

Faces Recognition I Score: ______ Percentile: ______

Faces Recognition II Score: ______ Percentile: ______

Spatial Span

Forward: ______ Backwards: ______

Total Score: ______ Percentile: ______

Letter Number Sequencing Total Score: ______ Percentile: ______

Logical Memory I

Recall Story A: ______ Recall Story B (1st): ______ Recall Story B (2nd): ______

Total Score: ______ Percentile: ______

Logical Memory II

Recall Story A: ______ Recall Story B: ______

Total Score: ______ Percentile: ______

Rey Auditory Verbal Learning Test

Trial I Score: ______ Percentile: ______

Trial 2: ______ Trial 3: ______ Trial 4: ______ Trial 5: ______ Trial 5 Percentile: ______

Trials 1-5 Total: ______ Percentile: ______

Short Delay Recall: ______ Percentile: ______

Long Delay Recall: ______ Percentile: ______

Recognition: ______ False positives: ______ Perseverations: ______ Intrusions: ______

Trailmaking Test

Trails A: ______ seconds Percentile: ______ Errors: ______

Trails B: ______ seconds Percentile: ______ Errors: ______

Color Trails

Trails A: ______ (seconds Percentile: ______ Errors: ______

Trails B: ______ (seconds Percentile: ______ Errors: ______

Symbol Digit Modalities Test Score: ______ Percentile: ______

Stroop Test

Word score: Color Score: Color Word Score: Interference:
Percentile: Percentile: Percentile: Percentile:

Verbal Fluency

F: A: S: Total Score: Percentile:

Figural Fluency

Trial 1: Preseverations:
Trial 2: Preseverations:
Trial 3: Preseverations:
Trial 4: Preseverations:
Trial 5: Preseverations:
Total Score: Preseverations: Percentile:

Source Completed By (Initials):

COGNBAT v1

Protocol Number: NIDA-CTO-0010

Bupropion for Methamphetamine Dependence

Study Day UNSCHD

Site Identification Number: 980202

Subject Identification Number: 0001

CONCOMITANT MEDICATIONS

Has the subject taken any Concomitant Medications during this study? ☐ Ye ☐ No *If yes, please list all below:*

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	UNK = unknown
	uL = microliter	TAB = tablet	QOD = every other day	REC = rectal	OTH = other, specify
	mg = milligram	UNK = unknown	PRN = as needed	VAG = vaginal	
	mL = milliliter	OTH = other, specify	OTH = other, specify	SQ = subcutaneous	
	OZ = ounce			SL = sublingual	

No.	Medication	Dose	Unit	Other (specify)	Frequency	Other (specify)
1						

Route	Other (specify)	Date Started (mm / dd / yyyy)	Date Stopped (mm / dd / yyyy)	Cont.?	Indication	Initials
				☐		

Protocol Number: NIDA-CTO-0010

Bupropion for Methamphetamine Dependence

Site Identification Number: 980202

Subject Identification Number: 0001

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-0010

Bupropion for Methamphetamine Dependence

Site Identification Number: 980202

Subject Identification Number: 0001

Study Day UNSCHD

Form Not Done ☐

Date: ____ (mm/dd/yyyy)

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, African American, or Negro
- ☐ 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:**

- ☐ 1 - Full time (35+ hours/week)
- ☐ 2 - Part time (regular hours)
- ☐ 3 - Part time (irregular hours, day work)
- ☐ 4 - Student
- ☐ 5 - Military Service
- ☐ 6 - Retired/Disabled
- ☐ 7 - Homemaker
- ☐ 8 - Unemployed
- ☐ 9 - In controlled environment

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

- ☐ 1 - Full time (35+ hours/week)
- ☐ 2 - Part time (regular hours)
- ☐ 3 - Part time (irregular hours, day work)
- ☐ 4 - Student
- ☐ 5 - Military Service
- ☐ 6 - Retired/Disabled
- ☐ 7 - Homemaker
- ☐ 8 - Unemployed
- ☐ 9 - In controlled environment

4) **Marital Status:**

- ☐ 1 - Legally married
- ☐ 2 - Living with partner/cohabitating
- ☐ 3 - Widowed
- ☐ 4 - Separated
- ☐ 5 - Divorced
- ☐ 6 - Never Married

