DataFax #012 **Plate #011** **Visit #000**

SITE NO. *SUBJECT ID.* *ALPHA CODE* *DATE FORM COMPLETED*

Month Day Year

FORM 01 - Entry Criteria and Randomization

INSTRUCTIONS: Please complete this form at screening/baseline for all subjects who signed informed consent. Complete the **entire** form, regardless of whether the subject is randomized in the study.

Demographic Information

1. Date of Birth . . . . . *Month* *Day* *Year*

2. Gender (at birth) . . . . . *Male* *Female*

3. Marital Status:

- ☐ Legally Married
- ☐ Separated
- ☐ Living with Partner/cohabitating
- ☐ Divorced
- ☐ Widowed
- ☐ Never Married
- ☐ Unknown

4. Ethnicity: . . . . . ☐ Hispanic or Latino ☐ Unknown/not given ☐ Not Hispanic or Latino

5. Race: (Mark 'X' for all that apply)

- ☐ American Indian, or Alaskan Native
- ☐ Native Hawaiian, or other Pacific Islander
- ☐ Asian
- ☐ White
- ☐ Black, or African-American
- ☐ Unknown

6. Years of Formal Education (GED = 12 years) . . . . .

7. Usual Employment Pattern in the last 30 days:

- ☐ Full-Time, 35+ hrs/week
- ☐ Student
- ☐ Homemaker
- ☐ Part-Time, regular hrs
- ☐ Military Service
- ☐ Unemployed
- ☐ Part-Time, irregular hrs/day work
- ☐ Retired/Disabled
- ☐ In controlled environment
- ☐ Unknown

DataFax #012 **Plate #012** **Visit #000**

SITE NO. *SUBJECT ID.* *ALPHA CODE*

Inclusion Criteria

For Inclusion Criteria questions 8-14, mark 'X' for the appropriate answers. All answers must be 'Yes' for inclusion in the study, unless otherwise indicated by an asterisk (*).

	No	Yes	Not Screened
8. Has the subject verbalized understanding of consent form, provided written informed consent, verbalized willingness to complete study procedures, and passed the study consent quiz with 100% accuracy?	☐	☐	

	No	Yes	Not Screened
9. Is the subject between 18 and 65 years-of-age?	☐	☐	☐
10. Does the subject have a DSM-IV diagnosis of methamphetamine dependence as determined by SCID?	☐	☐	☐
11. Is the subject seeking treatment for methamphetamine dependence?	☐	☐	☐
12. Does the subject have at least 1 amphetamine or meth-amphetamine positive urine specimen (> 500 ng/mL) during the 14 to 21-day screening/baseline period prior to the date the subject is eligible to be randomized, with a minimum of 4 samples tested?	☐	☐	☐
*13. If female, is the subject surgically sterile or 2 years post-menopausal? If of child bearing potential, does the subject agree to use an acceptable method of birth control (as defined in the protocol) and continue to use this method for at least 30 days after the last dose of study drug? *(For males mark 'Not Screened')*	☐	☐	☐
14. Is the subject willing and able to comply with the study procedures?	☐	☐	☐

DataFax #012 **Plate #013** **Visit #000**

SITE NO. *SUBJECT ID.* *ALPHA CODE*

Exclusion Criteria

For Exclusion Criteria questions 15-34, mark 'X' for the appropriate answers. All answers must be 'No' for inclusion in the study, unless otherwise indicated by an asterisk (*).

	No	Yes	Not Screened
15. Does the subject have current dependence, defined by DSM-IV criteria, on any psychoactive substance (e.g., opioids) other than methamphetamine, nicotine, or marijuana, or have physiological dependence on a sedative-hypnotic (e.g., a benzodiazepine) requiring medical detoxification, or have current or past alcohol dependence?	☐	☐	☐
16. Is the subject 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?	☐	☐	☐
17. In the opinion of the investigator, is the subject expected to fail to complete the study protocol due to probable incarceration or relocation from the clinic area?	☐	☐	☐
18. Does the subject have a psychiatric disorder, such as current major depression, psychosis, bipolar illness, organic brain disorder, or dementia as assessed by SCID interview; or ADHD by ACDS assessment which requires ongoing medication treatment or which would make medication compliance difficult; or have had electroconvulsive therapy within the past 90 days before screening; or have a history of Bipolar I Disorder?	☐	☐	☐
19. Does the subject have current suicidal ideation or plan as assessed by the SCID interview or by HAM-D question #3? *(Current is defined as within the past 30 days)*	☐	☐	☐
* 20. Is the subject a pregnant or lactating female? *(For males mark 'Not Screened')*	☐	☐	☐

DataFax #012 **Plate #014** **Visit #000**

SITE NO. *SUBJECT ID.* *ALPHA CODE*

	No	Yes	Not Screened
21. Does the subject have a serious medical illness including, but not limited to, uncontrolled hypertension or uncontrolled diabetes; history of syncope, presyncope, or chest pain associated with methamphetamine use; significant heart disease (including myocardial infarction within one year of enrollment), any clinically significant cardiovascular abnormality (ECG), mitral valve prolapse, or left ventricular hypertrophy; hepatic, renal or gastrointestinal disorders that could result in a clinically significant alteration of metabolism or excretion of the study agent; or a potentially life threatening or progressive medical illness other than addiction that may compromise subject safety or study conduct?	☐	☐	☐
22. Does the subject have clinically significant abnormal laboratory values, in the judgement of the investigator, or have liver function tests [LFTs] > 3 times normal?	☐	☐	☐
23. Does the subject have AIDS according to the current CDC criteria for AIDS?	☐	☐	☐
24. Does the subject have active syphilis that has not been treated or refused treatment for syphilis?	☐	☐	☐
25. Does the subject have active tuberculosis (positive tuberculin test and confirmatory diagnostic chest x-ray)?	☐	☐	☐
26. Is the subject undergoing HIV treatment with antiviral and/or non-antiviral therapy?	☐	☐	☐
27. Does the subject have a current or past history of anorexia nervosa or bulimia disorder?	☐	☐	☐
28. Does the subject have a diagnosis of adult (i.e., 21 years or older) asthma, or chronic obstructive pulmonary disease (COPD), including those with a history of acute asthma within the past two years, and those with current or recent (past 3 months) treatment with inhaled or oral beta-agonist or steroid therapy (because of potential serious adverse interactions with methamphetamine), or has an FEV_1 <70%?	☐	☐	☐

DataFax #012 **Plate #015** **Visit #000**

SITE NO. *SUBJECT ID.* *ALPHA CODE*

	No	Yes	Not Screened
29. Is the subject suspected of having adult obstructive airways disease, but without formal diagnosis, for example: 1) have a history of wheezing and/or chronic coughing, 2) have a history of adult obstuctive airways and/or treatment for this condition more than two years before the current application for the study, 3) have a history of other respiratory illness, e.g., complications of pulmonary disease (exclude if on beta-agonists), 4) uses 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.)	☐	☐	☐
30. Has the subject received a drug with known potential for toxicity to a major organ system within 30 days prior to screening including, but not limited to, chemotherapeutic agents for neoplastic disease (i.e., methotrexate, vincristine, vinblastine, fluorouracil), agents used for parasitic infections (i.e., isoniazid, chlorambucil, dactinomycin, chloramphenicol), or immunosuppressive and cytotoxic agents (i.e., cyclosporine, tacrolimus, indomethacin, protease inhibitors, amphotericin B, cephalosporins, aminoglycosides, interferon, and sulfonamides)?	☐	☐	☐
31. Has the subject received medication that could interact adversely with modafinil? (see protocol, exclusion criteria #17, pg. 38)	☐	☐	☐
32. Has the subject participated in any experimental study within 2 months preceding screening?	☐	☐	☐
33. Does the subject have known or suspected hypersensitivity to modafinil?	☐	☐	☐
34. Has the subject taken modafinil for any reason currently or during the past year?	☐	☐	☐

DataFax #012 **Plate #016** **Visit #000**

SITE NO. *SUBJECT ID.* *ALPHA CODE*

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

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

b. If subject declined randomization, indicate reason: _____

If subject is ineligible or declined randomization, this form is complete.

	No	*Yes*
36. Has the subject reported using methamphetamine in the 30 days prior to informed consent?	☐	☐

a. If **'Yes'**, enter the number of days used . . . . . ☐☐

(From the Timeline Followback Form 05)

	No	*Yes*
37. Does the subject meet the criteria for current adult ADHD *(from the ACDS Form 19)*?	☐	☐

If the subject is eligible and willing to be randomized, call the CSPCC to randomize the subject. The CSPCC will provide the following information:

38. Date of randomization . . . . . ☐☐ ☐☐ ☐☐☐☐
Month *Day* *Year*

39. Treatment Kit . . . . . ☐☐☐☐☐

Form Completed By: _____ Date: _____

Investigator's Signature: _____ Date: _____

Form 02 - Medical/Surgical/Smoking History

INSTRUCTIONS: This form is completed at screening/baseline only. Use the codes below to record all medical conditions reported by the subject. Codes may be used more than once if the subject has one or more of the same types of conditions (e.g., allergies to two different drugs). Indicate the **current** level of severity for each condition listed.

Medical Conditions Codes:

01 = Allergies, drug
02 = Allergies, other
03 = Sensitivity to Modafinil
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 = Reproductive system disorder
20 = Infectious disease
21 = Other

Severity Codes:

1 = Mild
2 = Moderate
3 = Severe

DataFax #012 Plate #021 Visit #000

SITE NO. *SUBJECT ID.* *ALPHA CODE* *DATE OF ASSESSMENT*

Month Day Year

FORM 02 - Medical/Surgical/Smoking History

Are there any prior medical conditions? . . . . . *No* ☐ *(Go to page 2)* *Yes* ☐ *(List medical conditions below)*

	Medical Conditions	**Current Severity**	**Explanation**
1.	☐☐	☐	
2.	☐☐	☐	
3.	☐☐	☐	
4.	☐☐	☐	
5.	☐☐	☐	
6.	☐☐	☐	
7.	☐☐	☐	
8.	☐☐	☐	
9.	☐☐	☐	
10.	☐☐	☐	

A description must be provided for all medical conditions recorded. *(Please print clearly)*

DataFax #012 Plate #022 Visit #000

SITE NO. *SUBJECT ID.* *ALPHA CODE*

Are there any prior medical conditions? . . . . . *No* ☐ *(Go to Q.21 page 3)* *Yes* ☐ *(List medical conditions below)*

	Medical Conditions	**Current Severity**	**Explanation** A description must be provided for all medical conditions recorded. *(Please print clearly)*
11.	☐☐	☐	
12.	☐☐	☐	
13.	☐☐	☐	
14.	☐☐	☐	
15.	☐☐	☐	
16.	☐☐	☐	
17.	☐☐	☐	
18.	☐☐	☐	
19.	☐☐	☐	
20.	☐☐	☐	

DataFax #012 Plate #023 Visit #000

SITE NO.	SUBJECT ID.	ALPHA CODE
☐☐☐	☐☐☐☐	☐☐☐☐

Surgical History

21. Has the subject had any major surgeries? ☐ *No* ☐ *Yes*

If '*Yes',* list MAJOR SURGERIES below. If *'No',* go to question 22.

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

Smoking History

22. Has the subject ever smoked cigarettes? ☐ *No* ☐ *Yes*
If '*Yes',* complete all items 22a - 22c. If '*No*', go to question 23.

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

b. Average NUMBER of cigarettes/day: ☐☐

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

23. Has the subject ever used other tobacco products? ☐ *No* ☐ *Yes*
If '*Yes',* complete all items 23a - 23c. If '*No*', form is complete, sign and date below.

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

Form Completed By: _____ Date: _____

Physician's Signature: _____ Date: _____

DataFax #012 Plate #031

WEEK *SITE NO.* *SUBJECT ID.* *ALPHA CODE* *DATE OF ASSESSMENT*

Month Day Year

FORM 03 - Physical Exam

INSTRUCTION: Complete this form at screening/baseline and at the last visit of week 12 or the termination visit, if prior to week 12.

Data collected for scheduled visit: ..... ☐ Screening/Baseline ☐ Week 12/Termination

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

2. Weight (to nearest pound) . . . . . ☐☐☐ lbs

For questions 3-12, mark 'X' in the appropriate box. If 'Abnormal' or 'Not Done' is marked, please provide comments.

	Normal	*Abnormal*	*Not Done*
3. HEENT (Incl. thyroid/neck)	☐	☐	☐

Comments:_____

	Normal	*Abnormal*	*Not Done*
4. Cardiovascular . . . . . *(Other than ECG findings on Form 07)*	☐	☐	☐

Comments:_____

	Normal	*Abnormal*	*Not Done*
5. Lungs	☐	☐	☐

Comments:_____

	Normal	*Abnormal*	*Not Done*
6. Abdomen (Incl. liver, spleen)	☐	☐	☐

Comments:_____

	Normal	*Abnormal*	*Not Done*
7. Extremities	☐	☐	☐

Comments:_____

DataFax #012 Plate #032

WEEK *SITE NO.* *SUBJECT ID.* *ALPHA CODE*

Data collected for scheduled visit: ..... ☐ Screening/Baseline ☐ Week 12/Termination

	Normal	*Abnormal*	*Not Done*
8. Skin	☐	☐	☐

Comments: _____

9. Neuropsychiatric:

	Normal	*Abnormal*	*Not Done*
9a. Mental Status	☐	☐	☐

Comments: _____

	Normal	*Abnormal*	*Not Done*
9b. Sensory/Motor	☐	☐	☐

Comments: _____

	Normal	*Abnormal*	*Not Done*
10. Lymph Nodes.	☐	☐	☐

Comments: _____

	Normal	*Abnormal*	*Not Done*
11. Musculoskeletal	☐	☐	☐

Comments: _____

	Normal	*Abnormal*	*Not Done*
12. General Appearance	☐	☐	☐

Comments: _____

DataFax #012 Plate #033

WEEK *SITE NO.* *SUBJECT ID.* *ALPHA CODE*

Data collected for scheduled visit: ..... ☐ Screening/Baseline ☐ Week 12/Termination

Complete questions 13-16 only if other body systems were assessed, if no other body systems were assessed, leave blank. For any assessment marked as 'Abnormal', please provide comments.

