Modafinilmeth CRFs

VERSION 6.1

July 29, 2005

NIDA-CPU-modafinilmeth-0001

Subject ID # _____ Screening

INFORMED CONSENT

Did subject sign informed consent? ___ Yes ___ No

If yes, date subject signed informed consent: ___ / ___ / _____

Was the subject entered into the study? ___ Yes ___ No

Subject ID # _____ Screening Date: ___ / ___ / _____

DEMOGRAPHICS

1. Gender: ___ Male ___ Female ___ Transgender

2. Date of Birth: ___ / ___ / _____

3. **Ethnicity (regardless of race)**: **Please mark only one:**

____ Hispanic or Latino (check all that apply):
- ___ Mexican, Mexican-American or Chicano
- ___ Puerto Rican
- ___ Cuban
- ___ South or Central American
- ___ Other, specify _____

____ Not Hispanic or Latino

Race:

Indicate which single major race applies and mark all that apply within the single race selected.

____ White

____ Black or African American

____ American Indian or Alaskan Native

____ Asian (check all that apply)
- ___ Asian Indian
- ___ Chinese
- ___ Filipino
- ___ Japanese
- ___ Korean
- ___ Vietnamese
- ___ Other, specify _____

____ Native Hawaiian or other Pacific Islander (check all that apply)
- ___ Native Hawaiian
- ___ Guamanian or Chamorro
- ___ Samoan
- ___ Other, specify _____

____ Other, specify _____

____ Unknown

____ Participant chooses not to answer

4. **Education Status**

1). Primary/Secondary education completed: ___ years

2). College completed: ___ years

3). Postgraduate studies completed: ___ years

5. **Usual employment pattern, past 30 days (please check one):**

___ Full Time (35+ hrs/wk) ___ Part time (regular hrs) ___ Part time (irregular hrs, day work)

___ Student ___ Military Service ___ Retired/Disabled

___ Homemaker ___ Unemployed ___ In Controlled Environment

6. **Usual employment pattern, past 3 years (please check one):**

___ Full Time (35+ hrs/wk) ___ Part time (regular hrs) ___ Part time (irregular hrs, day work)

___ Student ___ Military Service ___ Retired/Disabled

___ Homemaker ___ Unemployed ___ In Controlled Environment

7. **Marital Status:**

___ Legally Married ___ Living with Partner/ Cohabiting ___ Widowed

___ Separated ___ Divorced ___ Never Married

Subject ID # _____ Screening Date: ___ / ___ / _____

MEDICAL HISTORY

	A. Yes, Excludes	B. Yes, Not Excluded	C. No history Of	D. Not Evaluated	E. Explain or Describe (if yes)
1. Allergies, drug _____	_____	_____	_____	_____	_____
2. Allergies, other _____	_____	_____	_____	_____	_____
3. History of asthma	_____	_____	_____	_____	_____
4. HEENT Disorder	_____	_____	_____	_____	_____
5. Cardiovascular Disorder	_____	_____	_____	_____	_____
6. Renal Disorder	_____	_____	_____	_____	_____
7. Hepatic Disorder	_____	_____	_____	_____	_____
8. Pulmonary Disorder	_____	_____	_____	_____	_____
9. Gastrointestinal Disorder	_____	_____	_____	_____	_____
10. Musculoskeletal Disorder	_____	_____	_____	_____	_____
11. Neurologic Disorder	_____	_____	_____	_____	_____
12. Psychiatric Disorder	_____	_____	_____	_____	_____
13. Dermatologic Disorder	_____	_____	_____	_____	_____
14. Metabolic Disorder	_____	_____	_____	_____	_____
15. Hematologic Disorder	_____	_____	_____	_____	_____
16. Endocrine Disorder	_____	_____	_____	_____	_____
17. Genitourinary Disorder	_____	_____	_____	_____	_____
18. Reproductive System	_____	_____	_____	_____	_____
19. Seizure	_____	_____	_____	_____	_____
20. Infectious Disease	_____	_____	_____	_____	_____
21. Other _____	_____	_____	_____	_____	_____
22. Other _____	_____	_____	_____	_____	_____

23. Has subject had any major surgery? ___ Yes ___ No

If Yes, List MAJOR SURGERIES below.

TYPE OF SURGERY	YEAR	IS SURGERY RELEVANT TO STUDY PARTICIPATION? Yes, Excludes	Yes, Does Not Exclude	No
_____	_____	___	___	___
_____	_____	___	___	___
_____	_____	___	___	___
_____	_____	___	___	___
_____	_____	___	___	___
_____	_____	___	___	___
_____	_____	___	___	___

Tobacco History:

24. Does the subject smoke? ___ Yes ___ No

If yes, how many cigarettes/day? ___

25. Has the subject smoked in the last 3 months? ___Yes ___No

If yes, did the subject quit within the last 3 months? ___ Yes ___ No

If yes, when? __ within past month __ 2 months ago __ 3 months ago

Comments:

Subject ID # _____ Screening Date: ___ / ___ / _____

PHYSICAL EXAM

1. Height _____ . __ O inches O centimeters

2. Weight _____ . __ O pounds O kilograms

3. BMI _____ (kg / m2)

System	A. Not Done	B. Normal	C. Abnormal Not Sig.	D. Abnormal Significant	E. Comments (if abnormal)
4. Oral (mouth)	___	___	___	___	_____
5. Head and Neck	___	___	___	___	_____
6. Eyes, ears, nose/throat	___	___	___	___	_____
7. Cardiovascular	___	___	___	___	_____
8. Chest	___	___	___	___	_____
9. Lungs	___	___	___	___	_____
10. Abdomen (include liver/spleen)	___	___	___	___	_____
11. Extremities	___	___	___	___	_____
12. Skin, hair, nails	___	___	___	___	_____
13. Neuropsychiatric mental status	___	___	___	___	_____
14. Musculoskeletal	___	___	___	___	_____
15. General appearance	___	___	___	___	_____
16. Other _____	___	___	___	___	_____

Vital Signs

17. Blood Pressure (mmHg) _____ / _____

18. Heart Rate (beats/min) _____

19. Respiration Rate (breaths/min) ___

Subject ID # _____ Screening Date: ___ / ___ / _____

ELECTROCARDIOGRAM

1. QTc Interval __ . __ __ __ s

2. ECG overall results were:
   - O Normal
   - O Abnormal, not clinically significant
   - O Abnormal, clinically significant

3. If ECG is abnormal, please list ALL abnormalities:

4. Do any of the abnormalities preclude safe entry into or continuation in the study?

___ No ___ Yes. If yes, please list the abnormalities that are exclusionary:

Subject ID # _____ Screening Date: ___ / ___ / _____

BIRTH CONTROL/PREGNANCY ASSESSMENT

This form is to be filled out for female subjects only

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

What method of birth control is participant currently using?