DRUG/ALCOHOL USE

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

- ☐ 0 - No problem
- ☐ 1 - Alcohol (any)
- ☐ 2 - Alcohol to intoxication
- ☐ 3 - Heroin
- ☐ 4 - Methadone/LAAM (presc.)
- ☐ 5 - Methadone/LAAM (illicit)
- ☐ 6 - Opiates/analgesics
- ☐ 7 - Barbiturates
- ☐ 8 - Sed./hyp./tranq./benzos.
- ☐ 9 - Cocaine
- ☐ 10 - Amphetamines
- ☐ 11 - Methamphetamine
- ☐ 12 - Cannabis
- ☐ 13 - Hallucinogens
- ☐ 14 - Inhalants
- ☐ 15 - Nicotine
- ☐ 16 - Alcohol and Drug addictiion
- ☐ 17 - Polydrug addiction

Source Completed By (Initials): ______

DEMOG v1

Protocol Number: NIDA-CTO-0010

Bupropion for Methamphetamine Dependence

Site Identification Number: 980202

Subject Identification Number: 0014

Study Day UNSCHD

Form Not Done ☐

Date: ______ (mm/dd/yyyy)

DSCPTCFG (Day 9)

Hits: Count		**Mean RT**		ms
Misses: Count		**Mean RT**		ms
False Alarms: Count		**Mean RT**		ms

Sensitivity A: ______

Response Bias B: ______

Sensitivity D: ______

Cognitive Failures Questionnaire: ______

Source Completed By (Initials): ______

DSCPTCFG v1

Protocol Number: NIDA-CTO-0010

Bupropion for Methamphetamine Dependence

Site Identification Number: 980202

Subject Identification Number: 0001

Study Day UNSCHD

Form Not Done ☐

Date: ____ (mm/dd/yyyy)

ELECTROCARDIOGRAM 12-LEAD

A. ECG overall results were: ☐ **Normal** ☐ **Abnormal**

If ECG was normal, skip to question C; otherwise indicate if any result was ABNORMAL but does not exclude the subject from participation in the study, or ABNORMAL SIGNIFICANT and does preclude (continued) participation in the study.

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

C. Ventricular rate (bpm): ____

E. QRS (ms): ____

D. PR (ms): ____

F. QTc (ms): ____

Source Completed By ____

Protocol Number: NIDA-CTO-0010

Bupropion for Methamphetamine Dependence

Site Identification Number: 980202

Subject Identification Number: 0001

Study Day UNSCHD

END OF TRIAL

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

2) Was the subject terminated early from the trial? ☐ Yes ☐ No

Reason subject's participation has ended (Mark all that apply):

- ☐ Subject completed study.
- ☐ Subject was determined after enrollment to be ineligible. (Provide comments)
- ☐ Subject requested to withdraw. (Provide comments)
- ☐ Subject experienced an intercurrent illness, unrelated medical condition, or clinically significant adverse events which prompted early termination. (Complete AE form, provide comments)
- ☐ Subject terminated for administrative reasons. (Include protocol non-compliance in this category. Provide comments)
- ☐ Subject transferred to another treatment program (check all that apply)
  - ☐ Methadone ☐ Drug Free ☐ Inpatient Detox or Treatment
  - ☐ LAAM ☐ 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. (If subject died, a Death Report Case Report Form must be completed)
- ☐ Subject can no longer attend clinic.
- ☐ Subject no longer attends clinic.
- ☐ Subject is in a controlled environment.
- ☐ Subject is a screen failure
- ☐ Other (Provide comments)

Comments: ______

Source Completed By (Initials): ______

ENDTRIAL v1

Protocol Number: NIDA-CTO-0010

Bupropion for Methamphetamine Dependence

Site Identification Number: 980202

Subject Identification Number: 0001

Study Day UNSCHD

ENROLLMENT

Is subject eligible for participation based on the Eligibility Criteria? ☐ Yes ☐ No

If yes, was subject enrolled into the study? ☐ Yes ☐ No

If subject was enrolled in the study, date enrolled: ______ (mm/dd/yyyy)

If not enrolled, indicate reason
- ☐ failed to return to clinic
- ☐ declined study participation
- ☐ other, specify: ______

Source Completed By (Initials): ______

ENROLL v1

Protocol Number: NIDA-CTO-0010

Bupropion for Methamphetamine Dependence

Study Day UNSCHD

Site Identification Number: 980202

Subject Identification Number: 0001

Date: (mm/dd/yyyy)

EXCLUSION CRITERIA

Participant must not:

	Criterion	Response
1.	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
2.	Have a history of head trauma that resulted in neurological sequalae (e.g. loss of memory for greater than 5 minutes or that required hospitalization).	☐ Yes ☐ No
3.	Have physiological dependence on alcohol or a sedative-hypnotic (e.g. a benzodiazepine) that requires medical detoxification.	☐ Yes ☐ No
4.	Have any previous medically serious adverse reaction to methamphetamine, including loss of consciousness, chest pain or epileptic seizure resulting in hospitalization.	☐ Yes ☐ No
5.	Meet the diagnostic criteria for the following Axis I disorders: psychosis, bipolar I disorder, organic brain disease, dementia, major depression, schizoaffective disorder, or scizophrenia.	☐ Yes ☐ No
6.	Have any evidence of clinically significant heart disease, hypertension or significant medical illness.	☐ Yes ☐ No
7.	If female be pregnant or nursing.	☐ Yes ☐ No
8.	Have a significant family history of early cardiovascular morbidity or mortality.	☐ Yes ☐ No
9.	Have a diagnosis of adult asthma, including those with a history of acute asthma within the past two years, and those with current or recent (past 2 years) treatment with inhaled or oral beta-agonist or steroid therapy (due to potential serious adverse interactions with methamphetamine).	☐ Yes ☐ No
10.	Be actively using albuterol or other beta agonist medications, regardless of formal diagnosis of asthma. (Inhalers are sometimes used by methamphetamine addicts to enhance methamphetamine delivery to the lungs.) If respiratory disease is excluded and the subject will consent to discontinue agonist use, she/he may be considered for inclusion.	☐ Yes ☐ No
11.	For subjects suspect for asthma but without formal diagnosis, 1) have a history of coughing and/or wheezing, 2) have a history of asthma and/or asmtha treatment two or more years before, 3) have a history of other respiratory illness, e.g. complications of pulmonary disease (exclude if on beta agonists), 4) use over the counter agonist or allergy medication for respiratory problems, (e.g. Pimatene 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
12.	Have any illness, condition, and/or use of medications, in the opinion of the principal investigator and the admitting physician, which would preclude safe and/or successful completion of the study.	☐ Yes ☐ No
13.	Have active syphilis that has not been treated or refuse treatment for syphilis. (see note in protocol).	☐ Yes ☐ No
14.	Be undergoing HIV treatment with antiviral and non-antiviral therapy.	☐ Yes ☐ No
15.	Have AIDS according to the current CDC criteria for AIDS-MMWR 1999;48 (no.RR-13:29-31).	☐ Yes ☐ No

16. Have a current or past history of anorexia nervosa or bulimia disorder. ☐ Yes ☐ No

17. Have neurological disorder including Parkinson's disease. ☐ Yes ☐ No

18. Be using bupropion or any medication that could interact adversely with bupropion, within the following times of beginning administration of bupropion based on the longest time interval of A, B or C, below or as otherwise specified:
    A) Five half lives of other medication or active metabolite(s), whichever is longer
    B) Two weeks
    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. Antidepressants including monoamine oxidase (MAO) inhibitors
       (GlaxoSmithKlein recommends 14 days after stopping MAO inhibitors)
    c. Neuroleptics
    d. Psychotropics
    e. Systemic corticosteroids
    f. Xanthines, i.e., theophulline, theophilline sodium glycinate and aminophylline
    g. Nicotine replacement therapy for patients undergoing smoking cessation treatment
    h. Drugs that lower seizure threshold

☐ Yes ☐ No

Note: All answers to EXCLUSION CRITERIA must be NO.

Source Completed By (Initials): ______

EXCLUS v1

Protocol Number: NIDA-CTO-0010

Bupropion for Methamphetamine Dependence

Site Identification Number: 980202

Subject Identification Number: 0001

Study Day UNSCHD

Date: ____ (mm/dd/yyyy)

Form Not Done ☐

FOLLOW-UP COGNITIVE BATTERY SCORE SHEET

srt1:

mean reaction time ____

median reaction time ____

crt:

mean reaction time ____

median reaction time ____

1-back:

median reaction time ____

% accuracy ____

2-back:

median reaction time ____

% accuracy ____

srt2:

mean reaction time ____

median reaction time ____

Apathy Inventory ____

BPRS Total Score ____

Hillside Akathisia Scale Subjective ____

Hillside Akathisia Scale Objective ____

CGI ____

Young Mania Rating Scale ____

Schedule of Assessments of Negative Symptoms ____

Schedule of Assessments of Positive Symptoms ____

Source Completed By (Initials): ____

FCOGNBAT v1

Protocol Number: NIDA-CTO-0010

Bupropion for Methamphetamine Dependence

Site Identification Number: 980202

Subject Identification Number: 0001

Study Day UNSCHD

Form Not Done ☐

Date: ______ (mm/dd/yyyy)

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	
☐ Methamphetamine		☐ 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-0010	Site Identification Number: 980202
Bupropion for Methamphetamine Dependence	Subject Identification Number: 0001

Study Day UNSCHD

Form Not Done ☐

Date: (mm/dd/yyyy)

GENERAL CRAVING SCALE (GCS)