Normal *Abnormal*

13. Other, specify _____ ☐ ☐

Comments: _____

Normal *Abnormal*

14. Other, specify _____ ☐ ☐

Comments: _____

Normal *Abnormal*

15. Other, specify _____ ☐ ☐

Comments: _____

Normal *Abnormal*

16. Other, specify _____ ☐ ☐

Comments: _____

Form Completed By: _____ Date: _____

Physician's Signature: _____ Date: _____

DataFax #012 **Plate #041**

DATE OF ASSESSMENT

Month Day Year

WEEK *ASSESSMENT* *SITE NO.* *SUBJECT ID.* *ALPHA CODE*

FORM 04 - Vital Signs

INSTRUCTIONS: Complete this form for every vital signs assessment done throughout the study. Collect vital signs three times per week during screening/baseline, and weeks 1-3. Collect vitals at the first visit of the week during weeks 4-11, and at the last visit of week 12, or the termination visit.

1. Time of Collection: (use 24-hour clock). . . . . :

2. Temperature (oral). . . . . . *°F*

3. Blood Pressure - Sitting (5 mins) . . . . . / *mm/Hg*

4. Pulse Rate. . . . . *beats/min*

5. Respiratory Rate - Sitting . . . . . *breaths/min*

Category	Systolic (top number)		Diastolic (bottom number)
Normal	Less than 120	and	Less than 80
Prehypertension	120-139	or	80-89
High Blood Pressure			
Stage 1	140-159	or	90-99
Stage 2	160 or higher	or	100 or higher

Comments: _____

_____

_____

_____

_____

Form Completed By: _____ Date: _____

Medical Staff Signature: _____ Date: _____

DataFax #012 Plate #051 Visit #000

SITE NO.	*SUBJECT ID.*	*ALPHA CODE*	*DATE OF ASSESSMENT*
			Month / Day / Year

FORM 05 - Methamphetamine Timeline Followback

INSTRUCTIONS: Complete this form on the day the subject signs informed consent. Use the Timeline Followback method to assess methamphetamine use for the 30 days prior to signing the informed consent.

Day 1 = Day **prior** to the date subject signed informed consent.

Day 30 = 30 days **prior** to the date subject signed informed consent.

Month *Day* *Year*

Enter Date: ☐☐ ☐☐ ☐☐☐☐

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:**	☐	☐

Total days of use: . . . . . ☐☐

Form Completed By: _____ Date: _____

Form 06 - Prior and Concomitant Medications Log

INSTRUCTIONS: List all medications taken by the subject in the 60 days **prior** to the day the subject signed informed consent.

At each study visit <u>after the day of consent</u>, update medication use. Record the generic name of the medication, the reason the medication was taken, the date the subject started the medication and the dose; route, units, and frequency should be recorded using codes below. If a medication is linked to an adverse event, record all related adverse event (AE) numbers. When the medication is stopped, record the stop date; otherwise mark 'X' if continuing. If medication use is not linked to an AE, leave the AE # fields blank.

When a dosage and/or frequency change occurs, enter a stop date for the previous dose/frequency and make a new entry for the medication at the new dose/frequency.

Route

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

Units

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

Frequency

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

DataFax #012 Plate #061

PAGE | SITE NO. | SUBJECT ID. | ALPHA CODE

FORM 06 - Prior and Concomitant Medications Log

☐ *Mark 'X' in this box if **NO** prior or concomitant meds were reported during the entire study.*

Medication Name **Reason Taken** *Month Day Year*

1. _____ _____ **Medication Start Date** ☐☐ ☐☐ ☐☐☐☐

Dose ☐☐☐☐.☐☐ **Route** ☐ **Units** ☐☐ **Frequency** ☐

If med is linked to AE, enter associated AE #'s *(from AE Form 26)* ☐☐ ☐☐ ☐☐ ☐☐

Mark 'X' if continuing medication ☐ **Medication Stop Date** ☐☐ ☐☐ ☐☐☐☐

Medication Name **Reason Taken** *Month Day Year*

2. _____ _____ **Medication Start Date** ☐☐ ☐☐ ☐☐☐☐

Dose ☐☐☐☐.☐☐ **Route** ☐ **Units** ☐☐ **Frequency** ☐

If med is linked to AE, enter associated AE #'s *(from AE Form 26)* ☐☐ ☐☐ ☐☐ ☐☐

Mark 'X' if continuing medication ☐ **Medication Stop Date** ☐☐ ☐☐ ☐☐☐☐

Medication Name **Reason Taken** *Month Day Year*

3. _____ _____ **Medication Start Date** ☐☐ ☐☐ ☐☐☐☐

Dose ☐☐☐☐.☐☐ **Route** ☐ **Units** ☐☐ **Frequency** ☐

If med is linked to AE, enter associated AE #'s *(from AE Form 26)* ☐☐ ☐☐ ☐☐ ☐☐

Mark 'X' if continuing medication ☐ **Medication Stop Date** ☐☐ ☐☐ ☐☐☐☐

No Yes

• Will an additional page be used to record prior and/or concomitant medications? . . . . . ☐ ☐

• **If Yes**, record the next page number . . . . . ☐☐

Form Completed By: _____ Date: _____

Investigator's/Physician Signature: _____ Date: _____

DataFax #012 Plate #071

DATE OF ASSESSMENT

Month Day Year

WEEK *ASSESSMENT* *SITE NO.* *SUBJECT ID.* *ALPHA CODE*

FORM 07 - 12-Lead ECG Results

INSTRUCTIONS: Complete this form at screening/baseline and at the last visit of week 12 or the termination visit, if prior to week 12.

Data collected for scheduled visit: ..... ☐ Screening/Baseline ☐ Week 12/Termination ☐ Unscheduled

1. ECG overall results: ☐ *Normal* ☐ *Abnormal, not clinically significant* ☐ *Abnormal, clinically significant*
2. If abnormal, mark an 'X' in ALL applicable boxes 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*
t. ☐ *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*

Comments: _____

ECG read by: _____ Date Read *Month* *Day* *Year*

Form Completed By:_____ Date:_____

Physician's Signature: _____ Date:_____

DataFax #012 Plate #081

WEEK	*SITE NO.*	*SUBJECT ID.*	*ALPHA CODE*	*DATE OF ASSESSMENT*		
0 0						
				Month	Day	Year

FORM 08 - Birth Control/Pregnancy Assessment (Women Only)

INSTRUCTIONS: Complete this form at screening/baseline, on study day 1 prior to randomization, at weeks 4, 8, at the last visit of week 12 or the termination visit, if prior to week 12, and at the follow-up visit. (NOTE: When completing this form on study day 1 prior to randomization, record "01" in Week in header.)

Data collected for:

☐ Screening/Baseline ☐ Day 1 ☐ Week 4 ☐ Week 8 ☐ Week 12/Termination ☐ Follow-up Visit

1. What method(s) of birth control is the subject currently using? (Mark 'X' for all that apply)

☐ *Oral contraceptive

☐ *Contraceptive skin patch (Ortho Evra®)

☐ *Levonorgestrel implant (Norplant®)

☐ *Medroxyprogesterone Acetate Contraceptive injection (Depo-Provera®)

☐ *Hormonal vaginal contraceptive ring (NuvaRing®)

☐ Barrier (diaphragm or condom plus spermicide)

☐ Intrauterine Progesterone Contraceptive system (IUD)

☐ Contraceptive sponge

☐ Complete abstinence

NOTE: Methods marked with an asterisk(*) **must** be used in conjunction with a barrier method or IUD.

☐ Hysterectomy, record date of procedure: . . . . . Month ☐☐ Year ☐☐☐☐

☐ Tubal ligation, record date of procedure:. . . . . Month ☐☐ Year ☐☐☐☐

☐ Post-menopausal, record date of last menstrual period:. . . . Month ☐☐ Year ☐☐☐☐

☐ Other, specify _____

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

If 'YES', continue.

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

Form Completed By: _____Date: _____

Investigator's Signature: _____Date: _____

DataFax #012 Plate #091

SPECIMEN NO.	SITE NO.	SUBJECT ID.	ALPHA CODE	DATE OF ASSESSMENT		
				Month	Day	Year

FORM 09 - Urine Drug Toxicology

INSTRUCTIONS: Complete this form for all urine toxicology screens performed with an on-site test cup device. Subjects must provide a minimum of four urine specimens during the screening/baseline period, including at least 1 specimen that is positive for amphetamine or methamphetamine. These forms are pre-populated with sequential specimen numbers, please be sure to use these forms in the correct order.

1. Was urine temperature within the expected range on the first attempt? ☐ *No* ☐ *Yes*

   If Yes, go to Question 3, leave Question 2 blank.

2. Was urine temperature within the expected range on the second attempt? ☐ *No* ☐ *Yes*

   If the temperature is not within the expected range after two attempts, do not collect additional specimens. The subject must return for another visit. Sign and date form below.

3. **SCREEN FOR:**

	Negative	*Positive*
a. METHAMPHETAMINE	☐	☐
b. COCAINE	☐	☐
c. TETRAHYDROCANNABINOL	☐	☐
d. AMPHETAMINES	☐	☐
e. BARBITURATES	☐	☐
f. OPIATES	☐	☐
g. BENZODIAZEPINES	☐	☐

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

Form Completed By: _____ Date: _____

DataFax #012 Plate #101

DATE OF ASSESSMENT

Month Day Year

WEEK *ASSESSMENT* *SITE NO.* *SUBJECT ID.* *ALPHA CODE*

FORM 10 - Clinical Laboratory Report

INSTRUCTION: Complete this form at screening/baseline and the last visit of week 12 or the termination visit, if prior to week 12.

Data collected for scheduled visit: ☐ Screening/Baseline ☐ Week 12/Termination ☐ Unscheduled/Repeat

	Value	**Evaluation** 1=Normal 2=Abnormal, not clinically significant 3=Abnormal, clinically significant 9=Not done	**Comments** Must be provided if a '3' or a '9' is recorded under Evaluation.
CBC			
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 (%)	☐☐.☐	☐	

DataFax #012 Plate #102

DATE OF ASSESSMENT

Month Day Year

WEEK *ASSESSMENT* *SITE NO.* *SUBJECT ID.* *ALPHA CODE*

Data collected for scheduled visit: ☐ Screening/Baseline ☐ Week 12/Termination ☐ Unscheduled/Repeat

	Value	**Evaluation** 1=Normal 2=Abnormal, not clinically significant 3=Abnormal, clinically significant 9=Not done	**Comments** Must be provided if a '3' or a '9' is recorded under Evaluation.
9. Eosinophils (%)	☐☐.☐	☐	
10. Basophils (%)	☐☐.☐	☐	
CHEM 7 PANEL			
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)	☐☐☐	☐	

DataFax #012 Plate #103

DATE OF ASSESSMENT

Month Day Year

WEEK *ASSESSMENT* *SITE NO.* *SUBJECT ID.* *ALPHA CODE*

Data collected for scheduled visit: ☐ Screening/Baseline ☐ Week 12/Termination ☐ Unscheduled/Repeat

	Value	**Evaluation** 1=Normal 2=Abnormal, not clinically significant 3=Abnormal, clinically significant 9=Not done	**Comments** Must be provided if a '3' or a '9' is recorded under Evaluation.
LFTs			
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)	☐☐☐☐	☐	
URINALYSIS			
25. Specific gravity	☐.☐☐☐	☐	
26. pH	☐☐.☐	☐	

DataFax #012 Plate #104

DATE OF ASSESSMENT

Month Day Year

WEEK *ASSESSMENT* *SITE NO.* *SUBJECT ID.* *ALPHA CODE*

Data collected for scheduled visit: ☐ Screening/Baseline ☐ Week 12/Termination ☐ Unscheduled/Repeat

	Yellow	**Not Yellow**	**Not Done**	Provide Comments if 'Not Yellow' or 'Not Done'
27. Color	☐	☐	☐	

	Clear	**Not Clear**	**Not Done**	Provide Comments if 'Not Clear' or 'Not Done'
28. Appearance	☐	☐	☐	

	Negative	**Trace**	**Present**	**Not Done**	**Comments** Provide comments if anything other than 'Negative' is marked.
29. Glucose	☐	☐	☐	☐	
30. Bilirubin	☐	☐	☐	☐	
31. Ketones	☐	☐	☐	☐	
32. Protein	☐	☐	☐	☐	
33. Occult blood	☐		☐	☐	
34. Nitrite	☐		☐	☐	
35. Leukocyte esterase	☐		☐	☐	

Form Completed By: _____ Date: _____

Physician's Signature: _____ Date: _____

DataFax #012 Plate #111 Visit #000

SITE NO. *SUBJECT ID.* *ALPHA CODE* *DATE OF ASSESSMENT*

Month Day Year

FORM 11 - Infectious Disease

INSTRUCTION: Complete this form at screening/baseline only.

Result
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. PPD ☐ _____

a. Date PPD read: *Month* *Day* *Year* **b.** If positive, size of induration: ☐☐ *mm*

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

c. Date of chest x-ray: *Month* *Day* *Year* **d.** Chest x-ray result: ☐ *Normal* ☐ *Abnormal, study entry OK (comment required if marked)*

Comments: _____

6. Date of RPR: *Month* *Day* *Year* **a.** Result of RPR: ☐ *Reactive** ☐ *Non-reactive*

If reactive, a confirmatory assay for RPR must be performed and Questions 6b and 6c completed.

b. Date of confirmatory assay *Month* *Day* *Year*

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

Form Completed By: _____ Date:_____

Physician's Signature: _____ Date:_____

DataFax #012 Plate #121 Visit #000

SITE NO. *SUBJECT ID.* *ALPHA CODE* *DATE OF ASSESSMENT*

Month Day Year

FORM 12 - SCID

INSTRUCTIONS: Complete this form at screening/baseline only. Form items A-L, indicate the three, four or five-digit DSM-IV diagnostic code for all Axis I diagnoses. After the *"I",* use the sixth digit to indicate the following specificers:

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

*No Number '4'.

