Screening/Baseline

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

Inclusion Criteria

☐ Yes ☐ No 1. Subject is at least 18 years-of-age.

☐ Yes ☐ No 2. Subject has a DSM-IV diagnosis of cocaine dependence as determined by SCID.

☐ Yes ☐ No 3. Subject is seeking treatment for cocaine dependence.

☐ Yes ☐ No 4. Subject had at least 1 positive urine BE specimen (>300 ng/mL) within the three-week screening/baseline period prior to randomization with a minimum of six of the 9 scheduled samples tested, with no more than two specimens collected on consecutive days, no more than three specimens collected in one week, and no more than four days between samples (including between end of screening/baseline period and sample collected on Week 1, Day 1).

☐ Yes ☐ No 5. Subject has the ability to understand, and having understood, has provided written informed consent.

☐ Yes ☐ No ☐ N/A Male

6. If female, be surgically sterile, 2 years postmenopausal, or if of childbearing potential, agree to use an accepted method of birth control as follows, and agree to continue use of this method for at least 30 days after the last dose of study drug.

a) barrier method with spermicide
b) steroidal contraceptive [oral, Implanted, injected] used in conjunction with a barrier method
c) Contraceptive patch used in conjunction with a barrier method
d) Intrauterine device [IUD]

If any of Questions 1-6 above are answered "No" the subject is ineligible. Please proceed to the end of this form and complete the final questions.

Exclusion Criteria

☐ Yes ☐ No 1. Subject has current dependence, defined by DSM-IV criteria, on any psychoactive substance other than cocaine, alcohol, nicotine, or marijuana or physiological dependence on alcohol requiring medical detoxification.

☐ Yes ☐ No 2. Subject is mandated by the court to obtain treatment for cocaine-dependence.

☐ Yes ☐ No 3. Subject has been enrolled in an opiate-substitution program (methadone, LAAM, buprenorphine) within 2 months of screening.

☐ Yes ☐ No 4. Subject is someone who, in the opinion of the investigator, would not be expected to complete the study protocol due to probable incarceration or relocation from the clinic area.

☐ Yes ☐ No 5. Subject has a psychiatric disorder, as assessed by the SCID, or a neurological disorder, brain disease, dementia or any disorder that, in the opinion of the study physician requires ongoing treatment that would make study participation unsafe or which would make treatment compliance difficult.

Screening/Baseline

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

☐ Yes ☐ No 6. Subject has had electroconvulsive therapy within the past 3 months preceding screening.

☐ Yes ☐ No 7. Subject has a current suicidal ideation or plan (within the past 30 days) as assessed by the SCID.

☐ Yes ☐ No 8. Subject is pregnant or lactating.

☐ Yes ☐ No 9. Subject has a serious medical illnesses including, but not limited to,

a) uncontrolled hypertension,
b) significant heart disease (including myocardial infarction within one year of enrollment), or any clinically significant cardiovascular abnormality (ECG),
c) hepatic, renal or gastrointestinal disorders that could result in a clinically significant alteration of metabolism or excretion of the study agent,
d) potentially life-threatening or progressive medical illness other than addiction that may compromise subject safety or study conduct.

☐ Yes ☐ No 10. Subject has clinically significant abnormal laboratory values, including those referenced in Appendix I.

☐ Yes ☐ No 11. Subject has AIDS according to the current CDC criteria for AIDS MMWR 1999; 48 (No.RR-13:29-31).

☐ Yes ☐ No 12. Subject has active syphilis that has not been treated or refuses treatment for syphilis (see note below).

☐ Yes ☐ No 13. Subject has active tuberculosis (positive tuberculin test and confirmatory chest x-ray).

☐ Yes ☐ No 14. Subject has a diagnosis of adult (i.e. 21 years or older) asthma, or chronic obstructive pulmonary disease (COPD), or has a history of acute asthma within the past two years, or has current or recent (past 3 months) treatment with inhaled or oral beta-agonist or steroid therapy (because of potential serious adverse interactions with cocaine).

☐ Yes ☐ No 15. Subject is actively using albuterol or other beta agonist medications, regardless of formal diagnosis of asthma. (Inhalers are sometimes used by cocaine addicts to enhance cocaine delivery to the lungs).
A subject without respiratory disease who will consent to discontinue beta-agonist use, may be considered for inclusion.

☐ Yes ☐ No 16. Subject has received a drug with known potential for toxicity to a major organ system within 30 days prior to screening (e.g. isoniazid, methotrexate).

☐ Yes ☐ No 17. received medication that could interact adversely with modafinil, with the time of administration of study agent and other medications based on the longest time interval of A, B, or C, below:

A) Five half lives of other medication or metabolite(s), whichever is longer
B) Two weeks
C) Interval recommended by other medication's product labeling

Please see protocol for a list of medications that fall into this category.

Screening/Baseline

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

☐ Yes ☐ No 18. Subject has participated in any experimental study within 2 months preceding screening.

☐ Yes ☐ No 19. Subject has a known or suspected hypersensitivity to Modafinil.

☐ Yes ☐ No 20. Subject is taking Modafinil for any reason currently or within the past year.

☐ Yes ☐ No 21. Subject has alcohol dependence that requires medical detoxification in the opinion of the study physician.

If any of Questions 1-20 above are answered "Yes" the subject is ineligible. Please proceed to the end of this form and complete the final questions.

Notes on inclusion/exclusion criterion*: Although AIDS is an exclusion criteria, a positive antibody titer to HIV is not. Prospective subjects will be offered HIV testing. This test is offered as a courtesy to the prospective subject along with HIV education.*

Prospective subjects who are positive for syphilis by the RPR test will have a confirmatory test performed (see protocol). If this test is positive, prospective subjects must be treated for syphilis to be enrolled on the study or provide evidence of completion of treatment for syphilis.

The infectious disease panel for hepatitis is performed as an aid to determine if the prospective subject has been exposed to the hepatitis virus. Positive hepatitis results do not exclude a prospective subject from participation unless there is an indication of active liver disease. However, if liver function tests (e.g. ALT and AST) are over three times normal it is presumptive evidence that the subject has active hepatitis and should be excluded from the study (exclusion criterion #10). A positive PPD result does not exclude a prospective subject from participation, but if diagnostic tests (e.g. chest x -ray) indicate that active disease is present, subjects will be excluded from participation.

☐ **Yes** ☐ **No** **Is the subject eligible for randomization based on the above criteria?**

☐ **Yes** ☐ **No** **Was the subject randomized?**

If "No", please indicate the reason on the End of Trial form:

Physician Signature: _____ Date: _____
(mm/dd/yyyy)

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____

(mm/dd/yyyy)

General

1. Gender: ☐ Male ☐ Female

2. Date of Birth: _____

(mm/dd/yyyy)

Ethnicity (regardless of race)

☐ Hispanic or Latino

- ☐ Mexican, Mexican-American, or Chicano
- ☐ Puerto Rican
- ☐ Cuban
- ☐ South or Central American
- ☐ Other, specify _____

☐ Not Hispanic or Latino

Race

1. Indicate which single major race applies
(*within the single major race that you have selected, please check all that apply*):

☐ White
☐ Black or African American
☐ Asian

(check all that apply)

- ☐ Asian Indian
- ☐ Chinese
- ☐ Filipino
- ☐ Japanese
- ☐ Korean
- ☐ Vietnamese
- ☐ Other, specify _____

☐ American Indian or Alaska Native
☐ 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 race/ethnicity question

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____

(mm/dd/yyyy)

Education

1. Education Completed (GED = 12 years):

_____ years

_____ months

Employment/Support Status

1. Current Employment Pattern (Past 30 Days)

☐ 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

2. Past Employment Pattern (Past 3 Years)

☐ 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

Marital Status

☐ Legally Married	☐ Living with Partner/ Cohabiting	☐ Widowed
☐ Separated	☐ Divorced	☐ Never Married

NIDA-MDS-Modaf-0001 **Form 2 - DEMOGRAPHY**
Screening/Baseline

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

Drug/Alcohol Use

	# of Days in the Past 30	# of Years Lifetime	Route of Administration*
Alcohol – any use at all			
Alcohol – to intoxication			
Heroin			
Methadone (prescribed)			
Methadone (illicit)			
Other opiates/analgesics			
Barbiturates			
Sedatives including Benzodiazepines			
Cocaine			
Methamphetamines			
Other Amphetamines			
Cannabis			
Hallucinogens			
Inhalants			
Nicotine			
More than one substance per day ***including alcohol***			

Choose the most common route for each substance. 1 = Oral 2 = Nasal 3 = Smoking 4 = Non-IV Injection 5 = IV Injection

NIDA-MDS-Modaf-0001 **Form 2 - DEMOGRAPHY**
Screening/Baseline

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

According to the interviewer, which substance is the <u>major</u> problem?

Check only one.

☐ No problem	☐ Methamphetamines	☐ Other Amphetamines
☐ Heroin	☐ Methadone ***prescribed***	☐ Methadone ***illicit***
☐ Opiates/analgesics	☐ Barbiturates	☐ Sedatives including Benzodiazepines
☐ Cocaine	☐ Cannabis	☐ Hallucinogens
☐ Inhalants	☐ Nicotine	
☐ Alcohol Addiction	☐ Polydrug addiction	

Completed by (Initials): _____

Screening/Baseline

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

Axis I Diagnosis

Please list all CURRENT Substance Abuse or Dependence Diagnoses (Including DSM-IV code)

Please list all PAST Substance Abuse or Dependence Diagnoses (Including DSM-IV code)

Please list all other CURRENT Axis I Diagnoses (Including DSM-IV code)

Please list all other PAST Axis I Diagnoses (Including DSM-IV code)

Completed by (Initials): _____

Site ID: | Subject ID #. | Subject Initials | Week

Date: *(mm/dd/yyyy)*

	A. Yes, Excludes	B. Yes, Does Not Exclude	C. No History Of	D. Did Not Evaluate	E. Specify or Describe (Required if yes)
1. Allergies, drug (specify)	☐	☐	☐	☐	
2. Allergies, other (specify)	☐	☐	☐	☐	
3. Sensitivity to study medication or related compounds	☐	☐	☐	☐	
4. History of asthma	☐	☐	☐	☐	
5. HEENT Disorder	☐	☐	☐	☐	
6. Cardiovascular Disorder	☐	☐	☐	☐	
7. Renal Disorder	☐	☐	☐	☐	
8. Hepatic Disorder	☐	☐	☐	☐	
9. Pulmonary Disorder	☐	☐	☐	☐	
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	☐	☐	☐	☐	
20. Seizure	☐	☐	☐	☐	
21. Infectious Disease	☐	☐	☐	☐	
22. Other 1 (specify)	☐	☐	☐	☐	
23. Other 2 (specify)	☐	☐	☐	☐	

Site ID: | Subject ID #. | Subject Initials | Week

Date: *(mm/dd/yyyy)*

Surgical History

24. Has patient ever had any major surgery? ☐ Yes ☐ No

If 'Yes', list major surgeries bel ow.

	Type of Surgery	Date of Surgery *(mm/dd/yyyy)*	Is Surgery Relevant to Study Participation? Yes, Excludes	Yes, Does Not Exclude	No
25.			☐	☐	☐
26.			☐	☐	☐
27.			☐	☐	☐
28.			☐	☐	☐
29.			☐	☐	☐
30.			☐	☐	☐
31.			☐	☐	☐

Tobacco History

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

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

34. If yes, number of years tobacco product used:

Comments:

NIDA-MDS-Modaf-0001 **Form 5 PRIOR MEDICATIONS**

Screening/Baseline

Site ID: | Subject ID #. | Subject Initials | Week

Date: *(mm/dd/yyyy)*

Has the subject taken any medications in the PAST 30 DAYS? ☐ Yes ☐ No *(If yes, please complete table)*

Unit of Medication

CAP = capsule
g = gram
GR = grain
GTT = drop
ug = microgram
uL = microliter
mg = milligram
mL = milliliter
oz = ounce
PUF = puff
SPY = spray/squirt
SUP = suppository
TSP = teaspoon
TBS = tablespoon
TAB = tablet
UNK = unknown

Frequency

ONCE = one dose
QD = once daily
BID = twice daily
TID = 3 times/day
QID = 4 times/day
QOD = every other day
PRN = as needed

Route of Administration

PO = oral
TD = transdermal
INH = inhaled
IM = intramuscular
IV = intravenous
REC = rectal
VAG = vaginal
SQ = subcutaneous
SL = sublingual
AUR = auricular
IA = intra-articular
NAS = nasal
IO = intraocular
UNK = unknown

Medication	Dose	Units	Frequency	Route of Administration	Start Date	Stop Date	Continuing? (check If yes)	Indication

Screening/Baseline

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____

(mm/dd/yyyy)

Hepatitis

Provide comments for any positive value.