When I am experiencing a craving:

32. Other activities will satisfy my craving	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Source Completed By (Initials):

GENCRAV v1

Protocol Number: NIDA-CTO-0010

Bupropion for Methamphetamine Dependence

Site Identification Number: 980202

Subject Identification Number: 0001

Study Day UNSCHD

Form Not Done ☐

Date: (mm/dd/yyyy)

HEMATOLOGY

Complete Blood Count	Std. Quantity	Standard Unit	Other Unit	Normal	Abnormal	Abnormal Significant	Not Done
				☐	☐	☐	☐
				☐	☐	☐	☐
				☐	☐	☐	☐
				☐	☐	☐	☐
				☐	☐	☐	☐
				☐	☐	☐	☐
				☐	☐	☐	☐
				☐	☐	☐	☐
				☐	☐	☐	☐
				☐	☐	☐	☐
				☐	☐	☐	☐

Provide comments for any abnormal value(s)

Source Completed By (Initials):

HEMAT v1

Protocol Number: NIDA-CTO-0010

Bupropion for Methamphetamine Dependence

Site Identification Number: 980202

Subject Identification Number: 0001

Study Day UNSCHD

Form Not Done ☐

Date: ______ (mm/dd/yyyy)

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? ○ Ye ○ No ○ Unknown

Sex Score ______

HRBS Score ______

Source Completed By (Initials): ______

HRBS v1

Protocol Number: NIDA-CTO-0010	Site Identification Number:	980202
Bupropion for Methamphetamine Dependence	Subject Identification Number:	0001

Study Day UNSCHD

Date: (mm/dd/yyyy)

INCLUSION CRITERIA

Participant must:

	Criterion	Response
1.	Be volunteers who meet DSM-IV criteria for methamphetamine abuse or dependence and are non-treatment seeking at time of study.	☐ Yes ☐ No
2.	Be between 18 - 45 years of age.	☐ Yes ☐ No
3.	Be able to verbalize understanding of consent form, able to provide written informed consent, and verbalize willingness to complete study procedures.	☐ Yes ☐ No
4.	Use methamphetamine by the smoked or i.v. route on average at least twice per week for at least four of the past six weeks, as assessed by self report and a positive urine test during screening.	☐ Yes ☐ No
5.	Have a history and physical examination that demonstrate no clinically significant contraindication for participating in the study, in the judgement of the admitting physician and the site investigator.	☐ Yes ☐ No
6.	Have vital signs as follows: resting heart rate between 50 and 90 bpm, systolic BP below 150 mm Hg and diastolic below 90 mm Hg.	☐ Yes ☐ No
7.	Have electrolytes (Na, K, Cl, HCO3) and Hematocrit that is clinically normal (+/- 10% of laboratory limits).	☐ Yes ☐ No
8.	Have liver function tests (total bilirubin, ALT, AST and alkaline phosphatase) less than three times the upper limit of normal.	☐ Yes ☐ No
9.	Have kidney function tests (creatinine and BUN) less than twice the upper limit of normal.	☐ Yes ☐ No
10.	Have an EKG performed that demonstrates normal sinus rhythm, normal conduction, and no clinically significant arrhythmias.	☐ Yes ☐ No
11.	Be female and have a negative pregnancy test and agree to use one of the following methods of birth control, or be postmenopausal, have had a hysterectomy or have been sterilized, or be male. a. oral contraceptives b. barrier (diaphragm or condom) with spermicide or condom only c. intrauterine progesterone, or non-hormonal contraceptive system d. levonorgestrel implane e. medroxyprogesterone acetate contraceptive injection f. complete abstinence from sexual intercourse	☐ Yes ☐ No

Note: All answers to INCLUSION CRITERIA must be YES.

Source Completed By (Initials):

INCLUS v1

Protocol Number: NIDA-CTO-0010

Bupropion for Methamphetamine Dependence

Site Identification Number: 980202

Subject Identification Number: 0001

Study Day UNSCHD

Form Not Done ☐

Date: ____ (mm/dd/yyyy)

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-0010

Bupropion for Methamphetamine Dependence

Site Identification Number: 980202

Subject Identification Number: 0001

Study Day UNSCHD

Form Not Done ☐

INFUSION COLLECTION OF URINE SPECIMENS

Time Relative to Infusion	Sample #	Date	Study Day	Start Time	Stop Time

Source Completed By (Initials):

INFURINE v1

Protocol Number: NIDA-CTO-0010

Bupropion for Methamphetamine Dependence

Site Identification Number: 980202

Subject Identification Number: 0001

Study Day UNSCHD

Form Not Done ☐

Date: ________ (mm/dd/yyyy)