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

A. ___.___/___ E. ___.___/___ I. ___.___/___

B. ___.___/___ F. ___.___/___ J. ___.___/___

C. ___.___/___ G. ___.___/___ K. ___.___/___

D. ___.___/___ H. ___.___/___ L. ___.___/___

Form Completed By: _____Date: _____

DataFax #012 Plate #131

Form 13 - Addiction Severity Index Lite (ASI)

WEEK | SITE NO. | SUBJECT ID. | ALPHA CODE | DATE OF ASSESSMENT (Month / Day / Year)

Data collected for scheduled visit: ☐ Screening/Baseline ☐ Week 6 ☐ Week 12/Termination

Comments
(Include question number with your notes.)

G18. Do you have a religious preference?
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.

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.

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

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

DataFax #012 *Plate #132*

WEEK	*SITE NO.*	*SUBJECT ID.*	*ALPHA CODE*

Data collected for scheduled visit:

☐ Screening/ Baseline ☐ Week 6 ☐ Week 12/Term.

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.

DataFax #012 *Plate #133*

WEEK	*SITE NO.*	*SUBJECT ID.*	*ALPHA CODE*

Data collected for scheduled visit:

☐ Screening/ Baseline ☐ Week 6 ☐ Week 12/Term.

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 & E21, 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 <u>significantly</u> 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 <u>usual or most recent</u> 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			

DataFax #012 *Plate #134*

WEEK	*SITE NO.*	*SUBJECT ID.*	*ALPHA CODE*

Data collected for scheduled visit:

☐ Screening/ Baseline ☐ Week 6 ☐ Week 12/Term.

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, D30, D29, & D31, 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?

DataFax #012 *Plate #135*

WEEK *SITE NO.* *SUBJECT ID.* *ALPHA CODE*

Data collected for scheduled visit:

☐ Screening/ Baseline ☐ Week 6 ☐ Week 12/Term.

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.

DataFax #012 *Plate #136*

WEEK	*SITE NO.*	*SUBJECT ID.*	*ALPHA CODE*

Data collected for scheduled visit:

☐ Screening/ Baseline ☐ Week 6 ☐ Week 12/Term.

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

LEGAL STATUS *continued*

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 & L29, 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

DataFax #012 *Plate #137*

WEEK	*SITE NO.*	*SUBJECT ID.*	*ALPHA CODE*

Data collected for scheduled visit:

☐ Screening/ Baseline ☐ Week 6 ☐ Week 12/Term.

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

FAMILY/SOCIAL RELATIONSHIPS

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	☐	☐

DataFax #012 *Plate #138*

WEEK *SITE NO.* *SUBJECT ID.* *ALPHA CODE*

Data collected for scheduled visit:

☐ Screening/ Baseline ☐ Week 6 ☐ Week 12/Term.

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?	☐	☐
• Caused you physical harm.		
F29. Sexually?	☐	☐
• Forced sexual advances/acts.		

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

F30. With your family? ☐☐

For questions F32 & F34, 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)? ☐☐

For questions F33 & F35, ask the patient to use the Patient Rating Scale.

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

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

DataFax #012 **Plate #139**

WEEK *SITE NO.* *SUBJECT ID.* *ALPHA CODE*

Data collected for scheduled visit:

☐ Screening/ Baseline ☐ Week 6 ☐ Week 12/Term.

PSYCHIATRIC STATUS

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

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:

	Past 30 days	Lifetime
0 = No 1 = Yes		
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 & P14, 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? ☐

CONFIDENCE RATINGS

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

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

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

Form completed by:

_____

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 numbers circled are to be asked at the first visit of week 6 and the last visit of week 12 or the termination visit, if prior to week 12. Items with an asterisk(*) are cumulatve and should be rephrased at week 6 and week 12. Items under CONFIDENCE RATINGS are questions for the interviewer. Do not ask these questions of 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 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 of 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, spot 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, Ecstacy
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 = Ventolin 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 applies 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 14 - Substance Use Report (SUR) - Revised 01.30.2008

INSTRUCTIONS: Make entries on this form at every screening/baseline and study visit including the follow-up visit. **Report alcohol and illicit drug use on this form, including prescription drug abuse.**

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. SUR forms completed during the screening/baseline period have been prepopulated with week "00" and sequence number 01 thru 04 (potential number of weeks SUR data could be collected during the screening/baseline period, a maximum of 25 days). PLEASE be careful to complete these screening forms in the correct sequence order.

Enter the dates for each day of the study week in the column headings.
Indicate whether substance use occurred by marking an 'X' in the appropriate box to indicate No (no use) or Yes (use for each substance listed in the rows). Enter the route of administration for each substance reported except alcohol. If more than one route of administration is used for a substance, record the most severe route. If alcohol was used, enter the number of standard drinks. Refer to codes below to complete these items.

New Instruction: For Nicotine - If subject smokes cigarettes, route must always be recorded as "4", inhalation, and the # of cigarettes smoked must be recorded in the boxes provided. If the subject inhaled nicotine other than cigarettes, record "000" in the boxes.

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

DataFax #012 Plate #141

WEEK *SEQ. #* *SITE NO.* *SUBJECT ID.* *ALPHA CODE*

FORM 14 - Substance Use Report (SUR)

	Day 1 (mm/dd/yy)	Day 2 (mm/dd/yy)	Day 3 (mm/dd/yy)	Day 4 (mm/dd/yy)
	No Yes Route	No Yes Route	No Yes Route	No Yes Route
Nicotine?	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐	☐ ☐ → ☐
If smoked cigarettes, # / # of cigarettes	☐☐☐	☐☐☐	☐☐☐	☐☐☐
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?	☐ ☐ → ☐☐	☐ ☐ → ☐☐	☐ ☐ → ☐☐	☐ ☐ → ☐☐

DataFax #012 Plate #142

WEEK *SEQ. #* *SITE NO.* *SUBJECT ID.* *ALPHA CODE*

Day 5 (mm/dd/yy) **Day 6 (mm/dd/yy)** **Day 7 (mm/dd/yy)**

	No	**Yes**	**Route**	**No**	**Yes**	**Route**	**No**	**Yes**	**Route**
Nicotine?	☐	☐ →	☐	☐	☐ →	☐	☐	☐ →	☐
If smoked cigarettes, #			☐☐☐	# of cigarettes		☐☐☐	# of cigarettes		☐☐☐
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:_____

DataFax #012 Plate #151

DATE OF ASSESSMENT

Month Day Year

WEEK *SEQ. #* *SITE NO.* *SUBJECT ID.* *ALPHA CODE*

FORM 15 - Brief Substance Craving Scale (BSCS)

INSTRUCTIONS: This form should be completed by the subject weekly during screening/baseline, at the first visit of weeks 1 - 11, and the last visit of week 12.

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):* ☐☐ : ☐☐ (60 min. should be entered as 01:00.)
Hours Minutes

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

☐ *All days the same (Go to question #8)*

☐ *Monday* ☐ *Tuesday* ☐ *Wednesday*

☐ *Thursday* ☐ *Friday* ☐ *Saturday* ☐ *Sunday*

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*

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DATE OF ASSESSMENT

Month Day Year

WEEK *SEQ. #* *SITE NO.* *SUBJECT ID.* *ALPHA CODE*

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*

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*

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DATE OF ASSESSMENT

Month Day Year

WEEK *SEQ. #* *SITE NO.* *SUBJECT ID.* *ALPHA CODE*

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.

Subject *Staff*

Form Completed By: . . . . . ☐ ☐

Form Reviewed By: _____ Date: _____

DataFax #012 Plate #161

DATE OF ASSESSMENT

Month Day Year

WEEK *SEQ. #* *SITE NO.* *SUBJECT ID.* *ALPHA CODE*

FORM 16 - Weekly Urine Collection/AE Assessment

INSTRUCTIONS: Complete this form weekly, screening/baseline through study week 12 and at follow-up (week 16). Follow directions in the Operations Manual for labeling and shipping urine specimens to CRL. Questions 1 and 4 should never be left blank or coded with a Missing Value Code.

1. Was a urine sample collected in this study week? ☐ *No* ☐ *Yes*

If no urine sample collected in this study week, go to Question 4.

a. Date first sample collected in this study week — *Month* *Day* *Year*

b. Place barcode label of this urine sample here

2. Was a second urine sample collected in this study week? ☐ *No* ☐ *Yes*

If no second urine sample was collected in this study week, go to Question 4.

a. Date second sample collected in this study week — *Month* *Day* *Year*

b. Place barcode label of this urine sample here

3. Was a third urine sample collected in this study week? ☐ *No* ☐ *Yes*

If no third urine sample was collected in this study week, go to Question 4.

a. Date third sample collected in this study week — *Month* *Day* *Year*

b. Place barcode label of this urine sample here

4. Were AE's assessed at each time the subject attended a clinic visit this study week? ☐ *No* ☐ *Yes* ☐ *Did not attend clinic this study week*

If 'No', comments are required: _____

If AE's were reported during this study week, complete the Adverse Event Form 26.

Form Completed By: _____ Date:_____

Medical Staff Signature: _____ Date:_____

DataFax #012 Plate #171

WEEK *SITE NO.* *SUBJECT ID.* *ALPHA CODE*

FORM 17 - Weekly Dosing Record

INSTRUCTIONS: Complete one entry on this form for each day of the study week, recording subject attendance, if blister card was brought to visit, and the number of tablets taken. If the number of tablets taken on any day is less than 4, comment in the space provided for that day. For items a-d, if no drug was dispensed, returned, taken, or missing, record 00s in the appropriate spaces. Update incomplete entries on the previous week's form during the following study week.

Day	Date (*Month* / *Day* / *Year*)	Attended Clinic (*No* / *Yes*)	Card Brought to Visit (*No* / *Yes*)	# Tablets Taken This Day	Comments
1					
2					
3					
4					
5					
6					
7					

a. Enter total # of tablets dispensed including emergency doses during this study week:

b. Enter total # of tablets returned from those dispensed:

c. Enter total # of tablets taken from those dispensed:

d. Enter total # of tablets missing/not accounted for from those dispensed:

*Comments must be provided for all emergency medication dispensing and for all medication discrepancies noted within the study week:

Form Completed By:_____ Date:_____

Investigator's Signature:_____ Date:_____

DataFax #012 *Plate #181*

WEEK	*SITE NO.*	*SUBJECT ID.*	*ALPHA CODE*	*DATE OF ASSESSMENT*		
				Month	Day	Year

FORM 18 - Barratt Impulsiveness Scale

INSTRUCTIONS: This form is completed by the subject during screening/baseline, at the 1st visit of week 6 and at the last visit of week 12 or the termination visit, if prior to week 12.

Data collected for scheduled visit: ☐ Screening/Baseline ☐ Week 6 ☐ Week 12/Termination

People differ in the way they act and think in different situations. This is a test to measure some of the ways in which you act and think. Read each statement and put an 'X' in the appropriate box. Do not spend too much time on any statement. Answer quickly and honestly.

	Rarely/ Never	Occasionally	Often	Almost Always/ Always
1. I plan tasks carefully	☐	☐	☐	☐
2. I do things without thinking	☐	☐	☐	☐
3. I make-up my mind quickly	☐	☐	☐	☐
4. I am happy-go-lucky	☐	☐	☐	☐
5. I don't "pay attention"	☐	☐	☐	☐
6. I have "racing" thoughts	☐	☐	☐	☐
7. I plan trips well ahead of time	☐	☐	☐	☐
8. I am self-controlled	☐	☐	☐	☐
9. I concentrate easily	☐	☐	☐	☐
10. I save regularly	☐	☐	☐	☐

DataFax #012 *Plate #182*

WEEK	*SITE NO.*	*SUBJECT ID.*	*ALPHA CODE*

Data collected for scheduled visit: ☐ Screening/Baseline ☐ Week 6 ☐ Week 12/Termination

	Rarely/ Never	Occasionally	Often	Almost Always/ Always
11. I "squirm" at plays or lectures	☐	☐	☐	☐
12. I am a careful thinker	☐	☐	☐	☐
13. I plan for job security	☐	☐	☐	☐
14. I say things without thinking	☐	☐	☐	☐
15. I like to think about complex problems	☐	☐	☐	☐
16. I change jobs	☐	☐	☐	☐
17. I act "on impulse"	☐	☐	☐	☐
18. I get easily bored solving thought problems	☐	☐	☐	☐
19. I act on the spur of the moment	☐	☐	☐	☐
20. I am a steady thinker	☐	☐	☐	☐
21. I change residences	☐	☐	☐	☐
22. I buy things on impulse	☐	☐	☐	☐
23. I can only think about one problem at a time	☐	☐	☐	☐
24. I change hobbies	☐	☐	☐	☐

DataFax #012 *Plate #183*

WEEK *SITE NO.* *SUBJECT ID.* *ALPHA CODE*

Data collected for scheduled visit: ☐ Screening/Baseline ☐ Week 6 ☐ Week 12/Termination

	Rarely/ Never	Occasionally	Often	Almost Always/ Always
25. I spend or charge more than I earn	☐	☐	☐	☐
26. I often have extraneous thoughts when I am thinking	☐	☐	☐	☐
27. I am more interested in the present than the future	☐	☐	☐	☐
28. I am restless at the theater or lectures	☐	☐	☐	☐
29. I like puzzles	☐	☐	☐	☐
30. I am future oriented	☐	☐	☐	☐

Thank You. This Form is Complete.

Subject *Staff*

Form completed by: . . . . . . ☐ ☐

Form Reviewed By: _____Date: _____

SITE NO. | *SUBJECT ID.* | *ALPHA CODE* | *DATE OF ASSESSMENT*

Month Day Year

FORM 19 - Adult ADHD Clinical Diagnostic Scale ACDS V 1.2

Complete this form at screening.

ADHD Childhood History - For the next questions regarding your childhood, we are asking about the period of of time before you became a teenager, roughly the time corresponding to elementary or primary school.

1. <u>Makes a Lot of Careless Mistakes:</u>

Did you make a lot of careless mistakes at school?

Did you often get problems wrong on tests because you didn't read the instructions right?

Did you often leave some questions blank by accident?

Forget to do the problems on both sides of a handout?

How often did these types of things happen?

Did your teacher ever say you should pay more attention to detail?

- ☐ 1 - Not present.
- ☐ 2 - Mild: Occasionally made careless mistakes.
- ☐ 3 - Moderate: Often failed to give close attention to details or made careless mistakes in schoolwork, work or other activities.
- ☐ 4 - Severe
- ☐ 6 - Absent or false due to therapeutic medication.
- ☐ 8 - Present or true due to medical condition.
- ☐ 9 - Inadequate information.

