Form 07 - 12-Lead ECG Results

Study025 **Plate008** **V401 (Screening #1)**

ID# ☐☐☐ ☐☐☐☐ ☐☐☐☐
Center No. **Subject ID No.** **Alpha Code**

Date of Assessment ☐☐ ☐☐ ☐☐ ☐☐
month *day* *year* **Week**

Form 07 - 12-Lead ECG Results

*Study staff, complete this form for every 12-lead ECG done throughout the study.

*Perform an ECG at screening and at week 12, or termination visit, if earlier.

Please indicate if the ECG results on this form are for: ☐ *Scheduled ECG* ☐ *Repeat ECG*

1. ECG overall results were: ☐ *Normal* ☐ *Abnormal, does not exclude*
2. If ECG is abnormal, CHECK ALL that apply below:

a. ☐ *Increased QRS voltage*
b. ☐ *Qt_c prolongation*
c. ☐ *Left ventricular hypertrophy*
d. ☐ *Right ventricular hypertrophy*
e. ☐ *Acute infarction*
f. ☐ *Right bundle branch block*
g. ☐ *Left bundle branch block*
h. ☐ *Old infarction*
i. ☐ *Myocardial ischemia*
j. ☐ *Symmetrical t-wave inversions*
k. ☐ *Poor R-wave progression*
l. ☐ *Other nonspecific ST/T*
m. ☐ *Sinus tachycardia*
n. ☐ *Sinus bradycardia*
o. ☐ *Supraventricular premature beat*
p. ☐ *Ventricular premature beat*
q. ☐ *Supraventricular tachycardia*
r. ☐ *Ventricular tachycardia*
s. ☐ *1st degree A-V block*
y. ☐ *2nd degree A-V block*
u. ☐ *3rd degree A-V block*
v. ☐ *Other, specify:* _____
w. ☐ *Other, specify:* _____

3. Ventricular rate ☐☐☐ *bpm*
4. PR ☐☐☐ *ms*
5. QRS ☐☐☐ *ms*
6. QT ☐☐☐ *ms*
7. QT_c ☐☐☐ *ms*

month *day* *year*

ECG read by: _____ **Date Read** ☐☐ ☐☐ ☐☐

Form completed by: _____ **Date** ☐☐ ☐☐ ☐☐

Physician's Signature: _____ **Date** ☐☐ ☐☐ ☐☐

Form 07 - 12-Lead ECG Results

Study025 **Plate008** **V402 (Additional - #2)**

ID# ☐☐☐ ☐☐☐☐ ☐☐☐☐ **Date of Assessment** ☐☐ ☐☐ ☐☐ ☐☐

Center No. **Subject ID No.** **Alpha Code** *month* *day* *year* **Week**

Form 07 - 12-Lead ECG Results

*Study staff, complete this form for every 12-lead ECG done throughout the study.

*Perform an ECG at screening and at week 12, or termination visit, if earlier.

Please indicate if the ECG results on this form are for: ☐ *Scheduled ECG* ☐ *Repeat ECG*

1. ECG overall results were: ☐ *Normal* ☐ *Abnormal, does not exclude*
2. If ECG is abnormal, CHECK ALL that apply below:

a. ☐ *Increased QRS voltage*
b. ☐ *Qt_c prolongation*
c. ☐ *Left ventricular hypertrophy*
d. ☐ *Right ventricular hypertrophy*
e. ☐ *Acute infarction*
f. ☐ *Right bundle branch block*
g. ☐ *Left bundle branch block*
h. ☐ *Old infarction*
i. ☐ *Myocardial ischemia*
j. ☐ *Symmetrical t-wave inversions*
k. ☐ *Poor R-wave progression*
l. ☐ *Other nonspecific ST/T*
m. ☐ *Sinus tachycardia*
n. ☐ *Sinus bradycardia*
o. ☐ *Supraventricular premature beat*
p. ☐ *Ventricular premature beat*
q. ☐ *Supraventricular tachycardia*
r. ☐ *Ventricular tachycardia*
s. ☐ *1st degree A-V block*
y. ☐ *2nd degree A-V block*
u. ☐ *3rd degree A-V block*
v. ☐ *Other, specify:* _____
w. ☐ *Other, specify:* _____

3. Ventricular rate ☐☐☐ *bpm*
4. PR ☐☐☐ *ms*
5. QRS ☐☐☐ *ms*
6. QT ☐☐☐ *ms*
7. QT_c ☐☐☐ *ms*

month *day* *year*

ECG read by: _____ **Date Read** ☐☐ ☐☐ ☐☐

Form completed by: _____ **Date** ☐☐ ☐☐ ☐☐

Physician's Signature: _____ **Date** ☐☐ ☐☐ ☐☐

Form 07 - 12-Lead ECG Results

Study025 **Plate008** **V403 ((Additional - #3)**

ID# ☐☐☐ ☐☐☐☐ ☐☐☐☐
Center No. **Subject ID No.** **Alpha Code**

Date of Assessment ☐☐ ☐☐ ☐☐ ☐☐
month *day* *year* **Week**

Form 07 - 12-Lead ECG Results

*Study staff, complete this form for every 12-lead ECG done throughout the study.

*Perform an ECG at screening and at week 12, or termination visit, if earlier.

Please indicate if the ECG results on this form are for: ☐ *Scheduled ECG* ☐ *Repeat ECG*

1. ECG overall results were: ☐ *Normal* ☐ *Abnormal, does not exclude*
2. If ECG is abnormal, CHECK ALL that apply below:

a. ☐ *Increased QRS voltage*
b. ☐ *Qt_c prolongation*
c. ☐ *Left ventricular hypertrophy*
d. ☐ *Right ventricular hypertrophy*
e. ☐ *Acute infarction*
f. ☐ *Right bundle branch block*
g. ☐ *Left bundle branch block*
h. ☐ *Old infarction*
i. ☐ *Myocardial ischemia*
j. ☐ *Symmetrical t-wave inversions*
k. ☐ *Poor R-wave progression*
l. ☐ *Other nonspecific ST/T*
m. ☐ *Sinus tachycardia*
n. ☐ *Sinus bradycardia*
o. ☐ *Supraventricular premature beat*
p. ☐ *Ventricular premature beat*
q. ☐ *Supraventricular tachycardia*
r. ☐ *Ventricular tachycardia*
s. ☐ *1st degree A-V block*
y. ☐ *2nd degree A-V block*
u. ☐ *3rd degree A-V block*
v. ☐ *Other, specify:* _____
w. ☐ *Other, specify:* _____

3. Ventricular rate ☐☐☐ *bpm*
4. PR ☐☐☐ *ms*
5. QRS ☐☐☐ *ms*
6. QT ☐☐☐ *ms*
7. QT_c ☐☐☐ *ms*

month *day* *year*

ECG read by: _____ **Date Read** ☐☐ ☐☐ ☐☐

Form completed by: _____ **Date** ☐☐ ☐☐ ☐☐

Physician's Signature: _____ **Date** ☐☐ ☐☐ ☐☐

Form 07 - 12-Lead ECG Results

Study025 **Plate008** **V404 (Additional - #4)**

ID# ☐☐☐ ☐☐☐☐ ☐☐☐☐
Center No. **Subject ID No.** **Alpha Code**

Date of Assessment ☐☐ ☐☐ ☐☐ ☐☐
month *day* *year* **Week**

Form 07 - 12-Lead ECG Results

*Study staff, complete this form for every 12-lead ECG done throughout the study.

*Perform an ECG at screening and at week 12, or termination visit, if earlier.

Please indicate if the ECG results on this form are for: ☐ *Scheduled ECG* ☐ *Repeat ECG*

1. ECG overall results were: ☐ *Normal* ☐ *Abnormal, does not exclude*
2. If ECG is abnormal, CHECK ALL that apply below:

a. ☐ *Increased QRS voltage*
b. ☐ *Qt_c prolongation*
c. ☐ *Left ventricular hypertrophy*
d. ☐ *Right ventricular hypertrophy*
e. ☐ *Acute infarction*
f. ☐ *Right bundle branch block*
g. ☐ *Left bundle branch block*
h. ☐ *Old infarction*
i. ☐ *Myocardial ischemia*
j. ☐ *Symmetrical t-wave inversions*
k. ☐ *Poor R-wave progression*
l. ☐ *Other nonspecific ST/T*
m. ☐ *Sinus tachycardia*
n. ☐ *Sinus bradycardia*
o. ☐ *Supraventricular premature beat*
p. ☐ *Ventricular premature beat*
q. ☐ *Supraventricular tachycardia*
r. ☐ *Ventricular tachycardia*
s. ☐ *1st degree A-V block*
y. ☐ *2nd degree A-V block*
u. ☐ *3rd degree A-V block*
v. ☐ *Other, specify:* _____
w. ☐ *Other, specify:* _____

3. Ventricular rate ☐☐☐ *bpm*
4. PR ☐☐☐ *ms*
5. QRS ☐☐☐ *ms*
6. QT ☐☐☐ *ms*
7. QT_c ☐☐☐ *ms*

ECG read by: _____ **Date Read** *month* ☐☐ *day* ☐☐ *year* ☐☐

Form completed by: _____ **Date** ☐☐ ☐☐ ☐☐

Physician's Signature: _____ **Date** ☐☐ ☐☐ ☐☐

Form 07 - 12-Lead ECG Results

Study025 **Plate008** **V405 (Additional - #5)**

ID# ___ ___ ___ (**Center No.**) ___ ___ ___ ___ (**Subject ID No.**) ___ ___ ___ ___ (**Alpha Code**)

Date of Assessment ___ ___ *month* ___ ___ *day* ___ ___ *year* ___ ___ **Week**

Form 07 - 12-Lead ECG Results

*Study staff, complete this form for every 12-lead ECG done throughout the study.

*Perform an ECG at screening and at week 12, or termination visit, if earlier.

Please indicate if the ECG results on this form are for: ☐ *Scheduled ECG* ☐ *Repeat ECG*

1. ECG overall results were: ☐ *Normal* ☐ *Abnormal, does not exclude*
2. If ECG is abnormal, CHECK ALL that apply below:

a. ☐ *Increased QRS voltage*
b. ☐ *Qt_c prolongation*
c. ☐ *Left ventricular hypertrophy*
d. ☐ *Right ventricular hypertrophy*
e. ☐ *Acute infarction*
f. ☐ *Right bundle branch block*
g. ☐ *Left bundle branch block*
h. ☐ *Old infarction*
i. ☐ *Myocardial ischemia*
j. ☐ *Symmetrical t-wave inversions*
k. ☐ *Poor R-wave progression*
l. ☐ *Other nonspecific ST/T*
m. ☐ *Sinus tachycardia*
n. ☐ *Sinus bradycardia*
o. ☐ *Supraventricular premature beat*
p. ☐ *Ventricular premature beat*
q. ☐ *Supraventricular tachycardia*
r. ☐ *Ventricular tachycardia*
s. ☐ *1st degree A-V block*
y. ☐ *2nd degree A-V block*
u. ☐ *3rd degree A-V block*
v. ☐ *Other, specify:* _____
w. ☐ *Other, specify:* _____

3. Ventricular rate ___ ___ ___ *bpm*
4. PR ___ ___ ___ *ms*
5. QRS ___ ___ ___ *ms*
6. QT ___ ___ ___ *ms*
7. QT_c ___ ___ ___ *ms*

ECG read by: _____ **Date Read** *month* ___ ___ *day* ___ ___ *year* ___ ___

Form completed by: _____ **Date** ___ ___ ___ ___ ___ ___

Physician's Signature: _____ **Date** ___ ___ ___ ___ ___ ___

Thomas McLellan, Ph.D.
John Cacciola, Ph.D.
Deni Carise, Ph.D.
Thomas H. Coyne, MSW

Remember: This is an interview, not a test

Item number circled are to be asked at follow-up.
Items with an asterisk are cumulative and should be rephrased at follow-up.*
CONFIDENCE RATINGS questions are for the interviewer. Do not ask these questions to the client.

INTRODUCING THE ASI: Seven potential problem areas: Medical, Employment/Support Status, Alcohol, Drug, Legal, Family/Social, and Psychological. All clients receive this same standard interview. All information gathered is confidential.
There are two time periods we will discuss:
1. The past 30 days
2. Lifetime Data

Patient Rating Scale: Patient input is important. For each area, I will ask you to use this scale to let me know how bothered you have been by any problems in each section. I will also ask you how important treatment is for you for the area being discussed.

The scale is:
0 - Not at all
1 - Slightly
2 - Moderately
3 - Considerably
4 - Extremely

If you are uncomfortable giving an answer, then don't answer.
Please do not give an inaccurate information!

INTERVIEWER INSTRUCTIONS:

1. Leave no blanks.
2. Make plenty of comments (if another person reads this ASI, they should have a relatively complete picture of the client's perceptions of his/her problems).
3. X = Question not answered
   N = Question not applicable
4. Terminate interview if client misrepresents two or more sections.
5. When noting comments, please write the question number.
6. Tutorial/clarification notes are preceded with a "•"

HALF TIME RULE: If a question asks the number of months, round up periods of 14 days or more to 1 month. Round up 6 months or more to 1 year.

CONFIDENCE RATINGS:
→ Last two items in each section.
→ Do not over interpret.
→ Denial does not warrant misrepresentation.
→ Misrepresentation = overt contradiction in information.

Probe and make plenty of comments!

HOLLINGSHEAD CATEGORIES:

1. Higher execs, major professionals, owner of large businesses.
2. Business managers if medium sized businesses, lesser professions, i.e., nurses, opticians, pharmacists, social workers, teachers.
3. Administrative personnel, managers, minor professionals, owners/proprietors of small businesses, i.e., bakery, car dealership, engraving business, plumbing business, florist, decorator, actor, reporter, travel agent.
4. Clerical and sales, technicians, small businesses (bank teller, bookkeeper, clerk, tradesman, timekeeper, secretary).
5. Skilled manual - usually having had training (baker, barber, brakeman, chef, electrician, fireman, lineman, machinist, mechanic, paper-hanger, painter, repairman, tailor, welder, policeman, plumber).
6. Semi-skilled (hospital aide, painter, bartender, bus driver, cutter, cook, drill press, garage guard, checker, waiter, sport welder, machine operator).
7. Unskilled (attendant, janitor, construction helper, unspecified labor, porter, including unemployed).
8. Homemaker.
9. Student, disabled, no occupation.

LIST OF COMMONLY USED DRUGS:

Alcohol:	Beer, wine, liquor
Methadone:	Dolophine, LAAM
Opiates:	Pain killers = Morphine, Dilaudid, Demerol, Percocet, Darvon, Talwin, Codeine, Tylenol 2, 3, 4, Syrups = Robitussin, Fentanyl
Barbiturates:	Nembutal, Seconal, Tuinol, Amytal, Pentobarbital, Secobarbital, Phenobarbital, Fiorinol
Sed/Hyp/Tranq:	Benzodiazepines = Valium, Librium, Ativan, Serax, Tranxene, Dalmane, Halcion, Xanax, Miltown, Other = ChloralHydrate (Noctex), Quaaludes
Cocaine:	Cocaine Crystal, Free-Base Cocaine or “Crack” and “Rock Cocaine”
Amphetamines:	Monster, Crank, Benzedrine, Dexedrine, Ritalin, Preludin, Methamphetamine, Speed, Ice, Crystal
Cannabis:	Marijuana, Hashish
Hallucinogens:	LSD (Acid), Mescaline, Mushrooms (Psilocybin), Peyote, Green, PCP (Phencyclidine), Angel Dust, Exstacy
Inhalants:	Nitrous Oxide, Amyl Nitrate (Whippits, Poppers), Glue, Solvents, Gasoline, Toluene, etc.
Just note if these are used:	Antidepressants, Ulcer Meds = Zantac, Tagamet Asthma Meds = Ventoline Inhaler, Theodur Other Meds = Antipsychotics, Lithium

ALCOHOL/DRUG USE INSTRUCTIONS:

The following questions look at two time periods: The past 30 days and lifetime. Lifetime refers to the time prior to the last 30 days. However, if the client has been incarcerated for more than 1 year, you would only gather lifetime information, unless the client admits to significant alcohol/drug use during incarceration. This guideline only applied to the Alcohol/Drug Section.

- 30 day questions only require the number of days used.
- Lifetime use is asked to determine extended periods of use.
- Regular use = 3+ times per week, binges, or problematic irregular use in which normal activities are compromised.
- Alcohol to intoxication does not necessarily mean “drunk”, use the words felt the effects, “got a buzz”, “high”, etc. instead of intoxication. As a rule of thumb, 5+ drinks in one setting, or within a brief period of time defines “intoxication”.
- How to ask these questions:
- How many days in the past 30 have you used.....?
- How many years in your life have you regularly used ....?

Form 13 - Addiction Severity Index Lite (ASI)

Study025 **Plate024** **V004 (Baseline)**

ID# | | | | | | | | | | | | | **Date** | | | | | | | | |

Center No. **Subject ID No.** **Alpha Code** *month* *day* *year*

Addiction Severity Index Lite (ASI)

Comments
(Include question number with your notes.)

G18. Do you have a religious preference? in the past 30 days? ☐

1 = Protestant 3 = Jewish 5 = Other
2 = Catholic 4 = Islamic 6 = None

G19. Have you been in a controlled environment in the past 30 days? ☐

1 = No 4 = Medical treatment 6 = Other: _____
2 = Jail 5 = Psychiatric treatment
3 = Alcohol/Drug treatment
•A place, theoretically, without access to drugs/alcohol

G20. How many days? ☐☐

•"NN" if Question G19 is No. Refers to total.

MEDICAL STATUS

M1. *How many times in your life have you been hospitalized for medical problems? ☐☐

•Include O.D.'s and D.T.'s.
°Exclude detox, alcohol/drug, psychiatric treatment and childbirth (if no complications).
°Enter the number of ***overnight*** hospitalizations for medical problems.

M3. Do you have any chronic medical problems which continue to interfere with your life? ☐

0 = No 1 = Yes
•***If Yes, specify in comments.***
•A chronic medical condition is a serious physical condition that requires regular care, (i.e., medication, dietary restriction) preventing full advantage of their abilities.

Medical Status Comments
(Include question number with your notes.)

M4. Are you taking any prescribed medication on a regular basis for a physical problem? ☐

0 = No 1 = Yes
•***If Yes, specify in comments.***
•Medication prescribed by a MD for medical conditions; ***not psychiatric medicines.*** Include medicines prescribed whether or not the patient is currently taking them. The intent is to verify chronic medical problems.

M5. Do you receive a pension for a physical disability? ☐

0 = No 1 = Yes
•***If Yes, specify in comments.***
•Include Workers' compensation, exclude psychiatric disability.

M6. How many days have you experienced medical problems in the past 30 days? ☐☐

•Do not include ailments directly caused by drugs/alcohol.
•Include flu, colds, etc. Include serious ailments related to drugs/alcohol, which would continue even if the patient were abstinent (e.g., cirrhosis of liver, abscesses from needles, etc.)

For questions M7 and M8, ask the patient to use the Patient Rating Scale.

M7. How troubled or bothered have you been by these medical problems in the past 30 days? ☐

•Restrict response to problem days of question M6.

M8. How important to you *now* is treatment for these medical problems? ☐

•Refers to the need for *new* or *additional* medical treatment by the patient.

CONFIDENCE RATINGS

Is the above information significantly distorted by:

M10. Patient's misrepresentation? 0 = No 1 = Yes ☐

M11. Patient's inability to understand? 0 = No 1 = Yes ☐

Study025 **Plate025** **V004 (Baseline)**

ID# **Center No.** **Subject ID No.** **Alpha Code** **Date** *month* *day* *year*

EMPLOYMENT/SUPPORT STATUS

Employment/support Comments
(Include question number with your notes.)

E1.* Education completed: *Years* *Months*
- GED = 12 years, note in comments.
- Include formal education only.

E2.* Training or technical education completed: *Months*
- Formal/organized training only. For military training, only include training that can be used in civilian life, i.e., electronics or computers.

E4. Do you have a valid driver's license?
0 = No 1 = Yes
- Valid license; not suspended/revoked.

E5. Do you have an automobile available?
0 = No 1 = Yes
- If answer to E4 is **No**, then E5 must be **No**. Does not require ownership, only availability on a regular basis.

E6. How long was your longest full time job? *Years* *Months*
- Full time = 35+ hours weekly;
Does not necessarily mean most recent job.