INFUSION MONITORING

Infusion Start Time: ________ (00:00 - 23:59)

Infusion Stop Time: ________ (00:00 - 23:59)

Infusion Administered By: ________ (Initials)

INFUSION v1

Protocol Number: NIDA-CTO-0010

Bupropion for Methamphetamine Dependence

Site Identification Number: 980202

Subject Identification Number: 0001

Study Day UNSCHD

Form Not Done ☐

INVESTIGATIONAL AGENT ADMINISTRATION

Line No.	Day of Week	Date	No. of Tablets Administered	Time Administered	Administered By

Source Completed By (Initials):

INVAGT v1

Protocol Number: NIDA-CTO-0010

Bupropion for Methamphetamine Dependence

Site Identification Number: 980202

Subject Identification Number: 0001

Study Day UNSCHD

Date: ______ (mm/dd/yyyy)

Form Not Done ☐

LAB TEST TRACKING FORM (DAY18 AND 19)

Time of Infusion	Methamphetamine Assay	Methamphetamine Time (00:00-23:59)	Bupropion Assay	Bupropion Time (00:00-23:59)
	☐		☐	
	☐		☐	
	☐		☐	
	☐		☐	
	☐		☐	
	☐		☐	
	☐		☐	
	☐		☐	
	☐		☐	
	☐		☐	
	☐		☐	
	☐		☐	
	☐		☐	
	☐		☐	
	☐		☐	
	☐		☐	

Source Completed By (Initials): ______

LABBUP v1

Protocol Number: NIDA-CTO-0010

Bupropion for Methamphetamine Dependence

Site Identification Number: 980202

Subject Identification Number: 0001

Study Day UNSCHD

Date: ______ (mm/dd/yyyy)

Form Not Done ☐

LAB TEST TRACKING FORM (DAY 5)

Time of Infusion	Methamphetamine Assay	Methamphetamine Time (00:00-23:59)
	☐	
	☐	
	☐	
	☐	
	☐	
	☐	
	☐	
	☐	
	☐	
	☐	
	☐	
	☐	
	☐	
	☐	
	☐	
	☐	
	☐	
	☐	

Source Completed By (Initials): ______

LABDAY5 v1

Protocol Number: NIDA-CTO-0010

Bupropion for Methamphetamine Dependence

Site Identification Number: 980202

Subject Identification Number: 0001

Study Day UNSCHD

Date: (mm/dd/yyyy)

Form Not Done ☐

LAB TEST TRACKING FORM (DAY 22)

Time of Infusion	Methamphetamine Assay	Methamphetamine Time (00:00-23:59)	Bupropion Assay	Bupropion Time (00:00-23:59)
	☐		☐	
	☐		☐	
	☐		☐	
	☐		☐	
	☐		☐	
	☐		☐	
	☐		☐	
	☐		☐	
	☐		☐	
	☐		☐	
	☐		☐	
	☐		☐	
	☐		☐	
	☐		☐	
	☐		☐	
	☐		☐	
	☐		☐	

Source Completed By (Initials):

LABDAY22 v1

Protocol Number: NIDA-CTO-0010

Bupropion for Methamphetamine Dependence

Site Identification Number: 980202

Subject Identification Number: 0001

Study Day UNSCHD

Date: (mm/dd/yyyy)

Form Not Done ☐

LAB TEST TRACKING FORM (DAY 2 AND DAY 3)

Time of Infusion	Methamphetamine Assay	Methamphetamine Time (00:00-23:59)
	☐	
	☐	
	☐	
	☐	
	☐	
	☐	
	☐	
	☐	
	☐	
	☐	
	☐	
	☐	
	☐	
	☐	

Source Completed By (Initials):

LABMETH v1

Protocol Number: NIDA-CTO-0010

Bupropion for Methamphetamine Dependence

Site Identification Number: 980202

Subject Identification Number: 0001

Study Day UNSCHD

Date: ____ (mm/dd/yyyy)

Form Not Done ☐

Please select appropriate study day: ☐ Day -3 ☐ Day -2 ☐ Day -1

LAB TEST TRACKING FORM (SCREENING)

Time	Methamphetamine Assay	Actual Time (00:00-23:59)
8 AM	☐	
8 PM	☐	

Source Completed By (Initials): ____

LABSCRN v1

Protocol Number: NIDA-CTO-0010

Bupropion for Methamphetamine Dependence

Site Identification Number: 980202

Subject Identification Number: 0001

Study Day UNSCHD

Form Not Done ☐

Date: (mm/dd/yyyy)

MULTIPLE CHOICE QUESTIONNAIRE

Time Administered (00:00-23:59)