_____ Condom (male or female)

_____ Diaphragm (with spermicide)

_____ Copper containing intrauterine device (IUD)

_____ Hysterectomy

_____ Tubal ligation

Was a pregnancy test performed? ___ Yes ___ No

If yes, what was the result? ___ Positive ___ Negative

Is the subject lactating? ___ Yes ___ No

Comments:

Subject ID # _____ Screening Date: ___ / ___ / _____

URINE TOXICOLOGY

SCREEN FOR:

Amphetamines	___ Positive	___ Negative	___ Not done
Barbiturates	___ Positive	___ Negative	___ Not done
Benzodiazepines	___ Positive	___ Negative	___ Not done
Cocaine	___ Positive	___ Negative	___ Not done
Ethanol	___ Positive	___ Negative	___ Not done
Opiate	___ Positive	___ Negative	___ Not done
THC	___ Positive	___ Negative	___ Not done

Subject ID # _____ Screening

URINALYSIS

Collection Date ___ / ___ / _____

	Value		*If abnormal, √ one:* Not Done	Abnormal NCS	Abnormal CS	Comment (if abnormal)
Glucose	O Positive	O Negative	O	O	O	_____
Bilirubin	O Positive	O Negative	O	O	O	_____
Ketones	O Positive	O Negative	O	O	O	_____
Specific Gravity	__ . _____		O	O	O	_____
Hemoglobin	O Positive	O Negative	O	O	O	_____
pH	__ . __		O	O	O	_____
Protein	O Positive	O Negative	O	O	O	_____
Nitrite	O Positive	O Negative	O	O	O	_____
Leukocyte Esterase	O Positive	O Negative	O	O	O	_____
RBC	___		O	O	O	_____

Subject ID # _____ Screening

HEMATOLOGY

Collection Date ___ / ___ / _____

	Quantity	Unit	Not Done	*If abnormal, √ one:* Abnormal: NCS	CS	Comment (if abnormal)
1. WBC	___ . __	thousand/mcL	O	O	O	_____
2. RBC	__ . ___	million/mcL	O	O	O	_____
3. Hemoglobin	___ . __	g/dL	O	O	O	_____
4. Hematocrit	___ . __	%	O	O	O	_____
5. MCV	_____	fL	O	O	O	_____
6. MCH	___ . __	pg	O	O	O	_____
7. MCHC	___ . __	g/dL	O	O	O	_____
8. Platelet count	_____	thousand/uL	O	O	O	_____
9. Neutrophils	___	%	O	O	O	_____
10. Lymphocytes	___	%	O	O	O	_____
11. Monocytes	___	%	O	O	O	_____
12. Eosinophils	__	%	O	O	O	_____
13. Basophils	__	%	O	O	O	_____

Subject ID # _____ Screening

BIOCHEMISTRY

Collection Date ___ / ___ / _____

	Quantity	Unit	Not Done	*If abnormal, √ one:* Abnormal: NCS	CS	Comment (if abnormal)
1. Glucose	_____	mg/dL	O	O	O	_____
2. Urea Nitrogen	___	mg/dL	O	O	O	_____
3. Creatinine	__ . __	mg/dL	O	O	O	_____
4. Calcium	___ . __	mg/dL	O	O	O	_____
5. Sodium	_____	mmol/L	O	O	O	_____
6. Potassium	__ . __	mmol/L	O	O	O	_____
7. CO2	___	mmol/L	O	O	O	_____
8. Chloride	_____	mmol/L	O	O	O	_____
9. Total protein	__ . __	g/dL	O	O	O	_____
10. Albumin	__ . __	g/dL	O	O	O	_____
11. Globulin	__ . __	g/dL	O	O	O	_____
12. A/G Ratio	__ . __	RATIO	O	O	O	_____
13. Bilirubin	__ . __	mg/dL	O	O	O	_____
14. Alkaline phosphatase	_____	U/L	O	O	O	_____
15. AST	____	U/L	O	O	O	_____
16. ALT	____	U/L	O	O	O	_____
17. HCG	O Positive	O Negative	O N/A	O		_____

Subject ID # _____ Screening Date: ___ / ___ / _____

ENTRY CRITERIA

Inclusion Criteria

1. Subject is methamphetamine experienced but not dependent, aged 18 to 45 years.		O Yes	O No
2. Body mass index (BMI) between 18 and 30.		O Yes	O No
3. Willing and able to give written consent		O Yes	O No
4. Not in the follow-up period of a preceding drug research study.		O Yes	O No
5. No medical contraindications from the medical history, physical examination including vital signs, 12-lead ECG, hematology, blood chemistry and urinalysis.		O Yes	O No
6. Use of an acceptable method of birth control:	O NA (Male)	O Yes	O No

a. male or female condoms
b. diaphragm (with spermicide)
c. copper-containing intrauterine device
d. surgical sterilization

7. Negative drug test (barbiturates, benzodiazepines, amphetamines, opiates, cocaine and ethanol)		O Yes	O No
8. Negative pregnancy test at screening	O NA (Male)	O Yes	O No

IF ANY INCLUSION CRITERION IS ANSWERED "NO," SUBJECT IS INELIGIBLE.

Exclusion Criteria

9. History of hematological, hepatic, respiratory, cardiovascular, renal or CNS disease or any other medical condition that is capable of altering the metabolism or elimination of drugs or of constituting a risk factor when taking the study drug	O Yes	O No
10. Recent history of methamphetamine or other drug addiction and/or alcoholism	O Yes	O No
11. Any medical condition that could relapse during or immediately after the study, and in the investigator's opinion, interferes with study evaluations or affects a subject's safety	O Yes	O No

12. Significant acute or chronic medical disease.	O Yes	O No
13. On standard 12-lead ECG, a QTc interval >440 msec for males or >450 msec for females	O Yes	O No
14. Likely to need concomitant treatment medication during the study period	O Yes	O No
15. Blood donation during the 30 days preceding study entry	O Yes	O No
16. Tobacco smoker or non-smoker for less than 3 months; i.e., a recent change in smoking status.	O Yes	O No
17. Alcohol consumption averaging > 40 g daily during the past 30 days	O Yes	O No
18. Coffee (or tea) consumption > 6 cups (6 x 0.24 L) per day or xanthine containing drinks > 1 liter/day (e.g. cola drinks, etc.)	O Yes	O No
19. No adequate means of contacting the investigator in case of emergency or not able to be contacted readily by the investigator	O Yes	O No
20. Female who is pregnant, lactating or plans to become pregnant during the study period and within one month after study drug administration O N/A (Male)	O Yes	O No
21. Exposure to any investigational new drug within 30 days of screening.	O Yes	O No
22. Regular use of any prescription or over-the-counter drugs.	O Yes	O No
23. Use of any herbal products likely to induce or inhibit hepatic microsomal enzyme CYP 2D6 within one month of the start of the study, including St. John's wort (Hypericum perforatum)	O Yes	O No

IF ANY EXCLUSION CRITERION IS ANSWERED "YES," SUBJECT IS INELIGIBLE.