Age:. . . . . ☐☐

Grade:. . . . . ☐☐

2. <u>Difficulty Sustaining Attention on Tasks/Play Activities?</u>

Has there ever been a time when you had trouble paying attention in school?

Did it affect your schoolwork?

Did you get into trouble because of this?

When you were working on your homework, did your mind wander?

What about when you were playing games?

Did you forget to go when it was your turn?

- ☐ 1 - Not present.
- ☐ 2 - Mild: Occasionally had difficulty sustaining attention on tasks or play activities.
- ☐ 3 - Moderate: Often had difficulty sustaining attention in tasks or play activities.
- ☐ 4 - Severe
- ☐ 6 - Absent or false due to therapeutic medication.
- ☐ 8 - Present or true due to medical condition.
- ☐ 9 - Inadequate information.

Age:. . . . . ☐☐

Grade:. . . . . ☐☐

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SITE NO.	*SUBJECT ID.*	*ALPHA CODE*

3. Doesn't Listen:

Was it hard for you to remember what your parents and teachers said?

Did your parents or teachers complain that you didn't listen to them when they talked to you?

Did you "tune people out"?

Did you get into trouble for not listening?

- ☐ 1 - Not present.
- ☐ 2 - Mild: Occasionally didn't listen.
- ☐ 3 - Moderate: Often did not seem to listen when spoken to directly.
- ☐ 4 - Severe
- ☐ 6 - Absent or false due to therapeutic medication.
- ☐ 8 - Present or true due to medical condition.
- ☐ 9 - Inadequate information.

Age:. . . . . ☐☐

Grade:. . . . . ☐☐

4. Difficulty Following Instructions:

Did your teachers complain that you didn't follow instructions?

When your parents or your teacher told you to do something, was it sometimes hard for you to remember what they had said to do?

Did it get you into trouble?

Did you lose points on your assignments for not following directions or not completing the work?

Did you forget to do your homework or forget to turn it in?

Did you get into trouble at home for not finishing your chores or other things your parents asked you to do?

How often?

- ☐ 1 - Not present.
- ☐ 2 - Mild: Occasionally had difficulty following instructions. Problem has only minimal effect on functioning.
- ☐ 3 - Moderate: Often did not follow through on instructions and failed to finish school work, chores, or duties in the, workplace (not due to oppositional behavior or failure to understand instructions).
- ☐ 4 - Severe
- ☐ 6 - Absent or false due to therapeutic medication.
- ☐ 8 - Present or true due to medical condition.
- ☐ 9 - Inadequate information.

Age:. . . . . ☐☐

Grade:. . . . . ☐☐

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SITE NO.	*SUBJECT ID.*	*ALPHA CODE*

5. Difficulty Organizing Tasks:

Was your desk or locker at school a mess?

Did it make it hard for you to find the things you needed?

Did your teacher complain that your assignments were messy or disorganized?

When you did your worksheets, did you usually start at the beginning and do all the problems in order, or did you like to skip around?

Did you often miss problems?

Did you have a hard time getting ready for school in the morning?

- ☐ 1 - Not present.
- ☐ 2 - Mild: Occasionally disorganized. Problem had only minimal effect on functioning.
- ☐ 3 - Moderate: Often had difficulty organizing tasks and activities.
- ☐ 4 - Severe
- ☐ 6 - Absent or false due to therapeutic medication.
- ☐ 8 - Present or true due to medical condition.
- ☐ 9 - Inadequate information.

Age:. . . . . ☐☐

Grade:. . . . . ☐☐

6. Dislikes/Avoids Tasks Requiring Attention:

Were there some kinds of schoolwork you hated doing more than others? Which ones? Why?

Did you try to get out of doing your assignments?

Did you pretend to forget about your homework to get out of doing it?

About how many times a week did you not do your homework?

- ☐ 1 - Not present.
- ☐ 2 - Mild: Occasionally avoided tasks that required sustained attention, and/or expressed mild dislike for these tasks.
- ☐ 3 - Moderate: Often avoided, disliked, or was reluctant to engage in tasks that required sustained mental effort such as homework.
- ☐ 4 - Severe
- ☐ 6 - Absent or false due to therapeutic medication.
- ☐ 8 - Present or true due to medical condition.
- ☐ 9 - Inadequate information.

Age:. . . . . ☐☐

Grade:. . . . . ☐☐

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7. Loses Things:

Did you lose things a lot?

Your pencils at school?

Homework assignments?

Things around home?

About how often did that happen?

- ☐ 1 - Not present.
- ☐ 2 - Mild: Occasionally lost things.
- ☐ 3 - Moderate: Often lost things necessary for tasks or activities (e.g., toys, school assignments, pencils, books, or tools).
- ☐ 4 - Severe
- ☐ 6 - Absent or false due to therapeutic medication.
- ☐ 8 - Present or true due to medical condition.
- ☐ 9 - Inadequate information.

Age:. . . . . ☐☐

Grade:. . . . . ☐☐

8. Easily Distracted:

Was there ever a time when little distractions would make it very hard for you to keep your mind on what you were doing?

Like if another kid in class asked the teacher a question while the class was working quietly, was it ever hard for you to keep your mind on your work?

When there was an interruption, like when the phone rang, was it hard to get back to what you were doing before the interruption?

Were there times when you could keep your mind on what you were doing, and little noises and things didn't bother you?

How often were they a problem?

- ☐ 1 - Not present.
- ☐ 2 - Mild: Occasionally distracted.
- ☐ 3 - Moderate: Was often distracted by extraneous stimuli (e.g., attention often disrupted by minor distractions other kids would be able to ignore).
- ☐ 4 - Severe
- ☐ 6 - Absent or false due to therapeutic medication.
- ☐ 8 - Present or true due to medical condition.
- ☐ 9 - Inadequate information.

Age:. . . . . ☐☐

Grade:. . . . . ☐☐

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9. <u>Forgetful in Daily Activities:</u>

Did you often leave your homework at home, or your books or coats on the bus?

Did you leave your things outside by accident?

How often did these things happen?

Did anyone ever complain that you were too forgetful?

☐ 1 - Not present.

☐ 2 - Mild: Occasionally forgetful.

☐ 3 - Moderate: Often was forgetful in daily activities.

☐ 4 - Severe

☐ 6 - Absent or false due to therapeutic medication.

☐ 8 - Present or true due to medical condition.

☐ 9 - Inadequate information.

Age:. . . . . ☐☐

Grade:. . . . . ☐☐

10. <u>Fidget:</u>

Did people often tell you to sit still, to stop moving, or stop squirming in your seat?

Your teachers?

Parents?

Did you sometimes get into trouble for squirming in your seat or playing with little things at your desk?

Did you have a hard time keeping your arms and legs still?

How often?

☐ 1 - Not present.

☐ 2 - Mild: Occasionally fidgeted with hands or feet or squirmed in seat.

☐ 3 - Moderate: Often fidgeted with hands or feet or squirmed in seat.

☐ 4 - Severe

☐ 6 - Absent or false due to therapeutic medication.

☐ 8 - Present or true due to medical condition.

☐ 9 - Inadequate information.

Age:. . . . . ☐☐

Grade:. . . . . ☐☐

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11. Difficulty Remaining Seated:

Was there ever a time when you got out of your seat a lot at school?

Did you get into trouble for this?

Was it hard to stay in your seat at school?

What about dinnertime?

- ☐ 1 - Not present.
- ☐ 2 - Mild: Occasionally had difficulty remaining seated when required to do so.
- ☐ 3 - Moderate: Often left seat in classroom or in other situations.
- ☐ 4 - Severe
- ☐ 6 - Absent or false due to therapeutic medication.
- ☐ 8 - Present or true due to medical condition.
- ☐ 9 - Inadequate information.

Age:. . . . . ☐☐

Grade:. . . . . ☐☐

12. Runs or Climbs Excessively:

Did you get into trouble for running down the hall in school?

Did your mom often have to remind you to walk instead of run when you were out together?

Did your parents or your teachers complain about you climbing things you shouldn't?

What kinds of things?

How often did this happen?

IF NECESSARY: When you were an adolescent, did you feel restless a lot? Feel like you had to move around, or that it was very hard to stay in one place?

- ☐ 1 - Not present.
- ☐ 2 - Mild: Occasionally ran about or climbed excessively. Problem had only minimal effect on functioning. (In adolescents, may be limited to a subjective feeling of restlessness.)
- ☐ 3 - Moderate: Often ran about or climbed excessively in situations in which it was inappropriate. (In adolescents, may be limited to a subjective feeling of restlessness.)
- ☐ 4 - Severe
- ☐ 6 - Absent or false due to therapeutic medication.
- ☐ 8 - Present or true due to medical condition.
- ☐ 9 - Inadequate information.

Age:. . . . . ☐☐

Grade:. . . . . ☐☐

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13. <u>Difficulty Playing Quietly:</u>

Did your parents or teachers often tell you to quiet down when you were playing?

Did you have a hard time playing quietly?

- ☐ 1 - Not present.
- ☐ 2 - Mild: Occasionally had difficulty playing quietly.
- ☐ 3 - Moderate: Often had difficulty playing or engaging in leisure activities quietly.
- ☐ 4 - Severe
- ☐ 6 - Absent or false due to therapeutic medication.
- ☐ 8 - Present or true due to medical condition.
- ☐ 9 - Inadequate information.

Age:. . . . . ☐☐

Grade:. . . . . ☐☐

14. <u>On the Go/Acts Like Driven by Motor:</u>

Was it hard for you to slow down?

Could you stay in one place for long, or were you always on the go?

How long could you sit and watch TV or play a game?

Did people tell you to slow down a lot?

- ☐ 1 - Not present.
- ☐ 2 - Mild: Occasionally acted “driven by a motor.”
- ☐ 3 - Moderate: Was often “on the go” or often acted as if “driven by a motor.”
- ☐ 4 - Severe
- ☐ 6 - Absent or false due to therapeutic medication.
- ☐ 8 - Present or true due to medical condition.
- ☐ 9 - Inadequate information.

Age:. . . . . ☐☐

Grade:. . . . . ☐☐

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15. <u>Talks Excessively:</u>

Did people say you talked too much?

Did you get into trouble at school for talking when you were not suppose to?

Did people in your family complain that you talked too much?

- ☐ 1 - Not present.
- ☐ 2 - Mild: Occasionally talked excessively.
- ☐ 3 - Moderate: Often talked excessively.
- ☐ 4 - Severe
- ☐ 6 - Absent or false due to therapeutic medication.
- ☐ 8 - Present or true due to medical condition.
- ☐ 9 - Inadequate information.

Age:. . . . . ☐☐

Grade:. . . . . ☐☐

16. <u>Blurts Out Answers:</u>

At school, did you sometimes call out the answers before you were called on?

Did you talk out of turn at home?

Answer questions your parents were asking your siblings?

How often?

- ☐ 1 - Not present.
- ☐ 2 - Mild: Occasionally talked out of turn.
- ☐ 3 - Moderate: Often blurted out answers before questions had been completed.
- ☐ 4 - Severe
- ☐ 6 - Absent or false due to therapeutic medication.
- ☐ 8 - Present or true due to medical condition.
- ☐ 9 - Inadequate information.

Age:. . . . . ☐☐

Grade:. . . . . ☐☐

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17. <u>Difficulty Waiting Turn:</u>

Was it hard for you to wait your turn in games?

What about in line in the cafeteria or at the water fountain?

- ☐ 1 - Not present.
- ☐ 2 - Mild: Occasionally had difficulty waiting his/her turn.
- ☐ 3 - Moderate: Often had difficulty waiting his/her turn.
- ☐ 4 - Severe
- ☐ 6 - Absent or false due to therapeutic medication.
- ☐ 8 - Present or true due to medical condition.
- ☐ 9 - Inadequate information.

Age:. . . . . ☐☐

Grade:. . . . . ☐☐

18. <u>Interrupts or Intrudes:</u>

Did you get into trouble for talking out of turn in school?

Did your parents, teachers, or any of the kids you knew complain that you cut them off when they were talking?

Did kids complain that you broke in on games?

Did this happen a lot?

- ☐ 1 - Not present.
- ☐ 2 - Mild: Occasionally interrupted others.
- ☐ 3 - Moderate: Often interrupted or intruded on others (e.g., butted into conversations or games).
- ☐ 4 - Severe
- ☐ 6 - Absent or false due to therapeutic medication.
- ☐ 8 - Present or true due to medical condition.
- ☐ 9 - Inadequate information.

Age:. . . . . ☐☐

Grade:. . . . . ☐☐

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19. Duration of Childhood Symptoms:

For how long did you have trouble (list symptoms that were positively endorsed)?

_____
_____
_____
_____
_____

- ☐ 1 - Not present.
- ☐ 2 - Symptoms persisted less than 6 months.
- ☐ 3 - Symptoms persisted at least 6 months.
- ☐ 9 - Inadequate information.

Age:. . . . . ☐☐

Grade:. . . . . ☐☐

20. Age of Onset:

If Necessary: How old were you when you first started having trouble (list symptoms)?

_____
_____
_____
_____
_____

Did you have these problems in kindergarten?

Specify age: (years) . . . . . ☐☐

- ☐ 1 - Not present.
- ☐ 2 - Onset of symptoms since 7 years of age.
- ☐ 3 - Some hyperactive-impulsive or inattentive symptoms that caused impairment were present before age 7.
- ☐ 9 - Inadequate information.

21. Some Impairment in 2 or more settings (childhood):

Did these things (list positive symptoms) cause trouble for you in school?

_____
_____
_____
_____
_____

With your family?

With other kids?

- ☐ 1 - Not present.
- ☐ 2 - Mild: Some impairment in only one setting.
- ☐ 3 - Moderate: Some impairment from the symptoms was present in two or more settings (e.g., at school and at home).
- ☐ 4 - Severe
- ☐ 6 - Absent or false due to therapeutic medication.
- ☐ 8 - Present or true due to medical condition.
- ☐ 9 - Inadequate information.

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22. <u>Assess clinically significant impairment:</u>

How much trouble did these things (list positive symptoms) cause for you in school?