Highest monetary value at which drug was preferred to money:

Source Completed By (Initials):

MCQ v1

Protocol Number: NIDA-CTO-0010

Bupropion for Methamphetamine Dependence

Site Identification Number: 980202

Subject Identification Number: 0001

Study Day UNSCHD

Form Not Done ☐

Date: (mm/dd/yyyy)

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? ☐ Ye ☐ No

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

COMMENTS

______

Source Completed By (Initials): ______

MEDHIST v1

Protocol Number: NIDA-CTO-0010

Bupropion for Methamphetamine Dependence

Site Identification Number: 980202

Subject Identification Number: 0001

Study Day UNSCHD

Form Not Done ☐

METHAMPHETAMINE TIMELINE FOLLOW BACK

Today's Date: ________ (mm/dd/yyyy)

Date 42 Days Prior to today's date: ________ (mm/dd/yyyy)

Day 27	Ye	No

Source Completed By (Initials):

METHTIME v1

Protocol Number: NIDA-CTO-0010

Bupropion for Methamphetamine Dependence

Site Identification Number: 980202

Subject Identification Number: 0001

Study Day UNSCHD

Form Not Done ☐

Date: ______ (mm/dd/yyyy)

MODIFIED WITHIN SESSION RATING SCALE (MWSRS)

Time (24 hr)

______ (00:00-23:59)

(1) How much do you desire or feel like using methamphetamine/cocaine right now?

0 10 20 30 40 50 60 70 80 90 100

☐ ☐

Not at all — Extremely

(2) If you had access to methamphetamine/cocaine right now, how likely would you be to use it?

0 10 20 30 40 50 60 70 80 90 100

☐ ☐

Not at all — Extremely

(3) I feel disgusted by the video and paraphernalia.

0 10 20 30 40 50 60 70 80 90 100

☐ ☐

Not at all — Extremely

(4) Please rate the effect of the medication you have taken today

In the past ten minutes, have you felt:

Not at all — Extremely

	0		10		20		30		40		50		60		70		80		90		100
Any drug effect?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
A rush?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Good effects?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Bad effects?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Did you like the drugs?	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Source Completed By (Initials): ______

Protocol Number: NIDA-CTO-0010

Bupropion for Methamphetamine Dependence

Site Identification Number: 980202

Subject Identification Number: 0001

Study Day: UNSCHD

Form Not Done ☐

Date: ______ (mm/dd/yyyy)

PHYSICAL EXAMINATION

Height: ______ ☐ inches ☐ centimeters

Weight: ______ ☐ pounds ☐ kilograms

General Exam	Normal	Abnormal	Abnormal Significant	Not Done	If Abnormal, explain below
Oral (mouth)	☐	☐	☐	☐	
Head and Neck	☐	☐	☐	☐	
EENT	☐	☐	☐	☐	
Cardiovascular	☐	☐	☐	☐	
Chest	☐	☐	☐	☐	
Lungs	☐	☐	☐	☐	
Abdomen (include liver/spleen)	☐	☐	☐	☐	
Extremities	☐	☐	☐	☐	
Skin, Hair, Nails	☐	☐	☐	☐	
Neuropsychiatric mental status	☐	☐	☐	☐	
Neuropsychiatric sensory/motor	☐	☐	☐	☐	
Musculoskeletal	☐	☐	☐	☐	
General Appearance	☐	☐	☐	☐	
Rectal	☐	☐	☐	☐	
Prostate	☐	☐	☐	☐	
Breast	☐	☐	☐	☐	
Lymph	☐	☐	☐	☐	
Genital	☐	☐	☐	☐	
Pelvic	☐	☐	☐	☐	
Forced Expiratory Volume (FEV1) ______ (%)	☐	☐	☐	☐	
Other *(specify)* ______	☐	☐	☐	☐	
Other *(specify)* ______	☐	☐	☐	☐	

Source Completed By (Initials): ______

PHYSEXAM v1

Protocol Number: NIDA-CTO-0010

Bupropion for Methamphetamine Dependence

Site Identification Number: 980202

Subject Identification Number: 0001

Study Day UNSCHD

Form Not Done ☐

Date: (mm/dd/yyyy)

PROFILE OF MOOD STATES (POMS)

How have you been feeling during the past week including today?