24. Is the subject eligible for study participation?	O Yes	O No

Subject ID # _____ Admission Date: ___ / ___ / _____

URINE TOXICOLOGY

SCREEN FOR:

Amphetamines	___ Positive	___ Negative	___ Not done
Barbiturates	___ Positive	___ Negative	___ Not done
Benzodiazepines	___ Positive	___ Negative	___ Not done
Cocaine	___ Positive	___ Negative	___ Not done
Ethanol	___ Positive	___ Negative	___ Not done
Opiate	___ Positive	___ Negative	___ Not done
THC	___ Positive	___ Negative	___ Not done

Subject ID # _____ Phase 1 Date: ___ / ___ / _____

URINE TOXICOLOGY, DAY 1

SCREEN FOR:

Methamphetamines	___ Positive	___ Negative	___ Not done
Cocaine	___ Positive	___ Negative	___ Not done
Opiate	___ Positive	___ Negative	___ Not done

Subject ID # _____ Phase 1 Date: ___ / ___ / _____

PREGNANCY ASSESSMENT, DAY -2

This form is to be filled out for female subjects only

Was a pregnancy test performed? ___ Yes ___ No

If yes, what was the result? ___ Positive ___ Negative

Subject ID # _____ Phase 1 Date: ___ / ___ / _____

METHAMPHETAMINE DOSING LOG, DAY -2

Methamphetamine Dose #1 Time: ___ : ___

Methamphetamine Dose #2 Time: ___ : ___

Subject ID # _____ Phase 1 to 3

MODAFINIL DOSING LOG, DAYS 1 TO 8

Day 1	Date: ___ / ___ / _____	Time: ____ : ____
Day 2	Date: ___ / ___ / _____	Time: ____ : ____
Day 3	Date: ___ / ___ / _____	Time: ____ : ____
Day 4	Date: ___ / ___ / _____	Time: ____ : ____
Day 5	Date: ___ / ___ / _____	Time: ____ : ____
Day 6	Date: ___ / ___ / _____	Time: ____ : ____
Day 7	Date: ___ / ___ / _____	Time: ____ : ____
Day 8	Date: ___ / ___ / _____	Time: ____ : ____

Subject ID # _____ Phase 1

BLOOD SAMPLE COLLECTION

	Date of Sample (mm/dd/yyyy)	Time of Sample (use 24-hour clock)	Tube Code
STUDY DAY -2			
Prior to dosing	___ / ___ / _____	____ : ____	___
5 minutes after dosing		____ : ____	___
15 minutes after dosing		____ : ____	___
30 minutes after dosing		____ : ____	___
60 minutes after dosing		____ : ____	___
65 minutes after dosing		____ : ____	___
75 minutes after dosing		____ : ____	___
90 minutes after dosing		____ : ____	___
2 hours after dosing		____ : ____	___
4 hours after dosing		____ : ____	___
6 hours after dosing		____ : ____	___
8 hours after dosing		____ : ____	___
12 hours after dosing		____ : ____	___
STUDY DAY -1			
24 hours after dosing	___ / ___ / _____	____ : ____	___
36 hours after dosing		____ : ____	___
STUDY DAY 1			
48 hours after dosing	___ / ___ / _____	____ : ____	___

Subject ID # _____ Phase 1 Date: ___ / ___ / _____

VITAL SIGNS

	Actual Time	RR	HR	SBP / DBP
STUDY DAY -2				
15 minutes before	____ : ____	____	_____	_____ / _____
5 minutes after	____ : ____	____	_____	_____ / _____
15 minutes after	____ : ____	____	_____	_____ / _____
30 minutes after	____ : ____	____	_____	_____ / _____
60 minutes after	____ : ____	____	_____	_____ / _____
65 minutes after	____ : ____	____	_____	_____ / _____
75 minutes after	____ : ____	____	_____	_____ / _____
90 minutes after	____ : ____	____	_____	_____ / _____
2 hours after	____ : ____	____	_____	_____ / _____
3 hours after	____ : ____	____	_____	_____ / _____
4 hours after	____ : ____	____	_____	_____ / _____
6 hours after	____ : ____	____	_____	_____ / _____
8 hours after	____ : ____	____	_____	_____ / _____
12 hours after	____ : ____	____	_____	_____ / _____
STUDY DAY -1				
24 hours after	____ : ____	____	_____	_____ / _____
STUDY DAY 1				
48 hours after	____ : ____	____	_____	_____ / _____

Subject ID # _____ Phase 1 Date: ___ / ___ / _____

ICG, DAY -2

	15 min Before	5 min after	15 min after	30 min after	60 min after	65 min after	75 min after	90 min after
Time	___:___	___:___	___:___	___:___	___:___	___:___	___:___	___:___
Mean Arterial Pressure	___	___	___	___	___	___	___	___
Cardiac Index	___.__	___.__	___.__	___.__	___.__	___.__	___.__	___.__
Cardiac Output	___.__	___.__	___.__	___.__	___.__	___.__	___.__	___.__
Stroke Index	___	___	___	___	___	___	___	___
Stroke Volume	___	___	___	___	___	___	___	___
Systemic Vascular Res. Index	_____	_____	_____	_____	_____	_____	_____	_____
Systemic Vascular Resistance	____	____	____	____	____	____	____	____
Acceleration Index	___	___	___	___	___	___	___	___
Velocity Index	___	___	___	___	___	___	___	___
Thoracic Fluid Content	___.__	___.__	___.__	___.__	___.__	___.__	___.__	___.__
Left Cardiac Work Index	___.__	___.__	___.__	___.__	___.__	___.__	___.__	___.__
Left Cardiac Work	___.__	___.__	___.__	___.__	___.__	___.__	___.__	___.__
Systolic Time Ratio	__.___	__.___	__.___	__.___	__.___	__.___	__.___	__.___
Pre-Ejection Period	___	___	___	___	___	___	___	___
Left Ventricular Ejection Time	____	____	____	____	____	____	____	____