_____

_____

_____

_____

_____

With your family?

With other kids?

Give me an example.

- ☐ 1 - Not present.
- ☐ 2 - Mild
- ☐ 3 - Moderate: There must be clear evidence of clinically significant impairment in social, academic or occupational functioning.
- ☐ 4 - Severe
- ☐ 6 - Absent or false due to therapeutic medication.
- ☐ 8 - Present or true due to medical condition.
- ☐ 9 - Inadequate information.

Please complete the Childhood ADHD Symptoms Summary on pages 12 and 13 before completing the Adult ADHD History beginning on page 14.

<u>Please note that pages 12 and 13 (with barcodes) must be faxed into DataFax.</u>

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DataFax #012 **Plate #191** **Visit #000**

SITE NO. *SUBJECT ID.* *ALPHA CODE* *DATE OF ASSESSMENT*

Month Day Year

Childhood ADHD Symptoms Summary *Mark with an 'X' either yes or no to symptoms that respondent has indicated he/she experienced in childhood and enter the score for each question in the appropriate box.*

I. INATTENTION	Yes	No	Score
23. Careless/Sloppy (score from Q.1)	☐	☐	☐
24. Difficulty sustaining attention (score from Q.2)	☐	☐	☐
25. Doesn't listen (score from Q.3)	☐	☐	☐
26. Difficulty following instructions (finishing) (score from Q.4)	☐	☐	☐
27. Difficulty organizing tasks/activities (score from Q.5)	☐	☐	☐
28. Avoidance of tasks with sustained mental effort (score from Q.6)	☐	☐	☐
29. Loses things (score from Q.7)	☐	☐	☐
30. Easily distracted (score from Q.8)	☐	☐	☐
31. Forgetful in daily activities (score from Q.9)	☐	☐	☐

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SITE NO. *SUBJECT ID.* *ALPHA CODE*

II. HY LSIVITY	**Yes**	**No**	**Score**
32. Fidgets/Squirms (score from Q.10)	☐	☐	☐
33. Difficulty remaining seated (score from Q.11)	☐	☐	☐
34. Runs/Climbs excessively/Inappropriately (score from Q.12)	☐	☐	☐
35. Difficulty playing quietly (score from Q.13)	☐	☐	☐
36. On the go/Driven by a motor (score from Q.14)	☐	☐	☐
37. Talks excessively (score from Q.15)	☐	☐	☐
38. Blurts out answers (score from Q.16)	☐	☐	☐
39. Difficulty waiting turn (score from Q.17)	☐	☐	☐
40. Interrupts or Intrudes (score from Q.18)	☐	☐	☐

	Yes	*No*
41. **Did respondent report ADHD symptoms <u>prior</u> to age 7?**	☐	☐

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ADHD Adult History - Think about only the past 12 months.

42. Makes a Lot of Careless Mistakes:

In the past 12 months....

Do you make a lot of mistakes (in school) or work?

Is this because you're careless?

Do you rush through your work, or activities?

Do you have trouble with detailed work?

Do you not check your work?

Do people complain that you're careless?

Are you messy or sloppy?

Is your desk or workspace so messy that you have difficulty finding things?

- ☐ 1 - Not present.
- ☐ 2 - Mild: Occasionally makes careless mistakes.
- ☐ 3 - Moderate: Often fails to give close attention to details or makes careless mistakes in schoolwork, work or other activities.
- ☐ 4 - Severe
- ☐ 6 - Absent or false due to therapeutic medication.
- ☐ 8 - Present or true due to medical condition.
- ☐ 9 - Inadequate information.

43. Difficulty Sustaining Attention on Tasks/Play Activities:

In the past 12 months....

Do you have trouble paying attention such as watching movies, reading or lectures?

Or on fun activities such as sports or board games?

Is it hard for you to keep your mind on school-work?

Do you have unusual trouble staying focused on boring or repetitive tasks?

Does it take a lot longer than it should to complete tasks because you can't keep your mind on the task?

Is it even harder for you than some others you know?

Do you have trouble remembering what you read and do you need to re-read the same passage several times?

- ☐ 1 - Not present.
- ☐ 2 - Mild: Occasionally has difficulty sustaining attention on tasks or play activities.
- ☐ 3 - Moderate: Often has difficulty sustaining attention in tasks or play activities.
- ☐ 4 - Severe
- ☐ 6 - Absent or false due to therapeutic medication.
- ☐ 8 - Present or true due to medical condition.
- ☐ 9 - Inadequate information.

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SITE NO.	*SUBJECT ID.*	*ALPHA CODE*

44. <u>Doesn't Listen:</u>

In the past 12 months....

Do people (your wife, boss, colleagues, friends) complain that you don't seem to listen or respond (or daydream) when spoken to or when asked to do tasks?

A lot?

Do people have to repeat directions?

Do you find that you miss the key parts of conversations because of drifting off in your own thoughts?

Does it cause problems?

- ☐ 1 - Not present.
- ☐ 2 - Mild: Occasionally doesn't listen.
- ☐ 3 - Moderate: Often does not seem to listen when spoken to directly.
- ☐ 4 - Severe
- ☐ 6 - Absent or false due to therapeutic medication.
- ☐ 8 - Present or true due to medical condition.
- ☐ 9 - Inadequate information.

45. <u>Difficulty Following Instructions:</u>

In the past 12 months....

Do you have trouble finishing things like work, or chores?

Do you often leave things half done and start another project?

Do you need consequences (such as deadlines) to finish?

Do you have trouble following instructions (especially complex, multi-step instructions that have to be done in a certain order with different steps)?

Do you need to write down instructions, otherwise you will forget the task at hand?

- ☐ 1 - Not present.
- ☐ 2 - Mild: Occasionally has difficult following instructions. Problem have only minimal effect on functioning.
- ☐ 3 - Moderate: Often does not follow through on instructions and fails to finish schoolwork, chores, or duties in the workplace (not due to oppositional behavior or failure to understand instructions).
- ☐ 4 - Severe
- ☐ 6 - Absent or false due to therapeutic medication.
- ☐ 8 - Present or true due to medical condition.
- ☐ 9 - Inadequate information.

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46. <u>Difficulty Organizing Tasks:</u>

In the past 12 months....

Do you have trouble organizing things into ordered steps?

Is it hard prioritizing work and chores?

Do you need others to plan for you?

Do you have trouble with time management?

Does it cause problems?

Do you procrastinate and put off tasks until the last moment possible?

- ☐ 1 - Not present.
- ☐ 2 - Mild: Occasionally disorganized. Problem has only minimal effect on functioning.
- ☐ 3 - Moderate: Often has difficulty organizing tasks and activities.
- ☐ 4 - Severe
- ☐ 6 - Absent or false due to therapeutic medication.
- ☐ 8 - Present or true due to medical condition.
- ☐ 9 - Inadequate information.

47. <u>Dislikes/Avoids Tasks Requiring Attention:</u>

In the past 12 months....

Do you avoid tasks (work, chores, reading, board games) that are challenging or lengthy because it's hard to stay focused on these things for a long time?

Do you have to force yourself to do these tasks?

How hard is it?

Do you procrastinate and put off tasks until the last moment possible?

- ☐ 1 - Not present.
- ☐ 2 - Mild: Occasionally avoids tasks that require sustained attention, and/or expresses mild dislike for these tasks.
- ☐ 3 - Moderate: Often avoids, dislikes, or is reluctant to engage in tasks that require sustained mental effort.
- ☐ 4 - Severe
- ☐ 6 - Absent or false due to therapeutic medication.
- ☐ 8 - Present or true due to medical condition.
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48. Loses Things:

In the past 12 months....

Do you lose things (i.e., important work papers, keys, wallet, coats, etc.)?

A lot? More than others?

Are you constantly looking for important items? Do you get into trouble for this (work, home)? Do you need to put items (e.g., glasses, wallet, keys) in the same place each time, otherwise you will lose them?

- ☐ 1 - Not present.
- ☐ 2 - Mild: Occasionally loses things.
- ☐ 3 - Moderate: Often loses things necessary for tasks or activities.
- ☐ 4 - Severe
- ☐ 6 - Absent or false due to therapeutic medication.
- ☐ 8 - Present or true due to medical condition.
- ☐ 9 - Inadequate information.

49. Easily Distracted:

In the past 12 months....

Are you ever very easily distracted by events around you such as noise (conversation, tv, radio), movement, or clutter?

Do you need relative isolation to get work done?

Can almost anything get your mind off of what you are doing...like work, chores or if you're talking to someone?

Is it hard to get back to a task once you stop?

- ☐ 1 - Not present.
- ☐ 2 - Mild: Occasionally distracted.
- ☐ 3 - Moderate: Is often distracted by extraneous stimuli.
- ☐ 4 - Severe
- ☐ 6 - Absent or false due to therapeutic medication.
- ☐ 8 - Present or true due to medical condition.
- ☐ 9 - Inadequate information.

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50. <u>Forgetful in Daily Activities:</u>

In the past 12 months....

Do you forget a lot of things in your daily routine?

Like what? chores? work? appointments or obligations?

Do you forget to bring things to work such as work materials or assignments due that day?

Do you need to write regular reminders to yourself to do most activities or tasks otherwise you will forget?

- ☐ 1 - Not present.
- ☐ 2 - Mild: Occasionally forgetful.
- ☐ 3 - Moderate: Often is forgetful in daily activities.
- ☐ 4 - Severe
- ☐ 6 - Absent or false due to therapeutic medication.
- ☐ 8 - Present or true due to medical condition.
- ☐ 9 - Inadequate information.

51. <u>Fidget:</u>

In the past 12 months....

Can you still or are you always moving your hands, feet, or in your chair?

Do you tap your pencil or your feet?

A lot?

Do people notice?

Do you regularly play with your hair or clothing?

Do you consciously resist fidgeting or squirming?

- ☐ 1 - Not present.
- ☐ 2 - Mild: Occasionally fidgets with hands or feet or squirms in seat.
- ☐ 3 - Moderate: Often fidgets with hands or feet or squirms in seat.
- ☐ 4 - Severe
- ☐ 6 - Absent or false due to therapeutic medication.
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52. Difficulty Remaining Seated:

In the past 12 months....

Do you have trouble staying in your seat? at work? in class? at home, i.e. watching t.v., eating dinner?

In church or temple?

Do you chose to walk around rather than sit?

- ☐ 1 - Not present.
- ☐ 2 - Mild: Occasionally has difficulty remaining seated when required to do so.
- ☐ 3 - Moderate: Often leaves seat in classroom or in other situations in which remaining seated is expected.
- ☐ 4 - Severe
- ☐ 6 - Absent or false due to therapeutic medication.
- ☐ 8 - Present or true due to medical condition.
- ☐ 9 - Inadequate information.

53. Restlessness (Runs or Climbs Excessively):

In the past 12 months....

Are you physically restless?

Do you feel restless inside?

A lot?

Do you feel more agitated when you cannot exercise on an almost daily basis?

- ☐ 1 - Not present.
- ☐ 2 - Mild: Occasionally runs about or climbs excessively. Problem has only minimal effect on functioning.
- ☐ 3 - Moderate: Often runs about or climbs excessively in situations in which it is inappropriate. (May be limited to a subjective feeling of restlessness).
- ☐ 4 - Severe
- ☐ 6 - Absent or false due to therapeutic medication.
- ☐ 8 - Present or true due to medical condition.
- ☐ 9 - Inadequate information.

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SITE NO.	*SUBJECT ID.*	*ALPHA CODE*

54. Difficulty Playing Quietly:

In the past 12 months....

Do you have a hard time playing quietly?

During leisure activity (non-structured times or on your own such as reading a book, listening to music, playing a board game), are you agitated or dysphoric?

Do you always need to be busy while on vacation?

- ☐ 1 - Not present.
- ☐ 2 - Mild: Occasionally has difficulty.
- ☐ 3 - Moderate: Often has difficulty playing or engaging in leisure activities quietly.
- ☐ 4 - Severe
- ☐ 6 - Absent or false due to therapeutic medication.
- ☐ 8 - Present or true due to medical condition.
- ☐ 9 - Inadequate information.

55. On the Go/Acts Like Driven by Motor:

In the past 12 months....

Is it hard for you to slow down?

Do you feel like you (often) have a lot of energy and that you always have to be moving, are always "on the go"?

Do you feel like you "you're driven by a motor"?

Do you feel unable to relax?

- ☐ 1 - Not present.
- ☐ 2 - Mild: Occasionally acts "driven by a motor".
- ☐ 3 - Moderate: Is often "on the go" or often acts as if "driven by a motor".
- ☐ 4 - Severe
- ☐ 6 - Absent or false due to therapeutic medication.
- ☐ 8 - Present or true due to medical condition.
- ☐ 9 - Inadequate information.

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SITE NO.	*SUBJECT ID.*	*ALPHA CODE*

56. <u>Talks Excessively:</u>

In the past 12 months....

Do you talk a lot? all the time? More than other people?

Do people complain about your talking? Is it a problem?

Are you often louder than the people you are talking to?

- ☐ 1 - Not present.
- ☐ 2 - Mild: Occasionally talks excessively.
- ☐ 3 - Moderate: Often talks excessively.
- ☐ 4 - Severe
- ☐ 6 - Absent or false due to therapeutic medication.
- ☐ 8 - Present or true due to medical condition.
- ☐ 9 - Inadequate information.

57. <u>Blurts Out Answers:</u>

In the past 12 months....

Do you give answers to questions before someone finishes asking?

Do you say things before it is your turn?

Do you say things that don't fit into the conversation?

Do you do things without thinking?

A lot?

- ☐ 1 - Not present.
- ☐ 2 - Mild: Occasionally talks out of turn.
- ☐ 3 - Moderate: Often blurts out answers before questions have completed.
- ☐ 4 - Severe
- ☐ 6 - Absent or false due to therapeutic medication.
- ☐ 8 - Present or true due to medical condition.
- ☐ 9 - Inadequate information.

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SITE NO.	*SUBJECT ID.*	*ALPHA CODE*

58. <u>Difficulty Waiting Turn:</u>

In the past 12 months....

Is it hard for you to wait your turn in conversation, in lines, while driving?

Are you frequently frustrated with delays? Does it cause problems?