Hepatitis B surface antigen result
- ☐ Negative
- ☐ Positive
- ☐ Positive, significant
- ☐ Indeterminate
- ☐ Not assessed

Hepatitis B surface antibody result
- ☐ Negative
- ☐ Positive
- ☐ Positive, significant
- ☐ Indeterminate
- ☐ Not assessed

Hepatitis B core antibody result
- ☐ Negative
- ☐ Positive
- ☐ Positive, significant
- ☐ Indeterminate
- ☐ Not assessed

Hepatitis C virus antibody result
- ☐ Negative
- ☐ Positive
- ☐ Positive, significant
- ☐ Indeterminate
- ☐ Not assessed

Purified Protein Derivative (PPD) Test

Has the subject ever had a positive PPD test or been treated for TB? ☐ Yes ☐ No

If 'Yes', do not perform PPD and leave the rest of the PPD section blank, however a chest X-ray is required.

PPD test administered: Date _____ Time _____
(mm/dd/yyyy) *(24-hour clock)*

PPD test read: Date _____ Time _____
(mm/dd/yyyy) *(24-hour clock)*

PPD test result: ☐ Negative ☐ Positive ☐ Unknown ☐ Test not done

If PPD test is positive or the test was not done, a chest X-ray is required.

Comments:

Required for any positive value.

Screening/Baseline

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____

(mm/dd/yyyy)

Chest X-Ray

Was a chest X-ray performed? ☐ Yes ☐ No

Date chest x-ray performed: _____

(mm/dd/yyyy)

Results of chest X-ray:

- ☐ Normal
- ☐ Abnormal, not significant
- ☐ Abnormal, significant
- ☐ Indeterminate
- ☐ Not assessed

Provide comments for any abnormal finding:

HIV

Was a consent to perform an HIV test signed by the subject? ☐ Yes ☐ No

Was an HIV test performed? ☐ Yes ☐ No

What was the result of the HIV test? ☐ Positive ☐ Negative ☐ Indeterminate

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

Rapid plasma reagin (RPR) test result:
- ☐ negative
- ☐ positive
- ☐ indeterminant
- ☐ not done

If RPR test is not done, state reason: _____

If RPR test is positive, fluorescent treponemal antibody absorbent (FTA-abs) confirmatory test is required. If RPR test is indeterminant, it must be repeated.

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

FTA-abs test result:
- ☐ negative
- ☐ positive
- ☐ indeterminant
- ☐ not done

If FTA-abs test is not done, state reason: _____

If FTA-abs result is positive, is subject willing to undergo treatment for syphilis?
- ☐ Yes
- ☐ No

If the subject is unwilling to undergo treatment for active syphilis, they are ineligible to participate in this research study.

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

Comments: _____

Completed by (Initials): _____

NIDA-MDS-Modaf-0001

Form 8 – PHYSICAL EXAM

Screening/Baseline

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

1. Height _____ inches

2. Weight _____ pounds

	A. Normal	B. Abnormal	C. Abnormal Significant	D. Not Done	E. Comments (required for abnormal values)
3. Oral (mouth)	☐	☐	☐	☐	
4. Head and Neck	☐	☐	☐	☐	
5. Eyes, ears, nose/throat	☐	☐	☐	☐	
6. Cardiovascular	☐	☐	☐	☐	
7. Chest	☐	☐	☐	☐	
8. Lungs	☐	☐	☐	☐	
9. Abdomen (include liver/spleen)	☐	☐	☐	☐	
10. Extremities	☐	☐	☐	☐	
11. Skin, hair, nails	☐	☐	☐	☐	
12. Neuropsychiatric mental status	☐	☐	☐	☐	
13. Neuropsychiatric sensory/motor	☐	☐	☐	☐	
14. Musculoskeletal	☐	☐	☐	☐	
15. General appearance	☐	☐	☐	☐	
16. Rectal	☐	☐	☐	☐	
17. Prostate	☐	☐	☐	☐	
18. Breast	☐	☐	☐	☐	

Site ID: | Subject ID #. | Subject Initials | Week

Date: *(mm/dd/yyyy)*

	A. Normal	B. Abnormal	C. Abnormal Significant	D. Not Done	E. Comments (required for abnormal values)
19. Lymph	☐	☐	☐	☐	
20. Genital	☐	☐	☐	☐	
21. Pelvic	☐	☐	☐	☐	
22. Other, specify	☐	☐	☐	☐	
22. Other, specify	☐	☐	☐	☐	

Screening/Baseline

Site ID: | Subject ID #. | Subject Initials | Week

Date: *(mm/dd/yyyy)*

	Value		Normal	Abnormal*	Abnormal* Significant	Not Done	Comments (required for abnormal values)
1. Hemoglobin		g/dL	☐	☐	☐	☐	
2. Hematocrit		%	☐	☐	☐	☐	
3. RBC		M/uL	☐	☐	☐	☐	
4. Platelet count		K/uL	☐	☐	☐	☐	
5. WBC		K/uL	☐	☐	☐	☐	
6. Neutrophils		%	☐	☐	☐	☐	
7. Lymphocytes		%	☐	☐	☐	☐	
8. Monocytes		%	☐	☐	☐	☐	
9. Eosinophils		%	☐	☐	☐	☐	
10. Basophils		%	☐	☐	☐	☐	

Please refer to Appendix I of the protocol when determining the significance of abnormal values.

****"Abnormal" is any value outside the normal laboratory range.***

million/uL = mil/cumm = mill/mcl = M/cmm = x10^6/cumm

x 10^3/uL = thou/cumm = thou/mcl = K/cmm = 1000/uL = x 10^3/cumm

☐ Check here if results on this form are retests of previous lab tests.

Date of original lab tests: *(mm/dd/yyyy)*

Screening/Baseline

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

	Value		Normal	Abnormal*	Abnormal* Significant	Not Done	Comments (Required for Abnormal values)
1. Sodium		mmol/L	☐	☐	☐	☐	
2. Potassium		mmol/L	☐	☐	☐	☐	
3. Chloride		mmol/L	☐	☐	☐	☐	
4. CO2		mmol/L	☐	☐	☐	☐	
5. Glucose		mg/dL	☐	☐	☐	☐	
6. Creatinine		mg/dL	☐	☐	☐	☐	
7. Albumin		g/dL	☐	☐	☐	☐	
8. Total protein		g/dL	☐	☐	☐	☐	
9. SGOT/AST		U/L	☐	☐	☐	☐	
10. SGPT/ALT		U/L	☐	☐	☐	☐	
11. GGT		U/L	☐	☐	☐	☐	
12. Bilirubin		mg/dL	☐	☐	☐	☐	
13. BUN		mg/dL	☐	☐	☐	☐	

Please refer to Appendix I of the protocol when determining significance of abnormal values.

**** "Abnormal" is any value outside the normal laboratory range.***

mmol/L = mEq/L

☐ Check here if this form is completed for retest of previous lab tests.

Date of original lab tests _____

Screening/Baseline

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

	Value	Normal	Abnormal*	Abnormal* Significant	Not Done	Comments (required for abnormal values)
1. Specific gravity		☐	☐	☐	☐	
2. pH		☐	☐	☐	☐	
3. Glucose		☐	☐	☐	☐	
4. Protein		☐	☐	☐	☐	
5. Ketones		☐	☐	☐	☐	
6. Occult Blood		☐	☐	☐	☐	
7. WBC		☐	☐	☐	☐	
8. RBC		☐	☐	☐	☐	
9. Epithelial Cells		☐	☐	☐	☐	

"Abnormal" is any value outside the normal laboratory range.

For Glucose, Protein, Ketones, and Occult Blood use the following scale to report Values:

-1 = Absent
0 = Trace
1
2
3
4

For WBC, RBC, and Epithelial Cells use the following scale to report Values:

1 = None (1 – 5)
2 = Few (6 – 10)
3 = Moderate (11 – 50)
4 = Heavy (>50)

☐ Check here if this form is completed for retest of previous lab tests.

Date of original lab tests: _____
(mm/dd/yyyy)

Completed by (Initials): _____

Screening/Baseline

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

This form is to be filled out for female subjects only. All female subjects must be tested at Screening/Baseline and have a negative pregnancy test in order to be eligible for this study.

What method of birth control is the participant currently using (prior to taking modafinil)?

- ☐ Oral contraceptive
- ☐ Barrier (diaphragm or condom plus spermicide)
- ☐ Levonorgestrel implant (Norplant)
- ☐ Intrauterine Contraceptive system (IUD)
- ☐ Medroxyprogesterone Acetate Contraceptive injection (Depo-Provera)
- ☐ Contraceptive patch
- ☐ Surgical Sterilization - Hysterectomy
- ☐ Surgical Sterilization - Tubal ligation

Unless surgically sterile or 2 years postmenopausal, does the subject agree to use an acceptable method of birth control during the study and 30 days after last dose of study drug?

☐ Yes ☐ No

If yes, mark below the acceptable method selected by the subject for use:

- ☐ barrier method with spermicide
- ☐ steroidal contraceptive [oral, Implanted, injected] used in conjunction with a barrier method
- ☐ Contraceptive patch used in conjunction with a barrier method
- ☐ Intrauterine device [IUD]

Was a pregnancy test performed? ☐ Yes ☐ No

If yes, date specimen collected _____
(mm/dd/yyyy)

Result: ☐ Negative ☐ Positive ☐ Unknown

If no, specify reason: _____

Is the subject lactating? ☐ Yes ☐ No

Comments: _____

Completed by (Initials): _____

Screening/Baseline

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

A. ECG overall results were: ☐ Normal ☐ Abnormal

If ECG is Normal please skip to Question C.

B. If ECG is abnormal, check below for all abnormalities.

	Abnormal	Abnormal Significant		Abnormal	Abnormal Significant
1. Increased QRS voltage	☐	☐	17. Supraventricular premature beat	☐	☐
2. Qtc prolongation	☐	☐	18. Ventricular premature beat	☐	☐
3. Left atrial hypertrophy	☐	☐	19. Supraventricular tachycardia	☐	☐
4. Right atrial hypertrophy	☐	☐	20. Ventricular tachycardia	☐	☐
5. Left ventricular hypertrophy	☐	☐	21. Atrial fibrillation	☐	☐
6. Right ventricular hypertrophy	☐	☐	22. Atrial flutter	☐	☐
7. Acute infarction	☐	☐	23. Other rhythm abnormalities	☐	☐
8. Subacute infarction	☐	☐	24. Implanted pacemaker	☐	☐
9. Old infarction	☐	☐	25. 1st degree A-V block	☐	☐
10. Myocardial ischemia	☐	☐	26. 2nd degree A-V block	☐	☐
11. Digitalis effect	☐	☐	27. 3rd degree A-V block	☐	☐
12. Symmetrical T-wave inversions	☐	☐	28. LBB block	☐	☐
13. Poor R-wave progression	☐	☐	29. RBB block	☐	☐
14. Other nonspecific ST/T	☐	☐	30. Pre-excitation syndrome	☐	☐
15. Sinus tachycardia	☐	☐	31. Other intraventricular condition	☐	☐
16. Sinus bradycardia	☐	☐	32. Other, specify _____	☐	☐

C. Ventricular rate (bpm) _____

D. PR (ms) _____

E. QRS (ms) _____

F. QTC (ms) _____

G. Are there any abnormalities noted above that preclude the subject from safe entry into or continuation in the study? ☐ **Yes** ☐ **No**

Screening/Baseline

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

Comments:

Screening/Baseline

Site ID:	Subject ID #.	Subject Initials	Week

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1. Depressed Mood
(sad, 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. Feelings of Guilt

- ☐ 0 = Absent
- ☐ 1 = Self-reproach, feels s/he 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. Suicide

- ☐ 0 = Absent
- ☐ 1 = Feels life is not worth living.
- ☐ 2 = Wishes s/he were dead or any thoughts of possible death to self.
- ☐ 3 = Suicide ideas or gesture.
- ☐ 4 = Attempts at suicide (any serious attempt rates 4).