Subject ID # _____ Phase 1

ICG, DAY -2 TO DAY 1

	D -2 2 hr after	D -2 3 hr after	D -2 4 hr after	D -2 6 hr after	D -2 8 hr after	D -2 12 hr after	D -1 24 hr after	D 1 48 hr after
Time	___:___	___:___	___:___	___:___	___:___	___:___	___:___	___:___
Mean Arterial Pressure	___	___	___	___	___	___	___	___
Cardiac Index	___.__	___.__	___.__	___.__	___.__	___.__	___.__	___.__
Cardiac Output	___.__	___.__	___.__	___.__	___.__	___.__	___.__	___.__
Stroke Index	___	___	___	___	___	___	___	___
Stroke Volume	___	___	___	___	___	___	___	___
Systemic Vascular Res. Index	_____	_____	_____	_____	_____	_____	_____	_____
Systemic Vascular Resistance	____	____	____	____	____	____	____	____
Acceleration Index	___	___	___	___	___	___	___	___
Velocity Index	___	___	___	___	___	___	___	___
Thoracic Fluid Content	___.__	___.__	___.__	___.__	___.__	___.__	___.__	___.__
Left Cardiac Work Index	___.__	___.__	___.__	___.__	___.__	___.__	___.__	___.__
Left Cardiac Work	___.__	___.__	___.__	___.__	___.__	___.__	___.__	___.__
Systolic Time Ratio	__.___	__.___	__.___	__.___	__.___	__.___	__.___	__.___
Pre-Ejection Period	___	___	___	___	___	___	___	___
Left Ventricular Ejection Time	____	____	____	____	____	____	____	____

Subject ID # _____ Phase 1

ELECTROCARDIOGRAM

STUDY DAY -2
Pre-Dose **Date:** ___ / ___ / _____ **Time** ____ : ____

A. QTc Interval: __ . __ __ __ sec

B. ECG overall results were:
O Normal
O Abnormal, not clinically significant
O Abnormal, clinically significant

C. If ECG is abnormal, Please specify and provide comments below:

1 hour after dosing **Time** ____ : ____ A. QTc Interval: __ . __ __ __ sec

2 hours after dosing **Time** ____ : ____ A. QTc Interval: __ . __ __ __ sec

8 hours after dosing **Time** ____ : ____ A. QTc Interval: __ . __ __ __ sec

STUDY DAY -1

24 hours after dosing **Date:** ___ / ___ / _____ **Time** ____ : ____

A. QTc Interval: __ . __ __ __ sec

B. ECG overall results were:
O Normal
O Abnormal, not clinically significant
O Abnormal, clinically significant

C. If ECG is abnormal, Please specify and provide comments below:

STUDY DAY 1

48 hours after dosing **Date:** ___ / ___ / _____ **Time** ____ : ____

A. QTc Interval: __ . __ __ __ sec

B. ECG overall results were:
O Normal
O Abnormal, not clinically significant
O Abnormal, clinically significant

C. If ECG is abnormal, Please specify and provide comments below:

Subject ID # _____ Phase 1 Date ___ / ___ / _____

VISUAL ANALOG SCALE, DAY -2

	Actual Time	Any Drug Effect	Good Drug Effect	Bad Drug Effect	Nervous	Tolerable
15 minutes before	___ : ___	_____	_____	_____	_____	_____
10 minutes after	___ : ___	_____	_____	_____	_____	_____
15 minutes after	___ : ___	_____	_____	_____	_____	_____
30 minutes after	___ : ___	_____	_____	_____	_____	_____
60 minutes after	___ : ___	_____	_____	_____	_____	_____
70 minutes after	___ : ___	_____	_____	_____	_____	_____
75 minutes after	___ : ___	_____	_____	_____	_____	_____
90 minutes after	___ : ___	_____	_____	_____	_____	_____
2 hours after	___ : ___	_____	_____	_____	_____	_____
3 hours after	___ : ___	_____	_____	_____	_____	_____
4 hours after	___ : ___	_____	_____	_____	_____	_____
6 hours after	___ : ___	_____	_____	_____	_____	_____
8 hours after	___ : ___	_____	_____	_____	_____	_____

Subject ID # _____ Phase 1 Date: ___ / ___ / _____

PROFILE OF MOODS SCALE

Please enter the total score for each category:

	Pre-Dose	4 Hours Post Dose
Actual Time	___ : ___	___ : ___
1. Tension	____	____
2. Depression	____	____
3. Anger	____	____
4. Vigor	____	____
5. Fatigue	____	____
6. Confusion	____	____
Total Mood Disturbance	____	____

TOLERABILITY QUESTIONNAIRE, DAY 1 (4 hours after dosing):

Actual Time: ___ : ___ Date: ___ / ___ / _____

1. Is subject willing to continue taking the medication? O Yes O No

2. Has subject developed a headache since the last dose? O Yes O No
(*If yes, please answer questions 3-5. If no, please leave questions 3-5 blank).*

3. Is the headache unusually severe and persistent? O Yes O No

4. Is the headache associated with vomiting? O Yes O No

5. Is the headache associated with any visual symptoms? O Yes O No

VITAL SIGNS:

Actual Time: ____ : ____ Date: ___ / ___ / _____

1. Blood Pressure (mmHg): _____ / _____

2. Heart Rate (bpm) _____

Subject ID # _____ Phase 1

BRIEF SUBSTANCE CRAVING SCALE, DAY -3 TO DAY 1

		Day -3	Day -2
	Date	___ / ___ / _____	___ / ___ / _____
	Actual Time	___ : ___	___ : ___
1.	Intensity	___	___
2.	Frequency	___	___
3.	Length of Time	___	___
4.	Number of times	___	___
5.	Minutes Craving	___	___

		Day -1	Day 1
	Date	___ / ___ / _____	___ / ___ / _____
	Actual Time	___ : ___	___ : ___
1.	Intensity	___	___
2.	Frequency	___	___
3.	Length of Time	___	___
4.	Number of times	___	___
5.	Minutes Craving	___	___

Subject ID # _____ Phase 2 Date: ___ / ___ / _____

DAY 2 PROCEDURES

TIME OF ARRIVAL: ____ : ____

TIME OF DEPARTURE: ____ : ____

PRE MODAFINIL DOSE
URINE TOXICOLOGY:

Methamphetamine	___ Positive	___ Negative	___ Not done
Cocaine	___ Positive	___ Negative	___ Not done
Opiate	___ Positive	___ Negative	___ Not done