31. Annoyed	0	1	2	3	4

Source Completed By (Initials):

POMS v1

Protocol Number: NIDA-CTO-0010

Bupropion for Methamphetamine Dependence

Study Day UNSCHD

Site Identification Number: 980202

Subject Identification Number: 0001

Form Not Done ☐

Date: (mm/dd/yyyy)

PREGNANCY

Was a pregnancy test performed? ○ Yes ○ No IF Yes, type: ○ Urine ○ Serum

(If no, skip to birth control method)

Pregnancy test result:
- ○ Positive
- ○ Negative
- ○ Unknown
- ○ Not applicable, subject is male

Pregnancy test comments:

Is the subject lactating? ○ Yes ○ No ○ Not Applicable

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

What method of birth control is the subject using?
- ○ oral contraceptives ("The Pill")
- ○ barrier (diaphragm or condom) with spermicide
- ○ intrauterine progesterone contraceptive (IUD)
- ○ lovenorgestrel implant (Norplant)
- ○ medroxyprogesterone acetate contraceptive injection
- ○ surgical sterilization
- ○ complete abstinence from sexual intercourse
- ○ same sex partner

Source Completed By (Initials):

PREGNANT v1

Protocol Number: NIDA-CTO-0010

Bupropion for Methamphetamine Dependence

Study Day: UNSCHD

Site Identification Number: 980202

Subject Identification Number: 0001

PRIOR MEDICATIONS

Has the subject taken any medications in the PAST 30 DAYS? ☐ Ye ☐ No *If yes, please list all below:*

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	UNK = unknown
	uL = microliter	TAB = tablet	QOD = every other day	REC = rectal	OTH = other, specify
	mg = milligram	UNK = unknown	PRN = as needed	VAG = vaginal	
	mL = milliliter	OTH = other, specify	OTH = other, specify	SQ = subcutaneous	
	OZ = ounce			SL = sublingual	

☐

PRIORMED v1

Protocol Number: NIDA-CTO-0010

Bupropion for Methamphetamine Dependence

Site Identification Number: 980202

Subject Identification Number: 0001

Study Day UNSCHD

Form Not Done ☐

Date: ________ (mm/dd/yyyy)

QUANTITY AND FREQUENCY DRUG HISTORY (QFI)

#	Drug Class	Ever Used	Types Used	When Last Used	Life Use Total	Main Type	Usual Route	# Days use Past 7	# Days use Past 30	Estimate Quantity Freq.	Duration of Pattern	Typical Freq.	Age First Began	Age Last Used	Patient Problem Y or N?	Heaviest Lifetime Pattern: Usual route	Heaviest Lifetime Pattern: Estimate Quan./Freq.	Heaviest Lifetime Pattern: Duration of pattern
		○ ○				○ ○												

Source Completed By (Initials): ________

QFI v1

Protocol Number: NIDA-CTO-0010

Bupropion for Methamphetamine Dependence

Site Identification Number: 980202

Subject Identification Number: 0001

Study Day: UNSCHD

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 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 Case Report Form must be completed.

☐ death
☐ life-threatening event
☐ hospitalization
☐ disability
☐ congenital anomaly
☐ 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) ☐ 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:

Protocol Number: NIDA-CTO-0010

Bupropion for Methamphetamine Dependence

Site Identification Number: 980202

Subject Identification Number: 0001

Study Day UNSCHD

Form Not Done ☐

Date: (mm/dd/yyyy)

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-0010

Bupropion for Methamphetamine Dependence

Site Identification Number: 980202

Subject Identification Number: 0001

Study Day UNSCHD

Form Not Done ☐

Date: ______ (mm/dd/yyyy)

COGNITIVE BATTERY SUBSET SCORE SHEET

Spatial Span

Forward: ______ Backwards: ______

Total Score: ______ Percentile: ______

Letter Number Sequencing Total Score: ______ Percentile: ______

Rey Auditory Verbal Learning Test

Trial I Score: ______ Percentile: ______

Trial 2: ______ Trial 3: ______ Trial 4: ______ Trial 5: ______ Trial 5 Percentile: ______

Trials 1-5 Total: ______ Percentile: ______

Short Delay Recall: ______ Percentile: ______

Long Delay Recall: ______ Percentile: ______

Recognition: ______ False positives: ______ Perseverations: ______ Intrusions: ______

Trailmaking Test

Trails A: ______ seconds Percentile: ______ Errors: ______

Trails B: ______ seconds Percentile: ______ Errors: ______

Symbol Digit Modalities Test Score: ______ Percentile: ______

Stroop Test

Word score: ______ Color Score: ______ Color Word Score: ______ Interference: ______