4. Insomnia Early

- ☐ 0 = No difficulty falling asleep.
- ☐ 1 = Complains of occasional difficulty falling asleep. (i.e., more than ½ hour)
- ☐ 2 = Complains of nightly difficulty falling asleep.

5. 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. 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.

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7. Work and 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 patient, or indirect in listlessness, indecision and vacillation *(feels s/he has to push self to work or activities).*
- ☐ 3 = Decrease in actual time spent in activities or decrease in productivity.
- ☐ 4 = Stopped working because of present illness.

8. 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. Agitation

- ☐ 0 = None
- ☐ 1 = Fidgetiness
- ☐ 2 = Playing with hands, hair, etc.
- ☐ 3 = Moving about, can't sit still
- ☐ 4 = Hand-wringing, nail-biting, hair-pulling, biting of lips

10. 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. Anxiety Somatic

(Physiological concomitants of anxiety such as: Gastrointestinal: dry mouth, wind, indigestion, diarrhea, cramps, belching. Cardiovascular: palpitations, headaches. Respiratory: hyperventilation, sighing. Urinary frequency. Sweating.)

- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Moderate
- ☐ 3 = Severe
- ☐ 4 = Incapacitating

12. Somatic Symptoms Gastrointestinal

- ☐ 0 = None
- ☐ 1 = Loss of appetite but eating without encouragement. Heavy feelings in abdomen.
- ☐ 2 = Difficulty eating without urging. Requests or requires laxatives or medication for bowels or medication for G.I. symptoms.

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13. Somatic Symptoms General

- ☐ 0 = None
- ☐ 1 = Heaviness in limbs, back or head. Backaches, headache, muscle aches. Loss of energy and fatigability.
- ☐ 2 = Any clear-cut symptom rates 2.

14. Genital Symptoms
(such as loss of libido and menstrual disturbances)

- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Severe

15. Hypochondriasis

- ☐ 0 = Not present
- ☐ 1 = Self-absorption (bodily)
- ☐ 2 = Preoccupation with health
- ☐ 3 = Frequent complaints, requests for help, etc.
- ☐ 4 = Hypochondriacal delusions

16. Loss of Weight

- ☐ 0 = No weight loss
- ☐ 1 = Probable weight loss associated with present illness.
- ☐ 2 = Definite weight loss (according to subject)

17. 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

18. Diurnal Variation

- ☐ 0 = No variation
- ☐ 1 = (Mild) Doubtful or slight variation
- ☐ 2 = (Severe) Clear or marked variation

If answer is 1 or 2, note whether the symptoms are worse in: O A.M. O P.M.

19. Depersonalization and Derealization
(symptoms such as feelings of unreality and nihilistic ideas)

- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Moderate
- ☐ 3 = Severe
- ☐ 4 = Incapacitating

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20. Paranoid Symptoms

- ☐ 0 = None
- ☐ 1 = Suspicious
- ☐ 2 = Ideas of reference
- ☐ 3 = Delusions of reference and persecution

21. Obsessive and Compulsive Symptoms

- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Severe

22. 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 chores or personal hygiene.
- ☐ 4 = Despite urging, does not perform necessary chores or personal hygiene.

23. 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. Worthlessness

(ranges from mild loss of self-esteem, feelings of inferiority, self-depreciation (loss of self-esteem) to delusion notions of 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 s/he is “no good,” “inferior,” etc.
- ☐ 4 = Expresses feelings of total worthlessness – e.g. “I am a heap of garbage” or equivalent

Completed by (Initials): _____

Screening/Baseline

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

General Information

G4. Date of admission _____
(mm/dd/yyyy)

G8. Class ☐ Intake ☐ Follow-up

G9. Contact code ☐ In person ☐ Telephone ☐ Mail

G10. Gender ☐ Male ☐ Female

G12. Special ☐ Terminated ☐ Refused ☐ Unable to respond

G14. How long have you lived at your current address? _____ Years _____ Months

G16. Date of birth: _____
(mm/dd/yyyy)

G17. Of what race do you consider yourself?
☐ White (not Hispanic)
☐ Black (not Hispanic)
☐ American Indian
☐ Alaskan Native
☐ Asian/Pacific Islander
☐ Hispanic - Mexican
☐ Hispanic – Puerto Rican
☐ Hispanic - Cuban
☐ Hispanic - Other

G18. Do you have a religious preference?
☐ Protestant
☐ Catholic
☐ Jewish
☐ Islamic
☐ Other
☐ None

G19 Have you been in a controlled environment in the last 30 days?
☐ No
☐ Jail
☐ Alcohol/drug treatment
☐ Medical treatment
☐ Psychiatric treatment
☐ Other _____

G20 How many days? _____

MEDICAL STATUS

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

M3. Do you have any chronic medical problem(s) which continue to interfere with your life?
☐ Yes ☐ No
If "Yes", please specify in 'Comments'.

M4 Are you taking any prescribed medication on a regular basis for a physical problem?
If "Yes", please specify in 'Comments'.
☐ Yes ☐ No

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M5 Do you receive a pension for a physical disability? (Exclude psychiatric disabilities.) ☐ Yes ☐ No

If yes to #M5, please specify in Comments section below.

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

For #M7 and M8 please ask the subject to use the subject rating scale.

M7 How troubled or bothered have you been by these medical problems in the past 30 days?
☐ 0 = Not at all ☐ 1 = Slightly ☐ 2 = Moderately ☐ 3 = Considerably ☐ 4 = Extremely

M8 How important to you now is treatment for these medical problems?
☐ 0 = Not at all ☐ 1 = Slightly ☐ 2 = Moderately ☐ 3 = Considerably ☐ 4 = Extremely

Confidence Ratings

Is the above information significantly distorted by:

M10 Subject's misrepresentation? ☐ Yes ☐ No

M11 Subject's inability to understand? ☐ Yes ☐ No

Comments:

Employment/Support Status

E1* Education completed (GED = 12 years): Years Months

E2* Training or technical education completed: Months

E4 Do you have a valid driver's license? ☐ Yes ☐ No

E5 Do you have an automobile available for use? ☐ Yes ☐ No
Answer "no" if no valid driver's license.

E6. How long was your longest full-time job? Years Months

E7 Usual (or last) occupation:

Hollingshead occupational category: ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9

1 = Higher execs, major professionals, owners of large businesses
2 = Managers of medium sized businesses, nurses, opticians, pharmacists, social workers, teachers
3 = Administrative personnel, managers, owners/proprietors of small businesses (bakery, car dealership, engraving business, florist, decorator, actor, reporter, travel agent)
4 = Clerical and sales, technicians, bank teller, bookkeeper, clerk, draftsperson, timekeeper, secretary
5 = Skilled manual – usually having had training (baker, barber, brakeperson, chef, electrician, fireperson, lineperson, machinist, mechanic, paperhanger, painter, repairperson, tailor, welder, policeperson, 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)
8 = Homemaker
9 = Student, disabled, no occupation

E Does someone contribute the majority of your support? ☐ Yes ☐ No

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E10. Usual employment pattern, past 3 years.

- ☐ 1 = full time (35+ hrs/week)
- ☐ 2 = part time (regular hours)
- ☐ 3 = part time (irregular hours)
- ☐ 4 = student
- ☐ 5 = military service
- ☐ 6 = retired/disabled
- ☐ 7 = unemployed
- ☐ 8 = in controlled environment

E11 How many days were you paid for working in the past 30 days? _____

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

E12 Employment (net income) $ _____

E13 Unemployment compensation $ _____

E14 Welfare $ _____

E15 Pension, benefits or social security $ _____

E16 Mate, family or friends (money for personal expenses) $ _____

E17 Illegal $ _____

E18 How many people depend on you for the majority of their food, shelter, etc.? _____

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

For Questions E20 and E21 please ask the subject to use the subject rating scale.

E20 How troubled or bothered have you been by these employment problems in the past 30 days?
☐ 0 = Not at all ☐ 1 = Slightly ☐ 2 = Moderately ☐ 3 = Considerably ☐ 4 = Extremely

E21 How important to you now is counseling for these employment problems?
☐ 0 = Not at all ☐ 1 = Slightly ☐ 2 = Moderately ☐ 3 = Considerably ☐ 4 = Extremely

Confidence Ratings

Is the above information significantly distorted by:

E23 Subject's misrepresentation? ☐ Yes ☐ No

E24 Subject's inability to understand? ☐ Yes ☐ No

Comments: _____

Screening/Baseline

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____ *(mm/dd/yyyy)*

Drug/Alcohol Abuse

		Days in Past 30 Days	Lifetime Years	Route of Administration (1 = oral, 2 = nasal, 3 = smoking, 4 = non iv inj. 5 = iv inj.)
D1	Alcohol – any use at all			
D2	Alcohol – to intoxication			
D3	Heroin			
D4	Methadone			
D5	Other opiates/analgesics			
D6	Barbiturates			
D7	Other sedatives/hypnotics/tranquilizers			
D8	Cocaine			
D9	Amphetamines			
D10	Cannabis			
D11	Hallucinogens			
D12	Inhalants			
D13	More than one substance per day (including alcohol)			
D17	How many times have you had alcohol DTs?			

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

D19*	Alcohol abuse	
D20*	Drug abuse	

How many times of these were detox only?

D21	Alcohol	
D22	Drugs	

Enter "NN" if answers to Question D19 or D20 = "00"

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

D23	Alcohol	$	
D24	Drugs	$	

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

Screening/Baseline

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

D2 Alcohol problems _____

D2 Drug problems _____

For Questions D28-31 please ask the subject to use the subject rating scale.

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

D28 Alcohol problems
☐ 0 = Not at all ☐ 1 = Slightly ☐ 2 = Moderately ☐ 3 = Considerably ☐ 4 = Extremely

D29 Drug problems
☐ 0 = Not at all ☐ 1 = Slightly ☐ 2 = Moderately ☐ 3 = Considerably ☐ 4 = Extremely

How important to you now is treatment for these:

D30 Alcohol problems
☐ 0 = Not at all ☐ 1 = Slightly ☐ 2 = Moderately ☐ 3 = Considerably ☐ 4 = Extremely

D31 Drug problems
☐ 0 = Not at all ☐ 1 = Slightly ☐ 2 = Moderately ☐ 3 = Considerably ☐ 4 = Extremely

Confidence Ratings

Is the above information significantly distorted by:

D34 Subject's misrepresentation? ☐ Yes ☐ No

D35 Subject's inability to understand? ☐ Yes ☐ No

Comments: _____

Legal Status

L1. Was this admission prompted or suggested by the criminal justice system (judge, probation/parole officer, etc.)? ☐ Yes ☐ No

_____ Are you on probation or parole? ☐ Yes ☐ No

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

L3* Shoplifting/vandalism _____

L4* Parole/probation violation(s) _____

L5* Drug charge(s) _____

L6* Forgery _____

L7* Weapons offense _____

L8* Burglary, larceny, breaking and entering _____

L9* Robbery _____

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L10*	Assault	
L11*	Arson	
L12*	Rape	
L13*	Homicide, manslaughter	
L14*	Prostitution	
L15*	Contempt of court	
L16*	Other, specify: _____	
L17*	How many of these charges resulted in conviction?	

Enter "NN" if no arrests or charges.

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 (reckless driving, speeding, no license, etc.)?	
L21*	How many months were you incarcerated in your life?	Months
L24	Are you presently awaiting charges, trial or sentence? ☐ Yes ☐ No	
L25	What for?	

If multiple charges, use the number of the most severe from above(L3-L16), or use the following codes: 18=disorderly conduct, 19=driving while intoxicated, 20=major driving violation.

L26	How many days in the past 30 were you detained or incarcerated?	
L27	How many days in the past 30 have you engaged in illegal activities for profit?	

For Questions L28 and L29 please ask the subject to use the subject rating scale.