E7.* Usual (or last) occupation?
Specify: _____
(use Hollingshead Categories Reference Sheet)

E9. Does someone contribute to the majority of your support?
0 = No 1 = Yes

E10. Usual employment pattern, past three years?
1 = Full time (35+ hours) 4 = Student 7 = Unemployed
2 = Part time (regular hours) 5 = Service 8 = In controlled environment
3 = Part time (irregular hours) 6 = Retired/Disability
- Answer should represent the *majority* of the last 3 years, not just the most recent selection. If there are equal times for more than one category, select that which represents more current situation.

E11. How many days were you paid for working in the past 30 days?
- Include "under the table" work, paid sick days and vacation.

For questions E12-17: How much money did you receive from the following sources in the past 30 days?

E12. Employment
- Net or "take home" pay, include any "under the table" money.

E13. Unemployment compensation

E14. Welfare
- Include food stamps, transportation money provided by an agency to go to and from treatment.

E15. Pensions, benefits or social security.
- Include disability, pensions, retirement, veteran's benefits, SSI and worker's compensation.

E16. Mate, family, or friends
- Money for personal expenses, (i.e., clothing), include unreliable sources of income (e.g. gambling). Record ***cash*** payments only, include windfalls (unexpected), money from loans, gambling, inheritance, tax returns, etc.).

E17. Illegal
- ***Cash*** obtained from drug dealing, stealing, fencing stolen goods, gambling, prostitution, etc. ***Do not*** attempt to convert drugs exchanged to a dollar value.

E18. How many people depend on you for the majority of their food, shelter, etc.?
- Must be regularly depending on patient, do include alimony/ child support, do not include the patient or self-supporting spouse, etc.

Study025 **Plate026** **V004 (Baseline)**

ID# **Center No.** **Subject ID No.** **Alpha Code** **Date** *month* *day* *year*

EMPLOYMENT/SUPPORT STATUS

Employment/support Comments
(Include question number with your notes.)

E19. How many days have you experienced employment problems in the past 30 days?

- Include inability to work, if they are actively looking for work, or problems with present job in which that job is jeopardized.

For question E20, ask the patient to use the Patient Rating Scale.

E20. How troubled or bothered have you been by these employment problems in the past 30 days?

- If the patient has been incarcerated or detained during the past 30 days, they cannot have employment problems.

E21. How important to you *now* is counseling for these employment problems?

- The patient's ratings in questions E20-21 refer to question E19.
- Stress help in finding or preparing for a job, not giving them a job.

CONFIDENCE RATINGS

Is the above information significantly distorted by:

E23. Patient's misrepresentation?
0 = No 1 = Yes

E24. Patient's inability to understand?
0 = No 1 = Yes

ALCOHOL/DRUGS

Alcohol/drugs Comments
(Include question number with your notes.)

Route of Administration Types:
1. Oral 2. Nasal 3. Smoking 4. Non-IV injection 5. IV

- Note the usual or most recent route. For more than one route, choose the most severe. The routes are listed from least severe to most severe.

	Past 30 days	Lifetime (years)	Route of Admin
D1. Alcohol (any use at all)			
D2. Alcohol (to intoxication)			
D3. Heroin			
D4. Methadone			
D5. Other opiates/analgesics			
D6. Barbiturates			
D7. Sedatives/hypnotics/tranquilizers			
D8. Cocaine			
D9. Amphetamines			

Study025 **Plate027** **V004 (Baseline)**

ID# **Center No.** **Subject ID No.** **Alpha Code** **Date** *month* *day* *year*

ALCOHOL/DRUGS *continued*

Alcohol/drugs Comments
(Include question number with your notes.)

Route of Administration Types:
1. Oral 2. Nasal 3. Smoking 4. Non-IV injection 5. IV

•Note the usual or most recent route. For more than one route, choose the most severe. The routes are listed from least severe to most severe.

	Past 30 days	Lifetime (years)	Route of Admin
D10. Cannabis			
D11. Hallucinogens			
D12. Inhalants			
D13. More than one substance per day (including alcohol)			

D17. How many times have you had Alcohol DT's?

•***Delirium Tremens*** (DT's): Occur 24-48 hours after last drink, or significant decrease in alcohol intake, shaking, severe disorientation, fever, hallucinations, they usually require medical attention.

How many times in your life have you been treated for:

D19*. Alcohol abuse?

D20*. Drug abuse?

•Include detoxification, halfway houses, in/outpatient counseling, and AA or NA (if 3+ meetings within one month period)

How many of these were detox only:

D21. Alcohol?

D22. Drugs?

•If D19 = 00, then question D21 is NN
If D20 = 00, then question D22 is NN

How much money would you say you spent during the past 30 days on:

D23. Alcohol?

D24. Drugs?

•Only count actual ***money*** spent.
What is the financial burden caused by drugs/alcohol?

D25. How many days have you been treated as an outpatient for alcohol or drugs in the past 30 days? •Include AA/NA

For questions D28-31, ask the patient to use the Patient Rating Scale
The patient is rating the need for additional substance abuse treatment.

How many days in the past 30 days have you experienced:

D26. Alcohol problems?

Study025 **Plate028** **V004 (Baseline)**

ID# Center No. Subject ID No. Alpha Code **Date** *month* *day* *year*

ALCOHOL/DRUGS *continued*

Alcohol/drugs Comments
(Include question number with your notes.)

How troubled or bothered have you been in the past 30 days by these?

D28. Alcohol problems?

How important to you now is treatment for :

D30. Alcohol problems?

How many days in the past 30 have you experienced:

D27. Drug problems?

•Include only: craving, withdrawal symptoms, disturbing effects of use, or wanting to stop and being unable to.

How troubled or bothered have you been in the past 30 days by these?

D29. Drug problems?

How important to you now is treatment for these:

D31. Drug problems?

CONFIDENCE RATINGS

Is the above information significantly distorted by:

D34. **Patient's misrepresentation?**
0 = No 1 = Yes

D35. **Patient's inability to understand?**
0 = No 1 = Yes

LEGAL STATUS

Legal Status Comments
(Include question number with your notes.)

L1. **Was this admission prompted or suggested by the criminal justice system?** 0 = No 1 = Yes
•Judge, probation/parole officer, etc.

L2. **Are you on parole or probation?** 0 = No 1 = Yes
•Note duration and level in comments.

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

L3*	**Shoplift/vandal**	**L10***	**Assault**
L4*	**Parole/probation**	**L11***	**Arson**
L5*	**Drug charges**	**L12***	**Rape**
L6*	**Forgery**	**L13***	**Homicide/Mansl.**
L7*	**Weapons offense**	**L14***	**Prostitution**
L8*	**Burglary/larceny/B&E**	**L15***	**Contempt of court**
L9*	**Robbery**	**L16***	**Other**

•Include the total number of counts, not just convictions. Do not include juvenile (pre-age 18) crimes, unless they were charged as an adult.
•Include formal charges only.

Study025 **Plate029** **V004 (Baseline)**

ID# **Center No.** **Subject ID No.** **Alpha Code** **Date** *month* *day* *year*

LEGAL STATUS *continued*

Legal Status Comments
(Include question number with your notes.)

L17*. How many of these charges resulted in convictions?
- If L03-16 = 00, then question L17 = NN.
- Do not include misdemeanor offenses from questions L18-20 below.
- Convictions include fines, probation, incarcerations, suspended sentences, and guilty pleas.

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

L18*. Disorderly conduct, vagrancy, public intoxication?

L19*. Driving while intoxicated?

L20*. Major driving violations?
- Moving violations: speeding, reckless driving, no license, etc.

L21*. How many months were you incarcerated in your life?
- If incarcerated *2 weeks or more*, round this up to 1 month. List total number of months incarcerated.

L24. Are you presently awaiting charges, trial, or sentence?
0 = No 1 = Yes

L25. What for?
- Use the number of the type of crime committed: 03-16 and 18-20
- Refers to question L24. If more than one, choose most severe.
- Don't include civil cases, unless a criminal offense is involved.

L26. How many days in the past 30, were you detained or incarcerated?
- Include being arrested and released on the same day.

L27. How many days in the past 30, have you engaged in illegal activities for profit?
- Exclude simple drug possession. Include drug dealing, prostitution, selling stolen goods, etc. May be cross checked with question E17 under Employment/Family Support Section.

For questions L28-29, ask the patient to use the Patient Rating Scale

L28. How serious do you feel your present legal problems are?
- Exclude civil problems

L29. How important to you *now* is counseling or referral for these legal problems?
- Patient is rating a need for ***additional*** referral to legal counsel for defense against criminal charges.

CONFIDENCE RATINGS

Is the above information <u>significantly</u> distorted by:

L31. Patient's misrepresentation?
0 = No 1 = Yes

L32. Patient's inability to understand?
0 = No 1 = Yes

Study025 **Plate030** **V004 (Baseline)**

ID# **Center No.** **Subject ID No.** **Alpha Code** **Date** *month* *day* *year*

FAMILY/SOCIAL RELATIONSHIPS

Family/Social Comments
(Include question number with your notes.)

F1. Marital status:
1 = Married 3 = Widowed 5 = Divorced
2 = Remarried 4 = Separated 6 = Never married
•Common-law marriage = 1. Specify in comments.

F3. Are you satisfied with this situation?
0 = No 1 = Indifferent 2 = Yes
•Satisfied = generally liking the situation. - Refers to question F1

F4.* Usual living arrangements (past 3 years):
1 = With sexual partner and children
2 = With sexual partner alone
3 = With children alone
4 = With parents
5 = With family
6 = With friends
7 = Alone
8 = Controlled Environment
9 = No stable arrangement
•Choose arrangements most representative of the past 3 years. If there is an even split in time between these arrangements, choose the most recent arrangements.

F6. Are you satisfied with these arrangements?
0 = No 1 = Indifferent 2 = Yes

Do you live with anyone who:

F7. Has a current alcohol problem? 0 = No 1 = Yes

F8. Uses non-prescribed drugs? 0 = No 1 = Yes

F9. With whom do you spend most of your free time?
1 = Family 2 = Friends 3 = Alone
•If a girlfriend/boyfriend is considered as family by patient, then they must refer to them as family throughout this section, not friend.

F10. Are you satisfied with spending your free time this way?
0 = No 1 = Indifferent 2 = Yes
•A satisfied response must indicate that the person generally likes the situation. Referring to question F9.

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

0 = No 1 = Yes

	Past 30 days	In your life
F18. Mother		
F19. Father		
F20. Brother/Sister		
F21. Sexual partner/Spouse		
F22. Children		
F23. Other significant family _____ (specify)		

Study025 **Plate031** **V004 (Baseline)**

ID# **Center No.** **Subject ID No.** **Alpha Code** **Date** *month* *day* *year*

FAMILY/SOCIAL RELATIONSHIPS *continued*

Family/Social Comments
(Include question number with your notes.)

0 = No 1 = Yes

		Past 30 days	In your life
F24.	**Close friends**		
F25.	**Neighbors**		
F26.	**Co-workers**		

- "Serious problems" mean those that endangered the relationship
- A "problem" requires contact of some sort, either by telephone or in person

Did anyone abuse you?

0 = No 1 = Yes

		Past 30 days	In your life
F28.	**Physically?**		
F29.	**Sexually?**		

- Caused you physical harm.
- Forced sexual advances/acts.

How many days in the past 30 have you had serious conflicts:

F30. **With your family?**

For questions F32-34, ask the patient to use the Patient Rating Scale.

How troubled or bothered have you been in the past 30 days by these:

F32. **Family problems?**

How important to you *now* is treatment or counseling for these:

F34. **Family problems**

- Patient is rating *his/her* need for counseling for family problems, not whether the family would be willing to attend.

How many days in the past 30 have you had serious conflicts:

F31. **With other people (excluding family)?**

F33. **Social problems?**

How important to you *now* is treatment or counseling for these:

F35. **Social problems**

- Include patient's need to seek treatment for such social problems as loneliness inability to socialize, and dissatisfaction with friends. Patient rating should refer to dissatisfaction, conflicts, or other serious problems.

CONFIDENCE RATINGS

Is the above information significantly distorted by:

F37. **Patient's misrepresentation?**

0 = No 1 = Yes

F38. **Patient's inability to understand?**

0 = No 1 = Yes

Study025 **Plate032** **V004 (Baseline)**

ID# **Center No.** **Subject ID No.** **Alpha Code** **Date** *month* *day* *year*

PSYCHIATRIC STATUS

How many times have you been treated for any psychological or emotional problems?

P1*. In a hospital or inpatient setting?

P2*. Outpatient/private patient?

*Do not include substance abuse, employment, or family counseling.
Treatment episode = a series of more or less continuous visits or treatment days, not the number of visits or treatment days.
*Enter diagnosis in comments if known.

P3. Do you receive a pension for a psychiatric disability? 0 = No 1 = Yes

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

0 = No 1 = Yes	Past 30 days	Lifetime
P4. Experienced serious depression-sadness, hopelessness, loss of interest, difficulty with daily function?		
P5. Experienced serious anxiety/tension, uptight, unreasonably worried, inability to feel relaxed?		
P6. Experienced hallucinations-saw things or heard voices that were not there?		
P7. Experienced trouble understanding, concentrating, or remembering?		

For questions P8-10, patient can have been under the influence of alcohol/drugs.

P8. Experienced trouble controlling violent behavior, including episodes of rage, or violence?		
P9. Experienced serious thoughts of suicide? *Patient seriously considered a plan for taking his/her life.		
P10. Attempted suicide? *Include actual suicidal gestures or attempts.		
P11. Been prescribed medication for any psychological or emotional problems? *Prescribed for the patient by MD. Record **Yes** if a medication was prescribed *even if* the patient is not taking it.		

P12. How many days in the past 30 have you experienced these psychological or emotional problems?
*This refers to problems noted in questions P4-10

For questions P13-14, ask the patient to use the Patient Rating Scale

P13. How much have you been troubled or bothered by these psychological or emotional problems in the past 30 days?
*Patient should be rating the problem days from question P12.

P14. How important to you *now* is treatment for these psychological or emotional problems?

Psychiatric Status Comments
(Include question number with your notes.)

Form completed by:

CONFIDENCE RATINGS

Is the above information significantly distorted by:

P22. Patient's misrepresentation? 0 = No 1 = Yes

P23. Patient's inability to understand? 0 = No 1 = Yes

Date *month* *day* *year*

Form 24 - AE Log

Form 24 is a log form used to separately record and track each AE that occurs during the study. If the severity of any pre-existing condition recorded on the Medical History Form (Form 02) worsens, record it as an AE on Form 24 and continue to track it throughout the study. Assess AEs at every study visit, starting on the day the subject signs the Informed Consent through week 13, and again at follow-up. Complete one log for each AE reported. Assess and record adverse events at every study visit by asking the subject a non-leading question such as, "How have you been feeling since I saw you last?" For every AE reported by the subject, begin a separate Form 24.

Assess all AEs at subsequent visits and make updated entries to each log, including updates to severity, relatedness, outcome, etc. If AE continues over several weeks with no resolution, indicate that the AE is continuing and start a new page (Form 24) in the log. Carry the unique AE number to the new page and continue to record subsequent assessments of that particular AE on the new page.

For all items, I - VII, use the response codes located at the bottom of this page. These codes are also located in the Adverse Events Section of the Patient Binder.

Specific Instructions

- AE Number - assign all AEs reported by the subject a unique AE number. This number should be sequential and care should be taken not to repeat numbers.
- Nature of Illness, Event or Abnormal Lab Value - PRINT a brief description of the AE as told to you verbatim by the subject. Keep this description consistent across pages when multiple pages are used for one AE. *For example, if a subject reports a chronic headache that does not abate over subsequent assessments, subsequent pages/references to the same AE should read 'headache' versus another description such as 'migraine.'*
- Date of Onset - Record the date that the AE began, NOT the date that it is being recorded.
- Date AE First Reported - Record the date of the visit when the AE is first reported by the subject.
- Date AE Reassessed - Enter dates of subsequent visits when AE is reassessed.
- Type of Report - If the AE occurs prior to the first dose of study drug, indicate that the AE is a screening/baseline AE by selecting (1). If the AE occurs after the first dose of study drug is given, the AE is to be considered treatment emergent. Indicate whether the AE is Anticipated, (2), Unanticipated, (3), or due to an Intercurrent Illness (4).
- Relation to Study Agent - Indicate the assessment of the AE's relationship to the study drug, in the opinion of the investigator. If attribution of the AE's relation to the study agent changes over time, record the new code in subsequent entries.
- Highest Level of Severity - Indicate the highest level of severity reported for this AE. For subsequent entries, indicate the highest level of severity since the last assessment.
- Reported as SAE - Indicate if this AE was recorded as an SAE by marking (x) the appropriate box.
- Action Taken - Indicate the action that was taken in response to the AE. If no action was taken, enter (6), Not Applicable.
- Outcome - Indicate the outcome of this Adverse Event. If the AE continues over time, the outcome may change. Record changes in outcome in subsequent entries.
- Date of Resolution - Record a date only if the AE is resolved. If resolved, Indicate the date that the AE resolved NOT the date of the visit when the subject reported it was resolved.
- Continuing - If the AE has a Date of Resolution, indicate that the AE is not continuing by marking (x) the response box to indicate 'No'. If the AE has not resolved, indicate that it is continuing by marking (x) 'Yes' and begin a new page for that particular AE. Be sure to carry the unique number to the new page.

USE THE FOLLOWING RESPONSE CODES TO COMPLETE THE FORM

I. Result of Withdrawal Symptoms?
0 = No
1 = Yes

II. Type of Report
1 = Screening/Baseline
2 = Tx Emergent, Anticipated
3 = Tx Emergent, Unanticipated
4 = Tx Emergent, Intercurrent Illness

III. Relation to Study Agent
1 = Unknown
2 = Definitely Not Related
3 = Possibly Related
4 = Remotely Related
5 = Probably Related
6 = Definitely Related

IV. Highest Level of Severity
(since last assessment)
1 = Mild
2 = Moderate
3 = Severe

V. Reported as SAE?
0 = No
1 = Yes

VI. Action Taken
1 = Agent Withdrawn
2 = Agent Dose Reduced
3 = Agent Dose Increased
4 = Agent Dose Unchanged
5 = Unknown
6 = Not Applicable

VII. Outcome
1 = Resolved; No Sequelae
2 = Not Yet Resolved, but Improving
3 = Not Yet Resolved, No Change
4 = Not Yet Resolved, but worsening
5 = Resulted in Chronic Condition, Severe &/or Permanent Disability
6 = Deceased
7 = Unknown

Study025 **Plate053**

AE Number **Page Number**

ID# **Center No.** **Subject ID No.** **Alpha Code**

Form 24-AE Log

Study staff, assess adverse events at each study visit, beginning on the day the subject signs the Informed Consent. Give each AE a unique AE #. Keep one log for each AE and complete subsequent pages as needed. Submit this form to the CSPCC once the page is complete, or once the AE resolves. If AE is continuing, carry AE # to a new page and continue to update at each study visit.

Nature of Illness, Event, or Abnormal Lab Value	Date of Onset (month / day / year)	Date AE First Reported (month / day / year)	Withdrawal Symptoms? I (No / Yes)	Type of Report II	Relation to Study Agent III	Highest Level of Severity IV	Reported as SAE? V (No / Yes)	Action Taken VI	Outcome VII
		Date AE Reassessed (month / day / year)							
		Date AE Resolved (month / day / year)	Continuing? (No / Yes)	If continuing record next page # to be used					

Form completed by: _____ **Date** (month / day / year)

Site Investigator's Signature: _____ **Date** (month / day / year)

NIDA/VA CS # 1025
Topiramate for Methamphetamine Dependence

Notice of Review & Approval

Date: August 16, 2006

Changes to Form 22, BBCET Compliance, Version 1, 06.15.2006, have been approved for distribution to clinical sites & subsequent data collection. These changes are reflected in the Forms Change Log and will bear an amended date of 08.15.2006 in the page footer.

_____ _____

Erin Iturriaga, RN (NIDA Representative) Date

Study025 **Plate037** **V004 (Baseline / Week -1)**

ID# ☐☐☐ ☐☐☐☐ ☐☐☐☐ **Date of Assessment** ☐☐ ☐☐ ☐☐ ☐☐
Center No. **Subject ID No.** **Alpha Code** *month* *day* *year* **Week**

Form 22-BBCET Compliance

*Study staff, complete this form once during baseline and weekly during study weeks 1 -12.

Complete the following questions for the study week indicated at the top of the form.

1. Did subject attend a BBCET session during the last study week? ☐ *No* ☐ *Yes*
   if NO, skip to question 4.
2. Date of BBCET study session. ☐☐ ☐☐ ☐☐ *month* *day* *year*
3. Enter initials of BBCET provider ☐☐☐
4. During the last study week, did subject take part in any non-study related treatment? ☐ *No* ☐ *Yes*
   Answer NO for randomization visit.
   If NO, stop, form complete.