PREGNANCY TEST
to be filled out for female subjects only

Was a pregnancy test performed? ___ Yes ___ No

If yes, what was the result? ___ Positive ___ Negative

BRIEF SUBSTANCE CRAVING SCALE

Actual Time ____ : ____

1. Intensity ___
2. Frequency ___
3. Length of Time ___
4. Number of times ___
5. Minutes Craving ___

Subject ID # _____ Phase 2

DAY 2 PROCEDURES

VITAL SIGNS:

Actual Time: ____ : ____

1. Blood Pressure (mmHg): _____ / _____

2. Heart Rate (bpm) _____

3. Respiration Rate (bpm) ___

2 HOURS POST MODAFINIL DOSE

TOLERABILITY QUESTIONNAIRE:

Actual Time: ____ : ____

1. Is subject willing to continue taking the medication? O Yes O No

2. Has subject developed a headache since the last dose? O Yes O No
(*If yes, please answer questions 3-5. If no, please leave questions 3-5 blank).*

3. Is the headache unusually severe and persistent? O Yes O No

4. Is the headache associated with vomiting? O Yes O No

5. Is the headache associated with any visual symptoms? O Yes O No

VITAL SIGNS:

Actual Time: ____ : ____

1. Blood Pressure (mmHg): _____ / _____

2. Heart Rate (bpm) _____

Subject ID # _____ Phase 2 Date: ___ / ___ / _____

DAY 3 PROCEDURES

TIME OF ARRIVAL: ____ : ____

TIME OF DEPARTURE: ____ : ____

PRE MODAFINIL DOSE
URINE TOXICOLOGY:

Methamphetamine	___ Positive	___ Negative	___ Not done
Cocaine	___ Positive	___ Negative	___ Not done
Opiate	___ Positive	___ Negative	___ Not done

PREGNANCY TEST:
to be filled out for female subjects only

Was a pregnancy test performed? ___ Yes ___ No

If yes, what was the result? ___ Positive ___ Negative

BRIEF SUBSTANCE CRAVING SCALE

Actual Time ____ : ____

1. Intensity ___
2. Frequency ___
3. Length of Time ___
4. Number of times ___
5. Minutes Craving ___

Subject ID # _____ Phase 2

DAY 3 PROCEDURES

VITAL SIGNS:

Actual Time: ____ : ____

1. Blood Pressure (mmHg): _____ / _____

2. Heart Rate (bpm) _____

3. Respiration Rate (bpm) ___

2 HOURS POST MODAFINIL DOSE

TOLERABILITY QUESTIONNAIRE:

Actual Time: ____ : ____

1. Is subject willing to continue taking the medication? O Yes O No

2. Has subject developed a headache since the last dose? O Yes O No
(*If yes, please answer questions 3-5. If no, please leave questions 3-5 blank).*

3. Is the headache unusually severe and persistent? O Yes O No

4. Is the headache associated with vomiting? O Yes O No

5. Is the headache associated with any visual symptoms? O Yes O No

VITAL SIGNS:

Actual Time: ____ : ____

1. Blood Pressure (mmHg): _____ / _____

2. Heart Rate (bpm) _____

Subject ID # _____ Phase 2 Date: ___ / ___ / _____

DAY 4 PROCEDURES

TIME OF ARRIVAL: ____ : ____

TIME OF DEPARTURE: ____ : ____

PRE MODAFINIL DOSE
URINE TOXICOLOGY:

Methamphetamine	___ Positive	___ Negative	___ Not done
Cocaine	___ Positive	___ Negative	___ Not done
Opiate	___ Positive	___ Negative	___ Not done

PREGNANCY TEST:
to be filled out for female subjects only

Was a pregnancy test performed? ___ Yes ___ No

If yes, what was the result? ___ Positive ___ Negative

BRIEF SUBSTANCE CRAVING SCALE

Actual Time ____ : ____

1. Intensity ___
2. Frequency ___
3. Length of Time ___
4. Number of times ___
5. Minutes Craving ___

Subject ID # _____ Phase 2

DAY 4 PROCEDURES

VITAL SIGNS:

Actual Time: ____ : ____

1. Blood Pressure (mmHg): _____ / _____

2. Heart Rate (bpm) _____

3. Respiration Rate (bpm) ___

TIME OF BLOOD SAMPLE FOR TROUGH MODAFINIL LEVEL (TML #1): ____ : ____

TUBE CODE #: ___

2 HOURS POST MODAFINIL DOSE

TOLERABILITY QUESTIONNAIRE:

Actual Time: ____ : ____

1. Is subject willing to continue taking the medication? O Yes O No

2. Has subject developed a headache since the last dose? O Yes O No
(*If yes, please answer questions 3-5. If no, please leave questions 3-5 blank).*

3. Is the headache unusually severe and persistent? O Yes O No

4. Is the headache associated with vomiting? O Yes O No

5. Is the headache associated with any visual symptoms? O Yes O No

VITAL SIGNS:

Actual Time: ____ : ____

1. Blood Pressure (mmHg): _____ / _____

2. Heart Rate (bpm) _____

Subject ID # _____ Phase 2 Date: ___ / ___ / _____

DAY 5 PROCEDURES

TIME OF ARRIVAL: ____ : ____

TIME OF DEPARTURE: ____ : ____

PRE MODAFINIL DOSE
URINE TOXICOLOGY:

Methamphetamine	___ Positive	___ Negative	___ Not done
Cocaine	___ Positive	___ Negative	___ Not done
Opiate	___ Positive	___ Negative	___ Not done

PREGNANCY TEST:
to be filled out for female subjects only

Was a pregnancy test performed? ___ Yes ___ No

If yes, what was the result? ___ Positive ___ Negative

BRIEF SUBSTANCE CRAVING SCALE:

Actual Time ____ : ____

1. Intensity ___
2. Frequency ___
3. Length of Time ___
4. Number of times ___
5. Minutes Craving ___

Subject ID # _____ Phase 2

DAY 5 PROCEDURES

VITAL SIGNS:

Actual Time: ____ : ____

1. Blood Pressure (mmHg): _____ / _____

2. Heart Rate (bpm) _____

3. Respiration Rate (bpm) ___

2 HOURS POST MODAFINIL DOSE

TOLERABILITY QUESTIONNAIRE:

Actual Time: ____ : ____

1. Is subject willing to continue taking the medication? O Yes O No

2. Has subject developed a headache since the last dose? O Yes O No
(*If yes, please answer questions 3-5. If no, please leave questions 3-5 blank).*

3. Is the headache unusually severe and persistent? O Yes O No

4. Is the headache associated with vomiting? O Yes O No

5. Is the headache associated with any visual symptoms? O Yes O No

VITAL SIGNS:

Actual Time: ____ : ____

1. Blood Pressure (mmHg): _____ / _____

2. Heart Rate (bpm) _____

Subject ID # _____ Phase 2 Date: ___ / ___ / _____

DAY 6 PROCEDURES

TIME OF ARRIVAL: ____ : ____

TIME OF DEPARTURE: ____ : ____

PRE MODAFINIL DOSE
URINE TOXICOLOGY:

Methamphetamine	___ Positive	___ Negative	___ Not done
Cocaine	___ Positive	___ Negative	___ Not done
Opiate	___ Positive	___ Negative	___ Not done

PREGNANCY TEST:
to be filled out for female subjects only

Was a pregnancy test performed? ___ Yes ___ No

If yes, what was the result? ___ Positive ___ Negative

BRIEF SUBSTANCE CRAVING SCALE:

Actual Time ____ : ____

1. Intensity ___
2. Frequency ___
3. Length of Time ___
4. Number of times ___
5. Minutes Craving ___

Subject ID # _____ Phase 2

DAY 6 PROCEDURES

VITAL SIGNS:

Actual Time: ____ : ____

1. Blood Pressure (mmHg): _____ / _____

2. Heart Rate (bpm) _____

3. Respiration Rate (bpm) ___

TIME OF BLOOD SAMPLE FOR TROUGH MODAFINIL LEVEL (TML #2): ____ : ____

TUBE CODE #: ___

2 HOURS POST MODAFINIL DOSE

TOLERABILITY QUESTIONNAIRE:

Actual Time: ____ : ____

1. Is subject willing to continue taking the medication? O Yes O No

2. Has subject developed a headache since the last dose? O Yes O No
(*If yes, please answer questions 3-5. If no, please leave questions 3-5 blank).*

3. Is the headache unusually severe and persistent? O Yes O No

4. Is the headache associated with vomiting? O Yes O No

5. Is the headache associated with any visual symptoms? O Yes O No

VITAL SIGNS:

Actual Time: ____ : ____

1. Blood Pressure (mmHg): _____ / _____

2. Heart Rate (bpm) _____

Subject ID # _____ Phase 2 Date: ___ / ___ / _____

DAY 7 PROCEDURES

TIME OF ARRIVAL: ____ : ____

TIME OF DEPARTURE: ____ : ____

PRE MODAFINIL DOSE
URINE TOXICOLOGY:

Methamphetamine	___ Positive	___ Negative	___ Not done
Cocaine	___ Positive	___ Negative	___ Not done
Opiate	___ Positive	___ Negative	___ Not done

PREGNANCY TEST:
to be filled out for female subjects only

Was a pregnancy test performed? ___ Yes ___ No

If yes, what was the result? ___ Positive ___ Negative

BRIEF SUBSTANCE CRAVING SCALE:

Actual Time ____ : ____

1. Intensity ___
2. Frequency ___
3. Length of Time ___
4. Number of times ___
5. Minutes Craving ___

Subject ID # _____ Phase 2

DAY 7 PROCEDURES

VITAL SIGNS:

Actual Time: ____ : ____

1. Blood Pressure (mmHg): _____ / _____

2. Heart Rate (bpm) _____

3. Respiration Rate (bpm) ___

TIME OF BLOOD SAMPLE FOR TROUGH MODAFINIL LEVEL (TML #3): ____ : ____

TUBE CODE #: ___

2 HOURS POST MODAFINIL DOSE

TOLERABILITY QUESTIONNAIRE:

Actual Time: ____ : ____

1. Is subject willing to continue taking the medication? O Yes O No

2. Has subject developed a headache since the last dose? O Yes O No
(*If yes, please answer questions 3-5. If no, please leave questions 3-5 blank).*

3. Is the headache unusually severe and persistent? O Yes O No

4. Is the headache associated with vomiting? O Yes O No

5. Is the headache associated with any visual symptoms? O Yes O No

VITAL SIGNS:

Actual Time: ____ : ____

1. Blood Pressure (mmHg): _____ / _____

2. Heart Rate (bpm) _____

Subject ID # _____ Phase 3 Date: ___ / ___ / _____

PREGNANCY ASSESSMENT, DAY 8

This form is to be filled out for female subjects only

Was a pregnancy test performed? ___ Yes ___ No

If yes, what was the result? ___ Positive ___ Negative

Subject ID # _____ Phase 3 Date: ___ / ___ / _____

METHAMPHETAMINE DOSING LOG, DAY 8

PRE MODAFINIL DOSE
URINE TOXICOLOGY:

Methamphetamine	___ Positive	___ Negative	___ Not done
Cocaine	___ Positive	___ Negative	___ Not done
Opiate	___ Positive	___ Negative	___ Not done

Methamphetamine Dose #3 Time: ____ : ____

Methamphetamine Dose #4 Time: ____ : ____

Subject ID # _____ Phase 3

BLOOD SAMPLE COLLECTION

	Date of Sample (mm/dd/yyyy)	Time of Sample (use 24-hour clock)	Tube Code
STUDY DAY 8			
Blood Sample for TML #4	___ / ___ / _____	____ : ____	___
Pre-Meth Dose		____ : ____	___
5 minutes after dosing		____ : ____	___
15 minutes after dosing		____ : ____	___
30 minutes after dosing		____ : ____	___
60 minutes after dosing		____ : ____	___
65 minutes after dosing		____ : ____	___
75 minutes after dosing		____ : ____	___
90 minutes after dosing		____ : ____	___
2 hours after dosing		____ : ____	___
4 hours after dosing		____ : ____	___
6 hours after dosing		____ : ____	___
8 hours after dosing		____ : ____	___
12 hours after dosing		____ : ____	___
STUDY DAY 9			
Blood Sample for TML #5	___ / ___ / _____	____ : ____	___
24 hours after Meth dosing		____ : ____	___
36 hours after dosing		____ : ____	___
STUDY DAY 10			
Blood Sample for TML #6	___ / ___ / _____	____ : ____	___
48 hours after Meth dosing		____ : ____	___

Subject ID # _____ Phase 3 Date: ___ / ___ / _____

VITAL SIGNS

	Actual Time	RR	HR	SBP / DBP
STUDY DAY 8				
2 hours before	____ : ____	____	_____	_____ / _____
15 minutes before	____ : ____	____	_____	_____ / _____
5 minutes after	____ : ____	____	_____	_____ / _____
15 minutes after	____ : ____	____	_____	_____ / _____
30 minutes after	____ : ____	____	_____	_____ / _____
60 minutes after	____ : ____	____	_____	_____ / _____
65 minutes after	____ : ____	____	_____	_____ / _____
75 minutes after	____ : ____	____	_____	_____ / _____
90 minutes after	____ : ____	____	_____	_____ / _____
2 hours after	____ : ____	____	_____	_____ / _____
3 hours after	____ : ____	____	_____	_____ / _____
4 hours after	____ : ____	____	_____	_____ / _____
6 hours after	____ : ____	____	_____	_____ / _____
8 hours after	____ : ____	____	_____	_____ / _____
12 hours after	____ : ____	____	_____	_____ / _____
STUDY DAY 9				
24 hours after	____ : ____	____	_____	_____ / _____
STUDY DAY 10				
48 hours after	____ : ____	____	_____	_____ / _____