Do you plan your day around not being in situations where you might have to wait?

- ☐ 1 - Not present.
- ☐ 2 - Mild: Occasionally has difficulty waiting his/her turn.
- ☐ 3 - Moderate: Often has difficulty waiting his/her turn.
- ☐ 4 - Severe
- ☐ 6 - Absent or false due to therapeutic medication.
- ☐ 8 - Present or true due to medical condition.
- ☐ 9 - Inadequate information.

59. <u>Interrupts or Intrudes:</u>

In the past 12 months....

Do you talk when others are talking without waiting until they're finished?

Do you butt into others conversations before being involved?

Do you interrupt others activities?

Is it hard for you to wait to get your point across in conversations or meetings?

- ☐ 1 - Not present.
- ☐ 2 - Mild: Occasionally interrupts others.
- ☐ 3 - Moderate: Often interrupts or intrudes on others (e.g., butts into conversations or games).
- ☐ 4 - Severe
- ☐ 6 - Absent or false due to therapeutic medication.
- ☐ 8 - Present or true due to medical condition.
- ☐ 9 - Inadequate information.

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SITE NO.	*SUBJECT ID.*	*ALPHA CODE*

60. <u>Duration of Adult Symptoms:</u>

For how long have you had trouble (list symptoms that were positively endorsed)?

_____

_____

_____

_____

_____

- ☐ 1 - Not present.
- ☐ 2 - Symptoms persisted less than 6 months.
- ☐ 3 - Symptoms persisted at least 6 months.
- ☐ 9 - Inadequate information.

61. <u>Some Impairment in 2 or more settings:</u>

In the past 12 months...

Have these things (list positive symptoms) caused trouble for you at work?

_____

_____

_____

_____

_____

With your family?

With friends and colleagues?

- ☐ 1 - Not present.
- ☐ 2 - Mild: Some impairment in only one setting.
- ☐ 3 - Moderate: Some impairment from the symptoms was present in two or more settings (e.g., at school and at home).
- ☐ 4 - Severe
- ☐ 6 - Absent or false due to therapeutic medication.
- ☐ 8 - Present or true due to medical condition.
- ☐ 9 - Inadequate information.

62. <u>Assess clinically significant impairment:</u>

In the past 12 months...

How much trouble have these things (list positive symptoms) caused for you at work?

_____

_____

_____

With your family?

With other friends and colleagues?

Give an example.

- ☐ 1 - Not present.
- ☐ 2 - Mild.
- ☐ 3 - Moderate: There must be clear evidence of clinically significant impairment in social, academic or occupational functioning.
- ☐ 4 - Severe
- ☐ 6 - Absent or false due to therapeutic medication.
- ☐ 8 - Present or true due to medical condition.
- ☐ 9 - Inadequate information.

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DataFax #012 **Plate #193** **Visit #000**

SITE NO. *SUBJECT ID.* *ALPHA CODE* *DATE OF ASSESSMENT*

Month Day Year

Adult ADHD Symptoms Summary *Mark with an 'X' either yes or no to symptoms that respondent has indicated he/she experienced in adulthood and enter the score for each question in the appropriate box.*

I. INATTENTION	Yes	No	Score
63. Careless/Sloppy (score from Q.42)	☐	☐	☐
64. Difficulty sustaining attention (score from Q.43)	☐	☐	☐
65. Doesn't listen (score from Q.44)	☐	☐	☐
66. Difficulty following instructions (finishing) (score from Q.45)	☐	☐	☐
67. Difficulty organizing tasks/activities (score from Q.46)	☐	☐	☐
68. Avoidance of tasks with sustained mental effort (score from Q.47)	☐	☐	☐
69. Loses things (score from Q.48)	☐	☐	☐
70. Easily distracted (score from Q.49)	☐	☐	☐
71. Forgetful in daily activities (score from Q.50)	☐	☐	☐
II. HYPERACTIVITY/IMPULSIVITY	**Yes**	**No**	**Score**
72. Fidgets/Squirms (score from Q.51)	☐	☐	☐
73. Difficulty remaining seated (score from Q.52)	☐	☐	☐

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DataFax #012 **Plate #194** **Visit #000**

SITE NO. *SUBJECT ID.* *ALPHA CODE*

	Yes	No	Score
74. Runs/Climbs excessively/Inappropriately (score from Q.53)	☐	☐	☐
75. Difficulty playing quietly (score from Q.54)	☐	☐	☐
76. On the go/Driven by a motor (score from Q.55)	☐	☐	☐
77. Talks excessively (score from Q.56)	☐	☐	☐
78. Blurts out answers (score from Q.57)	☐	☐	☐
79. Difficulty waiting turn (score from Q.58)	☐	☐	☐
80. Interrupts or Intrudes (score from Q.59)	☐	☐	☐

Adult ADHD Diagnostic Checklist Summary

	Yes	No
81. Childhood onset of ADHD (Prior to age 7)?	☐	☐
82. Significant and sufficient current ADHD symptoms?	☐	☐
83. Significant impairment in two or more settings?	☐	☐
84. Are symptoms primarily due to ADHD and not another mental health disorder?	☐	☐

☐ ADHD, Inattentive Subtype

☐ ADHD, Hyperactive-Impulsive Subtype

☐ ADHD, Combined Subtype

Please note that pages 12, 13, 24, and 25 (with barcodes), must be faxed into DataFax.

Form Administered By: _____ Date: _____
(This form should only be administered by certified staff).

Investigator's Signature: _____ Date: _____

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DataFax #012 ***Plate #201***

WEEK	*SITE NO.*	*SUBJECT ID.*	*ALPHA CODE*	*DATE OF ASSESSMENT*
				Month / Day / Year

FORM 20 - Adult ADHD Investigator Symptom Rating Scale (AISRS)

INSTRUCTIONS: Complete this form at screening/baseline, at the 1st visit of weeks 4 and 8, and at the last visit of week 12 or the termination visit, if prior to week 12. Please mark an 'X' in the appropriate box.

Data collected for: ☐ Screening/Baseline ☐ Week 4 ☐ Week 8 ☐ Week 12/Termination

	None	Mild	Moderate	Severe
1. Do you make careless mistakes when working on a boring or difficult project? *Do you make a lot of mistakes (in school) or work? Is this because you are careless? Do you rush through work, or activities? Do you have trouble with detailed work? Do you not check your work? Do people complain that you are careless? Are you messy or sloppy? Is your desk or workplace so messy that you have difficulty finding things?*	☐	☐	☐	☐
2. Do you fidget or squirm with your hands or feet when you have to sit down for a long time? *Can you sit still or are you always moving your hands, feet, or in your chair? Do you tap your pencil or your feet a lot? Do people notice? Do you regularly play with your hair or clothing? Do you consciously resist fidgeting or squirming?*	☐	☐	☐	☐
3. Do you have difficulty keeping your attention when you are doing boring or repetitive work? *Do you have trouble paying attention when watching movies, reading or lectures? Or on fun activities such as sports or board games? Is it hard for you to keep your mind on school or work? Do you have unusual trouble staying focused on boring or repetitive tasks? Does it take a lot longer than it should to complete tasks because you can't keep your mind on the task? Is it even harder for you than some others you know? Do you have trouble remembering what you read and do you need to reread the same passage several times?*	☐	☐	☐	☐

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DataFax #012 ***Plate #202***

WEEK *SITE NO.* *SUBJECT ID.* *ALPHA CODE*

Data collected for: ☐ Screening/Baseline ☐ Week 4 ☐ Week 8 ☐ Week 12/Termination

	None	Mild	Moderate	Severe
4. Do you leave your seat in meetings or other situations in which you are expected to remain seated? *Do you have trouble staying in your seat? at work? in class? at home, i.e. watching t.v., eating dinner? in church or temple? Do you chose to walk around rather than sit? Do you have to force yourself to remain seated? Is it difficult for you to sit through a long meeting or lecture? Do you try to avoid going to functions that require you to sit still for long periods of time?*	☐	☐	☐	☐
5. Do you have difficulty concentrating on what people say to you, even when they are speaking to you directly? *Do people (your wife, boss, colleagues, friends) complain that you don't seem to listen or respond (or daydream) when spoken to or when asked to do tasks? A lot? Do people have to repeat directions? Do you find that you miss the key parts of conversations because of drifting off in your own thoughts? Does it cause a problem?*	☐	☐	☐	☐
6. Do you feel restless or fidgety? *Are you physically restless? Do you feel restless inside? A lot? Do you feel more agitated when you cannot exercise on an almost daily basis?*	☐	☐	☐	☐
7. Do you have trouble wrapping up the final details of a project, once the challenging parts have been done? *Do you have trouble finishing things...work, chores? Do you often leave things half done and start another project? Do you need consequences (such as deadlines) to finish? Do you have trouble following instructions (especially complex, multistep instructions that have to be done in a certain order with different steps)? Do you need to write down instructions, otherwise you will forget them?*	☐	☐	☐	☐

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DataFax #012 ***Plate #203***

WEEK *SITE NO.* *SUBJECT ID.* *ALPHA CODE*

Data collected for: ☐ Screening/Baseline ☐ Week 4 ☐ Week 8 ☐ Week 12/Termination

	None	Mild	Moderate	Severe
8. Do you have difficulty unwinding and relaxing when you have time to yourself? *Do you have a hard time playing quietly? During leisure activity (non-structured times or on your own such as reading a book, listening to music, playing a board game), are you agitated or dysphoric? Do you always need to be busy after work or while on vacation?*	☐	☐	☐	☐
9. Do you have difficulty getting things in order when you have to do a task that requires organization? *Do you have trouble organizing tasks into ordered steps? Is it hard prioritizing work and chores? Do you need others to plan for you? Do you have trouble with time management? Does it cause a problem? Does difficulty in planning lead to procrastination and putting off tasks until the last moment possible?*	☐	☐	☐	☐
10. Do you feel overly active and compelled to do things, like you were driven by a motor? *Is it hard for you to slow down? Do you feel like you (often) have a lot of energy and that you always have (had) to be moving, are (were) always "on the go"? Do you feel like you're driven by a motor? Do you feel unable to relax?*	☐	☐	☐	☐
11. Do you avoid or delay getting started on a task that requires a lot of thought? *Do you avoid tasks (work, chores, reading board games) that are challenging or lengthy because it's hard to stay focused on these things for a long time? Do you have to force yourself to do these tasks? how hard is (was) it? Do you procrastinate and put off tasks until the last moment possible?*	☐	☐	☐	☐

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DataFax #012 ***Plate #204***

WEEK *SITE NO.* *SUBJECT ID.* *ALPHA CODE*

Data collected for: ☐ Screening/Baseline ☐ Week 4 ☐ Week 8 ☐ Week 12/Termination

	None	Mild	Moderate	Severe
12. Do you find yourself talking too much when you are in social situations? *Do you talk a lot? All the time? More than other people? Do people complain about your talking? Is it a problem? Are you often louder than the people you are talking to?*	☐	☐	☐	☐
13. Do you misplace or have difficulty finding things at home or work? *Do you lose things (i.e. important work papers, keys, wallet, coats, etc.)? A lot? More than others? Are you constantly looking for important items? Do you get into trouble for this (work, home)? Do you need to put items (e.g. glasses, wallet, keys) in the same place each time, otherwise you will lose them?*	☐	☐	☐	☐
14. When you're in a conversation, do you find yourself finishing the sentences of the people that you are talking to, before they can finish them themselves? *Do you give answers to questions before someone finishes asking? Do you say things before it is your turn? Do you say things that don't fit into the conversation? Do you do things without thinking? A lot?*	☐	☐	☐	☐
15. Do you find yourself being distracted by activity or noise around you? *Are (were) you ever very easily distracted by events around you such as noise (conversation, tv, radio), movement, or clutter? Do you need relative isolation to get work done? Can almost anything get your mind off of what you are (were) doing...like work, chores or if you're talking to someone? Is it hard to get back to a task once you stop?*	☐	☐	☐	☐

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DataFax #012 ***Plate #205***

WEEK *SITE NO.* *SUBJECT ID.* *ALPHA CODE*

Data collected for: ☐ Screening/Baseline ☐ Week 4 ☐ Week 8 ☐ Week 12/Termination

	None	Mild	Moderate	Severe
16. Do you have difficulty waiting your turn in situations when turn taking is required? *Is it hard for you to wait your turn in conversation, in lines, while drivng? Are you frequently frustrated with delays? Does it cause problems? Do you put a great deal of effort into planning to not be in situations where you might have to wait?*	☐	☐	☐	☐
17. Do you have problems remembering appointments or obligations? *Do you forget a lot of things in your daily routine? Like what? Chores? Work? Appointments or obligations? Do you forget to bring things to work such as work materials or assignments due that day? Do you need to write regular reminders to yourself to do most activities or tasks, otherwise you will forget?*	☐	☐	☐	☐
18. Do you interrupt others when they are busy? *Do you talk when others are talking without waiting until you are acknowledged? Do you butt into others conversations before being invited? Do you interrupt other activities? Is it hard for you to wait to get your point across in conversations or at meetings?*	☐	☐	☐	☐

Form Administered By: _____ Date: _____
(This form should only be administered by certified staff).

Investigator's Signature: _____ Date: _____

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DataFax #012 Plate #211

WEEK	SITE NO.	SUBJECT ID.	ALPHA CODE	DATE OF ASSESSMENT
				Month / Day / Year

FORM 21 - Hamilton Depression Rating Scale (HAM-D)

INSTRUCTIONS: For each item, write the number in the space corresponding with the "CUE" which best characterizes the subject. This form should be completed at screening/baseline, at the 1st visit of weeks 4 and 8, and at the last visit of week 12 or the termination visit, if prior to week 12.

Data collected for: ☐ Screening/Baseline ☐ Week 4 ☐ Week 8 ☐ Week 12/Termination

1. What's your mood been like this past week (compared to when you feel OK)?

Have you been feeling down or depressed or sad?

IF YES: How often in the last week have you felt this way? Every day? All day?

Have you been crying at all?

IF SCORED 1-4, ASK: How long have you been feeling this way?