   If YES, indicate which services were used below in Q. 5 - Q. 8 and the total length of time the subject spent in each type of treatment.

Other Informal Treatment

5. Did subject take part in a 12-Step Program (i.e., Narcotics Anonymous) during the last study week? *if NO, skip to question 6.* ☐ *No* ☐ *Yes*
   a. Record total number of sessions attended for a 12-step Program during the last study week. ☐☐
   b. Enter total amount of time subject spent in a 12-step Program during the last study week. ☐☐ : ☐☐ *hh* *mm*
6. Did subject use any self-help materials such as books, audiotapes, CDs *if NO, skip to question 7.* ☐ *No* ☐ *Yes*
   a. Record total number of times subject used self-help materials during the last study week. ☐☐
   b. Enter total amount of time subject used self-help materials during the last study week. ☐☐ : ☐☐ *hh* *mm*
7. Did subject take part in any other informal treatment for methamphetamine dependence during the last study week? ☐ *No* ☐ *Yes*
   If NO, skip to question 8.
   a. Total # of times subject used other informal treatment during the last study week. ☐☐
   b. Enter total amount of time subject used informal treatment during the last study week. ☐☐ : ☐☐ *hh* *mm*
   c. List other type of informal treatment: _____

Other Formal Treatment

8. Did subject take part in any formal* treatment for methamphetamine dependence during the last study week? ☐ *No* ☐ *Yes*
   *formal is defined as any treatment provided by a healthcare provider for which they could be reimbursed by an insurance company.

   If YES, complete termination assessments.

Form completed by: _____ **Date** *month* ☐☐ *day* ☐☐ *year* ☐☐

Form 08 - Birth Control/Pregnancy

Study025 **Plate009** **V005 (Randomization)**

ID# [ ][ ][ ] [ ][ ][ ][ ] [ ][ ][ ][ ] **Date of Assessment** [ ][ ] [ ][ ] [ ][ ] [ ][ ]

Center No. **Subject ID No.** **Alpha Code** *month* *day* *year* **Week**

Form 08-Birth Control/Pregnancy - ***This is a source document for VA/NIDA Cooperative Study #1025***

Study staff, complete this form for every pregnancy/birth control assessment done throughout the study. Perform pregnancy/birth control assessments on female subjects at the following intervals.

* Screening
* Immediately prior to receiving 1st dose of study drug.
* The first visit of weeks 4, 8,12 and at follow-up (week-17).
* Termination Visit, if earlier than week 12.

1. What method(s) of birth control is subject currently using? *(Check all that apply below):*
   - ☐ *Prescription oral contraceptive*
   - ☐ *Contraceptive skin patch (Ortho Evra®)*
   - ☐ *Barrier (diaphragm, condom)*
   - ☐ *Spermicide*
   - ☐ *Intrauterine Progesterone or non-hormonal contraceptive system (IUD)*
   - ☐ *Levonorgestrel implant (Norplant®)*
   - ☐ *Medroxyprogesterone Acetate Contraceptive injection (Depo-Provera®)*
   - ☐ *Complete abstinence from sexual intercourse*
   - ☐ *Hormonal vaginal contraceptive ring (NuvaRing®)*
   - ☐ *Contraceptive sponge*
   - ☐ *Hysterectomy, record date of procedure:* *month* [ ][ ] *year* [ ][ ][ ][ ]
   - ☐ *Tubal ligation, record date of procedure:* [ ][ ] [ ][ ][ ][ ]
   - ☐ *Post-menopausal, record date of last menstrual period:* [ ][ ] [ ][ ][ ][ ]
   - ☐ *Other method(s) of birth control, specify:* ______________________

2. Was a pregnancy test performed? ☐ *No* ☐ *Yes*

   If *Yes:*

   a. Result of pregnancy test: ☐ *Positive** ☐ *Negative*

   ***If pregnancy test is positive, complete Form 24, Adverse Event Log and Form 25, Serious Adverse Events, as well as Pregnancy Form A & B.**

Form completed by: ______________________ **Date** *month* [ ][ ] *day* [ ][ ] *year* [ ][ ]

Site Investigator's Signature: ______________________ **Date** [ ][ ] [ ][ ] [ ][ ]

Form 15 - Brief Substance Abuse Craving Scale

Study025 **Plate020** **V005 (Randomization)**

ID# ☐☐☐ ☐☐☐☐ ☐☐☐☐ **Date of Assessment** ☐☐ ☐☐ ☐☐ ☐☐
Center No. **Subject ID No.** **Alpha Code** *month* *day* *year* **Week**

Form 15-Brief Substance Abuse Craving Scale

*To be completed by the subject.
*To be completed weekly during baseline, study weeks 1-12, and at follow-up.

Please answer the following questions about your methamphetamine craving:

1. The INTENSITY of my craving, that is, how much I desired methamphetamine in the past 24 hours was:
*(mark (**x**) one)*

☐ *None at all* ☐ *Slight* ☐ *Moderate* ☐ *Considerable* ☐ *Extreme*

2. The FREQUENCY of my craving, that is, how often I desired methamphetamine in the past 24 hours was:
*(mark (**x**) one)*

☐ *Never* ☐ *Almost never* ☐ *Several times* ☐ *Regularly* ☐ *Almost constantly*

3. The LENGTH of time I spent in craving for methamphetamine during the past 24 hours was:
*(mark (**x**) one)*

☐ *None at all* ☐ *Very short* ☐ *Short* ☐ *Somewhat long* ☐ *Very long*

4. Write in the NUMBER of times you think you had craving for methamphetamine in the past 24 hours: ☐☐ *Times*

5. Write in the total TIME you spent craving methamphetamine during the past 24 hours *(enter as hours and minutes):* ☐☐ : ☐☐
Hours Minutes

6. WORST day: During the past week, my most intense craving occurred on the following day:
*(mark (**x**) one)*

☐ *Sunday* ☐ *Tuesday* ☐ *Thursday* ☐ *Saturday*
☐ *Monday* ☐ *Wednesday* ☐ *Friday* ☐ *All days the same (go to question #8)*

7. The date of that day was*:* *month* ☐☐ *day* ☐☐ *year* ☐☐

8. The INTENSITY of my craving, that is, how much I desired methamphetamine on that WORST day was:
*(mark (**x**) one)*

☐ *None at all* ☐ *Slight* ☐ *Moderate* ☐ *Considerable* ☐ *Extreme*

9. A second drug I have craved during the past 24 hours was:
Mark ONLY ONE of the following. If no 2nd drug was craved, Mark *None* and leave questions 10-16 blank.

☐ *None* ☐ *Alcohol*
☐ *Downers or Sedatives* ☐ *Heroin or other Opiates (Morphine, etc.)*
☐ *Benzos (valium, Xanax, etc.)* ☐ *Marijuana*
☐ *Nicotine* ☐ *Others*

Study025 **Plate021** **V005 (Randomization)**

ID# ☐☐☐ ☐☐☐☐ ☐☐☐☐ ☐☐
Center No. **Subject ID No.** **Alpha Code** **Week**

Form 15-Brief Substance Abuse Craving Scale *continued*

10. The INTENSITY of my craving, that is, how much I desired this second drug in the past 24 hours was: *(mark (**x**) one)*

☐ *None at all* ☐ *Slight* ☐ *Moderate* ☐ *Considerable* ☐ *Extreme*

11. The FREQUENCY of my craving, that is, how often I desired this second drug in the past 24 hours was: *(mark (**x**) one)*

☐ *Never* ☐ *Almost never* ☐ *Several times* ☐ *Regularly* ☐ *Almost constantly*

12. The LENGTH of time I spent craving this second drug during the past 24 hours was: *(mark (**x**) one)*

☐ *None at all* ☐ *Very short* ☐ *Short* ☐ *Somewhat long* ☐ *Very long*

13. A third drug I have craved during the past 24 hours was:
Mark ONLY ONE of the following. If no 3rd drug was craved, Mark *None* and leave questions 14-16 blank.

☐ *None* ☐ *Alcohol*
☐ *Downers or Sedatives* ☐ *Heroin or other Opiates (Morphine, etc.)*
☐ *Benzos (valium, Xanax, etc.)* ☐ *Marijuana*
☐ *Nicotine* ☐ *Others*

14. The INTENSITY of my craving, that is, how much I desired this third drug in the past 24 hours was: *(mark (**x**) one)*

☐ *None at all* ☐ *Slight* ☐ *Moderate* ☐ *Considerable* ☐ *Extreme*

15. The FREQUENCY of my craving, that is, how often I desired this third drug in the past 24 hours was: *(mark (**x**) one)*

☐ *Never* ☐ *Almost never* ☐ *Several times* ☐ *Regularly* ☐ *Almost constantly*

16. The LENGTH of time I spent craving this 3rd drug during the past 24 hours was: *(mark (**x**) one)*

☐ *None at all* ☐ *Very short* ☐ *Short* ☐ *Somewhat long* ☐ *Very long*

THANK YOU. THIS FORM IS COMPLETE.

Do not Sign the Form Below.

Form reviewed by: ______________________ **Date** ☐☐ ☐☐ ☐☐ (*month* *day* *year*)

Study025 **Plate033** **V005 (Randomization)**

ID# **Center No.** **Subject ID No.** **Alpha Code**

Date of Assessment *month* *day* *year* **Week**

Form 19-Clinical Global Impression Scale - Observer (CGI-O)

*Study staff, complete weekly during baseline, at the first visit of study weeks 1-12, and at follow-up (Week 17)

Rate the current severity of the eight specific problem areas below. Use the **Table of Descriptive Anchors For Specific Methamphetamine Dependence Problems** on the previous page. Indicate **one** answer for each question.

	Severity Ratings						
1. Reported methamphetamine use: frequency and amount of methamphetamine use	☐ *1*	☐ *2*	☐ *3*	☐ *4*	☐ *5*	☐ *6*	☐ *7*
2. Methamphetamine seeking: craving for methamphetamine, effort to stop, and drug seeking behavior	☐ *1*	☐ *2*	☐ *3*	☐ *4*	☐ *5*	☐ *6*	☐ *7*
3. Reported use of other drugs: frequency and amount of methamphetamine use	☐ *1*	☐ *2*	☐ *3*	☐ *4*	☐ *5*	☐ *6*	☐ *7*
4. Observable psychiatric symptoms: orientation, memory, comprehension, disorganized thinking, rapid/retarded speech, agitation, grooming, hostility, irritability, affective disturbance, paranoia, suspiciousness	☐ *1*	☐ *2*	☐ *3*	☐ *4*	☐ *5*	☐ *6*	☐ *7*
5. Reported psychiatric symptoms: mood disturbance, depression, anxiety, inner restlessness, covert anger, somatic symptoms, energy level, motivation, sleep, appetite, libido, anhedonia, paranoia, suspiciousness	☐ *1*	☐ *2*	☐ *3*	☐ *4*	☐ *5*	☐ *6*	☐ *7*
6. Physical/medical problems: those that have emerged or gotten worse after drug use	☐ *1*	☐ *2*	☐ *3*	☐ *4*	☐ *5*	☐ *6*	☐ *7*
7. Maladaptive coping in the family/social area: movement away from healthy relationship	☐ *1*	☐ *2*	☐ *3*	☐ *4*	☐ *5*	☐ *6*	☐ *7*
8. Maladaptive coping in other areas: e.g., employment, legal, housing, etc. movement away from problem solving in those areas	☐ *1*	☐ *2*	☐ *3*	☐ *4*	☐ *5*	☐ *6*	☐ *7*

9. Global severity of methamphetamine dependence:
Considering your total clinical experience with the methamphetamine population, how severe are his/her cocaine dependence symptoms at this time? *(use codes below)* ☐

1 = Normal no symptoms
2 = Borderline symptoms
3 = Mild symptoms
4 = Moderate symptoms
5 = Marked symptoms
6 = Severe symptoms
7 = Among the most extreme symptoms

10. <u>Do not complete question 10 during baseline</u>

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 status at randomization, how much has he/she changed? (use codes below) ☐

1 = Very much improved
2 = Much improved
3 = Minimally improved
4 = No change
5 = Minimally worse
6 = Much worse
7 = Very much worse

Form completed by: _____

Date *month* *day* *year*

Study025 **Plate034** **V005 (Randomization)**

ID# ☐☐☐ ☐☐☐☐ ☐☐☐☐ **Date of Assessment** ☐☐ ☐☐ ☐☐ ☐☐

Center No. **Subject ID No.** **Alpha Code** *month* *day* *year* **Week**

Form 20-Clinical Global Impression Scale - Self Report (CGI-S)

*To be completed by the subject weekly during baseline, at the first visit of study weeks 1-12, and at follow-up (Week 17).

Please respond to each question below with the number that best represents your answer. Record the number in the space next to the each question.

1. **Methamphetamine severity:**
At this time, overall, how would you rate yourself for methamphetamine use and methamphetamine related symptoms? *(use codes below)* ☐

1 = No symptoms	5 = Marked symptoms
2 = Borderline symptoms	6 = Severe symptoms
3 = Mild symptoms	7 = Among the most extreme symptoms
4 = Moderate symptoms	

This question is only to be answered from study week 2-12 and, again at follow-up (week 17)

2. **Methamphetamine improvement:**
How would you rate yourself for changes in methamphetamine use and methamphetamine related symptoms since the beginning of this study? *(use codes below)* ☐

1 = Very much improved	5 = Minimally worse
2 = Much improved	6 = Much worse
3 = Minimally improved	7 = Very much worse
4 = No change	

THANK YOU.
YOU HAVE COMPLETED THIS FORM.

DO NOT SIGN THE FORM BELOW

Form reviewed by: ____________________ **Date** ☐☐ ☐☐ ☐☐ (*month* *day* *year*)

Clinical Laboratory Report Form

*Complete this form in accordance with the schedule of laboratory tests located in the protocol.

B. Evaluation

1 = Normal

2 = Abnormal, not clinically significant

3 = Abnormal, clinically significant

9 = Not done

C. Comments

Must provide comments if a '**3**', or a '**9**' is recorded under Evaluation.

Study025 Plate012 Visit 01 (Screening)

ID# ___ ___ ___ (Center No.) ___ ___ ___ ___ (Subject ID No.) ___ ___ ___ ___ (Alpha Code)

Date of Assessment ___ ___ (month) ___ ___ (day) ___ ___ (year) Week ___ ___

Form 11-Clinical Laboratory Report Form

Please indicate if the lab values reported on this form are for: ☐ *Scheduled Labs* ☐ *Repeat Labs*

CBC (to be performed at screening and week 12, or termination visit)

	A. Value	B. Evaluation*	C. Comments
1. WBC (K/mm^3)	___.___	___	_____
2. RBC (M/mm^3)	___.___	___	_____
3. Hemoglobin (g/dL)	___.___	___	_____
4. Hematocrit (%)	___.___	___	_____
5. Platelet count (K/mm^3)	___.___	___	_____
6. Neutrophils (%)	___.___	___	_____
7. Lymphocytes (%)	___.___	___	_____
8. Monocytes (%)	___.___	___	_____
9. Eosinophils (%)	___.___	___	_____
10. Basophils (%)	___.___	___	_____

CHEM 7 PANEL (to be performed at screening and at weeks 4, 8, and 12)

11. Urea Nitrogen (BUN) (mg/dL)	___	___	_____
12. Creatinine (mg/dL)	___.___	___	_____
13. Sodium (mEq/L)	___	___	_____
14. Potassium (mEq/L)	___.___	___	_____
15. Chloride (mEq/L)	___	___	_____
16. Bicarbonate (mEq/L)	___.___	___	_____
17. Glucose (mg/dL)	___	___	_____

Form 11- Clinical Laboratory Report Form

Study025 **Plate013** **Visit** 01 **(Screening)**

ID# **Center No.** **Subject ID No.** **Alpha Code**

Date of Assessment *month* *day* *year* **Week**

LFTs (to be completed at screening, weeks 4, 8, and 12)

	A. Value	B. Evaluation*	C. Comments
18. Albumin (g/dL)	__.__		
19. Total bilirubin (mg/dL)	__.__		
20. Direct bilirubin (mg/dL)	__.__		
21. Alkaline phosphatase (ALP)	___		
22. GGT (U/L)	____		
23. SGPT/ALT (U/L)	____		
24. SGOT/AST (U/L)	____		

Other (to be performed at screening only)

25. Hemoglobin A1c (%)	__.__		

Urinalysis (to be performed at screening and week 12, or termination visit)

26. Color	☐ *yellow* ☐ *not yellow*		
27. Appearance	☐ *clear* ☐ *not clear*		
28. Specific gravity	__.___		
29. pH	__.__		
30. Glucose	☐ *Neg* ☐ *Trace* ☐ *Pres*		
31. Bilirubin	☐ *Neg* ☐ *Trace* ☐ *Pres*		
32. Ketones	☐ *Neg* ☐ *Trace* ☐ *Pres*		
33. Protein	☐ *Neg* ☐ *Trace* ☐ *Pres*		
34. Occult blood	☐ *Absent* ☐ *Pres*		
35. Nitrite	☐ *Absent* ☐ *Pres*		
36. Leukocyte esterase	☐ *Absent* ☐ *Pres*		

Form completed by: _____ **Date** *month* *day* *year*

Site Investigator's Signature: _____ **Date**

Concomitant Medications Log

* Study staff, use this log to assess any meds taken after the 1st dose of study drug is given. If medications from Form 06 continue after the first dose of study drug, make a new entry on this form to show them as concomitant meds. Complete this log at every visit from the 2nd visit of study week 1 - Week 13 and at follow-up visit (week 17). Assess any concomitant medications taken since the last entry. Enter all prescription and over-the-counter drugs taken therapeutically during the study including herbal preparations. Make a new entry when a dosage and/or frequency change occurs. Use additional pages as necessary. Number completed pages and forward to the VA CSPCC after the subject has discontinued from the study.

* *If medication taken as a result of an **Adverse Event**, list number(s) of event(s) from Form 24. If NOT, please be sure to list indication.*

Route		**Units**		**Frequency**
1 = Oral	6 = Intramuscular	01 = Capsule/Tablet	06 = Spray/squirt	1 = Once a day
2 = Nasal	7 = Sublingual	02 = Drop	07 = Tablespoon	2 = Twice a day
3 = Intravenous	8 = Subcutaneous	03 = Milligram	08 = Teaspoon	3 = Three times a day
4 = Inhalation	9 = Other	04 = Milliliter	09 = Unknown	4 = Four times a day
5 = Topical/transdermal		05 = Puff	10 = Other	5 = PRN

Form 23 - Concomitant Medications Log

Study025 **Plate038** **Page Number**

ID# **Center No.** **Subject ID No.** **Alpha Code**

Date Form Completed *month* *day* *year*

Form 23-Concomitant Medications Log

☐ *Check if **NO** concomitant meds were reported during study*

Generic Name of Med **Purpose/Indication** **Medication Start Date** *month day year*

1. _____ _____ **Medication Stop Date**

Related Adverse Event Numbers *(from Form 24 Adverse Event Log)*

Dose . **Route** **Units** **Frequency** ☐ *Mark (x) if continuing*

Generic Name of Med **Purpose/Indication** **Medication Start Date** *month day year*

2. _____ _____ **Medication Stop Date**

Related Adverse Event Numbers *(from Form 24 Adverse Event Log)*

Dose . **Route** **Units** **Frequency** ☐ *Mark (x) if continuing*

Generic Name of Med **Purpose/Indication** **Medication Start Date** *month day year*

3. _____ _____ **Medication Stop Date**

Related Adverse Event Numbers *(from Form 24 Adverse Event Log)*

Dose . **Route** **Units** **Frequency** ☐ *Mark (x) if continuing*

Generic Name of Med **Purpose/Indication** **Medication Start Date** *month day year*

4. _____ _____ **Medication Stop Date**

Related Adverse Event Numbers *(from Form 24 Adverse Event Log)*

Dose . **Route** **Units** **Frequency** ☐ *Mark (x) if continuing*

Will an additional page be used to record **concomitant medications?** ☐ *No* ☐ *Yes* → If ***Yes***, record the next page number *month day year*

Form completed by: _____ **Date** *month day year*

Form 26 - End of Study Status

Study025 **Plate051** **V018**

ID# Center No. | Subject ID No. | Alpha Code

Date of Last On-Study Clinic Visit: *month* *day* *year* | Week

Form 26-End of Study Status

*Study staff, complete for **all** randomized subjects after termination/completion.