Percentile: ______ Percentile: ______ Percentile: ______ Percentile: ______

Verbal Fluency

F: ______ A: ______ S: ______ Total Score: ______ Percentile: ______

Figural Fluency

Trial 1: ______ Preseverations: ______

Trial 2: ______ Preseverations: ______

Trial 3: ______ Preseverations: ______

Trial 4: ______ Preseverations: ______

Trial 5: ______ Preseverations: ______

Total Score: ______ Preseverations: ______ Percentile: ______

Source Completed By (Initials): ______

SCOGNBAT v1

Protocol Number: NIDA-CTO-0010

Bupropion for Methamphetamine Dependence

Site Identification Number: 980202

Subject Identification Number: 0001

Study Day UNSCHD

Form Not Done ☐

SCREENING COLLECTION OF URINE SPECIMENS

Time	Sample #	Date	Study Day	Start Time	Stop Time

Source Completed By (Initials):

SCRURINE v1

Protocol Number: NIDA-CTO-0010

Bupropion for Methamphetamine Dependence

Site Identification Number: 980202

Subject Identification Number: 0001

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-0010

Bupropion for Methamphetamine Dependence

Site Identification Number: 980202

Subject Identification Number: 0014

Study Day DAY18

Form Not Done ☐

Date: ____ (mm/dd/yyyy)

VISUAL ANALOG SCALE (Days 2,3,18, and 19)

Time Interval	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?
-25 Minutes						

Time Interval	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
10 Minutes Post	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?

Time Interval	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
180 Minutes Post						
	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?

Source Completed By (Initials):

VAS4DAYS v1

Protocol Number: NIDA-CTO-0010

Bupropion for Methamphetamine Dependence

Site Identification Number: 980202

Subject Identification Number: 0014

Study Day DAY1

Form Not Done ☐

Date: ________ (mm/dd/yyyy)

VISUAL ANALOG SCALE (Day 1)

Time Interval						
	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
-25 Minutes	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?

Time Interval	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
15 Minutes Post						
	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?

Source Completed By (Initials):

VASDAY1 v1

Protocol Number: NIDA-CTO-0010

Bupropion for Methamphetamine Dependence

Site Identification Number: 980202

Subject Identification Number: 0001

Study Day UNSCHD

Form Not Done ☐

Date: (mm/dd/yyyy)

VISUAL ANALOG SCALE

Time Interval	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?
-15 Minutes						

Time Interval	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
30 Minutes Post	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?

Time Interval	Actual Time (00:00 - 23:59)	Any drug Effect?	High?	Good Effects?	Bad Effects?	Liking?
300 Minutes Post	Desire for Drug?	Depressed?	Anxious?	Stimulated?	Likely to Use?	Pay for Drug?

Source Completed By (Initials):

VISLANA1 v1

Protocol Number: NIDA-CTO-0010

Bupropion for Methamphetamine Dependence

Site Identification Number: 980202

Subject Identification Number: 0001

Study Day UNSCHD

Form Not Done ☐

Date: ______ (mm/dd/yyyy)

VITAL SIGNS RECORD

Line No.	Time (00:00 - 23:59)	Temp (oral) Fahrenheit or Celcius	Sitting Resp. Rate (Breaths/Min)	Sitting Blood Pressure (systolic) / (diastolic)	Sitting Heart Rate (Beats/Min)	Comp.By: (Initials)
		☐ ☐		/		

VITALS v1

Protocol Number: NIDA-CTO-0010

Bupropion for Methamphetamine Dependence

Site Identification Number: 980202

Subject Identification Number: 0014

Study Day DAY1

Form Not Done ☐

Date: (mm/dd/yyyy)

VITAL SIGNS RECORD (Day 1)

Time Point (Minutes)	Actual Time (00:00 - 23:59)	Temp (oral) Fahrenheit or Celcius	Sitting Resp. Rate (Breaths/Min)	Sitting Blood Pressure (systolic) / (diastolic)		Sitting Heart Rate (Beats/Min)	Comp.By: (Initials)
		☐ ☐					
		☐ ☐					
		☐ ☐					
		☐ ☐					
		☐ ☐					
		☐ ☐					
		☐ ☐					
		☐ ☐					
		☐ ☐					

VITALS1 v1

Protocol Number: NIDA-CTO-0010

Bupropion for Methamphetamine Dependence

Site Identification Number: 980202

Subject Identification Number: 0001

Study Day UNSCHD

Form Not Done ☐

Date: ____ (mm/dd/yyyy)

WITHIN SESSION RATING SCALE (WSRS)

Time (24 hr)

____ (00:00-23:59)

(1) **How much do you desire or feel like using methamphetamine/cocaine right now?**

0 10 20 30 40 50 60 70 80 90 100

☐ ☐

Not at all **Extremely**

(2) **If you had access to methamphetamine/cocaine right now, how likely would you be to use it?**

0 10 20 30 40 50 60 70 80 90 100

☐ ☐

Not at all **Extremely**

Source Completed By (Initials): ____

WSRS v1