DEPRESSED MOOD (sadness, hopeless, helpless, worthless) . ☐

(0) Absent

(1) These feeling states indicated only on questioning

(2) These feeling states spontaneously reported verbally

(3) Communicates feeling states nonverbally - i.e., through facial expression, posture, voice, and tendency to weep

(4) Subject reports VIRTUALLY ONLY these feeling states in his/her spontaneous verbal and nonverbal communication

2. Have you been putting yourself down this past week, feeling you've done things wrong, or let others down?

IF YES: What have your thoughts been?

Have you been feeling guilty about anything you've done or not done? What about things that happened a long time ago?

Have you thought that you've brought this (depression) on yourself in some way? Or that your illness is a punishment?

(Have you been hearing voices or seeing visions in the last week? IF YES: Tell me about them.)

FEELINGS OF GUILT . . . . . ☐

(0) Absent

(1) Self-reproach, feels he/she has let people down

(2) Ideas of guilt or rumination over past errors or sinful deeds

(3) Present illness is a punishment. Delusions of guilt.

(4) Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations

3. This past week, have you had any thoughts that life is not worth living, or that you'd be better off dead? Have you had thoughts of hurting or killing yourself?

IF YES: What have you thought about? Have you actually done anything to hurt yourself?

SUICIDE . . . . . ☐

(0) Absent

(1) Feels life is not worth living

(2) Wishes he/she were dead or any thoughts of possible death to self

(3) Suicide ideas or gesture

(4) Attempts at suicide *(any serious attempt rates 4)*

DataFax #012 **Plate #212**

WEEK *SITE NO.* *SUBJECT ID.* *ALPHA CODE*

Data collected for: ☐ Screening/Baseline ☐ Week 4 ☐ Week 8 ☐ Week 12/Termination

4. How have you been sleeping during the last week?

Have you had any trouble falling asleep at the beginning of the night?

(Right after you go to bed, how long has it been taking you to fall asleep?)

How many nights this week have you had trouble falling asleep?

INSOMNIA EARLY . . . . . ☐

(0) No difficulty falling asleep

(1) Complains of occasional difficulty falling asleep - i.e., more than 1/2 hour

(2) Complains of nightly difficulty falling asleep

5. This past week, have you been waking up during the middle of the night?

IF YES: Do you get out of bed? What do you do?

When you get back in bed are you able to fall right back asleep?

Have you felt your sleeping has been restless or disturbed?

IF YES: How many nights this last week have you had that kind of trouble.

INSOMNIA MIDDLE . . . . . ☐

(0) No difficulty

(1) Subject complains of being restless and disturbed during the night

(2) Waking during the night - any getting out of bed rates 2 *(except for purposes of voiding)*

6. What time have you been waking up in the morning, for the last time, this past week?
Do you wake up earlier then you like?

Are you waking up with an alarm clock or do you just wake up yourself?

What time did you usually wake up (when you felt well)?

How many mornings this past week have you awakened early?

INSOMNIA LATE . . . . . ☐

(0) No difficulty

(1) Waking in early hours of the morning but goes back to sleep

(2) Unable to fall asleep again if gets out of bed

DataFax #012 **Plate #213**

WEEK | *SITE NO.* | *SUBJECT ID.* | *ALPHA CODE*

Data collected for: ☐ Screening/Baseline ☐ Week 4 ☐ Week 8 ☐ Week 12/Termination

7. How have you been spending your time this past week (when not at work)?

Have you felt interested in doing (those things), or do you have to push yourself to do them?

Have you stopped doing anything you used to do?

IF YES: Why?

Is there anything you look forward to?

IF WORKING: Have you been able to get as much (work) done as you usually do?

WORK & ACTIVITIES . . . . . ☐

(0) No difficulty

(1) Thoughts and feelings of incapacity, fatigue or weakness related to activities, work or hobbies

(2) Loss of interest in activity; hobbies or work - either directly reported by subject,or indirect in listlessness, indecision and vacillation *(feels he/she has to push self to work or activities)*

(3) Decrease in actual time spent in activities or decrease in productivity. *(In hospital, rate 3 if subject does not spend at least three hours a day in activities exclusive of ward chores.)*

(4) Stopped working because of present illness. *(In hospital, rate 4 if subject engages in no activities except ward chores, or if subject fails to perform ward chores unassisted.)*

8. (Rate this item primarily based on observation.)

During the past week, have you been feeling that your speech or movement have been slowed down? Has anyone else commented on this?

RETARDATION (slowness of thought and speech; impaired ability to concentrate; decreased motor activity) . . . . . ☐

(0) Normal speech and thought

(1) Slight retardation at interview

(2) Obvious retardation at interview

(3) Interview difficult

(4) Complete stupor

9. (Rate this item primarily based on observation.)

During the past week, have you been feeling fidgety or restless? Have other people commented on your restlessness?

AGITATION . . . . . ☐

(0) None

(1) Fidgetiness

(2) “Playing with” hands, hair, etc.

(3) Moving about, cannot sit still

(4) Hand-wringing, nail-biting, hair pulling, biting of lips

DataFax #012 **Plate #214**

WEEK | *SITE NO.* | *SUBJECT ID.* | *ALPHA CODE*

Data collected for: ☐ Screening/Baseline ☐ Week 4 ☐ Week 8 ☐ Week 12/Termination

10. Have you been feeling especially tense this past week?

IF YES: Is this more than is normal for you?

Have you been unusually argumentative or impatient?

Have you been worrying a lot about little things, things you don't ordinarily worry about?

IF YES: Like what, for example

ANXIETY PSYCHIC . . . . . ☐

(0) No difficulty

(1) Subjective tension and irritability

(2) Worrying about minor matters

(3) Apprehensive attitude apparent in face or speech

(4) Fears expressed without questioning

11. Have you had any of the following physical symptoms in the past week?

(READ THE LIST: dry mouth, gas, indigestion, diarrhea, stomach cramps, belching, heart palpitations, headaches, hyperventilating, sighing, urinary frequency, sweating)

For each symptom acknowledged as present: How much has (the sx) been bothering you this past week? (How bad has it gotten? How much of the time, or how often have you had it?)

Note: DO NOT RATE SXS THAT ARE CLEARLY RELATED TO A DOCUMENTED PHYSICAL CONDITION.

ANXIETY SOMATIC . . . . . ☐

(0) Absent

(1) Mild

(2) Moderate

(3) Severe

(4) Incapacitating

12. How has your appetite been this past week?

(What about compared to your usual appetite?)

Have you had to force yourself to eat?

Have other people had to urge you to eat? (Have you skipped meals?)

SOMATIC SYMPTOMS GASTROINTESTINAL . . . . . ☐

(0) None

(1) Loss of appetite but eating without staff encouragement. Heavy feelings in abdomen

(2) Difficulty eating without staff urging. Requests or requires laxatives or medication for bowels or medication for G.I. symptoms

13. How has your energy been this past week?

IF LOW ENERGY: Have you felt tired? (How much of the time? How bad has it been?)

This week, have you had any aches or pains? (What about backaches, headaches, or muscle aches?)

Have you felt any heaviness in your limbs, back, or head?

SOMATIC SYMPTOMS GENERAL . . . . . ☐

(0) None

(1) Heaviness in limbs, back and head. Backaches, headache, muscle ache, Loss of energy and fatigability

(2) Any clear-cut symptom rates 2

DataFax #012 **Plate #215**

WEEK *SITE NO.* *SUBJECT ID.* *ALPHA CODE*

Data collected for: ☐ Screening/Baseline ☐ Week 4 ☐ Week 8 ☐ Week 12/Termination

14. How has your interest in sex been this week?

How much do you think about sex? Is that unusual for you?

Has there been any change in your interest in sex (from when you were feeling well)?

GENITAL SYMPTOMS . . . . . ☐

(0) Absent

(1) Mild

(2) Severe

15. In the last week, how much have your thoughts been focused on your physical health or how your body is working (compared to your normal thinking)?

(Have you worried a lot about being or becoming physically ill? Have you really been preoccupied with this?)

Do you complain much about how you feel physically?

Have you found yourself asking for help with things you could really do yourself?

IF YES: Like what, for example? How often has that happened?

HYPOCHONDRIASIS . . . . . ☐

(0) Not present

(1) Self-absorption (bodily)

(2) Preoccupation with health

(3) Frequent complaints, requests for help, etc.

(4) Hypochondriacal delusions

16. Have you lost any weight since this (depression) began?

IF YES: Did you lose any weight this last week? (Was it because of feeling depressed or down?) How much did you lose?

IF NOT SURE: Do you think your clothes are any looser on you?

LOSS OF WEIGHT . . . . . ☐

(0) No weight loss

(1) Probable weight loss associated with present illness

(2) Definite (according to subject) weight loss

17. (Rating based on observation during the interview.)

What do you attribute your illness to?

INSIGHT . . . . . ☐

(0) Acknowledges being depressed and ill

(1) Acknowledges illness but attributes cause to bad food, climate, overwork, virus, need for rest, etc.

(2) Denies being ill at all

DataFax #012 **Plate #216**

WEEK	*SITE NO.*	*SUBJECT ID.*	*ALPHA CODE*

Data collected for: ☐ Screening/Baseline ☐ Week 4 ☐ Week 8 ☐ Week 12/Termination

18. This past week have you been feeling better or worse at any particular time of the day? Morning or evening? How is the morning compared to the afternoon? This question should be answered by entering the appropriate number that best describes the variation.

IF VARIATION EXISTS: Check the appropriate box that shows when the symptoms are the worst (A.M. or P.M.)

DIURNAL VARIATION . . . . . ☐

(0) No variation (go to Q.19)

(1) Mild

(2) Severe

☐ *Worse in A.M.*

☐ *Worse in P.M.*

19. In the past week, have you ever suddenly had the feeling that everything is unreal, or that you are in a dream, or cut off from people in some strange way?

How often this week have you felt this way?

Any "spacey" feelings? How bad has that been? How often this week?

DEPERSONALIZATION AND DEREALIZATION . . . . . ☐

(0) Absent

(1) Mild

(2) Moderate

(3) Severe

(4) Incapacitating

20. This past week, have you felt that anyone was trying to give you a hard time or hurt you?

IF YES: Describe.

Have you felt that people are talking about you behind your back?

IF YES: Describe.

PARANOID SYMPTOMS . . . . . ☐

(0) None

(1) Suspicious

(2) Ideas of reference

(3) Delusions of reference and persecution

(4) Incapacitating

21. This past week, have there been things you've had to do over and over again, like checking the locks on the doors several times?

IF YES: Can you give me an example.

OBSESSIVE AND COMPULSIVE SYMPTOMS . . . . . ☐

(0) Absent

(1) Mild

(2) Severe

DataFax #012 **Plate #217**

WEEK *SITE NO.* *SUBJECT ID.* *ALPHA CODE*

Data collected for: ☐ Screening/Baseline ☐ Week 4 ☐ Week 8 ☐ Week 12/Termination

22. In the past week, have there been times when you were overwhelmed or unable to handle the pressure on you?

Do you feel that you have no control or influence over what happens to you?

HELPLESSNESS . . . . . ☐

(0) Not present

(1) Subjective feelings which are elicited only by inquiry

(2) Subject volunteers his helpless feelings

(3) Requires urging, guidance, and reassurance to accomplish ward chores or personal hygiene

(4) Requires physical assistance for dress, grooming, eating, bedside tasks or personal hygiene

23. In the past week, how have you felt about the future?

Can anyone reassure you?

HOPELESSNESS . . . . . ☐

(0) Not present

(1) Intermittently doubts that "things will improve" but can be reassured

(2) Consistently feels "hopeless" but accepts reassurances

(3) Expresses feelings of discouragement, despair, pessimism about future, which cannot be dispelled

(4) Spontaneously and inappropriately perseverates, "I'll never get well" or its equivalent

24. How have you been feeling about yourself in the past week?

How have you felt about your own value and worth?

WORTHLESSNESS . . . . . ☐

(0) Not present

(1) Indicates feelings of worthlessness (loss of self-esteem) only on questioning

(2) Spontaneously indicates feelings of worthlessness (loss of self-esteem)

(3) Different from 2 by degree: subject volunteers that she/he is "no good," "inferior," etc.

(4) Delusional notions of worthless -e.g., "I am a heap of garbage" or its equivalent

Score:_____

Form Completed By: _____ Date: _____

Physician's Signature: _____ Date: _____

DataFax #012 Plate #221

DATE OF ASSESSMENT

Month Day Year

WEEK SEQ. # SITE NO. SUBJECT ID. ALPHA CODE

FORM 22 - Clinical Global Impression Scale - Observer (CGI-O)

INSTRUCTIONS: Complete this form weekly during screening/baseline, at the 1st visit of weeks 1-11, and the last visit of week 12 or the termination visit, if prior to week 12.

PART A: Please rate the Current Severity of the eight specific problem areas below. Use the "Table of Descriptive Anchors for Specific Methamphetamine Dependence Problems" to rate severity. Indicate one answer for each question.

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 non-methamphetamine use/ alcohol 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*

DataFax #012 **Plate #222**

DATE OF ASSESSMENT

Month Day Year

WEEK *SEQ. #* *SITE NO.* *SUBJECT ID.* *ALPHA CODE*

PART B.

9. Global severity of methamphetamine dependence:

Considering your total clinical experience with the methamphetamine population, how severe are his/her methamphetamine 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

ONLY COMPLETE QUESTION 10 AT STUDY WEEKS 2-12.