1. Using the list below, choose the answer that best describes the subject's status at the end of the study.
(check only ONE box below):

- ☐ *1. Completed 13 weeks of the protocol* (with at least 1 visit in week 13)
- ☐ *2. Termination due to toxicity or side effects related to study medication*
- ☐ *3. Termination due to medical reason unrelated to study medication. Specify:* _____
- ☐ *4. Subject failed to return to clinic. If contacted, specify reason:* _____
- ☐ *5. Termination at subject's request. Subject does not allow follow-up. Specify reason for termination.* _____
- ☐ *6. Termination at subject's request. Subject agrees to follow-up. Specify reason for termination.* _____
- ☐ *7. Subject moved from area*
- ☐ *8 Subject became incarcerated*
- ☐ *9. Subject was terminated by clinic physician because of intercurrent illness or medical complications precluding safe administration of study medication*
- ☐ *10. Subject was administratively discharged. Specify incident:* _____
- ☐ *11. Birth control non-compliance*
- ☐ **12. Pregnancy* - Females only **- COMPLETE AE FORM 24, SAE FORM 25 & PREGNANCY A & B FORM.**
- ☐ **13. Death* **- COMPLETE SAE FORM 25**

Date of death *month* *day* *year*

Cause of death (if known): _____

- ☐ *14. Other reason, specify:* _____

2. Was subject referred to another treatment program?

- ☐ *No*
- ☐ *Yes*

Form completed by: _____ **Date** *month* *day* *year*

Site Investigator's Signature: _____ **Date**

Form 01-Entry Criteria and Enrollment

Study025 **Plate041** **V005 (Titration)**

ID# **Center No.** **Subject ID No.** **Alpha Code**

Date Form Completed *month* *day* *year* **Week**

Form 01-Entry Criteria and Enrollment

- Study staff: Complete the entire form, regardless of whether or not the subject is enrolled in the study.
- Record the subject ID number and ALPHA code above and submit this form to the VA CSPCC.

Demographic Information

1. Gender *(at birth)* ☐ *Male* ☐ *Female*
2. Date of birth ☐☐ *month* ☐☐ *day* ☐☐☐☐ *year*
3. Marital status *(enter one code from below)* ☐
   1 = Legally married; 2 = Living with partner/cohabitating; 3 = Widowed; 4 = Separated; 5 = Divorced; 6 = Never married; 7 = Unknown
4. Ethnicity *(enter code from below)* ☐
   1 = Hispanic, or Latino; 2 = Not Hispanic or Latino; 3 = Unknown/Not Given
   * Please see instructions on categorizing race/ethnicity in the Operations Manual
5. Race *(mark (x) all that apply)*
   ☐ *American Indian or Alaskan Native* ☐ *Asian* ☐ *Black or African-American* ☐ *Native Hawaiian, or Pacific Islander* ☐ *White*
6. Years of formal education *(GED = 12 years)* ☐☐ *years*
7. Usual employment pattern in the last 30 days? *(enter code from below)* ☐☐
   1 = Full-time, 35+ hrs/week; 2 = Part-time, regular hrs; 3 = Part-time, irregular hrs/day work; 4 = Student; 5 = Military Service; 6 = Retired/Disabled; 7 = Homemaker; 8 = Unemployed; 9 = In controlled environment; 10 = Unknown

- For Inclusion Criteria questions 8-16, mark (x) **No, Yes**, or **NS** (Not Screened).
- All answers must be **Yes** for inclusion in the study, unless otherwise indicated by an asterisk*.

Inclusion Criteria	**No**	**Yes**	**NS**
8. Did subject provide written Informed Consent?	☐	☐	☐
9. Subject is at least 18 years old?	☐	☐	☐
10. Has a DSM-IV diagnosis of current methamphetamine dependence (as defined by SCID)?	☐	☐	☐
11. Is seeking treatment for methamphetamine dependence, but is not currently in a "formal" treatment program? *(formal is defined as any treatment provided by a health care provider within 2 months preceding screening for which they could be reimbursed by an insurance company)*	☐	☐	☐
12. Is willing and able to comply with the study procedures?	☐	☐	☐
13. Has a BMI > 18 kg/m^2 *(due to the potential anorexic effects of topiramate)?*	☐	☐	☐
14. Has provided at least one methamphetamine or amphetamine positive urine specimen (>500 ng/mL) within the 14-day screening period)?	☐	☐	☐
15. Has provided at least four urine specimens, including one specimen within 7 days prior to randomization, and the accompanying other baseline repeated measures within the required 14-day baseline measurements period?	☐	☐	☐
*16. If female, has a negative urine pregnancy test and agrees to use an acceptable method of birth control (as defined within the protocol)? **For males, mark **NS**.*	☐	☐	☐

Study025 **Plate042** **V005 (Titration)**

ID# **Center No.** **Subject ID No.** **Alpha Code**

Date Form Completed *month* *day* *year* **Week**

Form 01-Entry Criteria and Enrollment *continued*

- For Exclusion Criteria questions 17-40, mark (x) **No, Yes**, or **NS** (Not Screened)
- All answers must be **No** for inclusion in the study, unless otherwise indicated by an asterisk*.

Exclusion Criteria	**No**	**Yes**	**NS**
17. Has current dependence, defined by DSM-IV criteria, on any psychoactive substance (i.e., opioids) other than methamphetamine, nicotine, or marijuana, or has psychological dependence on alcohol or a sedative-hypnotic (e.g. a benzodiazepine) that requires medical detoxification?	☐	☐	☐
18. Has clinically significant depression, defined by a total MADRS score of > 24 during screening, or current (w/in the past 30 days) suicidal ideation/plan (MADRS item #10 ≥*4)?*	☐	☐	☐
19. Has a urine drug screen positive for benzodiazepines (w/in 7 days prior to starting treatment), or barbiturates (w/in 14 days prior to starting treatment) per compliance with the washout period for prohibited drugs listed in Appendix II of the protocol?	☐	☐	☐
20. Has psychiatric disorders, such as current major depression, psychosis, bipolar illness, organic brain disorder, dementia, as assessed by the SCID interview, which require ongoing medication treatment, or which would make medication compliance difficult, or has had electroconvulsive therapy w/in the past 90 days before screening, or has a history of Bipolar I Disorder or a diagnosis of attention deficit (hyperactivity) disorder '(ADHD or ADD) by history or by SCID? *(see notes on inclusion/exclusion in protocol)*	☐	☐	☐
21. Has a current diagnosis of anorexia nervosa or bulimia disorder?	☐	☐	☐
22. Has serious medical illnesses or neurological disorders including, but not limited to: uncontrolled hypertension; significant heart disease (including myocardial infarction w/in one year of enrollment); angina, hepatic or renal disorders; Parkinson's disease; epilepsy; active syphilis that has not been treated or refuse treatment for syphilis (see note); or have had therapy with any opioid substitutes (methadone, buprenorphine) w/in 2 months prior to enrollment; or have any gastrointestinal disorder that could result in a clinically significant alteration of metabolism or excretion of topiramate; or any serious potentially life threatening or progressive medical illness other than addiction that may compromise subject safety or study conduct; or any ECG/cardiovascular abnormality (e.g., QTc interval prolongation > 450 milliseconds in men or > 470 milliseconds in women), which in the judgement of the investigator is clinically significant?	☐	☐	☐
23. Has clinically significant renal disease and/or impaired renal function defined as an estimated serum creatinine clearance of ≤ 60mL/min?	☐	☐	☐
24. Has Hemoglobin A1c >7%?	☐	☐	☐
25. Has diabetes with unstable control of blood glucose in the past year before screening? *(Controlled diabetic subjects should be monitored more closely during the study.)*	☐	☐	☐
26. Has glaucoma?	☐	☐	☐
27. Has a history of nephrolithiasis?	☐	☐	☐
28. In the opinion of the investigator, is expected to fail to complete the study protocol due to possible incarceration or relocation from the clinic area?	☐	☐	☐
*29. Is pregnant or lactating? *(Topiramate is a pregnancy category C drug.) *For males, mark **NS**.*	☐	☐	☐

Study025 **Plate043** **V005 (Titration)**

ID# **Center No.** **Subject ID No.** **Alpha Code**

Date Form Completed *month* *day* *year* **Week**

Form 01-Entry Criteria and Enrollment *continued*

Exclusion Criteria *continued*

	No	Yes	NS
30. Has clinically significant laboratory values (outside of normal limits) in the judgement of the investigator?	☐	☐	☐
31. Has AST or ALT >3 x upper limit of normal, or bilirubin > 2 x upper limit of normal?	☐	☐	☐
32. Has active tuberculosis (positive tuberculin skin test and confirmatory diagnostic chest X-ray)?	☐	☐	☐
33. Has participated in any behavioral and/or pharmacological intervention study, or received "formal" psychosocial treatments w/in two months preceding the beginning of screening, *(with "formal" defined as any treatment provided by a healthcare provider for which they could be reimbursed by an insurance company)?*	☐	☐	☐
34. Is suspect of adult obstructive airway disease, but without formal diagnosis, for example: 1) has a history of wheezing and/or chronic coughing, 2) has a history of adult obstructive airways and/or treatment for this condition more than 2 years before the current application for the study, 3) has a history of other respiratory illnesses, e.g. complications of pulmonary disease (exclude if on beta-agonist), 4) use over-the-counter agonist or allergy medication for respiratory problems (e.g. Primatene Mist)? *If suspect, a detailed history and physical exam should be performed, and possibly pulmonary consult and/or pulmonary function tests, prior to including or excluding from the study.*	☐	☐	☐
35. Has a diagnosis of adult (i.e., 21 years or older) asthma, or chronic obstructive pulmonary disease (COPD), including a history of acute asthma within the past 2 years, or current or recent (past 3 months) treatment with inhaled or oral beta-agonist therapy *(because of potential serious adverse interactions with methamphetamine) or has an* $FEV_1 < 70\%$*?*	☐	☐	☐
36. Has received a drug with known potential toxicity to a major organ system within 30 days prior to screening (e.g. isoniazid, methotrexate)?	☐	☐	☐
37. Is undergoing medication HIV treatment with antiviral and/or non-antiviral therapy?	☐	☐	☐
38. Is taking a medication that could interact adversely with topiramate *(unless the medication is discontinued and the washout criteria specified in Appendix II of the protocol is met)?*	☐	☐	☐
39. Is mandated by the court to obtain treatment for methamphetamine dependence where such mandate requires the results of urine toxicology tests to be reported to the court?	☐	☐	☐
40. Has previously been treated with topiramate for any reason, including research protocols, and has discontinued treatment due to an adverse event, or due to a hyper-sensitivity reaction to topiramate, or is currently taking topiramate for any reason? *(the 7-day washout period as shown in Appendix II of the protocol applies in this case)*	☐	☐	☐

Study025 **Plate044** **V005 (Titration)**

ID# ☐☐☐ ☐☐☐☐ ☐☐☐☐ **Date Form Completed** ☐☐ ☐☐ ☐☐ ☐☐

Center No. **Subject ID No.** **Alpha Code** *month* *day* *year* **Week**

Form 01-Entry Criteria and Enrollment *continued*

Randomization

41. Is subject eligible for randomization? ☐ *No* ☐ *Yes* ☐ *Yes, but declined randomization*

41a. If subject is ineligible for randomization indicate reason: _____

41b. If subject declined randomiztion, indicate reason: _____

42. Did subject provide consent for the Pharmacogenetics arm of the study? ☐ *No* ☐ *Yes**

***** If subject has provided consent for the Pharmacogenetics arm of the study, please call CSPCC to enroll the subject in the Pharmacogenetics arm of the study.

- **Complete questions 43-45 for eligible subjects only.**

43. Has subject reported using methamphetamine within the past 7 days OR had a urine drug screen positive for methamphetamine within the past 7 days? ☐ *No* ☐ *Yes*

If subject is eligible and willing to be randomized, call the CSPCC to randomize the subject.

1-888-831-3325
#1025

The CSPCC will provide the following information:

44. Date of randomization. ☐☐ ☐☐ ☐☐
month *day* *year*

45. Study kit number ☐☐☐☐

month *day* *year*

Form completed by: _____ **Date** ☐☐ ☐☐ ☐☐

Site Investigator's Signature: _____ **Date** ☐☐ ☐☐ ☐☐

Form 10 - Estimated Serum Creatinine Clearance

Study025 **Plate011** **V001 (Screening)**

ID# ☐☐☐ ☐☐☐☐ ☐☐☐☐ **Date of Assessment** ☐☐ ☐☐ ☐☐ ☐☐

Center No. **Subject ID No.** **Alpha Code** *month* *day* *year* **Week**

Form 10-Estimated Serum Creatinine Clearance

*Study staff, complete this form at screening.

1. Gender *(at birth)* ☐ *Male* ☐ *Female*
2. Enter age in years ☐☐ *years*
3. Enter weight at screening *(to nearest pound)* ☐☐☐ *lbs*
4. Enter serum creatinine at screening *(from Form 11 - Clinical Lab Report)* ☐.☐ *mg/dL*

Use the Creatinine Clearance Calculator Excel File to compute estimated creatinine clearance.

5. Enter estimated serum creatinine clearance ☐☐☐.☐☐ *mL/min*

month *day* *year*

Form completed by: _____ **Date** ☐☐ ☐☐ ☐☐

Form 30 - Family History Interview

Schedule of Assessment:

* This form is to be completed at screening only for those subjects who provide consent for the Pharmacogenetics arm of the study.

Interviewer:

* Inform the subject that you are interviewing that to better understand his/her substance abuse problems, it is important to know whether his/her other biological relatives have had psychological, emotional or developmental problems. Many such disorders run in families and may contribute genetically to the subject's substance abuse.

Instructions:

* For each of the relatives listed, note whether they have any of the disorders listed under Column A.
* Assign each aunt, uncle, brother and/or sister an ID (e.g. Uncle 1, 2, or 3).
* For each aunt and uncle, indicate which side of the family they are from by marking (x) 'Pat." for paternal side and 'Mat.' for maternal side in the column heading.
* For each of the problems listed, indicate whether or not each relative experienced that problem by placing an X under the appropriate columns for that relative.
* In cases where there are no relatives with that problem, leave blank

Study025 **Plate060** **V001 (Screening)**

ID# ☐☐☐ ☐☐☐☐ ☐☐☐☐ **Date of Assessment** ☐☐ ☐☐ ☐☐ ☐☐

Center No. **Subject ID No.** **Alpha Code** *month* *day* *year* **Week**

Form 30-Family History Interview

I. PARENTS AND GRANDPARENT

A Problems/Disorders	B Mother	C Father	D Mat. Grand-mother	E Mat. Grand-father	F Pat. Grand-mother	G Pat. Grand-father	H None
1. Psychosis or Schizophrenia	☐	☐	☐	☐	☐	☐	☐
2. Anxiety Disorder that impaired adjustment	☐	☐	☐	☐	☐	☐	☐
3. Depression for more than 2 weeks	☐	☐	☐	☐	☐	☐	☐
4. Tics or Tourette's Syndrome	☐	☐	☐	☐	☐	☐	☐
5. Mental Retardation	☐	☐	☐	☐	☐	☐	☐
6. Problems w/aggressiveness, defiance, & oppositional behavior as a child	☐	☐	☐	☐	☐	☐	☐
7. Problems w/attention, activity & impulse control as a child	☐	☐	☐	☐	☐	☐	☐
8. Learning Disabilities	☐	☐	☐	☐	☐	☐	☐
9. Failed to graduate from High School	☐	☐	☐	☐	☐	☐	☐
10. Antisocial Behavior (assaults, thefts, etc.)	☐	☐	☐	☐	☐	☐	☐
11. Arrests	☐	☐	☐	☐	☐	☐	☐
12. Alcohol Abuse	☐	☐	☐	☐	☐	☐	☐
13. Substance Abuse	☐	☐	☐	☐	☐	☐	☐
14. Tobacco Use/Abuse	☐	☐	☐	☐	☐	☐	☐
15. Physical Abuse	☐	☐	☐	☐	☐	☐	☐
16. Sexual Abuse	☐	☐	☐	☐	☐	☐	☐

Study025 **Plate061** **V001 (Screening)**

ID# **Center No.** **Subject ID No.** **Alpha Code** **Date of Assessment** *month* *day* *year* **Week**

II. UNCLES

A	B	C	D	E	F	G	H	I	J	K	L
Problems/Disorders	☐ *Pat.* ☐ *Mat.* Uncle 1	☐ *Pat.* ☐ *Mat.* Uncle 2	☐ *Pat.* ☐ *Mat.* Uncle 3	☐ *Pat.* ☐ *Mat.* Uncle 4	☐ *Pat.* ☐ *Mat.* Uncle 5	☐ *Pat.* ☐ *Mat.* Uncle 6	☐ *Pat.* ☐ *Mat.* Uncle 7	☐ *Pat.* ☐ *Mat.* Uncle 8	☐ *Pat.* ☐ *Mat.* Uncle 9	☐ *Pat.* ☐ *Mat.* Uncle 10	None
1. Psychosis or Schizophrenia	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
2. Anxiety Disorder that impaired adjustment	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
3. Depression for more than two weeks	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
4. Tics or Tourette's Syndrome	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
5. Mental Retardation	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
6. Problems w/aggressiveness, defiance, & oppositional behavior as a child	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
7. Problems w/attention, activity & impulse control as a child	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
8. Learning Disabilities	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
9. Failed to graduate from High School	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
10. Antisocial Behavior (assaults, thefts, etc.)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
11. Arrests	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
12. Alcohol Abuse	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
13. Substance Abuse	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
14. Tobacco Use/Abuse	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
15. Physical Abuse	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
16. Sexual Abuse	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Study025 **Plate062** **V001 (Screening)**

ID# **Center No.** **Subject ID No.** **Alpha Code** **Date of Assessment** *month* *day* *year* **Week**

III. AUNTS

A	B	C	D	E	F	G	H	I	J	K	L
Problems/Disorders	☐ *Pat.* ☐ *Mat.* Aunt 1	☐ *Pat.* ☐ *Mat.* Aunt 2	☐ *Pat.* ☐ *Mat.* Aunt 3	☐ *Pat.* ☐ *Mat.* Aunt 4	☐ *Pat.* ☐ *Mat.* Aunt 5	☐ *Pat.* ☐ *Mat.* Aunt 6	☐ *Pat.* ☐ *Mat.* Aunt 7	☐ *Pat.* ☐ *Mat.* Aunt 8	☐ *Pat.* ☐ *Mat.* Aunt 9	☐ *Pat.* ☐ *Mat.* Aunt 10	None
1. Psychosis or Schizophrenia	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
2. Anxiety Disorder that impaired adjustment	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
3. Depression for more than two weeks	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
4. Tics or Tourette's Syndrome	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
5. Mental Retardation	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
6. Problems w/aggressiveness, defiance, & oppositional behavior as a child	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
7. Problems w/attention, activity & impulse control as a child	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
8. Learning Disabilities	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
9. Failed to graduate from High School	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
10. Antisocial Behavior (assaults, thefts, etc.)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
11. Arrests	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
12. Alcohol Abuse	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
13. Substance Abuse	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
14. Tobacco Use/Abuse	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
15. Physical Abuse	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
16. Sexual Abuse	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

Study025 **Plate063** **V001 (Screening)**

ID# **Center No.** **Subject ID No.** **Alpha Code** **Date of Assessment** *month* *day* *year* **Week**

IV. SIBLINGS

	A	B	C	D	E	F	G	H	I	J	K	L
		Brother	Brother	Brother	Brother	Brother	Sister	Sister	Sister	Sister	Sister	None
	Problems/Disorders	1	2	3	4	5	1	2	3	4	5	
1.	Psychosis or Schizophrenia	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
2.	Anxiety Disorder that impaired adjustment	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
3.	Depression for more than two weeks	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
4.	Tics or Tourette's Syndrome	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
5.	Mental Retardation	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
6.	Problems w/aggressiveness, defiance, & oppositional behavior as a child	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
7.	Problems w/attention, activity & impulse control as a child	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
8.	Learning Disabilities	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
9.	Failed to graduate from High School	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
10.	Antisocial Behavior (assaults, thefts, etc.)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
11.	Arrests	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
12.	Alcohol Abuse	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
13.	Substance Abuse	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
14.	Tobacco Use/Abuse	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
15.	Physical Abuse	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
16.	Sexual Abuse	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐

month *day* *year*

Form completed by: _____ **Date**

Form 27 - Follow-Up Questionnaire

Study025 **Plate052** **V019 (Follow-Up)**

ID# ☐☐☐ ☐☐☐☐ ☐☐☐☐
Center No. **Subject ID No.** **Alpha Code**

Date of Assessment ☐☐ ☐☐ ☐☐ ☐☐
month *day* *year* **Week**

Form 27-Follow-Up Questionnaire

- To be completed by study staff.
- To be completed for subjects 30 days after termination visit.
- Do not complete this form for subjects who have formally withdrawn and do not permit follow-up
- May be completed via phone interview if subject is unable to return to the clinic.