Subject ID # _____ Phase 3 Date: ___ / ___ / _____

ICG, DAY 8

	15 min Before	5 min after	15 min after	30 min after	60 min after	65 min after	75 min after	90 min after
Time	___:___	___:___	___:___	___:___	___:___	___:___	___:___	___:___
Mean Arterial Pressure	___	___	___	___	___	___	___	___
Cardiac Index	___.__	___.__	___.__	___.__	___.__	___.__	___.__	___.__
Cardiac Output	___.__	___.__	___.__	___.__	___.__	___.__	___.__	___.__
Stroke Index	___	___	___	___	___	___	___	___
Stroke Volume	___	___	___	___	___	___	___	___
Systemic Vascular Res. Index	_____	_____	_____	_____	_____	_____	_____	_____
Systemic Vascular Resistance	____	____	____	____	____	____	____	____
Acceleration Index	___	___	___	___	___	___	___	___
Velocity Index	___	___	___	___	___	___	___	___
Thoracic Fluid Content	___.__	___.__	___.__	___.__	___.__	___.__	___.__	___.__
Left Cardiac Work Index	___.__	___.__	___.__	___.__	___.__	___.__	___.__	___.__
Left Cardiac Work	___.__	___.__	___.__	___.__	___.__	___.__	___.__	___.__
Systolic Time Ratio	__.___	__.___	__.___	__.___	__.___	__.___	__.___	__.___
Pre-Ejection Period	___	___	___	___	___	___	___	___
Left Ventricular Ejection Time	____	____	____	____	____	____	____	____

Subject ID # _____ Phase 3

ICG, DAYS 8 to 10

	D 8 2 hr after	D 8 3 hr after	D 8 4 hr after	D 8 6 hr after	D 8 8 hr after	D 8 12 hr after	D 9 24 hr after	D 10 48 hr after
Time	___:___	___:___	___:___	___:___	___:___	___:___	___:___	___:___
Mean Arterial Pressure	___	___	___	___	___	___	___	___
Cardiac Index	___.__	___.__	___.__	___.__	___.__	___.__	___.__	___.__
Cardiac Output	___.__	___.__	___.__	___.__	___.__	___.__	___.__	___.__
Stroke Index	___	___	___	___	___	___	___	___
Stroke Volume	___	___	___	___	___	___	___	___
Systemic Vascular Res. Index	_____	_____	_____	_____	_____	_____	_____	_____
Systemic Vascular Resistance	____	____	____	____	____	____	____	____
Acceleration Index	___	___	___	___	___	___	___	___
Velocity Index	___	___	___	___	___	___	___	___
Thoracic Fluid Content	___.__	___.__	___.__	___.__	___.__	___.__	___.__	___.__
Left Cardiac Work Index	___.__	___.__	___.__	___.__	___.__	___.__	___.__	___.__
Left Cardiac Work	___.__	___.__	___.__	___.__	___.__	___.__	___.__	___.__
Systolic Time Ratio	__.___	__.___	__.___	__.___	__.___	__.___	__.___	__.___
Pre-Ejection Period	___	___	___	___	___	___	___	___
Left Ventricular Ejection Time	____	____	____	____	____	____	____	____

Subject ID # _____ Phase 3

ELECTROCARDIOGRAM

STUDY DAY 8
Pre-Dose **Date:** ___ / ___ / _____ **Time** ____ : ____

A. QTc Interval: __ . __ __ __ sec

B. ECG overall results were:
O Normal
O Abnormal, not clinically significant
O Abnormal, clinically significant

C. If ECG is abnormal, Please specify and provide comments below:

1 hour after dosing **Time** ____ : ____ A. QTc Interval: __ . __ __ __ sec

2 hours after dosing **Time** ____ : ____ A. QTc Interval: __ . __ __ __ sec

8 hours after dosing **Time** ____ : ____ A. QTc Interval: __ . __ __ __ sec

STUDY DAY 9
24 hours after dosing **Date:** ___ / ___ / _____ **Time** ____ : ____

A. QTc Interval: __ . __ __ __ sec

B. ECG overall results were:
O Normal
O Abnormal, not clinically significant
O Abnormal, clinically significant

C. If ECG is abnormal, Please specify and provide comments below:

STUDY DAY 10
48 hours after dosing **Date:** ___ / ___ / _____ **Time** ____ : ____

A. QTc Interval: __ . __ __ __ sec

B. ECG overall results were:
O Normal
O Abnormal, not clinically significant
O Abnormal, clinically significant

C. If ECG is abnormal, Please specify and provide comments below:

Subject ID # _____ Phase 3 Date ___ / ___ / _____

VISUAL ANALOG SCALE, DAY 8

	Actual Time	Any Drug Effect	Good Drug Effect	Bad Drug Effect	Nervous	Tolerable
15 minutes before	___ : ___	_____	_____	_____	_____	_____
10 minutes after	___ : ___	_____	_____	_____	_____	_____
15 minutes after	___ : ___	_____	_____	_____	_____	_____
30 minutes after	___ : ___	_____	_____	_____	_____	_____
60 minutes after	___ : ___	_____	_____	_____	_____	_____
70 minutes after	___ : ___	_____	_____	_____	_____	_____
75 minutes after	___ : ___	_____	_____	_____	_____	_____
90 minutes after	___ : ___	_____	_____	_____	_____	_____
2 hours after	___ : ___	_____	_____	_____	_____	_____
3 hours after	___ : ___	_____	_____	_____	_____	_____
4 hours after	___ : ___	_____	_____	_____	_____	_____
6 hours after	___ : ___	_____	_____	_____	_____	_____
8 hours after	___ : ___	_____	_____	_____	_____	_____

Subject ID # _____ Phase 3 Date: ___ / ___ / _____

PROFILE OF MOODS SCALE, DAY 8

Please enter the total score for each category:

	Pre-Dose	4 Hours Post Dose
Actual Time	___ : ___	___ : ___
1. Tension	____	____
2. Depression	____	____
3. Anger	____	____
4. Vigor	____	____
5. Fatigue	____	____
6. Confusion	____	____
Total Mood Disturbance	____	____