L28 How serious do you feel your present legal problems are?
☐ 0 = Not at all ☐ 1 = Slightly ☐ 2 = Moderately ☐ 3 = Considerably ☐ 4 = Extremely

L29 How important to you now is counseling or referral for these legal problems?
☐ 0 = Not at all ☐ 1 = Slightly ☐ 2 = Moderately ☐ 3 = Considerably ☐ 4 = Extremely

Confidence Ratings

Is the above information significantly distorted by:

L3	Subject's misrepresentation?	☐ Yes	☐ No
L3	Subject's inability to understand?	☐ Yes	☐ No

Comments: _____

Screening/Baseline

Site ID: | Subject ID #. | Subject Initials | Week

Date: *(mm/dd/yyyy)*

Family/Social Relationships

F1 Marital status ☐ Married ☐ Remarried ☐ Widowed ☐ Separated ☐ Divorced ☐ Never Married

F3 Are you satisfied with this situation? ☐ Yes ☐ No ☐ Indifferent

F4* Usual living arrangements (past three years)

☐ 1 = with sexual partner and children ☐ 4 = with parents ☐ 7 = alone
☐ 2 = with sexual partner alone ☐ 5 = with family ☐ 8 = controlled environment
☐ 3 = with children alone ☐ 6 = with friends ☐ 9 = no stable arrangements

F6 Are you satisfied with these living arrangements? ☐ Yes ☐ No ☐ Indifferent

Do you live with anyone who:

F7 Has a current alcohol problem? ☐ Yes ☐ No

F8 Uses non-prescribed drugs? ☐ Yes ☐ No

F9 With whom do you spend most of your free time? ☐ Family ☐ Friends ☐ Alone

F10 Are you satisfied with spending your free time this way? ☐ Yes ☐ No ☐ Indifferent

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

		In the past 30 days			Lifetime		
		Yes	No	N/A	Yes	No	N/A
F18	Mother	☐	☐	☐	☐	☐	☐
F19	Father	☐	☐	☐	☐	☐	☐
F20	Siblings	☐	☐	☐	☐	☐	☐
F21	Sexual partner/ Spouse	☐	☐	☐	☐	☐	☐
F22	Children	☐	☐	☐	☐	☐	☐
F23	Other significant family	☐	☐	☐	☐	☐	☐
	Please specify if "Yes":						
F24	Close friends	☐	☐	☐	☐	☐	☐
F25	Neighbors	☐	☐	☐	☐	☐	☐
F26	Co-workers	☐	☐	☐	☐	☐	☐

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Did anyone abuse you?

F2 Physically (caused you physical harm)
In the past 30 days ☐ Yes ☐ No Lifetime ☐ Yes ☐ No

F2 Sexually (forced sexual advances or sexual acts)
In the past 30 days ☐ Yes ☐ No Lifetime ☐ Yes ☐ No

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

F30 With your family:

F31 With other people excluding family:

For Questions F32-35 please ask the subject to use the subject rating scale.
How troubled or bothered have you been in the past 30 days by these:

F32 Family problems
☐ 0 = Not at all ☐ 1 = Slightly ☐ 2 = Moderately ☐ 3 = Considerably ☐ 4 = Extremely

F33 Social problems
☐ 0 = Not at all ☐ 1 = Slightly ☐ 2 = Moderately ☐ 3 = Considerably ☐ 4 = Extremely

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

F34 Family problems
☐ 0 = Not at all ☐ 1 = Slightly ☐ 2 = Moderately ☐ 3 = Considerably ☐ 4 = Extremely

F35 Social problems
☐ 0 = Not at all ☐ 1 = Slightly ☐ 2 = Moderately ☐ 3 = Considerably ☐ 4 = Extremely

Confidence Ratings

Is the above information significantly distorted by:

F3 Subject's misrepresentation? ☐ Yes ☐ No

F3 Subject's inability to understand? ☐ Yes ☐ No

Comments:

Psychiatric Status

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

P1 In a hospital or inpatient setting

P2 As an outpatient or private patient

P Do you receive a pension for a psychiatric disability? ☐ Yes ☐ No

Screening/Baseline

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

		In the past 30 days		Lifetime	
P4	Experienced serious depression (sadness, hopelessness, loss of interest, difficulty with daily functioning)?	☐ Yes	☐ No	☐ Yes	☐ No
P5	Experienced serious anxiety/tension (uptight, unreasonably worried, inability to feel relaxed)?	☐ Yes	☐ No	☐ Yes	☐ No
P6	Experienced hallucinations (saw things or heard voices that were not there)?	☐ Yes	☐ No	☐ Yes	☐ No
P7	Experienced trouble understanding, concentrating, or remembering?	☐ Yes	☐ No	☐ Yes	☐ No

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

P8	Experienced trouble controlling violent behavior?	☐ Yes	☐ No	☐ Yes	☐ No
P9	Experienced serious thoughts of suicide?	☐ Yes	☐ No	☐ Yes	☐ No
P10	Attempted suicide?	☐ Yes	☐ No	☐ Yes	☐ No
P11	Been prescribed medication for any psychological or emotional problem?	☐ Yes	☐ No	☐ Yes	☐ No

P12 How many days in the past 30 have you experienced these psychological or emotional problems? _____

For Questions P13 and P14 please ask the subject to use the subject rating scale.

P13 How much have you been troubled or bothered by these psychological or emotional problems in the past 30 days?

☐ 0 = Not at all ☐ 1 = Slightly ☐ 2 = Moderately ☐ 3 = Considerably ☐ 4 = Extremely

P14 How important to you now is treatment for these psychological problems?

☐ 0 = Not at all ☐ 1 = Slightly ☐ 2 = Moderately ☐ 3 = Considerably ☐ 4 = Extremely

Confidence Ratings

Is the above information significantly distorted by:

P22	Subject's misrepresentation?	☐ Yes	☐ No
P23	Subject's inability to understand?	☐ Yes	☐ No

Comments: _____

Completed by (Initials): _____

Screening/Baseline

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Ask subject to read each of the items and choose only one answer for each question

Drug Use

1. How many times have you hit up (i.e. injected any drugs) in the last month?
   - ☐ I haven't hit up
     If you have not injected drugs in the last month, go to Question 7.
   - ☐ Once a week or less
   - ☐ More than once a week but less than once a day
   - ☐ Once a day
   - ☐ 2--3 times a day
   - ☐ More than three times a day
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 past month?
   - ☐ None
   - ☐ One person
   - ☐ Two people
   - ☐ 3-5 people
   - ☐ 6-10 people
   - ☐ More than 10 people
4. How many times in the last month has someone used a needle after you?
   - ☐ 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?
   - ☐ I do not re-use
   - ☐ Every time
   - ☐ Often
   - ☐ Sometimes
   - ☐ Rarely
   - ☐ Never
6. Before using needles again, how often in the past month did you use bleach to clean them?
   - ☐ I do not re-use
   - ☐ Every time
   - ☐ Often
   - ☐ Sometimes
   - ☐ Rarely
   - ☐ Never

Screening/Baseline

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Sexual Behavior

7. How many people, including clients, have you had sex with in the last month?
   - ☐ None

   If you have not had sex in the last month, skip to Question 12.
   - ☐ One
   - ☐ Two
   - ☐ 3-5 people
   - ☐ 6-10 people
   - ☐ More than 10 people

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

9. How often have you used condoms when you had sex with casual partners?
   - ☐ No casual partner/no penetrative sex
   - ☐ Every time
   - ☐ Often
   - ☐ Sometimes
   - ☐ Rarely
   - ☐ Never

10. How often have you used condoms when you have been paid for sex in the last month?
   - ☐ No paid partner/no penetrative sex
   - ☐ Every time
   - ☐ Often
   - ☐ Sometimes
   - ☐ Rarely
   - ☐ Never

11. How many times have you had anal sex in the last month?
   - ☐ No times
   - ☐ One time
   - ☐ Two times
   - ☐ 3-5 times
   - ☐ 6-10 times
   - ☐ More than 10 times

Everyone should answer Question 12.

12. Have you had an HIV test come back positive?
   - ☐ Yes
   - ☐ No
   - ☐ Don't know

Completed by (Initials): _____

Screening/Baseline

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Indicate how much you agree or disagree with each of the following statements by circling the number which best shows how you feel. The lower the number, the more you disagree; the higher the number, the more you agree with the statement. Please complete every item. We are interested in how you are thinking or feeling RIGHT NOW as you are filling out the questionnaire.

	Strongly Disagree						**Strongly Agree**
1. If I were using cocaine, I could think more clearly.	1	2	3	4	5	6	7
2. Right now I am not making plans to use “coke.”	1	2	3	4	5	6	7
3. My desire to use cocaine seems overpowering.	1	2	3	4	5	6	7
4. I am thinking of ways to get cocaine.	1	2	3	4	5	6	7
5. I don’t want to use “coke”.	1	2	3	4	5	6	7
6. If I were offered some “coke”, I would use it immediately.	1	2	3	4	5	6	7
7. Using cocaine would make me feel less depressed.	1	2	3	4	5	6	7
8. I could easily control how much cocaine I use right now.	1	2	3	4	5	6	7
9. I crave “coke” right now.	1	2	3	4	5	6	7
10. Using cocaine would make me feel powerful.	1	2	3	4	5	6	7
11. If there were cocaine in front of me, it would be hard not to use it.	1	2	3	4	5	6	7
12. Using cocaine would not help me calm down right now.	1	2	3	4	5	6	7
13. I would feel very alert if I used cocaine right now.	1	2	3	4	5	6	7
14. If I had the chance to use “coke”, I don’t think I would use it.	1	2	3	4	5	6	7
15. I would not enjoy using cocaine right now.	1	2	3	4	5	6	7
16. I would do almost anything for cocaine right now.	1	2	3	4	5	6	7
17. I could control things better right now if I could use cocaine.	1	2	3	4	5	6	7
18. Even if it were possible, I probably would not use cocaine right now.	1	2	3	4	5	6	7
19. Using “coke” would not be pleasant.	1	2	3	4	5	6	7
20. I think that I could resist using “coke” right now.	1	2	3	4	5	6	7

Screening/Baseline

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

	Strongly Disagree						**Strongly Agree**
21. I have an urge for cocaine.	1	2	3	4	5	6	7
22. I would not be able to control how much cocaine I used if I had some here.	1	2	3	4	5	6	7
23. Starting now, I could go without using cocaine for long time.	1	2	3	4	5	6	7
24. I would be less irritable now if I could use cocaine.	1	2	3	4	5	6	7
25. I would feel energetic if I used cocaine.	1	2	3	4	5	6	7
26. All I want to use right now is cocaine.	1	2	3	4	5	6	7
27. Using cocaine would not sharpen my concentration.	1	2	3	4	5	6	7
28. I do not need to use cocaine now.	1	2	3	4	5	6	7
29. It would be difficult to turn down cocaine this minute.	1	2	3	4	5	6	7
30. If I use cocaine right now, I would not feel less restless.	1	2	3	4	5	6	7
31. I will use cocaine as soon as I get a chance.	1	2	3	4	5	6	7
32. Using cocaine now would make things seem just perfect.	1	2	3	4	5	6	7
33. I want to use cocaine so bad that I can almost taste it.	1	2	3	4	5	6	7
34. Nothing would be better than using “coke” right now.	1	2	3	4	5	6	7
35. If I used cocaine, my anger would not decrease.	1	2	3	4	5	6	7
36. It would be easy to pass up the chance to use cocaine.	1	2	3	4	5	6	7
37. I am going to use cocaine as soon as possible.	1	2	3	4	5	6	7
38. I have no desire for cocaine right now.	1	2	3	4	5	6	7
39. I could not stop myself from using cocaine if I had some here now.	1	2	3	4	5	6	7
40. Using “coke” right now would make me feel less tired.	1	2	3	4	5	6	7
41. Using cocaine would not be very satisfying right now.	1	2	3	4	5	6	7
42. If I tried a little “coke” now, I would not be able to stop using more of it.	1	2	3	4	5	6	7
43. I would not feel less anxious if I used “coke”.	1	2	3	4	5	6	7
44. I am not missing using cocaine now.	1	2	3	4	5	6	7
45. If I had some “coke” with me right now, I probably would not use it.	1	2	3	4	5	6	7

Completed by (Initials): _____

Screening/Baseline

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

Did Subject receive HIV Counseling during Screening?