1. Has contact been made with the subject? ☐ *No* ☐ *Yes*

If **Yes**, complete questions 1a through 1f and Question 5. (If **No**, go to question 2.)

1a. If **Yes,** date of contact: ☐☐ ☐☐ ☐☐
month *day* *year*

1b. Does the subject report currently using methamphetamine illicitly? ☐ *No* ☐ *Yes*

1c. Does the subject report currently using other drugs illicitly? ☐ *No* ☐ *Yes*

1d. Does the subject report currently receiving treatment for drug or alcohol abuse/dependence? ☐ *No* ☐ *Yes*

1e. Does the subject report that he/she would take the study medication again if it were generally available for methamphetamine-dependence treatment? ☐ *No* ☐ *Yes*

1f. Indicate whether the subject thinks that he/she received placebo or the active drug during the treatment phase of the study? ☐ *Placebo* ☐ *Active drug*

2. If <u>contact has not been made</u> with the subject specify reason: _____

3. If <u>unable to contact subject</u>, has contact been made with someone who can verify his/her status? ☐ *No* ☐ *Yes*

3a. If **Yes,** date of contact: ☐☐ ☐☐ ☐☐
month *day* *year*

3b. *(if Yes, go to question 4)* If **No,** explain: _____

4. Has the subject died? ☐ *No* ☐ *Yes* ☐ *Unknown*

4a. If **Yes,** date of death: ☐☐ ☐☐ ☐☐
month *day* *year*

4b. If **Yes,** cause of death: _____

4c. Information verified by site staff *(e.g. coroner's office, death certificate)* ☐ *No* ☐ *Yes*

5. Additional comments: _____

Form completed by: _____ **Date** *month* ☐☐ *day* ☐☐ *year* ☐☐

Form 21 - HIV Risk-Taking Behavior Scale (HRBS)

Study025 **Plate035** **V004 (Baseline / Week -2 or Week -1)**

ID# ☐☐☐ ☐☐☐☐ ☐☐☐☐ **Date of Assessment** ☐☐ ☐☐ ☐☐ ☐☐

Center No. **Subject ID No.** **Alpha Code** *month* *day* *year* **Week**

Form 21-HIV Risk-Taking Behavior Scale (HRBS)

*To be completed by the subject.
*To be completed once at baseline, week 12 (or termination visit), and at follow-up.

Answer the following questions using the codes below. Record your answers in the space provided to the right of each question.

Drug Use

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

1 = Haven't hit up
2 = Once a week or less
3 = More than once a week (but less than once a day)
4 = Once a day
5 = 2-3 times a day
6 = More than 3 times a day

2. How many times in the last month have you used a needle after someone else had already used it? ☐

1 = No times
2 = One time
3 = Two times
4 = 3-5 times
5 = 6-10 times
6 = More than 10 times

3. How many different people have used a needle before you in the last month? ☐

1 = None
2 = One person
3 = Two people
4 = 3-5 people
5 = 6-10 people
6 = More than 10 people

4. How many times in the last month has someone used a needle after you have used it? ☐

1 = No times
2 = One time
3 = Two times
4 = 3-5 times
5 = 6-10 times
6 = More than 10 times

5. How often, in the last month, have you cleaned needles before re-using them? ☐

1 = Does not reuse
2 = Every time
3 = Often
4 = Sometimes
5 = Rarely
6 = Never

6. Before using needles again, how often in the last month did you use bleach to clean them? ☐

1 = Does not reuse
2 = Every time
3 = Often
4 = Sometimes
5 = Rarely
6 = Never

Study025 **Plate036** **V004 (Baseline / Week -2 or Week -1)**

ID# ☐☐☐ ☐☐☐☐ ☐☐☐☐ ☐☐

Center No. **Subject ID No.** **Alpha Code** **Week**

Form 21-HIV Risk-Taking Behavior Scale (HRBS) *continued*

Sexual Behavior

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

1 = None
2 = One person
3 = Two people
4 = 3-5 people
5 = 6-10 people
6 = More than 10 people

8. How often have you used condoms when having sex with your regular partner(s) in the last month? ☐

1 = No regular partner/no penetrative sex
2 = Every time
3 = Often
4 = Sometimes
5 = Rarely
6 = Never

9. How often have you used condoms when you had sex with casual partners? ☐

1 = No casual partners/no penetrative sex
2 = Every time
3 = Often
4 = Sometimes
5 = Rarely
6 = Never

10. How often have you used condoms when you have been paid for sex in the last month? ☐

1 = No paid sex/no penetrative sex
2 = Every time
3 = Often
4 = Sometimes
5 = Rarely
6 = Never

11. How many times have you had anal sex in the last month? ☐

1 = No times
2 = One time
3 = Two times
4 = 3-5 times
5 = 6-10 times
6 = More than 10 times

12. Have you had an HIV test come back positive?
☐ *No*
☐ *Yes*
☐ *Unknown/Never tested*

13. If positive, date of most recent HIV test: ☐☐ *month* ☐☐☐☐ *year*

THANK YOU.
THIS FORM IS COMPLETE. DO NOT SIGN YOUR NAME BELOW.

Form reviewed by: _____ **Date** *month* ☐☐ *day* ☐☐ *year* ☐☐

Form 12 - Infectious Diseases

Study025 **Plate014** **V001 (Screening)**

ID# Center No. | Subject ID No. | Alpha Code

Date Form Completed *month* *day* *year* **Week**

Form 12-Infectious Diseases

*Study staff, complete at screening.

	Result (ENTER CODE BELOW: 1 = Positive, 2 = Negative, 3 = Indeterminate PPD, 9 = Not Done)	**Comments** (Provide comments if a 1, 3 or a 9 is recorded under **Result.**)
1. Hepatitis B Surface Antigen (HBs Ag)		
2. Hepatitis B Surface Antibody (Anti-HBs)		
3. Hepatitis B Core Antibody (Anti-HBc)		
4. Hepatitis C Virus Antibody (HCV Ab)		
5. HIV (optional) *If not done, code 9*		
6. PPD		

6a. If positive, size of induration: ___ *mm* 6b. Date PPD read: *month* *day* *year*

If PPD is positive, indeterminate, or not done, a chest x-ray is required.

6c. Date of chest x-ray: *month* *day* *year* 6d. Chest x-ray result: ☐ *Normal* ☐ *Abnormal, study entry OK*

Comments: _____

7. Date of RPR: *month* *day* *year* 7a. Result of RPR: ☐ *Reactive** ☐ *Non-reactive*

***If reactive, a confirmatory assay for RPR must be performed.**

7b. Date of confirmatory assay *month* *day* *year*

7c. Result of confirmatory assay ☐ *Negative, titer <1:8* ☐ *Positive*

Form completed by: _____ **Date** *month* *day* *year*

Site Investigator's Signature: _____ **Date**

Form 02 - Medical/Surgical/Smoking History

- Study staff, complete at screening
- Use the Codes below to indicate all medical conditions reported by the subject. Codes may be repeated for conditions of the same type.
- Indicate the highest level of severity ever experienced for each condition listed.

Medical Conditions Codes:

01 = Allergies, drug
02 = Allergies, other
03 = Sensitivity to Topiramate
04 = HEENT disorder
05 = Cardiovascular disorder
06 = Renal disorder
07 = Hepatic disorder
08 = Pulmonary disorder, asthma
09 = Pulmonary disorder, other
10 = Gastrointestinal disorder
11 = Musculoskeletal disorder
12 = Neurologic disorder
13 = Psychiatric disorder
14 = Dermatologic disorder
15 = Metabolic disorder
16 = Hematologic disorder
17 = Endocrine disorder
18 = Genitourinary disorder
19 = Reproductory systerm disorder
20 = Infectious disease disorder
21 = Glaucoma
22 = Other

Highest SeverityCodes:

1 = Mild
2 = Moderate
3 = Severe

Form 02 - Medical/Surgical/Smoking History

Study025 **Plate001** **V001 (Screening)**

ID# **Center No.** **Subject ID No.** **Alpha Code**

Date of Assessment *month* *day* *year* **Week**

Form 02-Medical/Surgical/Smoking History

	Medical Conditions Enter applicable code(s) from previous page	**Highest Severity** Record the highest level of severity for the condition listed	**Explanation** A description must be provided for all medical conditions recorded. *(Please print clearly)*
1.			
2.			
3.			
4.			
5.			
6.			
7.			
8.			
9.			
10.			
11.			
12.			
13.			
14.			
15.			
16.			
17.			
18.			
19.			
20.			
21.			
22.			

Study025 **Plate002** **V001 (Screening)**

ID# | **Center No.** | **Subject ID No.** | **Alpha Code** | **Date of Assessment** *month* *day* *year* | **Week**

Form 02-Medical/Surgical/Smoking History

Surgical History

23. Has the subject had any major surgeries? ☐ *No* ☐ *Yes*
If *Yes,* list MAJOR SURGERIES below. If *No,* skip to Question 24.

	Type of Surgery	**Date of Surgery (mm/yyyy)**
a.	_____	
b.	_____	
c.	_____	
d.	_____	
e.	_____	

Smoking History

24. Has the subject ever smoked cigarettes? ☐ *No* ☐ *Yes*
If *Yes,* complete items 24a - 24c. If *No*, skip to Question 25.

a. Currently using cigarettes? ☐ *No* ☐ *Yes*

b. Number of years smoked:
If <6 months, record as '00'; if >6 months, but <1 year, record as '01'.

c. Average NUMBER of cigarettes/day:

25. Has the subject ever used other tobacco products? ☐ *No* ☐ *Yes*
If *Yes,* complete items 25a - 25c. If *No*, form complete.

	CIGAR	**CHEW**	**SNUFF**	**PIPE**
a. Currently using?	☐ *No* ☐ *Yes*	☐ *No* ☐ *Yes*	☐ *No* ☐ *Yes*	☐ *No* ☐ *Yes*
b. Number of years used: If <6 months, record as '00'; if >6 months, but <1 year, record as '01'.				
c. Average NUMBER of times used per day:				

Form completed by: _____ **Date** *month* *day* *year*

Study025 **Plate006** **V001 (Screening)**

ID# **Center No.** **Subject ID No.** **Alpha Code**

Date of Assessment *month* *day* *year* **Week**

Form 04-Methamphetamine Timeline Followback

* Study staff, complete this form at screening. Use the Timeline Followback method to assess methamphetamine use for the 30 days prior to study entry.
* Begin with the day before the subject signed informed consent (Day 1). Indicate methamphetamine use for each day by marking (x) under the column heading, 'yes', or no use by marking (x) under the column heading, 'no'.

month *day* *year*

Day 1 = Day Prior to the Date Subject Signed Informed Consent. Enter Date:

Day 30 =30 Days Prior to the Date Subject Signed Informed Consent. Enter Date:

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

month *day* *year*

Form completed by: _____ **Date**

Study025 **Plate017** **V005 (Randomization)**

ID# **Center No.** **Subject ID No.** **Alpha Code** **Date of Assessment** *month* *day* *year* **Week**

Form 18-Montgomery & Asberg Depression Rating Scale

*Study staff, complete once during screening, weekly during baseline, at the first visit of study weeks 1 - 13, and at follow-up (week 17).

Clinical ratings should be based on symptoms and signs occurring during the WEEK prior to the interview. Record the number that corresponds to the rating scale in the space provided next to each item.

1. Apparent Sadness ☐

Representing despondency, gloom and despair, (more than just ordinary transient low spirits) reflected in speech, facial expression and posture.

Rate by depth and inability to brighten up.

0 No sadness.
1
2 Looks dispirited, but does brighten up without difficulty.
3
4 Appears sad and unhappy most of the time.
5
6 Looks miserable all of the time. Extremely despondent.

2. Reported Sadness ☐

Representing reports of depressed mood, regardless of whether it is reflected in appearance or not. Includes low spirits, despondency or the feeling of being beyond help and without hope.

Rate according to intensity, duration and the extent to which the mood is reported to be influenced by events.

0 Occasional sadness in keeping with the circumstances.
1
2 Sad or low, but brightens up without difficulty.
3
4 Pervasive feeling of sadness or gloominess. The mood is still influenced by external circumstances.
5
6 Continuous or unvarying sadness, misery or despondency.

3. Inner Tension ☐

Representing feelings of ill-defined discomfort, edginess, inner turmoil, mental tension mounting to either panic, dread or anguish.

Rate according to intensity, frequency, duration and the extent of reassurance called for.

0 Placid. Only fleeting inner tension.
1
2 Occasional feelings of edginess and ill defined discomfort.
3
4 Continuous feelings of inner tension or intermittent panic which the patient can only master with some difficulty.
5
6 Unrelenting dread or anguish. Overwhelming panic.

Study025 **Plate018** **V005 (Randomization)**

ID# **Center No.** **Subject ID No.** **Alpha Code** **Week**

Form 18-Montgomery & Asberg Depression Rating Scale *continued*

4. Reduced Sleep ☐

Representing the experience of reduced duration or depth of sleep compared to the subject's own normal pattern when well.

0 Sleeps as usual
1
2 Slight difficulty dropping off to sleep or slightly reduced, light or fitful sleep.
3
4 Sleep reduced or broken by at least two hours
5
6 Less than two or three hours sleep.

5. Reduced Appetite ☐

Representing the feeling of a loss of appetite compared with when well.

Rate by loss of desire for food or the need to force oneself to eat.

0 Normal or increased appetite.
1
2 Slightly reduced appetite.
3
4 No appetite. Food is tasteless.
5
6 Needs persuasion to eat.

6. Concentration Difficulties ☐

Representing difficulties in collecting one's thoughts mounting to incapacitating lack of concentration.

Rate according to intensity, frequency and degree of incapacity produced.

0 No difficulties in concentrating.
1
2 Occasional difficulties in collecting one's thoughts.
3
4 Difficulties concentrating and sustaining thought which reduces ability to read or hold a conversation.
5
6 Unable to read or converse without great difficulty.

7. Lassitude ☐

Representing a difficulty getting started or slowness initiating and performing everyday activities.

0 Hardly any difficulty in getting started. No sluggishness.
1
2 Difficulties in starting activities.
3
4 Difficulties in starting simple routine activities which are carried out with effort.
5
6 Complete lassitude. Unable to do anything without help.

Study025 **Plate019** **V005 (Randomization)**

ID# [ ][ ][ ] [ ][ ][ ][ ] [ ][ ][ ][ ] [ ][ ]
Center No. **Subject ID No.** **Alpha Code** **Week**

Form 18-Montgomery & Asberg Depression Rating Scale *continued*

8. Inability to Feel [ ]

Representing the subjective experience of reduced interest in the surroundings, or activities that normally give pleasure. The ability to react with adequate emotion to circumstance or people is reduced.

0 Normal interest in the surroundings and in other people.
1
2 Reduced ability to enjoy usual interests.
3
4 Loss of interest in surroundings. Loss of feelings for friends and acquaintances.
5
6 The experience of being emotionally paralyzed; inability to feel anger, grief or pleasure and a complete, or even painful, failure to feel for close relatives and friends.

9. Pessimistic Thoughts [ ]

Representing thoughts of guilt, inferiority, self-reproach, sinfulness, remorse and ruin.

0 No pessimistic thoughts.
1
2 Fluctuating ideas of failure, self-reproach or self-deprecation.
3
4 Persistent self accusations or definite but still rational ides of guilt or sin. Increasingly pessimistic about the future.
5
6 Delusions of ruin, remorse or unredeemable sin. Self-accusations which are absurd and unshakable.

10. Suicidal Thoughts [ ]

Representing the feeling that life is not worth living, that a natural death would be welcome, suicidal thoughts and preparations for suicide.

Suicidal attempts should not, in themselves, influence the rating.

0 Enjoys life or takes it as it comes.
1
2 Weary of life. Only fleeting suicidal thoughts.
3
4 Probably better off dead. Suicidal thoughts are common, and suicide is considered as a possible solution, but without specific plans or intentions.
5
6 Explicit plans for suicide when there is an opportunity. Active preparations for suicide.

11. Total Score [ ][ ]

Calculate total score by summing all responses items 1-10.

Form completed by: ______________________

Date [ ][ ] [ ][ ] [ ][ ]
month *day* *year*

Form 29 - Pharmacogenetic (PGx) Sampling

Study025 **Plate056** **V018 (Study completion/Termination)**

ID# ☐☐☐ ☐☐☐☐ ☐☐☐☐

Center No. **Subject ID No.** **Alpha Code**

Form 29-Pharmacogenetic (PGx) Sampling

*Study staff, complete an entry in this log for every PGx blood sample collection throughout the study. Retain this form until the subject completes, or is terminated from the study. If the subject provides blood at screening for the PGx arm of the study, but is not randomized, record the subject ID number above, complete Q. 1 and 2 and submit this form to the CSPCC.

1. Screening DNA sample for Pharmacogenetics Protocol (to be collected in BLUE tube)

a. Was the screening DNA sample collected for this subject? ☐ *No* ☐ *Yes*

b. Date sample collected ☐☐ ☐☐ ☐☐ (*month* *day* *year*)

c. Time sample collected (24 hour clock) ☐☐ : ☐☐ (Hours Minutes)

2. Screening RNA sample for Pharmacogenetics Protocol (to be collected in RED tube)

a. Were the screening RNA samples collected for this subject? ☐ *No* ☐ *Yes*

b. Date sample collected ☐☐ ☐☐ ☐☐ (*month* *day* *year*)

c. Time sample collected (24 hour clock) ☐☐ : ☐☐ (Hours Minutes)

3. Week 8 RNA sample for Pharmacogenetics Protocol (to be collected in RED tube)

a. Were the week 8 RNA samples collected for this subject? ☐ *No* ☐ *Yes*

b. Date sample collected ☐☐ ☐☐ ☐☐ (*month* *day* *year*)

c. Time sample collected (24 hour clock) ☐☐ : ☐☐ (Hours Minutes)

4. Week 12 RNA sample for Pharmacogenetics Protocol (to be collected in RED tube)

a. Were the week 12 RNA samples collected for this subject? ☐ *No* ☐ *Yes*

b. Date sample collected ☐☐ ☐☐ ☐☐ (*month* *day* *year*)

c. Time sample collected (24 hour clock) ☐☐ : ☐☐ (Hours Minutes)

Form completed by: _____ **Date** ☐☐ ☐☐ ☐☐ (*month* *day* *year*)

Study025 **Plate003** **V005 (Screening-Titration day 1)**

ID# ☐☐☐ ☐☐☐☐ ☐☐☐☐
Center No. **Subject ID No.** **Alpha Code**

Date of Assessment ☐☐ ☐☐ ☐☐ ☐☐
month *day* *year* **Week**

Form 03-Physical Exam/SCID

- Study staff, complete this form at screening and update on study day 1, before first dose of study drug is given.
- Complete this form at week 12, or termination visit, if prior to week 12.

1. Height *(complete at Screening Only)* ☐☐.☐ *inches*

	Results of Exam 1 = Normal 2 = Abnormal, Does Not Exclude 3 = Abnormal, Excludes 9 = Not Done	**Explanation** You must provide details if a 2, 3, or a 9 is recorded under **Results** *(Please Print Clearly)*
2. HEENT (incl. thyroid/neck)	☐	_____
3. Cardiovascular	☐	_____
4. Lungs	☐	_____
5. Abdomen (incl. liver, spleen)	☐	_____
6. Extremities	☐	_____
7. Skin	☐	_____
8. Neuropsychiatric:		
a. Mental status	☐	_____
b. Sensory/Motor	☐	_____
9. Lymph nodes	☐	_____
10. Musculoskeletal	☐	_____
11. General appearance	☐	_____
12. Other _____ *(specify)*	☐	_____
13. Other _____ *(specify)*	☐	_____
14. Other _____ *(specify)*	☐	_____
15. Other _____ *(specify)*	☐	_____

Study025 **Plate004** **V005 (Screening-Titration day 1)**

ID# ☐☐☐ ☐☐☐☐ ☐☐☐☐ ☐☐

Center No. **Subject ID No.** **Alpha Code** **Week**

Form 03-Physical Exam/SCID **COMPLETE THIS PAGE AT SCREENING ONLY**

16. **SCID - Summary of Axis I Diagnoses:**
For items a - l, indicate the three, four, or five-digit DSM-IV diagnostic code for all Axis I diagnoses. After the '/' use the sixth digit to indicate the following specifiers:

0 = Current, severity not specified *2 = Current, moderate* *5 = in partial remission*
1 = Current, mild *3 = Current, severe* *6 = in full remission*

Note: When the specifier information is already included in the fifth digit of the code, repeat the specifier as the sixth digit.

a. ☐☐☐.☐☐/☐ **e.** ☐☐☐.☐☐/☐ **i.** ☐☐☐.☐☐/☐
b. ☐☐☐.☐☐/☐ **f.** ☐☐☐.☐☐/☐ **j.** ☐☐☐.☐☐/☐
c. ☐☐☐.☐☐/☐ **g.** ☐☐☐.☐☐/☐ **k.** ☐☐☐.☐☐/☐
d. ☐☐☐.☐☐/☐ **h.** ☐☐☐.☐☐/☐ **l.** ☐☐☐.☐☐/☐

month *day* *year*

Form completed by: _____ **Date** ☐☐ ☐☐ ☐☐

Physician's Signature: _____ **Date** ☐☐ ☐☐ ☐☐

Form 06 - Prior Medications

Study staff, complete this form at every study visit from screening - study Day 1.