10. 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:_____

Form 22 - CLINICAL GLOBAL IMPRESSIONS – OBSERVER

Table of Descriptive Anchors for Specific Methamphetamine Dependence Problems

Severity Ratings 1-7 Scale

1	2	3	4	5	6	
none	non-repetitive use	sporadic use or (non-repetitive) use with large amounts	frequent use of sporadic use with large amounts	more days than not or frequent use with large amounts	almost every day or more days than not with large amounts	daily or alm with lar
none	non-repetitively	sporadically	frequently	more days than not	almost every day most of the time	every day
none	non-repetitive use	sporadic use or non-repetitive use with large amounts	frequent use or sporadic use with large amounts	more days than not or frequent use with large amounts	almost every day or more days than not with large amounts	daily or alm with lar
symptoms during the interview	some display of symptomatology and/or mild symptoms	infrequent intermittent display of symptomatology and/or mild symptoms	frequent display of symptomatology and/or moderate symptoms present	frequent display of symptomatology and moderate to severe symptoms present	constant display of symptomatology with moderate to severe symptoms present	constan severe sy of great perva
none	occasionally feels moderately symptomatic	occasionally feels moderately symptomatic or often feels somewhat symptomatic	occasionally feels very symptomatic or often feels moderately symptomatic	often feels very symptomatic	feels very symptomatic most of the time	feels very nearly a
none	non-repetitive	sporadic	frequent	more days than not	almost every day	bothered e th
ating appropriately all relationships/ teractions and/or ways taking the cessary steps to form positive relationships	minimum difficulties in relating appropriately in relationships/ interactions and/or minimum difficulties in taking necessary steps to form positive relationships but not of clinical significance	infrequent difficulties in relating appropriately in relationships/ interactions and/or infrequent difficulties in taking the necessary steps to form positive relationships	frequent difficulties in relating appropriately in relationships/ interactions and/or frequent difficulties in taking the necessary steps to form positive relationships	more often than not having difficulties in relating appropriately in relationships/inter-actions and/or more often than not difficulties in taking the necessary steps to form positive relationships	not relating appropriately in nearly every relationship/inter-action and/or nearly always having difficulties in taking the necessary steps to form positive relationships	not relatin in relationsh and/or a difficulties necessary positive
ing the necessary teps to maintain equate functioning	minimum difficulties in taking the necessary steps to maintain adequate functioning	infrequent difficulties in taking the necessary steps to maintain adequate functioning	frequent difficulties in taking the necessary steps to maintain adequate functioning	more often than not having difficulties in taking the necessary steps to maintain adequate functioning	nearly always having difficulties in taking the necessary steps to maintain adequate functioning	always ha in taking t steps t adequat

Heather - print this cover in word before you have Gary print subject binders!

DataFax #012 *Plate #231*

DATE OF ASSESSMENT

Month Day Year

WEEK *SEQ. #* *SITE NO.* *SUBJECT ID.* *ALPHA CODE*

FORM 23-Clinical Global Impression Scale-Self Report (CGI-S)

INSTRUCTIONS: This form should be completed by the subject weekly during screening/ baseline, at the 1st visit of weeks 1-11, and the last visit of week 12 or the termination visit, if prior to week 12.

Please respond to each question below with the number that best represents your answer. Record the number in the box next to 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
2 = Borderline symptoms
3 = Mild symptoms
4 = Moderate symptoms
5 = Marked symptoms
6 = Severe symptoms
7 = Among the most extreme symptoms

ONLY COMPLETE QUESTION 2 AT STUDY WEEKS 2-12.

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

Thank you. This form is complete.

Subject *Staff*

Form completed by? . . . . . ☐ ☐

Form Reviewed By: _____ Date:_____

DataFax #012 **Plate #241**

WEEK *SITE NO.* *SUBJECT ID.* *ALPHA CODE* *DATE OF ASSESSMENT*

Month Day Year

FORM 24 - HIV Risk-Taking Behavior Scale (HRBS)

INSTRUCTIONS: This form should be completed by an interviewer during screening/baseline, and at the last visit of week 12 or the termination visit, if prior to week 12.

Data collected for scheduled visit: ☐ Screening/Baseline ☐ Week 12/Termination

Before beginning each of the two sections of the scale, it is helpful to focus the subject's attention on the topic and the time frame of one month by saying something like: *I'm going to ask you a few questions about your drug use for the last month, and, The next part of the questionnaire concerns your sex life over the last month.* This introduces the topic to the subject and prepares them for the questions that follow.

Drug Use

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

☐ Haven't hit up
☐ Once a week or less
☐ More than once a week
☐ Once a day
☐ 2 - 3 times a day
☐ More than 3 times a day

If no injected drugs in the last month, go to Question 7.

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

☐ No times
☐ One time
☐ Two times
☐ 3 - 5 times
☐ 6 - 10 times
☐ More than 10 times

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

☐ None
☐ One person
☐ Two people
☐ 3 - 5 people
☐ 6 - 10 people
☐ More than 10 people

DataFax #012 **Plate #242**

WEEK *SITE NO.* *SUBJECT ID.* *ALPHA CODE*

Data collected for scheduled visit: ☐ Screening/Baseline ☐ Week 12/Termination

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

☐ No times
☐ One time
☐ Two times
☐ 3 - 5 times
☐ 6 - 10 times
☐ More than 10 times

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

☐ Does not reuse
☐ Every time
☐ Often
☐ Sometimes
☐ Rarely
☐ Never

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

☐ Does not reuse
☐ Every time
☐ Often
☐ Sometimes
☐ Rarely
☐ Never

Sexual Behavior

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

☐ None
☐ One person
☐ Two people
☐ 3 - 5 people
☐ 6 - 10 people
☐ More than 10 people

If no sex in the last month, skip to Question 12.

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

☐ No regular partner/no penetrative sex
☐ Every time
☐ Often
☐ Sometimes
☐ Rarely
☐ Never

DataFax #012 **Plate #243**

WEEK *SITE NO.* *SUBJECT ID.* *ALPHA CODE*

Data collected for scheduled visit: ☐ Screening/Baseline ☐ Week 12/Termination

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

☐ No casual partners/no penetrative sex ☐ Sometimes
☐ Every time ☐ Rarely
☐ Often ☐ Never

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

☐ No paid sex/no penetrative sex ☐ Sometimes
☐ Every time ☐ Rarely
☐ Often ☐ Never

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

☐ No times ☐ 3 - 5 times
☐ One time ☐ 6 - 10 times
☐ Two times ☐ 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*

Form Completed By: _____ Date:_____

DataFax #012 **Plate #251**

DATE OF ASSESSMENT

Month Day Year

WEEK *SEQ. #* *SITE NO.* *SUBJECT ID.* *ALPHA CODE*

FORM 25 - Cognitive Behavioral Therapy (CBT) Compliance

INSTRUCTIONS: Complete this form weekly during screening/baseline to record 'early recovery skills' sessions attended and during study weeks 1-12 to record CBT sessions attended. Update at subsequent visit to capture any therapy that may have occurred in the prior study week.

1. How many CBT sessions did the subject attend this study week? . . . . . ☐

Record the date and length of each CBT session attended below.

Session date and length: *Month* *Day* *Year* Min.

Session date and length: *Month* *Day* *Year* Min.

Session date and length: *Month* *Day* *Year* Min.

2. Did the subject receive any other non-study related treatment from someone other than the study therapist? . . . . . *No* ☐ *Yes* ☐

If 'Yes', record the source of therapy, date, and length of session for each day.

a. _____ *Month* *Day* *Year* Min.

b. _____ *Month* *Day* *Year* Min.

c. _____ *Month* *Day* *Year* Min.

d. _____ *Month* *Day* *Year* Min.

Form Completed By: _____ Date: _____

Form 26 - AE Log

INSTRUCTIONS: Assess adverse events at every study visit, starting on the day the subject signs the informed consent through week 12, and again at follow-up. Give each new AE a unique, sequential AE #. If the severity for an AE changes, it becomes a new AE.

If an AE is evaluated as serious, enter this event into the SAETRS system BEFORE completing this AE form and record the SAE number assigned by SAETRS for this event in the space provided on this form. Information reported on this AE form MUST duplicate the information reported in SAETRS. All fields, including text fields, MUST match the SAE.

USE THE FOLLOWING RESPONSE CODES TO COMPLETE THE FORM

Severity
1 = Mild
2 = Moderate
3 = Severe

Actions Taken
1 = No Action
2 = Study agent discontinued permanently
3 = Study agent discontinued temporarily
4 = Reduced dose study agent
5 = Increased dose study agent
6 = Delayed dose study agent
7 = Continued dose
9 = Unknown

Relationship
1 = Definitely
2 = Probably
3 = Possibly
4 = Remotely
5 = Definitely Not
9 = Unknown

Outcome
1 = Recovered/resolved
2 = Recovering/resolving
3 = Not recovered/not resolved
4 = Recovered/resolved with sequelae
5 = Fatal
9 = Lost to Follow-Up

DataFax #012 Plate #261

PAGE ☐☐ SITE NO. ☐☐☐ SUBJECT ID. ☐☐☐☐ ALPHA CODE ☐☐☐☐

FORM 26 - Adverse Event Log

☐ •*Mark 'X' in this box if **NO** adverse events were reported during the entire study.*

AE # ☐☐ **Adverse Event Name/Description** ____________________ **Start Date** ☐☐ *Month* ☐☐ *Day* ☐☐☐☐ *Year*

Severity ☐ **Relationship to study agent** ☐ **Action Taken** ☐ **Serious (SAE)** *No* ☐ *Yes* ☐

If SAE, record SAE # from SAETRS ☐☐☐ **Outcome** ☐ **Stop Date** ☐☐ *Month* ☐☐ *Day* ☐☐☐☐ *Year*

AE # ☐☐ **Adverse Event Name/Description** ____________________ **Start Date** ☐☐ *Month* ☐☐ *Day* ☐☐☐☐ *Year*

Severity ☐ **Relationship to study agent** ☐ **Action Taken** ☐ **Serious (SAE)** *No* ☐ *Yes* ☐

If SAE, record SAE # from SAETRS ☐☐☐ **Outcome** ☐ **Stop Date** ☐☐ *Month* ☐☐ *Day* ☐☐☐☐ *Year*

AE # ☐☐ **Adverse Event Name/Description** ____________________ **Start Date** ☐☐ *Month* ☐☐ *Day* ☐☐☐☐ *Year*

Severity ☐ **Relationship to study agent** ☐ **Action Taken** ☐ **Serious (SAE)** *No* ☐ *Yes* ☐

If SAE, record SAE # from SAETRS ☐☐☐ **Outcome** ☐ **Stop Date** ☐☐ *Month* ☐☐ *Day* ☐☐☐☐ *Year*

• If an additional page is needed record the next page number . . . . ☐☐

Form Completed By:____________________ Date:__________

Investigator's Signature:____________________ Date:__________

DataFax #012 Plate #271

WEEK	SITE NO.	SUBJECT ID.	ALPHA CODE	DATE OF LAST ON-STUDY CLINIC VISIT
				Month Day Year

FORM 27 - End of Study Status

INSTRUCTIONS: Complete this form for all randomized subjects at study completion or early termination.

1. Mark 'X' in one answer below that best describes the subject's status at the end of the study.

☐ Completed the study (took at least one dose of study drug in week 12, provided at least one urine sample in week 12, and provided self report of substance use through the last day of week 11).

☐ Completed the study but permanently discontinued study drug.
Date study drug discontinued: ☐☐ ☐☐ ☐☐☐☐
month *day* *year*

☐ Termination due to medical reason unrelated to study medication. Specify reason: _____

_____

☐ Termination due to medical reason related to study medication. Specify reason: _____

_____

☐ Subject failed to return to clinic.

☐ Termination at subject's request. Specify reason: _____

_____

☐ Subject moved from area.

☐ Subject became incarcerated.

☐ Subject was terminated by clinic physician because of intercurrent illness or medical complications precluding safe administration of study medication.

☐ Subject was terminated due to serious or unexpected adverse events. List AE number(s) that prompted the termination from the AE Log, Form 26.

☐☐ ☐☐ ☐☐ ☐☐ ☐☐

☐ Subject was administratively discharged. Specify incident: _____

_____

DataFax #012 **Plate #272**

WEEK *SITE NO.* *SUBJECT ID.* *ALPHA CODE*

☐ Birth control non-compliance - Females Only

☐ Pregnancy

☐ Failure to follow Protocol procedures

☐ Death - ***Enter SAE in SAETRS & on AE log*** Date of Death: ☐☐ ☐☐ ☐☐☐☐
Month *Day* *Year*

Cause of Death (if known): _____

	No	*Yes*
2. Was subject referred to another treatment program?	☐	☐

Form Completed By: _____Date: _____

Investigator's Signature: _____Date: _____

DataFax #012 Plate #281 Visit #016

SITE NO. *SUBJECT ID.* *ALPHA CODE* *DATE OF ASSESSMENT*

Month Day Year

FORM 28 - Follow-Up

INSTRUCTIONS: Complete this form for all subjects 4 weeks after the end of study/termination visit. This form may be completed via phone interview if the subject is unable to return to the clinic.

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

   If 'No', go to question 2. If 'Yes', complete Questions 1a through 1f and Question 5.

   a. Date of contact: *Month* *Day* *Year*

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

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

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

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

   f. 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*

   If 'No', go to 3b and continue. If 'Yes', complete 3a.

   a. Date of contact: *month* *day* *year*

   b. If 'No', explain: _____

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

   If 'No' or 'Unknown' go to Q5. If 'Yes', answer a-c.

   a. Date of death: *month* *day* *year*

   b. Cause of death: _____

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

5. Additional comments: _____

Form Completed By: _____ Date: _____

DataFax #012 Plate #291

PAGE	*SITE NO.*	*SUBJECT ID.*	*ALPHA CODE*

FORM 29 - GCP Non-Compliance

This form is to be completed and faxed 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.

The monitor should fax this form to Perry Point after each monitoring visit. If the Investigator is unavailable to sign at that time, please fax without the Investigator's signature. Please remind the site to re-fax this form to Perry Point, once the Investigator is able to sign.

	Date of Non-Compliance *Month*	*Day*	*Year*	**Event #**	**Non-Compliance Code**	**Reason for Non-Compliance**
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						

Non-compliance codes:

1 = Informed consent signed after subject started screening procedures (record date screening procedures were initiated as date of non-compliance)
2 = Inclusion/Exclusion criteria not met (record date subject was randomized as date of non-compliance)
3 = Pregnancy test not performed at screening (record date subject was randomized as date of non-compliance)
4 = Screening information incomplete (record date subject was randomized as date of non-compliance)
5 = Required study data not obtained or obtained late during study drug administration phase (record date data was due from starter sheet as date of non-compliance)
6 = Source data documentation not available (record date data collected as date of non-compliance)
7 = Serious adverse event not reported appropriately (record date of serious adverse event as date of non-compliance)
8 = Medication dosing error
9 = Other, if other please provide description and reason under "Reason for Non-compliance".

• If an additional page is needed record the next page number . . . . . .

Monitor's Name:_____ Date: _____

Investigator's Signature: _____ Date: _____