(If No, please comment below) ☐ Yes ☐ No

Additional comments:

Completed by (Initials): _____

Screening/Baseline Week -3 V1

Site ID:	Subject ID #.	Subject Initials	Week

Date:

First Study Visit of Week

☐ Vital signs not assessed at this visit

Date _____ *(mm/dd/yyyy)* Time Vital Signs taken _____ *(24 hour clock)*

Temperature (oral) _____ NR: 94-100.4 CS ☐ NCS ☐

Comments for Temperature

Blood Pressure (sitting) _____ _____ (mm Hg) NR: 90-140/50-90 CS ☐ NCS ☐

Comments for Blood Pressure:

Pulse Rate (sitting) _____ (beats/min) NR: 50-120 CS ☐ NCS ☐

Comments for Pulse Rate:

Respiratory Rate (sitting) _____ (breaths/min) NR: 8-20 CS ☐ NCS ☐

Comments for Respiratory Rate:

Completed by (Initials): _____

Screening/Baseline Week -3 V2

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

Second Study Visit of Week

☐ Vital signs not assessed at this visit

Date _____ *(mm/dd/yyyy)* Time Vital Signs taken _____ *(24 hour clock)*

Temperature (oral) _____ NR: 94-100.4 CS ☐ NCS ☐

Comments for Temperature

Blood Pressure (sitting) _____ _____ (mm Hg) NR: 90-140/50-90 CS ☐ NCS ☐

Comments for Blood Pressure:

Pulse Rate (sitting) _____ (beats/min) NR: 50-120 CS ☐ NCS ☐

Comments for Pulse Rate:

Respiratory Rate (sitting) _____ (breaths/min) NR: 8-20 CS ☐ NCS ☐

Comments for Respiratory Rate:

Completed by (Initials): _____

Screening/Baseline Week -3 V3

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____

(mm/dd/yyyy)

Third Study Visit of Week

☐ Vital signs not assessed at this visit

Date _____ *(mm/dd/yyyy)* Time Vital Signs taken _____ *(24 hour clock)*

Temperature (oral) _____ NR: 94-100.4 CS ☐ NCS ☐

Comments for Temperature

Blood Pressure (sitting) _____ _____ (mm Hg) NR: 90-140/50-90 CS ☐ NCS ☐

Comments for Blood Pressure:

Pulse Rate (sitting) _____ (beats/min) NR: 50-120 CS ☐ NCS ☐

Comments for Pulse Rate:

Respiratory Rate (sitting) _____ (breaths/min) NR: 8-20 CS ☐ NCS ☐

Comments for Respiratory Rate:

Completed by (Initials): _____

Screening/Baseline Week -3 V1

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____

(mm/dd/yyyy)

First Study Visit of Week Urine bar code sticker: _____

Date urine collected _____ *(mm/dd/yyyy)* Urine not collected ☐

Was urine temperature within expected range? ☐ Yes ☐ No

Franklin Cup: The temperature must be higher than 96.0 ° F and lower than 104.8 ° F
On-Trak Cup: The temperature must be higher than 90.0 ° F and lower than 99.0 ° F Split
Sample Cup: The temperature must be higher than 90.0 ° F and lower than 100.0 ° F

Results:

☐ Cocaine Positive	☐ Cocaine Negative	
☐ Amphetamine Positive	☐ Amphetamine Negative	☐ Not Completed
☐ Benzodiazepine Positive	☐ Benzodiazepine Negative	☐ Not Completed
☐ Barbiturates Positive	☐ Barbiturates Negative	☐ Not Completed
☐ Opiates Positive	☐ Opiates Negative	☐ Not Completed

Completed by (Initials): _____

Screening/Baseline Week –3 V2

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

Second Study Visit of Week Urine bar code sticker: _____

Date urine collected _____ Urine not collected ☐
(mm/dd/yyyy)

Was urine temperature within expected range? ☐ Yes ☐ No

Franklin Cup: The temperature must be higher than 96.0 ° F and lower than 104.8 ° F On-Trak Cup: The temperature must be higher than 90.0 ° F and lower than 99.0 ° F Split Sample Cup: The temperature must be higher than 90.0 ° F and lower than 100.0 ° F

Results:

☐ Cocaine Positive	☐ Cocaine Negative	
☐ Amphetamine Positive	☐ Amphetamine Negative	☐ Not Completed
☐ Benzodiazepine Positive	☐ Benzodiazepine Negative	☐ Not Completed
☐ Barbiturates Positive	☐ Barbiturates Negative	☐ Not Completed
☐ Opiates Positive	☐ Opiates Negative	☐ Not Completed

Completed by (Initials): _____

Screening/Baseline Week –3 V3

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

Third Study Visit of Week Urine bar code sticker*:* _____

Date urine collected _____ Urine not collected ☐
(mm/dd/yyyy)

Was urine temperature within expected range? ☐ Yes ☐ No

Franklin Cup: The temperature must be higher than 96.0 ° F and lower than 104.8 ° F On-Trak Cup: The temperature must be higher than 90.0 ° F and lower than 99.0 ° F Split Sample Cup: The temperature must be higher than 90.0 ° F and lower than 100.0 ° F

Results:

☐ Cocaine Positive	☐ Cocaine Negative	
☐ Amphetamine Positive	☐ Amphetamine Negative	☐ Not Completed
☐ Benzodiazepine Positive	☐ Benzodiazepine Negative	☐ Not Completed
☐ Barbiturates Positive	☐ Barbiturates Negative	☐ Not Completed
☐ Opiates Positive	☐ Opiates Negative	☐ Not Completed

Completed by (Initials): _____

NIDA-MDS-Modaf-0001 **Form 24 – SUBSTANCE USE INVENTORY**

Screening/Baseline Week -3

Site ID: | Subject ID #. | Subject Initials | Week

Date: *(mm/dd/yyyy)*

Using timeline follow-back method, record whether subject has on each day since the last visit used any amount of the substances listed below, along with the most common route of administration for each drug. Begin with yesterday and work back to the last visit. Please be sure that days are continuous with last week's form.

Date of last visit: *(mm/dd/yyyy)*

Day of week

Date

	Used? ROA	Used? ROA	Used? ROA	Used? ROA	Used? ROA	Used? ROA	Used? ROA
Cocaine	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Alcohol	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Marijuana	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Amphetamines	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Opiates	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Barbiturates	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Benzodiazepines	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N

Route of administration (ROA) codes: 1 = oral, 2 = nasal, 3 = smoking, 4 = non-intravenous injection, 5 = intravenous injection

Completed by (Initials):

Screening/Baseline -3

Site ID: | Subject ID #. | Subject Initials | Week

Date: *(mm/dd/yyyy)*

Cocaine

1. The intensity of my craving, that is, how much I desired cocaine in the past 24 hours was:

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

2. The frequency of my craving, that is, how often I desired cocaine in the past 24 hours was:

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

3. The length of time I spent craving for cocaine during the past 24 hours was:

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

4. Write in the number of times you think you had craving for cocaine during the past 24 hours:

5. Write in the total time spent craving cocaine during the past 24 hours:

hours minutes

6. The worst day: During the past week my most intense craving occurred on the following day:

☐ Sunday ☐ Monday ☐ Tuesday ☐ Wednesday
☐ Thursday ☐ Friday ☐ Saturday ☐ All days the same (go to Q. 8)

7. The date for that day was:

(mm/dd/yyyy)

8. The intensity of my craving, that is, how much I desired cocaine on that worst day was:

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

Second Drug

9. A **2nd** craved drug during the past 24 hours was:
Mark only one of the following. If no 2nd craved drug, mark "None" and leave Questions 10-16 blank.

☐ None ☐ Downers or Sedatives (Barbiturates, etc.) ☐ Benzos (Valium, Xanax, etc.) ☐ Nicotine
☐ Alcohol ☐ Heroin or other Opiates (Morphine, etc.) ☐ Marijuana ☐ Other Specify

10. The intensity of my craving, that is, how much I desired this **second** drug in the past 24 hours was:

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

Screening/Baseline -3

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

11. The frequency of my craving, that is, how often I desired this **second** drug in the past 24 hours was:

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

12. The length of time I spent in craving for this **second** drug during the past 24 hours was:

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

Third Drug

13. A **3rd** craved drug during the past 24 hours was:
Mark only one of the following. If no 3rd craved drug, mark "None" and leave questions 14-16 blank.

☐ None ☐ Downers or Sedatives (Barbiturates, etc.) ☐ Benzos (Valium, Xanax, etc.) ☐ Nicotine

☐ Alcohol ☐ Heroin or other Opiates (Morphine, etc.) ☐ Marijuana ☐ Other Specify _____

14. The intensity of my craving, that is, how much I desired this **third** drug in the past 24 hours was:

☐ 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:

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

16. The length of time I spent in craving for this third drug during the past 24 hours was:

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

Completed by (Initials): _____

Screening/Baseline Week -3

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

All questions except 4 and 5 are assessed by properly trained personnel. The subject is asked about each of the items in lay language and the response is recorded on a scale of 0-7 with 0 being normal or no symptoms. For question 4 and 5, the subject is asked to mark the appropriate place on the line (on page 3) that describes each of the questions. The rater then transcribes that as the response to those questions.

Date of last cocaine use: _____
(mm/dd/yyyy)

1. Hyperphagia _____

0 = normal appetite
3-4 = eats a lot more than usual
7 = eats more than twice usual amount of food

2. Hypophagia _____

0 = normal appetite
3-4 = eats less than half of normal amount of food
7 = no appetite at all

3. Carbohydrate Craving _____

0 = no craving
3-4 = strong craving for sweets, cakes, and cookies half the time
7 = strong craving for sweets, cakes, and cookies all the time

4. Cocaine Craving Intensity _____
Please use subject intensity rating from pg. 3 of this form.

5. Cocaine Craving Frequency _____
Please use subject frequency rating from pg. 3 of this form.

6. Bradycardia _____
Please use scale below.

	0	1	2	3	4	5	6	7
Pulse (BPM)	>64	64-63	62-61	60-59	58-57	56-55	54-53	<53

7. Insomnia _____

0 = normal amount of sleep
3-4 = half of normal amount of sleep
7 = no sleep at all

8. Hypersomnia _____

0 = normal amount of sleep
3-4 = could sleep or does sleep half the day
7 = sleep or could sleep all the time

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

9. Anxiety ☐

0 = usually does not feel anxious
3-4 = feels anxious half the time
7 = feels anxious all the time

10. Energy Level ☐

0 = feels alert and has usual amount of energy
3-4 = feels tired half the time
7 = feels tired all the time

11. Activity Level ☐

0 = no change in usual activities
3-4 = participates in half of usual activities
7 = no participation in usual activities

12. Tension ☐

0-1 = rarely feel tense
3-4 = feels tense half the time
7 = feels tense most or all the time

13. Attention ☐

0 = able to concentrate on reading, conversation, tasks, and make plans without difficulty
3-4 = has difficulty with the above half the time
7 = has difficulty with the above all the time

14. Paranoid Ideation ☐

0 = no evidence of paranoid thoughts
3-4 = unable to trust anyone
5 = feels people are out to get him/her
7 = feels a specific person/group is plotting against him/her

15. Anhedonia ☐

0 = ability to enjoy themselves remains unchanged
3-4 = able to enjoy themselves half of the time
7 = unable to enjoy themselves at all

16. Depression ☐

0 = no feelings related to sadness or depression
3-4 = feels sad or depressed half the time
7 = feels depressed all of the time

17. Suicidality ☐

0 = does not think about being dead
3-4 = feels like life is not worth living
7 = feels like actually ending life

18. Irritability ☐

0 = feels that most things are not irritating
3-4 = feels that many things are irritating
7 = feels that mostly everything is irritating and upsetting

Completed by (Initials): _____

Screening/Baseline Week -3

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

CSSA VISUAL ANALOG SCALE

Please do not mark on upright lines.

Please rate the highest intensity of the desire for cocaine you have felt in the last 24 hours:

|____|____|____|____|____|____|____|____|

No Desire at all ***Unable to Resist***

Please identify on the line below, how often you have felt the urge to use cocaine in the last 24 hours:

|____|____|____|____|____|____|____|____|

Never ***All the Time***

Screening/Baseline Week -3

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

Cocaine Global Severity

At this time, how would you rate yourself overall for cocaine use and cocaine related problems?