List all medications taken by the subject during the period 30 days prior to signing the Informed Consent through Study Day 1, prior to receiving first dose of study drug.

Enter all prescription and over-the-counter drugs taken therapeutically, including herbal preparations. Make a new entry when a dosage and/or frequency change occurs. Record any medications that continue to be taken after the first dose of study drug on Form 23, Concomitant Medications and continue to assess them at every study visit.

Submit this form to the CSPCC after randomization. Attach and number additional pages as needed.

Use the following codes to complete the form:

Route

1 = Oral
2 = Nasal
3 = Intravenous
4 = Inhalation
5 = Topical/transdermal
6 = Intramuscular
7 = Sublingual
8 = Subcutaneous
9 = Other

Units

01 = Capsule/Tablet
02 = Drop
03 = Milligram
04 = Milliliter
05 = Puff
06 = Spray/squirt
07 = Tablespoon
08 = Teaspoon
09 = Unknown
10 = Other

Frequency

1 = Once a day
2 = Twice a day
3 = Three times a day
4 = Four times a day
5 = PRN

Study025 **Plate007**

Page Number *(01, 02, ... etc.)*

ID# **Center No.** **Subject ID No.** **Alpha Code**

Date of Assessment *month* *day* *year*

Week

Prior Medications

I. Did the subject report any medications during the period 30 days prior to signing the Informed Consent through Study Day 1, prior to receiving first dose of study drug? ☐ *No* ☐ *Yes*

1.
Generic Name of Med _____ **Purpose/Indication** _____ **Medication Start Date** *month* *day* *year*
Medication Stop Date
Dose . **Route** **Units** **Frequency** ☐ *Mark (x) if continuing*

2.
Generic Name of Med _____ **Purpose/Indication** _____ **Medication Start Date** *month* *day* *year*
Medication Stop Date
Dose . **Route** **Units** **Frequency** ☐ *Mark (x) if continuing*

3.
Generic Name of Med _____ **Purpose/Indication** _____ **Medication Start Date** *month* *day* *year*
Medication Stop Date
Dose . **Route** **Units** **Frequency** ☐ *Mark (x) if continuing*

4.
Generic Name of Med _____ **Purpose/Indication** _____ **Medication Start Date** *month* *day* *year*
Medication Stop Date
Dose . **Route** **Units** **Frequency** ☐ *Mark (x) if continuing*

5.
Generic Name of Med _____ **Purpose/Indication** _____ **Medication Start Date** *month* *day* *year*
Medication Stop Date
Dose . **Route** **Units** **Frequency** ☐ *Mark (x) if continuing*

Will an additional page be used to record **prior medications?** ☐ *No* ☐ *Yes* → If ***Yes***, record the next page number

Form completed by: _____ **Date** *month* *day* *year*

Site Investigator's Signature: _____ **Date**

Form 28 - Protocol Non-Compliance

Study025 **Plate055** **Page Number**

ID# **Center No.** **Subject ID No.** **Alpha Code**

Form 28-Protocol Non-Compliance

*This form is to be completed by a study monitor to record every event of protocol non-compliance throughout the study. Use the Non-Compliance codes at the foot of this form to describe the event. For multiple events of non-compliance that occur on the same date, assign a sequential event number to each event. Single events for a date should be assigned an event number of 01.

	Date of Non-compliance *month*	*day*	*year*	Event #	Non-compliance Code	Reason for Non-compliance
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						
9.						
10.						

Non-compliance codes:
1 = Informed consent signed after patient started screening procedures (record date screening procedures were initiated as date of non-compliance)
2 = Inclusion/Exclusion criteria not met (record date patient was randomized as date of non-compliance)
3 = Pregnancy test not performed at screening (record date patient was randomized as date of non-compliance)
4 = Screening information incomplete (record date patient was randomized as date of non-compliance)
5 = Medication not given according to dosing instruction in protocol
6 = Required study data not obtained or obtained late during treatment phase (record date data was due from starter sheet as date of non-compliance)
7 = Source data documentation not available (record date data collected as date of non-compliance)
8 = Serious adverse event not reported appropriately (record date of serious adverse event as date of non-compliance)
9 = Other

month *day* *year*

Form completed by: _____ **Date**

Site Investigator's Signature: _____ **Date**

NIDA/VA CS # 1025
Topiramate for Methamphetamine Dependence

Notice of Review & Approval

Date: August 16, 2006

Changes to Form 25, SAE Data Entry Form, Version 1, 06.15.2006, have been approved for distribution to clinical sites & subsequent data collection. These changes are reflected in the Forms Change Log and will bear an amended date of 08.15.2006 in the page footer.

_____ _____

Erin Iturriaga, RN (NIDA Representative) Date

Study025 **Plate071** **SAE Number**

ID# **Center No.** **Subject ID No.** **Alpha Code** **Date Form Completed** *month* *day* *year* **Week**

Form 25-SAE Entry Form

- This form can be used to gather data about the SAE for entry into SAETRS. It is used as the source of record for the SAE. Keep a copy of this completed form in the patient's medical record.

Participant Data

*Mandatory Field

1. Sex ☐ *Male* ☐ *Female*
2. Ethnicity *(select one)* ☐ *Hispanic or Latino* ☐ *Not Hispanic or Latino* ☐ *Unknown/Not Given*
3. Race *(select as many as deemed appropriate)* ☐ *American Indian or Alaskan Native* ☐ *Asian* ☐ *Black or African-American* ☐ *Native Hawaiian, or Pacific Islander* ☐ *White*
4. Intervention/Treatment group assignment: ☐ *Active Medication* ☐ *Placebo* ☐ *Blinded*
5. First study consent date: *(partial allowed - mm/dd/yy || mm/yy)* *month* *day* *year*
6. First dose of study agent date *(partial allowed - mm/dd/yy || mm/yy)* *month* *day* *year*

General Information

7. *Birth date *month* *day* *year*
8. Age ____ *Years*
9. Weight ____.__ ☐ *Pounds* ☐ *Kilograms*
10. Height ____.__ ☐ *Inches* ☐ *Centimeters*
11. *Event onset date *month* *day* *year*
12. *Report date *month* *day* *year*
13. *Event name _____
14. *Description of adverse event *(symptoms, course, duration, treatment, and sequelae)* _____
15. Relevant test data *(relevant tests/laboratory data, including dates)* _____

Study025 **Plate072** **SAE Number** ☐☐

ID# ☐☐☐ ☐☐☐☐ ☐☐☐☐ ☐☐

Center No. **Subject ID No.** **Alpha Code** **Week**

16. Relevant medical psychiatric history
(AIDS, high blood pressure, hepatic/renal dysfunction, pregnancy, drug, alcohol, and smoking use, allergies, etc.)

17. Study phase *(select one)*
- ☐ *Screening/Baseline*
- ☐ *Treatment*
- ☐ *Follow-up*

	month	*day*	*year*
18. Last dose of study agent date *(partial allowed - mm/dd/yy || mm/yy)*	☐☐	☐☐	☐☐
19. Event end date *(partial allowed - mm/dd/yy || mm/yy)*	☐☐	☐☐	☐☐

Contact Person
(Please list the person at the clinical site to whom questions regarding the SAE should be addressed)

20. Name of person
21. Phone
22. Email address

Categorization
(Select as many as deemed appropriate)

23. Categorization
- ☐ *Death*
- ☐ *Life threatening*
- ☐ *Hospitalization (initial or prolonged)*
- ☐ *Disability*
- ☐ *Congenital (if checked, select one congenital from below)*
  - ☐ *Anomaly*
  - ☐ *Miscarriage*
  - ☐ *Aborted*
  - ☐ *Stillbirth*
  - ☐ *Infant death within first year of life*
- ☐ *Required intervention to prevent impairment/damage*
- ☐ *Other (if other, specify)*

Study025 **Plate073** **SAE Number** ☐☐

ID# ☐☐☐ ☐☐☐☐ ☐☐☐☐ ☐☐

Center No. **Subject ID No.** **Alpha Code** **Week**

Assessment of SAE

24. Severity *(select one)*
- ☐ *Severe*
- ☐ *Moderate*
- ☐ *Mild*

25. Expectedness *(select one)*
- ☐ *Expected*
- ☐ *Unexpected*

26. Study agent related *(select one)*
- ☐ *Definitely*
- ☐ *Probably*
- ☐ *Possibly*
- ☐ *Definitey not*
- ☐ *Unknown*

27. Outcome *(select one)*
- ☐ *Recovered/Resolved*
- ☐ *Recovering/Resolving*
- ☐ *Not recovered/Not resolved*
- ☐ *Recovered/Resolved w/sequelae*
- ☐ *Fatal*
- ☐ *Lost to follow-up*

28. Death date *(partial allowed - mm/dd/yy || mm/yy)* *month* ☐☐ *day* ☐☐ *year* ☐☐

29. Autopsy performed *(select one)*
- ☐ *Yes*
- ☐ *No*
- ☐ *Unknown*

30. Cause of death _____

_____

_____

Psychiatric History

31. Is there a history of psychotic episodes?
- ☐ *Yes*
- ☐ *No*

32. Is the participant taking psychotropic medications?
- ☐ *Yes**
- ☐ *No*

33. Is the participant taking any other type of medications?
- ☐ *Yes**
- ☐ *No*

** List all concomitant medications on Form 23. If concomitant meds are suspected to have contributed to the SAE, complete concomitant meds section on page 8.*

Study025 **Plate074** **SAE Number** ☐☐

ID# ☐☐☐ ☐☐☐☐ ☐☐☐☐ ☐☐
Center No. **Subject ID No.** **Alpha Code** **Week**

34. Is there a history of suicidal ideation?
☐ *Yes*
☐ *No*

35. Is there a history of suicidal behavior?
☐ *Yes*
☐ *No*

36. Is there a history of homicidal ideation?
☐ *Yes*
☐ *No*

37. Is there a history of homicidal behavior?
☐ *Yes*
☐ *No*

38. Is there a history of violent behavior?
☐ *Yes*
☐ *No*

Substance Use

39. Is there recent increased drug use?
☐ *Yes*
☐ *No*
☐ *Unknown*

40. Is there recent increased alcohol use
☐ *Yes*
☐ *No*
☐ *Unknown*

41. Describe drug/alcohol use during two weeks prior to event:

_____

_____

_____

42. Amount/Days of drug/alcohol use during two weeks prior to event: _____

Action Resulting from SAE

43. Study agent *(select one)*
☐ *No Action*
☐ *Discontinued permanently*
☐ *Discontinued temporarily*
☐ *Reduced dose*
☐ *Increased dose*
☐ *Delayed dose*
☐ *Continued dose*
☐ *Unknown*

Study025 **Plate075** **SAE Number** ☐☐

ID# ☐☐☐ ☐☐☐☐ ☐☐☐☐ ☐☐

Center No. **Subject ID No.** **Alpha Code** **Week**

44. Study treatment participation *(select one)*
- ☐ *Continue in study*
- ☐ *Discontinue from study*
- ☐ *Transferred to follow-up*

45. IRB notification date *(Date must be completed prior to authorization and validation)*

month ☐☐ *day* ☐☐ *year* ☐☐

46. Informed Consent *(select one)*
- ☐ *No change*
- ☐ *Changed Informed Consent*

47. Study protocol *(select one)*
- ☐ *No change*
- ☐ *Change in study protocol*
- ☐ *Pending*

Additional Comments

_____

_____

_____

Authorization Information - ***Authorization completed through SAETRS applicaiton.***

Study025 **Plate076** **SAE Number**

ID# **Center No.** **Subject ID No.** **Alpha Code** **Week**

*Mandatory Field

Add Comments

Note: Commented By and Date fields will be generated by the system as the SAETRS login used to enter the comment(s) and the date on which the comment(s) were entered into the system.

Enter On Behalf of:	***Comment:**

Route Types
(select one)

Auricular (otic)
Buccal
Intra-Articular
Intramuscular
Intraocular
Intravenous *(not otherwise specified)*
Opthalmic
Oral
Rectal
Inhaled
Nasal
Subcutaneous
Sublingual
Topical
Transdermal

Frequency Types
(select one)

As needed
Every other day
Four times a day
Once daily
Other-specify
Single dose
Three times a day
Twice daily

Dosage Types
(select one)

Grain(s)
Gram(s)
International units
Microcurie(s)
Microgram(s)
Microgram(s)/kilogram
Microgram(s)/sq. meter
Microliter(s)
Millicurie(s)
Milliequivalent(s)
Milligram(s)
Milligram(s)/kilogram
Milligram(s)/sq. meter
Milliliter(s)
Other-specify

Form Types
(select one)

Capsule
Drop
Gum
Lollipop
Lotion/Ointment
Lozenge
Ounce
Other-specify
Patch
Puff
Spray/squirt
suppository
Tablespoon
Tablet
Teaspoon
Wafer

Study025 **Plate077** **SAE Number**

ID# **Center No.** **Subject ID No.** **Alpha Code** **Week**

*Mandatory Field

Study Agent

* Name _____ Lot Number _____

Expiration date *(partial allowed - mm/dd/yy || mm/yy)* *month* *day* *year*

Route _____ Frequency _____ Blind ☐ *Blinded* ☐ *Unblinded* _____

Dosage _____ Form _____

Start date *(partial allowed mm/dd/yy || mm/yy)* *month* *day* *year*

Stopdate *(partial allowed mm/dd/yy || mm/yy)* *month* *day* *year*

Restart date *(partial allowed mm/dd/yy || mm/yy)* *month* *day* *year*

Continuing ☐ *Yes* ☐ *No*

Comments: _____

Study agents intake: _____

*Mandatory Field

Study Agent

* Name _____ Lot Number _____

Expiration date *(partial allowed - mm/dd/yy || mm/yy)* *month* *day* *year*

Route _____ Frequency _____ Strength ☐ *Blinded* ☐ *Unblinded* _____

Dosage _____ Form _____

Start date *(partial allowed mm/dd/yy || mm/yy)* *month* *day* *year*

Stopdate *(partial allowed mm/dd/yy || mm/yy)* *month* *day* *year*

Restart date *(partial allowed mm/dd/yy || mm/yy)* *month* *day* *year*

Continuing ☐ *Yes* ☐ *No*

Comments: _____

Study agents intake: _____

Study025 **Plate078** **SAE Number**

ID# **Center No.** **Subject ID No.** **Alpha Code** **Week**

Study staff, enter Concomitant Medications on this page only if they are suspected to have contributed to the SAE.
All concomitant medications taken during the study are to be listed on Form 23, Concomitant Meds.

Concomitant Medications *Mandatory Field

1. * Name _____ Indication _____ Lot Number _____

Expiration date (*month day year*) | Start date (*month day year*) | Stop date (*month day year*) | Continuing: ☐ *Yes* ☐ *No*

(partial allowed for Expiration, Start and Stop dates- mm/dd/yy || mm/yy)

Route _____ Frequency _____ Strength _____ Dosage _____ Form _____

2. * Name _____ Indication _____ Lot Number _____

Expiration date (*month day year*) | Start date (*month day year*) | Stop date (*month day year*) | Continuing: ☐ *Yes* ☐ *No*

(partial allowed for Expiration, Start and Stop dates- mm/dd/yy || mm/yy)

Route _____ Frequency _____ Strength _____ Dosage _____ Form _____

3. * Name _____ Indication _____ Lot Number _____

Expiration date (*month day year*) | Start date (*month day year*) | Stop date (*month day year*) | Continuing: ☐ *Yes* ☐ *No*

(partial allowed for Expiration, Start and Stop dates- mm/dd/yy || mm/yy)

Route _____ Frequency _____ Strength _____ Dosage _____ Form _____

4. * Name _____ Indication _____ Lot Number _____

Expiration date (*month day year*) | Start date (*month day year*) | Stop date (*month day year*) | Continuing: ☐ *Yes* ☐ *No*

(partial allowed for Expiration, Start and Stop dates- mm/dd/yy || mm/yy)

Route _____ Frequency _____ Strength _____ Dosage _____ Form _____

month day year

Form completed by: _____ **Date** ☐☐ ☐☐ ☐☐

Physician: _____ **Date** ☐☐ ☐☐ ☐☐

Site Investigator Signature: _____ **Date** ☐☐ ☐☐ ☐☐

See Operations Manual for more detailed completion instructions.

Make entries on this form at every screening, baseline and study visit.

Complete one form per study week and update at subsequent visit(s) to capture use that may have occurred later on the day of report.

Enter the dates for each day of the study week in the column headings.
Indicate whether substance use occurred by marking (**x**) No = No use, or Yes = Use for each substance listed in the rows. Enter the amount of alcohol used and the route(s) of administration for each substance. Refer to the tables below to complete these items. If no substance was used, enter '0' for these items.