Subject ID # _____ Phase 3

BRIEF SUBSTANCE CRAVING SCALE, DAYS 8 TO 10

		Day 8	Day9
	Date	___ / ___ / _____	___ / ___ / _____
	Actual Time	___ : ___	___ : ___
1.	Intensity	___	___
2.	Frequency	___	___
3.	Length of Time	___	___
4.	Number of times	___	___
5.	Minutes Craving	___	___

		Day 10
	Date	___ / ___ / _____
	Actual Time	___ : ___
1.	Intensity	___
2.	Frequency	___
3.	Length of Time	___
4.	Number of times	___
5.	Minutes Craving	___

Subject ID # _____ Post-Study Date: ___ / ___ / _____

END OF TRIAL

1. Date of final clinic visit ___ / ___ / _____

2. Was the subject terminated early from the trial? ___ Yes ___ No

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

___ Subject completed study.

___ Subject was determined after enrollment to be ineligible. (Provide comments)

___ Subject requested to withdraw. (Provide comments)

___ Subject experienced intercurrent illness, unrelated medical condition, or clinically significant adverse events which, in the judgment of the investigator, prompted early termination. (If subject experienced adverse event(s), an Adverse Event Case Report Form(s) must be completed.) (Provide comments.)

___ Subject terminated for administrative reasons. (Include protocol non-compliance in this category.) (Provide comments)

___ Subject was incarcerated.

___ Subject became pregnant.

___ Subject developed sensitivity to study agent.

___ Subject was lost to follow-up.

___ Subject moved from area.

___ Subject died.

___ Subject no longer attends lab.

___ Subject is in a controlled environment.

___ Subject is a screen failure.

___ Other (provide comments)

3. Comments:

Subject ID # _____

COMMENT LOG

Date of comment: ___ / ___ / _____

This comment applies to: Screening / Phase __ / Post-Study

Visit date: ___ / ___ / _____

Comments:

_____

_____

_____

_____

_____

_____

Signature _____

Date of comment: ___ / ___ / _____

This comment applies to: Screening / Phase __ / Post-Study

Visit date: ___ / ___ / _____

Comments:

_____

_____

_____

_____

_____

_____

Signature _____

NIDA-CPU-modafinilmeth-0001

Subject ID # __________

CONCOMITANT MEDICATIONS LOG

Has the subject taken any concomitant medications during this study? ___ No ___ Yes (*If yes, please complete table)*

	Unit of Medication		**Frequency**		**Route of Administration**		
CAP = capsule	mg = milligram	SUP = suppository	ONCE = one dose	QID = 4 times/day	PO = oral	REC = rectal	IA = intra-articular
g = gram	mL = milliliter	TSP = teaspoon	QD = once daily	QOD = every other day	TD = transdermal	VAG = vaginal	NAS = nasal
GR = grain	oz = ounce	TBS = tablespoon	BID = twice daily	PRN = as needed	INH = inhaled	SQ = subcutaneous	IO = intraocular
GTT = drop	PUF = puff	TAB = tablet	TID = 3 times/day	OTH = other	IM = intramuscular	SL = sublingual	UNK = unknown
ug = microgram	SPY = spray/squirt	UNK = unknown	QAM = every morn.	QPM = every evening	IV = intravenous	AUR = auricular	OTH = other
uL = microliter	PCH = patch	OTH = other			TOP = topical		

Line	Medication	Quantity	Units	Frequency	Route of Administration	Start Date	Stop Date	Continuing? (check If yes)	Indication
___	________________	______	_____	_________	____________	___________	___________	_____	_______________
___	________________	______	_____	_________	____________	___________	___________	_____	_______________
___	________________	______	_____	_________	____________	___________	___________	_____	_______________
___	________________	______	_____	_________	____________	___________	___________	_____	_______________
___	________________	______	_____	_________	____________	___________	___________	_____	_______________
___	________________	______	_____	_________	____________	___________	___________	_____	_______________
___	________________	______	_____	_________	____________	___________	___________	_____	_______________
___	________________	______	_____	_________	____________	___________	___________	_____	_______________

Signature ___________________________ Date ___ / ___ / ______ Page 51__

White -> Monitor -> BRCI Yellow -> Monitor -> BRCI Pink -> Retained by Investigator

NIDA-CPU-modafinilmeth-0001

Subject ID # __________

ADVERSE EVENTS LOG

Has the subject had any Adverse Events during the time period evaluated? ___ No ___ Yes (*If yes, please list below).*

D: Severity	**E: Relationship**	**F: Action Taken Regarding Study Drug**	**G: Other Action Taken**	**H: Outcome of AE**	**I: Serious?**	**J: Type of SAE**
1 = Mild	1 = Definitely	1 = None	1 = None	1 = Resolved, no sequelae	1 = Yes	1 = Death
2 = Moderate	2 = Probably	2 = Discontinued Perm.	2 = Pharmacologic Therapy	2 = Still present, no treatment	0 = No	2 = Life-threatening event
3 = Severe	3 = Possibly	3 = Discontinued Temp	3 = Nonpharm. Therapy	3 = Still present, being treated	*(If yes, mark all*	3 = Hospitalization
	4 = Remotely	4 = Reduced Dose	4 = Hospitalization	4 = Residual effects, no treatment	*categories in J*	4 = Disability
	5 = Definitely Not	5 = Increased Dose		5 = Residual effects, being treated	*that apply)*	5 = Congenital anomaly
	6 = Unknown	6 = Delayed Dose		6 = Death		6 = Other, specify
				7 = Unknown		

Line #	A Adverse Event	B Start Date	C Stop Date	D Severity	E Related	F Action	G Other Act.	H Outcome	I SAE?	J. Type of SAE (If Other, specify)	
___	____________________	_________	________	___	___	___	___	___	___	___	__________________________
___	____________________	_________	________	___	___	___	___	___	___	___	__________________________
___	____________________	_________	________	___	___	___	___	___	___	___	__________________________
___	____________________	_________	________	___	___	___	___	___	___	___	__________________________
___	____________________	_________	________	___	___	___	___	___	___	___	__________________________
___	____________________	_________	________	___	___	___	___	___	___	___	__________________________
___	____________________	_________	________	___	___	___	___	___	___	___	__________________________
___	____________________	_________	________	___	___	___	___	___	___	___	__________________________
___	____________________	_________	________	___	___	___	___	___	___	___	__________________________
___	____________________	_________	________	___	___	___	___	___	___	___	__________________________

Signature ___________________________ Date ___ / ___ / ______ Page 52__

White -> Monitor -> BRCI Yellow -> Monitor -> BRCI Pink -> Retained by Investigator