- ☐ No problems
- ☐ Borderline problems
- ☐ Mild problems
- ☐ Moderate problems
- ☐ Marked problems
- ☐ Severe symptoms
- ☐ Most extreme problems possible

Global Improvement of Cocaine Dependence

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

- ☐ Not assessed
- ☐ Very much improved
- ☐ Much improved
- ☐ Minimally improved
- ☐ No change
- ☐ Minimally worse
- ☐ Much worse
- ☐ Very much worse

Completed by (Initials): _____

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

Current Severity

Please rate the subject's current severity in the eight specific problem areas below.

	None, Least Severe						**Most Severe**
Reported Cocaine Use: (frequency and amount of cocaine used)	1	2	3	4	5	6	7
Cocaine Seeking: (craving for cocaine, effort to stop, and drug seeking behavior)	1	2	3	4	5	6	7
Reported Use of Other Drugs: (frequency and amount of non-cocaine drug/alcohol use)	1	2	3	4	5	6	7
Observable Psychiatric Symptoms: (orientation, memory, comprehension, disorganized thinking, rapid/retarded speech, agitation, grooming, hostility, irritability, affective disturbance)	1	2	3	4	5	6	7
Reported Psychiatric Symptoms: (mood disturbance, depression, anxiety,inner restlessness, covert anger, somatic symptoms, energy level,motivation, sleep, appetite, libido, anhedonia)	1	2	3	4	5	6	7
Physical/Medical Problems: (those that have emerged or gotten worse after drug use)	1	2	3	4	5	6	7
Maladaptive Coping in the Family/Social area: (movement away from healthy relationships)	1	2	3	4	5	6	7
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

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

Global Severity of Cocaine Dependence

Considering your total clinical experience with the cocaine dependent population, how severe are this subject's cocaine dependence symptoms at this time?

- ☐ Normal, no symptoms
- ☐ Borderline symptoms
- ☐ Mild symptoms
- ☐ Moderate symptoms
- ☐ Marked symptoms
- ☐ Severe symptoms
- ☐ Most extreme symptoms possible

Global Improvement of Cocaine Dependence

Rate the total improvement in the participant's cocaine dependence symptoms whether or not, in your judgment, it is due entirely to drug treatment. Compared to the subject's admission to the project, how
much has the subject changed?

- ☐ Not assessed, first rating
- ☐ Very much improved
- ☐ Much improved
- ☐ Minimally improved
- ☐ No change
- ☐ Minimally worse
- ☐ Much worse
- ☐ Very much worse

Completed by (Initials): _____

Screening/Baseline week –2 V1

Site ID:	Subject ID #.	Subject Initials	Week

Date:

First Study Visit of Week

☐ Vital signs not assessed at this visit

Date _____ *(mm/dd/yyyy)* Time Vital Signs taken _____ *(24 hour clock)*

Temperature (oral) _____ (°F) NR: 94-100.4 CS ☐ NCS ☐

Comments for Temperature

Blood Pressure (sitting) _____ _____ (mm Hg) NR: 90-140/50-90 CS ☐ NCS ☐

Comments for Blood Pressure:

Pulse Rate (sitting) _____ (beats/min) NR: 50-120 CS ☐ NCS ☐

Comments for Pulse Rate:

Respiratory Rate (sitting) _____ (breaths/min) NR: 8-20 CS ☐ NCS ☐

Comments for Respiratory Rate:

Completed by (Initials): _____

Screening/Baseline week –2 V2

Site ID:	Subject ID #.	Subject Initials	Week

Date:

Second Study Visit of Week

☐ Vital signs not assessed at this visit

Date _____ *(mm/dd/yyyy)* Time Vital Signs taken _____ *(24 hour clock)*

Temperature (oral) _____ (°F) NR: 94-100.4 CS ☐ NCS ☐

Comments for Temperature

Blood Pressure (sitting) _____/_____ (mm Hg) NR: 90-140/50-90 CS ☐ NCS ☐

Comments for Blood Pressure:

Pulse Rate (sitting) _____ (beats/min) NR: 50-120 CS ☐ NCS ☐

Comments for Pulse Rate:

Respiratory Rate (sitting) _____ (breaths/min) NR: 8-20 CS ☐ NCS ☐

Comments for Respiratory Rate:

Completed by (Initials): _____

Screening/Baseline week –2 V3

Site ID:	Subject ID #.	Subject Initials	Week

Date:

Third Study Visit of Week

☐ Vital signs not assessed at this visit

Date _____ *(mm/dd/yyyy)* Time Vital Signs taken _____ *(24 hour clock)*

Temperature (oral) _____ (°F) NR: 94-100.4 CS ☐ NCS ☐

Comments for Temperature

Blood Pressure (sitting) _____/_____ (mm Hg) NR: 90-140/50-90 CS ☐ NCS ☐

Comments for Blood Pressure:

Pulse Rate (sitting) _____ (beats/min) NR: 50-120 CS ☐ NCS ☐

Comments for Pulse Rate:

Respiratory Rate (sitting) _____ (breaths/min) NR: 8-20 CS ☐ NCS ☐

Comments for Respiratory Rate:

Completed by (Initials): _____

Form 22 – URINE BE and TOX. SPECIMEN COLLECTION FORM

Screening/Baseline Week -2 V1

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

First Study Visit of Week ***Urine bar code sticker:*** _____

Date urine collected: _____ Urine not collected ☐
(mm/dd/yyyy)

Was urine temperature within expected range? ☐ Yes ☐ No

Franklin Cup: The temperature must be higher than 96.0 ° F and lower than 104.8 ° F On-Trak Cup: The temperature must be higher than 90.0 ° F and lower than 99.0 ° F Split Sample Cup: The temperature must be higher than 90.0 ° F and lower than 100.0 ° F

Results:

☐ Cocaine Positive	☐ Cocaine Negative	
☐ Amphetamine Positive	☐ Amphetamine Negative	☐ Not Completed
☐ Benzodiazepine Positive	☐ Benzodiazepine Negative	☐ Not Completed
☐ Barbiturates Positive	☐ Barbiturates Negative	☐ Not Completed
☐ Opiates Positive	☐ Opiates Negative	☐ Not Completed

Completed by (Initials): _____

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

Second Study Visit of Week ***Urine bar code sticker:*** _____

Date urine collected: _____ Urine not collected ☐
(mm/dd/yyyy)

Was urine temperature within expected range? ☐ Yes ☐ No

Franklin Cup: The temperature must be higher than 96.0 ° F and lower than 104.8 ° F On-Trak Cup: The temperature must be higher than 90.0 ° F and lower than 99.0 ° F Split Sample Cup: The temperature must be higher than 90.0 ° F and lower than 100.0 ° F

Results:

☐ Cocaine Positive	☐ Cocaine Negative	
☐ Amphetamine Positive	☐ Amphetamine Negative	☐ Not Completed
☐ Benzodiazepine Positive	☐ Benzodiazepine Negative	☐ Not Completed
☐ Barbiturates Positive	☐ Barbiturates Negative	☐ Not Completed
☐ Opiates Positive	☐ Opiates Negative	☐ Not Completed

Completed by (Initials): _____

NIDA-MDS-Modaf-0001

Form 22 – URINE BE and TOX. SPECIMEN COLLECTION FORM

Screening/Baseline Week -2 V3

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

Third Study Visit of Week ***Urine bar code sticker:*** _____

Date urine collected _____ Urine not collected ☐
(mm/dd/yyyy)

Was urine temperature within expected range? ☐ Yes ☐ No

Franklin Cup: The temperature must be higher than 96.0 ° F and lower than 104.8 ° F On-Trak Cup: The temperature must be higher than 90.0 ° F and lower than 99.0 ° F Split Sample Cup: The temperature must be higher than 90.0 ° F and lower than 100.0 ° F

Results:

☐ Cocaine Positive	☐ Cocaine Negative	
☐ Amphetamine Positive	☐ Amphetamine Negative	☐ Not Completed
☐ Benzodiazepine Positive	☐ Benzodiazepine Negative	☐ Not Completed
☐ Barbiturates Positive	☐ Barbiturates Negative	☐ Not Completed
☐ Opiates Positive	☐ Opiates Negative	☐ Not Completed

Completed by (Initials): _____

Screening/Baseline Week -2

Site ID: | Subject ID #. | Subject Initials | Week

Date: (mm/dd/yyyy)

Using timeline follow-back method, record whether subject has on each day since the last visit used any amount of the substances listed below, along with the most common route of administration for each drug. Begin with yesterday and work back to the last visit. Please be sure that days are continuous with last week's form.

Date of last visit: (mm/dd/yyyy)

Day of week							
Date							
	Used? ROA	**Used? ROA**	**Used? ROA**	**Used? ROA**	**Used? ROA**	**Used? ROA**	**Used? ROA**
Cocaine	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Alcohol	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Marijuana	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Amphetamines	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Opiates	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Barbiturates	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Benzodiazepines	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N

Route of administration (ROA) codes: 1 = oral, 2 = nasal, 3 = smoking, 4 = non-intravenous injection, 5 = intravenous injection

Completed by (Initials):

Screening/Baseline Week -2

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

Cocaine

1. The intensity of my craving, that is, how much I desired cocaine in the past 24 hours was:

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

2. The frequency of my craving, that is, how often I desired cocaine in the past 24 hours was:

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

3. The length of time I spent craving for cocaine during the past 24 hours was:

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

4. Write in the number of times you think you had craving for cocaine during the past 24 hours:

☐

5. Write in the total time spent craving cocaine during the past 24 hours:

☐ hours ☐ minutes

6. The worst day: During the past week my most intense craving occurred on the following day:

☐ Sunday ☐ Monday ☐ Tuesday ☐ Wednesday
☐ Thursday ☐ Friday ☐ Saturday ☐ All days the same (go to Q. 8)

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

8. The intensity of my craving, that is, how much I desired cocaine on that worst day was:

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

Second Drug

9. A **2nd** craved drug during the past 24 hours was:
Mark only one of the following. If no 2nd craved drug, mark "None" and leave Questions 10-16 blank.

☐ None
☐ Alcohol
☐ Downers or Sedatives (Barbiturates, etc.)
☐ Heroin or other Opiates (Morphine, etc.)
☐ Benzos (Valium, Xanax, etc.)
☐ Marijuana
☐ Nicotine
☐ Other Specify ☐

10. The intensity of my craving, that is, how much I desired this **second** drug in the past 24 hours was:

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

Screening/Baseline Week -2

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

11. The frequency of my craving, that is, how often I desired this **second** drug in the past 24 hours was:

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

12. The length of time I spent in craving for this **second** drug during the past 24 hours was:

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

Third Drug

13. A **3rd** craved drug during the past 24 hours was:
Mark only one of the following. If no 3rd craved drug, mark "None" and leave questions 14-16 blank.

☐ None ☐ Downers or Sedatives (Barbiturates, etc.) ☐ Benzos (Valium, Xanax, etc.) ☐ Nicotine
☐ Alcohol ☐ Heroin or other Opiates (Morphine, etc.) ☐ Marijuana ☐ Other Specify _____

14. The intensity of my craving, that is, how much I desired this **third** drug in the past 24 hours was:

☐ 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:

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

16. The length of time I spent in craving for this third drug during the past 24 hours was:

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

Completed by (Initials): _____

Screening/Baseline Week -2

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

All questions except 4 and 5 are assessed by properly trained personnel. The subject is asked about each of the items in lay language and the response is recorded on a scale of 0-7 with 0 being normal or no symptoms. For question 4 and 5, the subject is asked to mark the appropriate place on the line (on page 3) that describes each of the questions. The rater then transcribes that as the response to those questions.