Routes of Administration

1 = Oral
2 = Nasal
3 = Intravenous
4 = Inhalation
5 = Topical Transdermal
6 = Intramuscular
7 = Sublingual
8 = Subcutaneous
9 = Other

Standard Drink Calculator

One standard drink is equal to:

12 oz. of beer
4 oz. of wine
2.5 oz. of fortified wine
1 oz. of hard liquor

Form 14 - Substance Use Report (SUR)

Study025 **Plate015** **V301 (Screening-Baseline #1)**

ID# Center No. | Subject ID No. | Alpha Code | Week

Form 14-Substance Use Report (SUR)

	Day 1 Date	Day 2 Date	Day 3 Date	Day 4 Date
	month day year	*month day year*	*month day year*	*month day year*
Nicotine?	No Yes → Route	No Yes → Route	No Yes → Route	No Yes → Route
Cannabinoids (THC)?	No Yes → Route	No Yes → Route	No Yes → Route	No Yes → Route
Barbiturates?	No Yes → Route	No Yes → Route	No Yes → Route	No Yes → Route
Metham-phetamine?	No Yes → Route	No Yes → Route	No Yes → Route	No Yes → Route
Cocaine?	No Yes → Route	No Yes → Route	No Yes → Route	No Yes → Route
Opiates?	No Yes → Route	No Yes → Route	No Yes → Route	No Yes → Route
Amphe-tamines?	No Yes → Route	No Yes → Route	No Yes → Route	No Yes → Route
Other substance?	No Yes → Route	No Yes → Route	No Yes → Route	No Yes → Route
Specify Substance:	_____	_____	_____	_____
Alcohol?	No Yes → #Std. Drinks	No Yes → #Std. Drinks	No Yes → #Std. Drinks	No Yes → #Std. Drinks

Study025 **Plate016** **V301 (Screening-Baseline #1)**

ID# **Center No.** **Subject ID No.** **Alpha Code** **Week**

Form 14-Substance Use Report (SUR) *continued*

	Day 5 Date *month day year*	**Day 6 Date** *month day year*	**Day 7 Date** *month day year*
	No Yes Route	**No Yes Route**	**No Yes Route**
Nicotine?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Cannabinoids (THC)?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Barbiturates?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Metham-phetamine?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Cocaine?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Opiates?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Amphe-tamines?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Other substance?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Specify Substance:	_____	_____	_____
	No Yes #Std. Drinks	**No Yes #Std. Drinks**	**No Yes #Std. Drinks**
Alcohol?	☐ ☐ → ☐☐	☐ ☐ → ☐☐	☐ ☐ → ☐☐

Form completed by: _____ **Date** *month* ☐☐ *day* ☐☐ *year* ☐☐

Form 14 - Substance Use Report (SUR)

Study025 **Plate015** **V302 (Screening-Baseline #2)**

ID# **Center No.** **Subject ID No.** **Alpha Code** **Week**

Form 14-Substance Use Report (SUR)

	Day 1 Date (month / day / year)	Day 2 Date (month / day / year)	Day 3 Date (month / day / year)	Day 4 Date (month / day / year)
Nicotine?	No ☐ Yes ☐ → Route ☐	No ☐ Yes ☐ → Route ☐	No ☐ Yes ☐ → Route ☐	No ☐ Yes ☐ → Route ☐
Cannabinoids (THC)?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Barbiturates?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Metham-phetamine?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Cocaine?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Opiates?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Amphe-tamines?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Other substance?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Specify Substance:	_____	_____	_____	_____
Alcohol?	No ☐ Yes ☐ → #Std. Drinks ☐☐	No ☐ Yes ☐ → #Std. Drinks ☐☐	No ☐ Yes ☐ → #Std. Drinks ☐☐	No ☐ Yes ☐ → #Std. Drinks ☐☐

Study025 **Plate016** **V302 (Screening-Baseline #2)**

ID# **Center No.** **Subject ID No.** **Alpha Code** **Week**

Form 14-Substance Use Report (SUR) *continued*

	Day 5 Date *month day year*	**Day 6 Date** *month day year*	**Day 7 Date** *month day year*
	No Yes Route	**No Yes Route**	**No Yes Route**
Nicotine?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Cannabinoids (THC)?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Barbiturates?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Metham-phetamine?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Cocaine?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Opiates?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Amphe-tamines?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Other substance?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Specify Substance:	_____	_____	_____
	No Yes #Std. Drinks	**No Yes #Std. Drinks**	**No Yes #Std. Drinks**
Alcohol?	☐ ☐ → ☐☐	☐ ☐ → ☐☐	☐ ☐ → ☐☐

Form completed by: _____ **Date** *month* ☐☐ *day* ☐☐ *year* ☐☐

Form 14 - Substance Use Report (SUR)

Study025 **Plate015** **V303 (Screening-Baseline #3)**

ID# **Center No.** **Subject ID No.** **Alpha Code** **Week**

Form 14-Substance Use Report (SUR)

	Day 1 Date (month / day / year)	Day 2 Date (month / day / year)	Day 3 Date (month / day / year)	Day 4 Date (month / day / year)
Nicotine?	No ☐ Yes ☐ → Route ☐	No ☐ Yes ☐ → Route ☐	No ☐ Yes ☐ → Route ☐	No ☐ Yes ☐ → Route ☐
Cannabinoids (THC)?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Barbiturates?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Metham-phetamine?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Cocaine?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Opiates?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Amphe-tamines?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Other substance?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Specify Substance:	_____	_____	_____	_____
Alcohol?	No ☐ Yes ☐ → #Std. Drinks ☐☐	No ☐ Yes ☐ → #Std. Drinks ☐☐	No ☐ Yes ☐ → #Std. Drinks ☐☐	No ☐ Yes ☐ → #Std. Drinks ☐☐

Study025 **Plate016** **V303 (Screening-Baseline #3)**

ID# **Center No.** **Subject ID No.** **Alpha Code** **Week**

Form 14-Substance Use Report (SUR) *continued*

	Day 5 Date *month day year*	**Day 6 Date** *month day year*	**Day 7 Date** *month day year*
	No Yes Route	**No Yes Route**	**No Yes Route**
Nicotine?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Cannabinoids (THC)?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Barbiturates?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Metham-phetamine?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Cocaine?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Opiates?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Amphe-tamines?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Other substance?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Specify Substance:	_____	_____	_____
	No Yes #Std. Drinks	**No Yes #Std. Drinks**	**No Yes #Std. Drinks**
Alcohol?	☐ ☐ → ☐☐	☐ ☐ → ☐☐	☐ ☐ → ☐☐

Form completed by: _____ **Date** *month* ☐☐ *day* ☐☐ *year* ☐☐

Form 14 - Substance Use Report (SUR)

Study025 **Plate015** **V304 (Screening-Baseline #4)**

ID# **Center No.** **Subject ID No.** **Alpha Code** **Week**

Form 14-Substance Use Report (SUR)

	Day 1 Date (month / day / year)	Day 2 Date (month / day / year)	Day 3 Date (month / day / year)	Day 4 Date (month / day / year)
Nicotine?	No / Yes → Route	No / Yes → Route	No / Yes → Route	No / Yes → Route
Cannabinoids (THC)?	No / Yes → Route	No / Yes → Route	No / Yes → Route	No / Yes → Route
Barbiturates?	No / Yes → Route	No / Yes → Route	No / Yes → Route	No / Yes → Route
Metham-phetamine?	No / Yes → Route	No / Yes → Route	No / Yes → Route	No / Yes → Route
Cocaine?	No / Yes → Route	No / Yes → Route	No / Yes → Route	No / Yes → Route
Opiates?	No / Yes → Route	No / Yes → Route	No / Yes → Route	No / Yes → Route
Amphe-tamines?	No / Yes → Route	No / Yes → Route	No / Yes → Route	No / Yes → Route
Other substance?	No / Yes → Route	No / Yes → Route	No / Yes → Route	No / Yes → Route
Specify Substance:	_____	_____	_____	_____
Alcohol?	No / Yes → #Std. Drinks	No / Yes → #Std. Drinks	No / Yes → #Std. Drinks	No / Yes → #Std. Drinks

Study025 **Plate016** **V304 (Screening-Baseline #4)**

ID# **Center No.** **Subject ID No.** **Alpha Code** **Week**

Form 14-Substance Use Report (SUR) *continued*

	Day 5 Date *month day year*	**Day 6 Date** *month day year*	**Day 7 Date** *month day year*
	No Yes Route	**No Yes Route**	**No Yes Route**
Nicotine?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Cannabinoids (THC)?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Barbiturates?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Metham-phetamine?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Cocaine?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Opiates?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Amphe-tamines?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Other substance?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Specify Substance:	_____	_____	_____
	No Yes #Std. Drinks	**No Yes #Std. Drinks**	**No Yes #Std. Drinks**
Alcohol?	☐ ☐ → ☐☐	☐ ☐ → ☐☐	☐ ☐ → ☐☐

Form completed by: _____ **Date** *month* ☐☐ *day* ☐☐ *year* ☐☐

Form 14 - Substance Use Report (SUR)

Study025 **Plate015** **V305 (Screening-Baseline #5)**

ID# **Center No.** **Subject ID No.** **Alpha Code** **Week**

Form 14-Substance Use Report (SUR)

	Day 1 Date (month / day / year)	Day 2 Date (month / day / year)	Day 3 Date (month / day / year)	Day 4 Date (month / day / year)
Nicotine?	No / Yes → Route	No / Yes → Route	No / Yes → Route	No / Yes → Route
Cannabinoids (THC)?	No / Yes → Route	No / Yes → Route	No / Yes → Route	No / Yes → Route
Barbiturates?	No / Yes → Route	No / Yes → Route	No / Yes → Route	No / Yes → Route
Metham-phetamine?	No / Yes → Route	No / Yes → Route	No / Yes → Route	No / Yes → Route
Cocaine?	No / Yes → Route	No / Yes → Route	No / Yes → Route	No / Yes → Route
Opiates?	No / Yes → Route	No / Yes → Route	No / Yes → Route	No / Yes → Route
Amphe-tamines?	No / Yes → Route	No / Yes → Route	No / Yes → Route	No / Yes → Route
Other substance?	No / Yes → Route	No / Yes → Route	No / Yes → Route	No / Yes → Route
Specify Substance:	_____	_____	_____	_____
Alcohol?	No / Yes → #Std. Drinks	No / Yes → #Std. Drinks	No / Yes → #Std. Drinks	No / Yes → #Std. Drinks

Study025 **Plate016** **V305 (Screening-Baseline #5)**

ID# **Center No.** **Subject ID No.** **Alpha Code** **Week**

Form 14-Substance Use Report (SUR) *continued*

	Day 5 Date *month day year*	**Day 6 Date** *month day year*	**Day 7 Date** *month day year*
	No Yes Route	**No Yes Route**	**No Yes Route**
Nicotine?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Cannabinoids (THC)?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Barbiturates?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Metham-phetamine?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Cocaine?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Opiates?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Amphe-tamines?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Other substance?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Specify Substance:	_____	_____	_____
	No Yes #Std. Drinks	**No Yes #Std. Drinks**	**No Yes #Std. Drinks**
Alcohol?	☐ ☐ → ☐☐	☐ ☐ → ☐☐	☐ ☐ → ☐☐

Form completed by: _____ **Date** *month* ☐☐ *day* ☐☐ *year* ☐☐

Form 14 - Substance Use Report (SUR)

Study025 **Plate015** **V306 (Screening-Baseline #6)**

ID# **Center No.** **Subject ID No.** **Alpha Code** **Week**

Form 14-Substance Use Report (SUR)

	Day 1 Date			Day 2 Date			Day 3 Date			Day 4 Date		
	month	*day*	*year*	*month*	*day*	*year*	*month*	*day*	*year*	*month*	*day*	*year*

	Day 1 Date			Day 2 Date			Day 3 Date			Day 4 Date		
	No	Yes	Route	No	Yes	Route	No	Yes	Route	No	Yes	Route
Nicotine?	☐	☐ →	☐	☐	☐ →	☐	☐	☐ →	☐	☐	☐ →	☐
Cannabinoids (THC)?	☐	☐ →	☐	☐	☐ →	☐	☐	☐ →	☐	☐	☐ →	☐
Barbiturates?	☐	☐ →	☐	☐	☐ →	☐	☐	☐ →	☐	☐	☐ →	☐
Metham-phetamine?	☐	☐ →	☐	☐	☐ →	☐	☐	☐ →	☐	☐	☐ →	☐
Cocaine?	☐	☐ →	☐	☐	☐ →	☐	☐	☐ →	☐	☐	☐ →	☐
Opiates?	☐	☐ →	☐	☐	☐ →	☐	☐	☐ →	☐	☐	☐ →	☐
Amphe-tamines?	☐	☐ →	☐	☐	☐ →	☐	☐	☐ →	☐	☐	☐ →	☐
Other substance?	☐	☐ →	☐	☐	☐ →	☐	☐	☐ →	☐	☐	☐ →	☐
Specify Substance:	_____			_____			_____			_____		
	No	Yes	#Std. Drinks	No	Yes	#Std. Drinks	No	Yes	#Std. Drinks	No	Yes	#Std. Drinks
Alcohol?	☐	☐ →	☐☐	☐	☐ →	☐☐	☐	☐ →	☐☐	☐	☐ →	☐☐

Study025 **Plate016** **V306 (Screening-Baseline #6)**

ID# **Center No.** **Subject ID No.** **Alpha Code** **Week**

Form 14-Substance Use Report (SUR) *continued*

	Day 5 Date *month day year*	**Day 6 Date** *month day year*	**Day 7 Date** *month day year*
	No Yes **Route**	**No Yes** **Route**	**No Yes** **Route**
Nicotine?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Cannabinoids (THC)?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Barbiturates?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Metham-phetamine?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Cocaine?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Opiates?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Amphe-tamines?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Other substance?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Specify Substance:	_____	_____	_____
	No Yes **#Std. Drinks**	**No Yes** **#Std. Drinks**	**No Yes** **#Std. Drinks**
Alcohol?	☐ ☐ → ☐☐	☐ ☐ → ☐☐	☐ ☐ → ☐☐
			month day year
			Date ☐☐ ☐☐ ☐☐

Form completed by: _____

Form 14 - Substance Use Report (SUR)

Study025 **Plate015** **V307 (Screening-Baseline #7)**

ID# **Center No.** **Subject ID No.** **Alpha Code** **Week**

Form 14-Substance Use Report (SUR)

	Day 1 Date			Day 2 Date			Day 3 Date			Day 4 Date		
	month	*day*	*year*	*month*	*day*	*year*	*month*	*day*	*year*	*month*	*day*	*year*

	Day 1 Date			Day 2 Date			Day 3 Date			Day 4 Date		
	No	Yes	Route	No	Yes	Route	No	Yes	Route	No	Yes	Route
Nicotine?	☐	☐ →	☐	☐	☐ →	☐	☐	☐ →	☐	☐	☐ →	☐
Cannabinoids (THC)?	☐	☐ →	☐	☐	☐ →	☐	☐	☐ →	☐	☐	☐ →	☐
Barbiturates?	☐	☐ →	☐	☐	☐ →	☐	☐	☐ →	☐	☐	☐ →	☐
Metham-phetamine?	☐	☐ →	☐	☐	☐ →	☐	☐	☐ →	☐	☐	☐ →	☐
Cocaine?	☐	☐ →	☐	☐	☐ →	☐	☐	☐ →	☐	☐	☐ →	☐
Opiates?	☐	☐ →	☐	☐	☐ →	☐	☐	☐ →	☐	☐	☐ →	☐
Amphe-tamines?	☐	☐ →	☐	☐	☐ →	☐	☐	☐ →	☐	☐	☐ →	☐
Other substance?	☐	☐ →	☐	☐	☐ →	☐	☐	☐ →	☐	☐	☐ →	☐
Specify Substance:	_____			_____			_____			_____		
	No	Yes	#Std. Drinks	No	Yes	#Std. Drinks	No	Yes	#Std. Drinks	No	Yes	#Std. Drinks
Alcohol?	☐	☐ →	☐☐	☐	☐ →	☐☐	☐	☐ →	☐☐	☐	☐ →	☐☐

Study025 **Plate016** **V307 (Screening-Baseline #7)**

ID# **Center No.** **Subject ID No.** **Alpha Code** **Week**

Form 14-Substance Use Report (SUR) *continued*

	Day 5 Date *month day year*	**Day 6 Date** *month day year*	**Day 7 Date** *month day year*
	No Yes Route	**No Yes Route**	**No Yes Route**
Nicotine?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Cannabinoids (THC)?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Barbiturates?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Metham-phetamine?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Cocaine?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Opiates?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Amphe-tamines?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Other substance?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Specify Substance:	_____	_____	_____
	No Yes #Std. Drinks	**No Yes #Std. Drinks**	**No Yes #Std. Drinks**
Alcohol?	☐ ☐ → ☐☐	☐ ☐ → ☐☐	☐ ☐ → ☐☐

Form completed by: _____ **Date** *month* ☐☐ *day* ☐☐ *year* ☐☐

Form 14 - Substance Use Report (SUR)

Study025 **Plate015** **V308 (Screening-Baseline #8)**

ID# **Center No.** **Subject ID No.** **Alpha Code** **Week**

Form 14-Substance Use Report (SUR)

	Day 1 Date (month / day / year)	Day 2 Date (month / day / year)	Day 3 Date (month / day / year)	Day 4 Date (month / day / year)
Nicotine?	No ☐ Yes ☐ → Route ☐	No ☐ Yes ☐ → Route ☐	No ☐ Yes ☐ → Route ☐	No ☐ Yes ☐ → Route ☐
Cannabinoids (THC)?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Barbiturates?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Metham-phetamine?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Cocaine?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Opiates?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Amphe-tamines?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Other substance?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Specify Substance:	_____	_____	_____	_____
Alcohol?	No ☐ Yes ☐ → #Std. Drinks ☐☐	No ☐ Yes ☐ → #Std. Drinks ☐☐	No ☐ Yes ☐ → #Std. Drinks ☐☐	No ☐ Yes ☐ → #Std. Drinks ☐☐

Study025 **Plate016** **V308 (Screening-Baseline #8)**

ID# **Center No.** **Subject ID No.** **Alpha Code** **Week**

Form 14-Substance Use Report (SUR) *continued*

	Day 5 Date *month day year*	**Day 6 Date** *month day year*	**Day 7 Date** *month day year*
	No Yes Route	**No Yes Route**	**No Yes Route**
Nicotine?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Cannabinoids (THC)?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Barbiturates?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Metham-phetamine?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Cocaine?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Opiates?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Amphe-tamines?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Other substance?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Specify Substance:	_____	_____	_____
	No Yes #Std. Drinks	**No Yes #Std. Drinks**	**No Yes #Std. Drinks**
Alcohol?	☐ ☐ → ☐☐	☐ ☐ → ☐☐	☐ ☐ → ☐☐

Form completed by: _____ **Date** *month* ☐☐ *day* ☐☐ *year* ☐☐

Form 14 - Substance Use Report (SUR)

Study025 **Plate015** **V309 (Screening-Baseline #9)**

ID# **Center No.** **Subject ID No.** **Alpha Code** **Week**

Form 14-Substance Use Report (SUR)

	Day 1 Date (month / day / year)	Day 2 Date (month / day / year)	Day 3 Date (month / day / year)	Day 4 Date (month / day / year)
Nicotine?	No / Yes → Route	No / Yes → Route	No / Yes → Route	No / Yes → Route
Cannabinoids (THC)?	No / Yes → Route	No / Yes → Route	No / Yes → Route	No / Yes → Route
Barbiturates?	No / Yes → Route	No / Yes → Route	No / Yes → Route	No / Yes → Route
Metham-phetamine?	No / Yes → Route	No / Yes → Route	No / Yes → Route	No / Yes → Route
Cocaine?	No / Yes → Route	No / Yes → Route	No / Yes → Route	No / Yes → Route
Opiates?	No / Yes → Route	No / Yes → Route	No / Yes → Route	No / Yes → Route
Amphe-tamines?	No / Yes → Route	No / Yes → Route	No / Yes → Route	No / Yes → Route
Other substance?	No / Yes → Route	No / Yes → Route	No / Yes → Route	No / Yes → Route
Specify Substance:	_____	_____	_____	_____
Alcohol?	No / Yes → #Std. Drinks	No / Yes → #Std. Drinks	No / Yes → #Std. Drinks	No / Yes → #Std. Drinks

Study025 **Plate016** **V309 (Screening-Baseline #9)**

ID# **Center No.** **Subject ID No.** **Alpha Code** **Week**

Form 14-Substance Use Report (SUR) *continued*

	Day 5 Date *month day year*	**Day 6 Date** *month day year*	**Day 7 Date** *month day year*
	No Yes Route	**No Yes Route**	**No Yes Route**
Nicotine?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Cannabinoids (THC)?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Barbiturates?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Metham-phetamine?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Cocaine?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Opiates?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Amphe-tamines?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Other substance?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
Specify Substance:	_____	_____	_____
	No Yes #Std. Drinks	**No Yes #Std. Drinks**	**No Yes #Std. Drinks**
Alcohol?	☐ ☐ → ☐☐	☐ ☐ → ☐☐	☐ ☐ → ☐☐

Form completed by: _____ **Date** *month* ☐☐ *day* ☐☐ *year* ☐☐

Study025 **Plate010** **V101 (Screening Phase - #1)**

ID# ☐☐☐ ☐☐☐☐ ☐☐☐☐
Center No. **Subject ID No.** **Alpha Code**

Date of Assessment ☐☐ ☐☐ ☐☐ ☐☐
month *day* *year* **Week**

Form 09-Urine Drug Screen - ***This is a source document for VA/NIDA Cooperative Study #1025***

- Study staff, complete this form for every urine drug screen performed on-site with a test cup device. Perform urine drug screens in accordance with the protocol.
- Perform urine drug screens as necessary during screening until the subject provides a urine specimen positive for methamphetamine or amphetamine.
- Subject must provide at least four urine sample specimens during the 14 day baseline period, including at least one specimen within 7 days prior to randomization until the subject provides a urine specimen positive for methamphetamine or amphetamine.

1. Urine Temperature within expected range? ☐ *No* ☐ *Yes*

SCREEN FOR:

A. METHAMPHETAMINE	☐ *Neg*	☐ *Pos*
B. COCAINE	☐ *Neg*	☐ *Pos*
C. TETRAHYDROCANNABINOL	☐ *Neg*	☐ *Pos*
D. AMPHETAMINES	☐ *Neg*	☐ *Pos*
E. BARBITURATES	☐ *Neg*	☐ *Pos*
F. OPIATES	☐ *Neg*	☐ *Pos*
G. BENZODIAZEPINES	☐ *Neg*	☐ *Pos*

ALIQUOTE AND RETAIN URINE SPECIMENS ON-SITE ACCORDING TO DIRECTIONS PROVIDED IN THE STUDY OPERATIONS MANUAL.

month *day* *year*

Form completed by: _____ **Date** ☐☐ ☐☐ ☐☐

Site Investigator's Signature: _____ **Date** ☐☐ ☐☐ ☐☐

Study025 **Plate008** **V102 (Screening Phase - #2)**

ID# ☐☐☐ ☐☐☐☐ ☐☐☐☐
Center No. **Subject ID No.** **Alpha Code**

Date of Assessment ☐☐ ☐☐ ☐☐ *month day year*

☐☐ **Week**

Form 09-Urine Drug Screen - ***This is a source document for VA/NIDA Cooperative Study #1025***

- Study staff, complete this form for every urine drug screen performed on-site with a test cup device. Perform urine drug screens in accordance with the protocol.
- Perform urine drug screens as necessary during screening until the subject provides a urine specimen positive for methamphetamine or amphetamine.
- Subject must provide at least four urine sample specimens during the 14 day baseline period, including at least one specimen within 7 days prior to randomization until the subject provides a urine specimen positive for methamphetamine or amphetamine.

1. Urine Temperature within expected range? ☐ *No* ☐ *Yes*

SCREEN FOR:

A. METHAMPHETAMINE	☐ *Neg*	☐ *Pos*
B. COCAINE	☐ *Neg*	☐ *Pos*
C. TETRAHYDROCANNABINOL	☐ *Neg*	☐ *Pos*
D. AMPHETAMINES	☐ *Neg*	☐ *Pos*
E. BARBITURATES	☐ *Neg*	☐ *Pos*
F. OPIATES	☐ *Neg*	☐ *Pos*
G. BENZODIAZEPINES	☐ *Neg*	☐ *Pos*

ALIQUOTE AND RETAIN URINE SPECIMENS ON-SITE ACCORDING TO DIRECTIONS PROVIDED IN THE STUDY OPERATIONS MANUAL.

month day year

Form completed by: _____ **Date** ☐☐ ☐☐ ☐☐

Site Investigator's Signature: _____ **Date** ☐☐ ☐☐ ☐☐

Study025 **Plate008** **V103 (Screening Phase - #3)**

ID# ☐☐☐ ☐☐☐☐ ☐☐☐☐
Center No. **Subject ID No.** **Alpha Code**

Date of Assessment ☐☐ ☐☐ ☐☐ *month day year*

☐☐ **Week**

Form 09-Urine Drug Screen - ***This is a source document for VA/NIDA Cooperative Study #1025***

- Study staff, complete this form for every urine drug screen performed on-site with a test cup device. Perform urine drug screens in accordance with the protocol.
- Perform urine drug screens as necessary during screening until the subject provides a urine specimen positive for methamphetamine or amphetamine.
- Subject must provide at least four urine sample specimens during the 14 day baseline period, including at least one specimen within 7 days prior to randomization until the subject provides a urine specimen positive for methamphetamine or amphetamine.

1. Urine Temperature within expected range? ☐ *No* ☐ *Yes*

SCREEN FOR:

A. METHAMPHETAMINE	☐ *Neg*	☐ *Pos*
B. COCAINE	☐ *Neg*	☐ *Pos*
C. TETRAHYDROCANNABINOL	☐ *Neg*	☐ *Pos*
D. AMPHETAMINES	☐ *Neg*	☐ *Pos*
E. BARBITURATES	☐ *Neg*	☐ *Pos*
F. OPIATES	☐ *Neg*	☐ *Pos*
G. BENZODIAZEPINES	☐ *Neg*	☐ *Pos*

ALIQUOTE AND RETAIN URINE SPECIMENS ON-SITE ACCORDING TO DIRECTIONS PROVIDED IN THE STUDY OPERATIONS MANUAL.

month day year

Form completed by: _____ **Date** ☐☐ ☐☐ ☐☐

Site Investigator's Signature: _____ **Date** ☐☐ ☐☐ ☐☐

Study025 **Plate008** **V104 (Screening Phase - #4)**

ID# ☐☐☐ ☐☐☐☐ ☐☐☐☐
Center No. **Subject ID No.** **Alpha Code**

Date of Assessment ☐☐ ☐☐ ☐☐ ☐☐
month *day* *year* **Week**

Form 09-Urine Drug Screen - ***This is a source document for VA/NIDA Cooperative Study #1025***

- Study staff, complete this form for every urine drug screen performed on-site with a test cup device. Perform urine drug screens in accordance with the protocol.
- Perform urine drug screens as necessary during screening until the subject provides a urine specimen positive for methamphetamine or amphetamine.
- Subject must provide at least four urine sample specimens during the 14 day baseline period, including at least one specimen within 7 days prior to randomization until the subject provides a urine specimen positive for methamphetamine or amphetamine.

1. Urine Temperature within expected range? ☐ *No* ☐ *Yes*

SCREEN FOR:

A. METHAMPHETAMINE	☐ *Neg*	☐ *Pos*
B. COCAINE	☐ *Neg*	☐ *Pos*
C. TETRAHYDROCANNABINOL	☐ *Neg*	☐ *Pos*
D. AMPHETAMINES	☐ *Neg*	☐ *Pos*
E. BARBITURATES	☐ *Neg*	☐ *Pos*
F. OPIATES	☐ *Neg*	☐ *Pos*
G. BENZODIAZEPINES	☐ *Neg*	☐ *Pos*

ALIQUOTE AND RETAIN URINE SPECIMENS ON-SITE ACCORDING TO DIRECTIONS PROVIDED IN THE STUDY OPERATIONS MANUAL.

month *day* *year*

Form completed by: _____ **Date** ☐☐ ☐☐ ☐☐

Site Investigator's Signature: _____ **Date** ☐☐ ☐☐ ☐☐

Study025 **Plate008** **V105 (Screening Phase - #5)**

ID# ☐☐☐ ☐☐☐☐ ☐☐☐☐
Center No. **Subject ID No.** **Alpha Code**

Date of Assessment ☐☐ ☐☐ ☐☐ ☐☐
month *day* *year* **Week**

Form 09-Urine Drug Screen - ***This is a source document for VA/NIDA Cooperative Study #1025***

- Study staff, complete this form for every urine drug screen performed on-site with a test cup device. Perform urine drug screens in accordance with the protocol.
- Perform urine drug screens as necessary during screening until the subject provides a urine specimen positive for methamphetamine or amphetamine.
- Subject must provide at least four urine sample specimens during the 14 day baseline period, including at least one specimen within 7 days prior to randomization until the subject provides a urine specimen positive for methamphetamine or amphetamine.

1. Urine Temperature within expected range? ☐ *No* ☐ *Yes*

SCREEN FOR:

A. METHAMPHETAMINE	☐ *Neg*	☐ *Pos*
B. COCAINE	☐ *Neg*	☐ *Pos*
C. TETRAHYDROCANNABINOL	☐ *Neg*	☐ *Pos*
D. AMPHETAMINES	☐ *Neg*	☐ *Pos*
E. BARBITURATES	☐ *Neg*	☐ *Pos*
F. OPIATES	☐ *Neg*	☐ *Pos*
G. BENZODIAZEPINES	☐ *Neg*	☐ *Pos*

ALIQUOTE AND RETAIN URINE SPECIMENS ON-SITE ACCORDING TO DIRECTIONS PROVIDED IN THE STUDY OPERATIONS MANUAL.

month *day* *year*

Form completed by: _____ **Date** ☐☐ ☐☐ ☐☐

Site Investigator's Signature: _____ **Date** ☐☐ ☐☐ ☐☐

Study025 **Plate008** **V106 (Screening Phase - #6)**

ID# ☐☐☐ ☐☐☐☐ ☐☐☐☐
Center No. **Subject ID No.** **Alpha Code**

Date of Assessment ☐☐ ☐☐ ☐☐ *month day year*

☐☐ **Week**

Form 09-Urine Drug Screen - ***This is a source document for VA/NIDA Cooperative Study #1025***

- Study staff, complete this form for every urine drug screen performed on-site with a test cup device. Perform urine drug screens in accordance with the protocol.
- Perform urine drug screens as necessary during screening until the subject provides a urine specimen positive for methamphetamine or amphetamine.
- Subject must provide at least four urine sample specimens during the 14 day baseline period, including at least one specimen within 7 days prior to randomization until the subject provides a urine specimen positive for methamphetamine or amphetamine.

1. Urine Temperature within expected range? ☐ *No* ☐ *Yes*

SCREEN FOR:

A. METHAMPHETAMINE	☐ *Neg*	☐ *Pos*
B. COCAINE	☐ *Neg*	☐ *Pos*
C. TETRAHYDROCANNABINOL	☐ *Neg*	☐ *Pos*
D. AMPHETAMINES	☐ *Neg*	☐ *Pos*
E. BARBITURATES	☐ *Neg*	☐ *Pos*
F. OPIATES	☐ *Neg*	☐ *Pos*
G. BENZODIAZEPINES	☐ *Neg*	☐ *Pos*

ALIQUOTE AND RETAIN URINE SPECIMENS ON-SITE ACCORDING TO DIRECTIONS PROVIDED IN THE STUDY OPERATIONS MANUAL.

month day year

Form completed by: _____ **Date** ☐☐ ☐☐ ☐☐

Site Investigator's Signature: _____ **Date** ☐☐ ☐☐ ☐☐

Study025 **Plate008** **V107 (Screening Phase - #7)**

ID# ☐☐☐ ☐☐☐☐ ☐☐☐☐
Center No. **Subject ID No.** **Alpha Code**

Date of Assessment ☐☐ ☐☐ ☐☐ *month day year*

☐☐ **Week**

Form 09-Urine Drug Screen - ***This is a source document for VA/NIDA Cooperative Study #1025***

- Study staff, complete this form for every urine drug screen performed on-site with a test cup device. Perform urine drug screens in accordance with the protocol.
- Perform urine drug screens as necessary during screening until the subject provides a urine specimen positive for methamphetamine or amphetamine.
- Subject must provide at least four urine sample specimens during the 14 day baseline period, including at least one specimen within 7 days prior to randomization until the subject provides a urine specimen positive for methamphetamine or amphetamine.

1. Urine Temperature within expected range? ☐ *No* ☐ *Yes*

SCREEN FOR:

A. METHAMPHETAMINE	☐ *Neg*	☐ *Pos*
B. COCAINE	☐ *Neg*	☐ *Pos*
C. TETRAHYDROCANNABINOL	☐ *Neg*	☐ *Pos*
D. AMPHETAMINES	☐ *Neg*	☐ *Pos*
E. BARBITURATES	☐ *Neg*	☐ *Pos*
F. OPIATES	☐ *Neg*	☐ *Pos*
G. BENZODIAZEPINES	☐ *Neg*	☐ *Pos*

ALIQUOTE AND RETAIN URINE SPECIMENS ON-SITE ACCORDING TO DIRECTIONS PROVIDED IN THE STUDY OPERATIONS MANUAL.

month day year

Form completed by: _____ **Date** ☐☐ ☐☐ ☐☐

Site Investigator's Signature: _____ **Date** ☐☐ ☐☐ ☐☐

Study025 **Plate008** **V108 (Screening Phase - #8)**

ID# [ ][ ][ ] [ ][ ][ ][ ] [ ][ ][ ][ ]
Center No. **Subject ID No.** **Alpha Code**

Date of Assessment [ ][ ] [ ][ ] [ ][ ] [ ][ ]
month *day* *year* **Week**

Form 09-Urine Drug Screen - ***This is a source document for VA/NIDA Cooperative Study #1025***

- Study staff, complete this form for every urine drug screen performed on-site with a test cup device. Perform urine drug screens in accordance with the protocol.
- Perform urine drug screens as necessary during screening until the subject provides a urine specimen positive for methamphetamine or amphetamine.
- Subject must provide at least four urine sample specimens during the 14 day baseline period, including at least one specimen within 7 days prior to randomization until the subject provides a urine specimen positive for methamphetamine or amphetamine.

1. Urine Temperature within expected range? ☐ *No* ☐ *Yes*

SCREEN FOR:

A. METHAMPHETAMINE ☐ *Neg* ☐ *Pos*

B. COCAINE ☐ *Neg* ☐ *Pos*

C. TETRAHYDROCANNABINOL ☐ *Neg* ☐ *Pos*

D. AMPHETAMINES ☐ *Neg* ☐ *Pos*

E. BARBITURATES ☐ *Neg* ☐ *Pos*

F. OPIATES ☐ *Neg* ☐ *Pos*

G. BENZODIAZEPINES ☐ *Neg* ☐ *Pos*

ALIQUOTE AND RETAIN URINE SPECIMENS ON-SITE ACCORDING TO DIRECTIONS PROVIDED IN THE STUDY OPERATIONS MANUAL.

month *day* *year*

Form completed by: _____ **Date** [ ][ ] [ ][ ] [ ][ ]

Site Investigator's Signature: _____ **Date** [ ][ ] [ ][ ] [ ][ ]

Study025 **Plate008** **V109 (Screening Phase - #9)**

ID# [ ][ ][ ] [ ][ ][ ][ ] [ ][ ][ ][ ]
Center No. **Subject ID No.** **Alpha Code**

Date of Assessment [ ][ ] [ ][ ] [ ][ ] [ ][ ]
month *day* *year* **Week**

Form 09-Urine Drug Screen - ***This is a source document for VA/NIDA Cooperative Study #1025***

- Study staff, complete this form for every urine drug screen performed on-site with a test cup device. Perform urine drug screens in accordance with the protocol.
- Perform urine drug screens as necessary during screening until the subject provides a urine specimen positive for methamphetamine or amphetamine.
- Subject must provide at least four urine sample specimens during the 14 day baseline period, including at least one specimen within 7 days prior to randomization until the subject provides a urine specimen positive for methamphetamine or amphetamine.

1. Urine Temperature within expected range? ☐ *No* ☐ *Yes*

SCREEN FOR:

A. METHAMPHETAMINE ☐ *Neg* ☐ *Pos*

B. COCAINE ☐ *Neg* ☐ *Pos*

C. TETRAHYDROCANNABINOL ☐ *Neg* ☐ *Pos*

D. AMPHETAMINES ☐ *Neg* ☐ *Pos*

E. BARBITURATES ☐ *Neg* ☐ *Pos*

F. OPIATES ☐ *Neg* ☐ *Pos*

G. BENZODIAZEPINES ☐ *Neg* ☐ *Pos*

ALIQUOTE AND RETAIN URINE SPECIMENS ON-SITE ACCORDING TO DIRECTIONS PROVIDED IN THE STUDY OPERATIONS MANUAL.

month *day* *year*

Form completed by: _____ **Date** [ ][ ] [ ][ ] [ ][ ]

Site Investigator's Signature: _____ **Date** [ ][ ] [ ][ ] [ ][ ]

Study025 **Plate008** **V110 (Screening Phase - #10)**

ID# ☐☐☐ ☐☐☐☐ ☐☐☐☐
Center No. **Subject ID No.** **Alpha Code**

Date of Assessment ☐☐ ☐☐ ☐☐ *month day year*

☐☐ **Week**

Form 09-Urine Drug Screen - ***This is a source document for VA/NIDA Cooperative Study #1025***

- Study staff, complete this form for every urine drug screen performed on-site with a test cup device. Perform urine drug screens in accordance with the protocol.
- Perform urine drug screens as necessary during screening until the subject provides a urine specimen positive for methamphetamine or amphetamine.
- Subject must provide at least four urine sample specimens during the 14 day baseline period, including at least one specimen within 7 days prior to randomization until the subject provides a urine specimen positive for methamphetamine or amphetamine.

1. Urine Temperature within expected range? ☐ *No* ☐ *Yes*

SCREEN FOR:

A. METHAMPHETAMINE	☐ *Neg*	☐ *Pos*
B. COCAINE	☐ *Neg*	☐ *Pos*
C. TETRAHYDROCANNABINOL	☐ *Neg*	☐ *Pos*
D. AMPHETAMINES	☐ *Neg*	☐ *Pos*
E. BARBITURATES	☐ *Neg*	☐ *Pos*
F. OPIATES	☐ *Neg*	☐ *Pos*
G. BENZODIAZEPINES	☐ *Neg*	☐ *Pos*

ALIQUOTE AND RETAIN URINE SPECIMENS ON-SITE ACCORDING TO DIRECTIONS PROVIDED IN THE STUDY OPERATIONS MANUAL.

month day year

Form completed by: _____ **Date** ☐☐ ☐☐ ☐☐

Site Investigator's Signature: _____ **Date** ☐☐ ☐☐ ☐☐

Study025 **Plate005** **V005 (Randomization)**

ID# ☐☐☐ ☐☐☐☐ ☐☐☐☐ **Date of Assessment** ☐☐ ☐☐ ☐☐ ☐☐

Center No. **Subject ID No.** **Alpha Code** *month* *day* *year* **Week**

Form 05-Vital Signs

- Study staff, complete this form for every vital signs/weight assessment done throughout the study.
- Perform vital signs/weight once per week during screening and baseline, at the first visit of the week during weeks 1-13, and at week 17 (follow-up)

Refer to the Guidelines for assessing vital signs and weight in the Operations Manual.

1. Time Vital Signs taken (use 24 hour clock) ☐☐:☐☐ *hh:mm*
2. Temperature (oral) ☐☐☐.☐ *^{o}F*
3. Respiratory rate - Sitting ☐☐ *breaths/min*
4. Blood pressure - Sitting (3 mins) ☐☐☐/☐☐☐ *mm/Hg*
5. Pulse rate ☐☐☐ *beats/min*
6. Weight ☐☐☐ *lbs*

Form completed by: _____ *month* *day* *year* **Date** ☐☐ ☐☐ ☐☐

Form 17 - Weekly Dosing Record

Study staff, complete one entry on this form for each day of the study week.

For each day of the study week, record the recommended daily dose, the # of 25 mg and 100 mg tablets dispensed, taken, counted and turned in. If no drug was dispensed, taken or turned into the clinic, enter 00.

Update incomplete entries on the previous week's form during the following study week to capture data for the period of time after clinic visits, or on days when no visit occurred.

Form 17 - Weekly Dosing Record

Study025 **Plate022** **V005 (Randomization/Titration)**

ID# **Center No.** **Subject ID No.** **Alpha Code** **Week**

Form 17-Weekly Dosing Record

Day	Date (*month* / *day* / *year*)	Recommended Daily Dose (mg)	#Tablets Dispensed	#Tablets Taken	#Tablets Counted	#Tablets Turned into Clinic
1.			25 mg / 100 mg	25 mg / 100 mg	25 mg / 100 mg	25 mg / 100 mg
	Attended clinic? No ☐ Yes ☐					
2.			25 mg / 100 mg	25 mg / 100 mg	25 mg / 100 mg	25 mg / 100 mg
	Attended clinic? No ☐ Yes ☐					
3.			25 mg / 100 mg	25 mg / 100 mg	25 mg / 100 mg	25 mg / 100 mg
	Attended clinic? No ☐ Yes ☐					
4.			25 mg / 100 mg	25 mg / 100 mg	25 mg / 100 mg	25 mg / 100 mg
	Attended clinic? No ☐ Yes ☐					
5.			25 mg / 100 mg	25 mg / 100 mg	25 mg / 100 mg	25 mg / 100 mg
	Attended clinic? No ☐ Yes ☐					
6.			25 mg / 100 mg	25 mg / 100 mg	25 mg / 100 mg	25 mg / 100 mg
	Attended clinic? No ☐ Yes ☐					
7.			25 mg / 100 mg	25 mg / 100 mg	25 mg / 100 mg	25 mg / 100 mg
	Attended clinic? No ☐ Yes ☐					

Comments must be provided for all medication discrepancies noted within the study week:

_____

_____

Form completed by: _____ **Date** *month* / *day* / *year*

Form 16 - Weekly Urine Collection/AE Assessment

Study025 **Plate045** **V005 (Randomization)**

ID# **Center No.** **Subject ID No.** **Alpha Code**

Date Form Completed *month* *day* *year*

Week

Weekly Urine Collection/AE Assessment

*Study staff, complete this form weekly, screening through study week 13 and at follow-up (week 17). Record the first study visit of the week as the first time the subject reported to the clinic in a given study week. If no subsequent visits were made, insert missing value codes.

1. First Visit of Study Week (date) *month* *day* *year*

a. Was a urine sample collected at this visit? ☐ *No* ☐ *Yes*

b*. Place barcode label of urine sample here

c. Were AEs assessed at this study visit? ☐ *No* ☐ *Yes*

2. Second Visit of Study Week (date) *month* *day* *year*

a. Was a urine sample collected at this visit? ☐ *No* ☐ *Yes*

b*. Place barcode label of urine sample here

c. Were AEs assessed at this study visit? ☐ *No* ☐ *Yes*

3. Third Visit of Study Week (date) *month* *day* *year*

a. Was a urine sample collected at this visit? ☐ *No* ☐ *Yes*

b*. Place barcode label of urine sample here

c. Were AEs assessed at this study visit? ☐ *No* ☐ *Yes*

***Follow directions in the Operations Manual on Labeling and Shipping Urine Specimens to NWT.**

If AEs were reported, complete AE Form 24.

Form completed by: _____ **Date:** *month* *day* *year*

Site Investigator's Signature: _____ **Date:**