Date of last cocaine use: _____
(mm/dd/yyyy)

1. Hyperphagia _____

0 = normal appetite
3-4 = eats a lot more than usual
7 = eats more than twice usual amount of food

2. Hypophagia _____

0 = normal appetite
3-4 = eats less than half of normal amount of food
7 = no appetite at all

3. Carbohydrate Craving _____

0 = no craving
3-4 = strong craving for sweets, cakes, and cookies half the time
7 = strong craving for sweets, cakes, and cookies all the time

4. Cocaine Craving Intensity _____ ***Please use subject intensity rating from pg. 3 of this form.***

5. Cocaine Craving Frequency _____ ***Please use subject frequency rating from pg. 3 of this form.***

6. Bradycardia _____ ***Please use scale below.***

	0	1	2	3	4	5	6	7
Pulse (BPM)	>64	64-63	62-61	60-59	58-57	56-55	54-53	<53

7. Insomnia _____

0 = normal amount of sleep
3-4 = half of normal amount of sleep
7 = no sleep at all

8. Hypersomnia _____

0 = normal amount of sleep
3-4 = could sleep or does sleep half the day
7 = sleep or could sleep all the time

Screening/Baseline Week -2

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

9. Anxiety _____

0 = usually does not feel anxious
3-4 = feels anxious half the time
7 = feels anxious all the time

10. Energy Level _____

0 = feels alert and has usual amount of energy
3-4 = feels tired half the time
7 = feels tired all the time

11. Activity Level _____

0 = no change in usual activities
3-4 = participates in half of usual activities
7 = no participation in usual activities

12. Tension _____

0-1 = rarely feel tense
3-4 = feels tense half the time
7 = feels tense most or all the time

13. Attention _____

0 = able to concentrate on reading, conversation, tasks, and make plans without difficulty
3-4 = has difficulty with the above half the time
7 = has difficulty with the above all the time

14. Paranoid Ideation _____

0 = no evidence of paranoid thoughts
3-4 = unable to trust anyone
5 = feels people are out to get him/her
7 = feels a specific person/group is plotting against him/her

15. Anhedonia _____

0 = ability to enjoy themselves remains unchanged
3-4 = able to enjoy themselves half of the time
7 = unable to enjoy themselves at all

16. Depression _____

0 = no feelings related to sadness or depression
3-4 = feels sad or depressed half the time
7 = feels depressed all of the time

17. Suicidality _____

0 = does not think about being dead
3-4 = feels like life is not worth living
7 = feels like actually ending life

18. Irritability _____

0 = feels that most things are not irritating
3-4 = feels that many things are irritating
7 = feels that mostly everything is irritating and upsetting

Completed by (Initials): _____

Screening/Baseline Week -2

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

CSSA VISUAL ANALOG SCALE

Please do not mark on upright lines.

Please rate the highest intensity of the desire for cocaine you have felt in the last 24 hours:

|____|____|____|____|____|____|____|____|

No Desire at all ***Unable to Resist***

Please identify on the line below, how often you have felt the urge to use cocaine in the last 24 hours:

|____|____|____|____|____|____|____|____|

Never ***All the Time***

Screening/Baseline Week -2

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

Cocaine Global Severity

At this time, how would you rate yourself overall for cocaine use and cocaine related problems?

- ☐ No problems
- ☐ Borderline problems
- ☐ Mild problems
- ☐ Moderate problems
- ☐ Marked problems
- ☐ Severe symptoms
- ☐ Most extreme problems possible

Global Improvement of Cocaine Dependence

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

- ☐ Not assessed
- ☐ Very much improved
- ☐ Much improved
- ☐ Minimally improved
- ☐ No change
- ☐ Minimally worse
- ☐ Much worse
- ☐ Very much worse

Completed by (Initials): _____

Screening/Baseline Week -2

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____

(mm/dd/yyyy)

Current Severity

Please rate the subject's current severity in the eight specific problem areas below.

	None, Least Severe						**Most Severe**
Reported Cocaine Use: (frequency and amount of cocaine used)	1	2	3	4	5	6	7
Cocaine Seeking: (craving for cocaine, effort to stop, and drug seeking behavior)	1	2	3	4	5	6	7
Reported Use of Other Drugs: (frequency and amount of non-cocaine drug/alcohol use)	1	2	3	4	5	6	7
Observable Psychiatric Symptoms: (orientation, memory, comprehension, disorganized thinking, rapid/retarded speech, agitation, grooming, hostility, irritability, affective disturbance)	1	2	3	4	5	6	7
Reported Psychiatric Symptoms: (mood disturbance, depression, anxiety,inner restlessness, covert anger, somatic symptoms, energy level,motivation, sleep, appetite, libido, anhedonia)	1	2	3	4	5	6	7
Physical/Medical Problems: (those that have emerged or gotten worse after drug use)	1	2	3	4	5	6	7
Maladaptive Coping in the Family/Social area: (movement away from healthy relationships)	1	2	3	4	5	6	7
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

Screening/Baseline Week -2

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____

(mm/dd/yyyy)

Global Severity of Cocaine Dependence

Considering your total clinical experience with the cocaine dependent population, how severe are this subject's cocaine dependence symptoms at this time?

- ☐ Normal, no symptoms
- ☐ Borderline symptoms
- ☐ Mild symptoms
- ☐ Moderate symptoms
- ☐ Marked symptoms
- ☐ Severe symptoms
- ☐ Most extreme symptoms possible

Global Improvement of Cocaine Dependence

Rate the total improvement in the participant's cocaine dependence symptoms whether or not, in your judgment, it is due entirely to drug treatment. Compared to the subject's admission to the project, how
much has the subject changed?

- ☐ Not assessed, first rating
- ☐ Very much improved
- ☐ Much improved
- ☐ Minimally improved
- ☐ No change
- ☐ Minimally worse
- ☐ Much worse
- ☐ Very much worse

Completed by (Initials): _____

Screening/Baseline Week -1 V1

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

First Study Visit of Week

☐ Vital signs not assessed at this visit

Date _____ *(mm/dd/yyyy)* Time Vital Signs taken _____ *(24 hour clock)*

Temperature (oral) _____ (°F) NR: 94-100.4 CS ☐ NCS ☐

Comments for Temperature

Blood Pressure (sitting) _____/_____ (mm Hg) NR: 90-140/50-90 CS ☐ NCS ☐

Comments for Blood Pressure:

Pulse Rate (sitting) _____ (beats/min) NR: 50-120 CS ☐ NCS ☐

Comments for Pulse Rate:

Respiratory Rate (sitting) _____ (breaths/min) NR: 8-20 CS ☐ NCS ☐

Comments for Respiratory Rate:

Completed by (Initials): _____

Screening/Baseline Week -1 V2

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____ *(mm/dd/yyyy)*

Second Study Visit of Week

☐ Vital signs not assessed at this visit

Date _____ *(mm/dd/yyyy)* Time Vital Signs taken _____ *(24 hour clock)*

Temperature (oral) _____ (°F) NR: 94-100.4 CS ☐ NCS ☐

Comments for Temperature

Blood Pressure (sitting) _____ _____ (mm Hg) NR: 90-140/50-90 CS ☐ NCS ☐

Comments for Blood Pressure:

Pulse Rate (sitting) _____ (beats/min) NR: 50-120 CS ☐ NCS ☐

Comments for Pulse Rate:

Respiratory Rate (sitting) _____ (breaths/min) NR: 8-20 CS ☐ NCS ☐

Comments for Respiratory Rate:

Completed by (Initials): _____

Screening/Baseline Week -1 V3

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____

(mm/dd/yyyy)

Third Study Visit of Week

☐ Vital signs not assessed at this visit

Date _____ *(mm/dd/yyyy)* Time Vital Signs taken _____ *(24 hour clock)*

Temperature (oral) _____ (°F) NR: 94-100.4 CS ☐ NCS ☐

Comments for Temperature

Blood Pressure (sitting) _____ / _____ (mm Hg) NR: 90-140/50-90 CS ☐ NCS ☐

Comments for Blood Pressure:

Pulse Rate (sitting) _____ (beats/min) NR: 50-120 CS ☐ NCS ☐

Comments for Pulse Rate:

Respiratory Rate (sitting) _____ (breaths/min) NR: 8-20 CS ☐ NCS ☐

Comments for Respiratory Rate:

Completed by (Initials): _____

Form 22 – URINE BE and TOX. SPECIMEN COLLECTION FORM

Screening/Baseline Week -1 V1

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____

(mm/dd/yyyy)

First Study Visit of Week *Urine bar code sticker:* _____

Date urine collected: _____ *(mm/dd/yyyy)*

Urine not collected ☐

Was urine temperature within expected range? ☐ Yes ☐ No

Franklin Cup: The temperature must be higher than 96.0 ° F and lower than 104.8 ° F On-Trak Cup: The temperature must be higher than 90.0 ° F and lower than 99.0 ° F Split Sample Cup: The temperature must be higher than 90.0 ° F and lower than 100.0 ° F

Results:

☐ Cocaine Positive	☐ Cocaine Negative	
☐ Amphetamine Positive	☐ Amphetamine Negative	☐ Not Completed
☐ Benzodiazepine Positive	☐ Benzodiazepine Negative	☐ Not Completed
☐ Barbiturates Positive	☐ Barbiturates Negative	☐ Not Completed
☐ Opiates Positive	☐ Opiates Negative	☐ Not Completed

Completed by (Initials): _____

Screening/Baseline Week -1 V2

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

Second Study Visit of Week ***Urine bar code sticker:*** _____

Date urine collected _____ Urine not collected ☐
(mm/dd/yyyy)

Was urine temperature within expected range? ☐ Yes ☐ No

Franklin Cup: The temperature must be higher than 96.0 ° F and lower than 104.8 ° F On-Trak Cup: The temperature must be higher than 90.0 ° F and lower than 99.0 ° F Split Sample Cup: The temperature must be higher than 90.0 ° F and lower than 100.0 ° F

Results:

☐ Cocaine Positive	☐ Cocaine Negative	
☐ Amphetamine Positive	☐ Amphetamine Negative	☐ Not Completed
☐ Benzodiazepine Positive	☐ Benzodiazepine Negative	☐ Not Completed
☐ Barbiturates Positive	☐ Barbiturates Negative	☐ Not Completed
☐ Opiates Positive	☐ Opiates Negative	☐ Not Completed

Completed by (Initials): _____

Form 22 – URINE BE and TOX. SPECIMEN COLLECTION FORM

Screening/Baseline Week -1 V3

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

Third Study Visit of Week ***Urine bar code sticker:*** _____

Date urine collected _____ Urine not collected ☐
(mm/dd/yyyy)

Was urine temperature within expected range? ☐ Yes ☐ No

Franklin Cup: The temperature must be higher than 96.0° F and lower than 104.8° F On-Trak Cup: The temperature must be higher than 90.0 ° F and lower than 99.0° F Split Sample Cup: The temperature must be higher than 90.0 ° F and lower than 100.0° F

Results:

☐ Cocaine Positive	☐ Cocaine Negative	
☐ Amphetamine Positive	☐ Amphetamine Negative	☐ Not Completed
☐ Benzodiazepine Positive	☐ Benzodiazepine Negative	☐ Not Completed
☐ Barbiturates Positive	☐ Barbiturates Negative	☐ Not Completed
☐ Opiates Positive	☐ Opiates Negative	☐ Not Completed

Completed by (Initials): _____

NIDA-MDS-Modaf-0001 **Form 24 – SUBSTANCE USE INVENTORY**

Screening/Baseline Week -1

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____ *(mm/dd/yyyy)*

Using timeline follow-back method, record whether subject has on each day since the last visit used any amount of the substances listed below, along with the most common route of administration for each drug. Begin with yesterday and work back to the last visit. Please be sure that days are continuous with last week's form.

Date of last visit: _____ *(mm/dd/yyyy)*

Day of week							
Date							
	Used? ROA	**Used? ROA**	**Used? ROA**	**Used? ROA**	**Used? ROA**	**Used? ROA**	**Used? ROA**
Cocaine	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Alcohol	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Marijuana	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Amphetamines	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Opiates	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Barbiturates	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Benzodiazepines	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N

Route of administration (ROA) codes: 1 = oral, 2 = nasal, 3 = smoking, 4 = non-intravenous injection, 5 = intravenous injection

Completed by (Initials): _____

Screening/Baseline Week -1

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

Cocaine

1. The intensity of my craving, that is, how much I desired cocaine in the past 24 hours was:
☐ None at all ☐ Slight ☐ Moderate ☐ Considerable ☐ Extreme

2. The frequency of my craving, that is, how often I desired cocaine in the past 24 hours was:
☐ Never ☐ Almost never ☐ Several times ☐ Regularly ☐ Almost constantly

3. The length of time I spent craving for cocaine during the past 24 hours was:
☐ None at all ☐ Very short ☐ Short ☐ Somewhat long ☐ Very long

4. Write in the number of times you think you had craving for cocaine during the past 24 hours:
☐

5. Write in the total time spent craving cocaine during the past 24 hours:
☐ hours ☐ minutes

6. The worst day: During the past week my most intense craving occurred on the following day:

☐ Sunday ☐ Monday ☐ Tuesday ☐ Wednesday
☐ Thursday ☐ Friday ☐ Saturday ☐ All days the same (go to Q. 8)

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

8. The intensity of my craving, that is, how much I desired cocaine on that worst day was:
☐ None at all ☐ Slight ☐ Moderate ☐ Considerable ☐ Extreme

Second Drug

9. A **2nd** craved drug during the past 24 hours was:
Mark only one of the following. If no 2nd craved drug, mark "None" and leave Questions 10-16 blank.

☐ None ☐ Downers or Sedatives (Barbiturates, etc.) ☐ Benzos (Valium, Xanax, etc.) ☐ Nicotine
☐ Alcohol ☐ Heroin or other Opiates (Morphine, etc.) ☐ Marijuana ☐ Other Specify ☐

10. The intensity of my craving, that is, how much I desired this **second** drug in the past 24 hours was:
☐ None at all ☐ Slight ☐ Moderate ☐ Considerable ☐ Extreme

Screening/Baseline Week -1

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

11. The frequency of my craving, that is, how often I desired this **second** drug in the past 24 hours was:

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

12. The length of time I spent in craving for this **second** drug during the past 24 hours was:

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

Third Drug

13. A **3rd** craved drug during the past 24 hours was:
Mark only one of the following. If no 3rd craved drug, mark "None" and leave questions 14-16 blank.

☐ None ☐ Downers or Sedatives (Barbiturates, etc.) ☐ Benzos (Valium, Xanax, etc.) ☐ Nicotine
☐ Alcohol ☐ Heroin or other Opiates (Morphine, etc.) ☐ Marijuana ☐ Other Specify _____

14. The intensity of my craving, that is, how much I desired this **third** drug in the past 24 hours was:

☐ 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:

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

16. The length of time I spent in craving for this third drug during the past 24 hours was:

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

Completed by (Initials): _____

All questions except 4 and 5 are assessed by properly trained personnel. The subject is asked about each of the items in lay language and the response is recorded on a scale of 0-7 with 0 being normal or no symptoms. For question 4 and 5, the subject is asked to mark the appropriate place on the line (on page 3) that describes each of the questions. The rater then transcribes that as the response to those questions.

_____

Screening/Baseline Week -1

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

Date of last cocaine use: _____
(mm/dd/yyyy)

1. Hyperphagia ☐

0 = normal appetite
3-4 = eats a lot more than usual
7 = eats more than twice usual amount of food

2. Hypophagia ☐

0 = normal appetite
3-4 = eats less than half of normal amount of food
7 = no appetite at all

3. Carbohydrate Craving ☐

0 = no craving
3-4 = strong craving for sweets, cakes, and cookies half the time
7 = strong craving for sweets, cakes, and cookies all the time

4. Cocaine Craving Intensity ☐ ***Please use subject intensity rating from pg. 3 of this form.***

5. Cocaine Craving Frequency ☐ ***Please use subject frequency rating from pg. 3 of this form.***

6. Bradycardia ☐ ***Please use scale below.***

	0	1	2	3	4	5	6	7
Pulse (BPM)	>64	64-63	62-61	60-59	58-57	56-55	54-53	<53

7. Insomnia ☐

0 = normal amount of sleep
3-4 = half of normal amount of sleep
7 = no sleep at all

8. Hypersomnia ☐

0 = normal amount of sleep
3-4 = could sleep or does sleep half the day
7 = sleep or could sleep all the time

Screening/Baseline Week -1

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

9. Anxiety ☐

0 = usually does not feel anxious
3-4 = feels anxious half the time
7 = feels anxious all the time

10. Energy Level ☐

0 = feels alert and has usual amount of energy
3-4 = feels tired half the time
7 = feels tired all the time

11. Activity Level ☐

0 = no change in usual activities
3-4 = participates in half of usual activities
7 = no participation in usual activities

12. Tension ☐

0-1 = rarely feel tense
3-4 = feels tense half the time
7 = feels tense most or all the time

13. Attention ☐

0 = able to concentrate on reading, conversation, tasks, and make plans without difficulty
3-4 = has difficulty with the above half the time
7 = has difficulty with the above all the time

14. Paranoid Ideation ☐

0 = no evidence of paranoid thoughts
3-4 = unable to trust anyone
5 = feels people are out to get him/her
7 = feels a specific person/group is plotting against him/her

15. Anhedonia ☐

0 = ability to enjoy themselves remains unchanged
3-4 = able to enjoy themselves half of the time
7 = unable to enjoy themselves at all

16. Depression ☐

0 = no feelings related to sadness or depression
3-4 = feels sad or depressed half the time
7 = feels depressed all of the time

17. Suicidality ☐

0 = does not think about being dead
3-4 = feels like life is not worth living
7 = feels like actually ending life

18. Irritability ☐

0 = feels that most things are not irritating
3-4 = feels that many things are irritating
7 = feels that mostly everything is irritating and upsetting

Completed by (Initials): _____

Screening/Baseline Week -1

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

CSSA VISUAL ANALOG SCALE

Please do not mark on upright lines.

Please rate the highest intensity of the desire for cocaine you have felt in the last 24 hours:

|_____|_____|_____|_____|_____|_____|_____|_____|

No Desire at all ***Unable to Resist***

Please identify on the line below, how often you have felt the urge to use cocaine in the last 24 hours:

|_____|_____|_____|_____|_____|_____|_____|_____|

Never ***All the Time***

Screening/Baseline Week -1

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

Cocaine Global Severity

At this time, how would you rate yourself overall for cocaine use and cocaine related problems?

- ☐ No problems
- ☐ Borderline problems
- ☐ Mild problems
- ☐ Moderate problems
- ☐ Marked problems
- ☐ Severe symptoms
- ☐ Most extreme problems possible

Global Improvement of Cocaine Dependence

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

- ☐ Not assessed
- ☐ Very much improved
- ☐ Much improved
- ☐ Minimally improved
- ☐ No change
- ☐ Minimally worse
- ☐ Much worse
- ☐ Very much worse

Completed by (Initials): _____

Screening/Baseline Week -1

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____

(mm/dd/yyyy)

Current Severity

Please rate the subject's current severity in the eight specific problem areas below.

	None, Least Severe						**Most Severe**
Reported Cocaine Use: (frequency and amount of cocaine used)	1	2	3	4	5	6	7
Cocaine Seeking: (craving for cocaine, effort to stop, and drug seeking behavior)	1	2	3	4	5	6	7
Reported Use of Other Drugs: (frequency and amount of non-cocaine drug/alcohol use)	1	2	3	4	5	6	7
Observable Psychiatric Symptoms: (orientation, memory, comprehension, disorganized thinking, rapid/retarded speech, agitation, grooming, hostility, irritability, affective disturbance)	1	2	3	4	5	6	7
Reported Psychiatric Symptoms: (mood disturbance, depression, anxiety,inner restlessness, covert anger, somatic symptoms, energy level,motivation, sleep, appetite, libido, anhedonia)	1	2	3	4	5	6	7
Physical/Medical Problems: (those that have emerged or gotten worse after drug use)	1	2	3	4	5	6	7
Maladaptive Coping in the Family/Social area: (movement away from healthy relationships)	1	2	3	4	5	6	7
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

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____

(mm/dd/yyyy)

Global Severity of Cocaine Dependence

Considering your total clinical experience with the cocaine dependent population, how severe are this subject's cocaine dependence symptoms at this time?

- ☐ Normal, no symptoms
- ☐ Borderline symptoms
- ☐ Mild symptoms
- ☐ Moderate symptoms
- ☐ Marked symptoms
- ☐ Severe symptoms
- ☐ Most extreme symptoms possible

Global Improvement of Cocaine Dependence

Rate the total improvement in the participant's cocaine dependence symptoms whether or not, in your judgment, it is due entirely to drug treatment. Compared to the subject's admission to the project, how
much has the subject changed?

- ☐ Not assessed, first rating
- ☐ Very much improved
- ☐ Much improved
- ☐ Minimally improved
- ☐ No change
- ☐ Minimally worse
- ☐ Much worse
- ☐ Very much worse

Completed by (Initials): _____

Screening/Baseline Week -1

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

Did subject receive standardized, manual-guided individual psychotherapy this week?

(If No, please comment below) ☐ Yes ☐ No

If yes, length of psychotherapy session _____ minutes

Did subject require emergency crisis management sessions this week? ☐ Yes ☐ No

If yes, how many? _____

Additional comments:

Completed by (Initials): _____

Randomization

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____

(mm/dd/yyyy)

Eligibility for Randomization

1. Is the subject eligible for randomization? ☐ Yes ☐ No

Obtain this information from Page 3 of Entry Criteria CRF (Form 19)

Randomization Information

2. At the time the informed consent to screen (Part I) was signed, indicate the number of self-reported days of cocaine use in the past 30 days . _____

Obtain this information from Demographics CRF, Drug and Alcohol Use section (Form2).

3. Gender ☐ Male ☐ Female

After entering the above information into randomization system, please record Date of randomization, and Kit Number below.

Randomization

3. Date of randomization _____
(mm/dd/yyyy)

5. Treatment kit number assigned _____

It is assumed that the first dose will be received on the same day as randomization. Therefore, Day of Randomization = Study Day 1.

Completed by (Initials): _____

Treatment Week 1 V1

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

First Study Visit of Week

☐ Vital signs not assessed at this visit

Date _____ *(mm/dd/yyyy)* Time Vital Signs taken _____ *(24 hour clock)*

Temperature (oral) _____ (°F) NR: 94-100.4 CS ☐ NCS ☐

Comments for Temperature

Blood Pressure (sitting) _____ _____ (mm Hg) NR: 90-140/50-90 CS ☐ NCS ☐

Comments for Blood Pressure:

Pulse Rate (sitting) _____ (beats/min) NR: 50-120 CS ☐ NCS ☐

Comments for Pulse Rate:

Respiratory Rate (sitting) _____ (breaths/min) NR: 8-20 CS ☐ NCS ☐

Comments for Respiratory Rate:

Completed by (Initials): _____

Treatment Week 1 V2

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

Second Study Visit of Week

☐ Vital signs not assessed at this visit

Date _____ *(mm/dd/yyyy)* Time Vital Signs taken _____ *(24 hour clock)*

Temperature (oral) _____ (°F) NR: 94-100.4 CS ☐ NCS ☐

Comments for Temperature

Blood Pressure (sitting) _____/_____ (mm Hg) NR: 90-140/50-90 CS ☐ NCS ☐

Comments for Blood Pressure:

Pulse Rate (sitting) _____ (beats/min) NR: 50-120 CS ☐ NCS ☐

Comments for Pulse Rate:

Respiratory Rate (sitting) _____ (breaths/min) NR: 8-20 CS ☐ NCS ☐

Comments for Respiratory Rate:

Completed by (Initials): _____

Treatment Week 1 V3

Site ID:	Subject ID #.	Subject Initials	Week

Date:

Third Study Visit of Week

☐ Vital signs not assessed at this visit

Date _____ *(mm/dd/yyyy)* Time Vital Signs taken _____ *(24 hour clock)*

Temperature (oral) _____ (°F) NR: 94-100.4 CS ☐ NCS ☐

Comments for Temperature

Blood Pressure (sitting) _____ _____ (mm Hg) NR: 90-140/50-90 CS ☐ NCS ☐

Comments for Blood Pressure:

Pulse Rate (sitting) _____ (beats/min) NR: 50-120 CS ☐ NCS ☐

Comments for Pulse Rate:

Respiratory Rate (sitting) _____ (breaths/min) NR: 8-20 CS ☐ NCS ☐

Comments for Respiratory Rate:

Completed by (Initials): _____

Treatment Week 1 V1

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

First Study Visit of Week ***Urine bar code sticker:*** _____

Date urine collected: _____ Urine not collected ☐
(mm/dd/yyyy)

Was urine temperature within expected range? ☐ Yes ☐ No

Franklin Cup: The temperature must be higher than 96.0° F and lower than 104.8° F
On-Trak Cup: The temperature must be higher than 90.0° F and lower than 99.0° F Split
Sample Cup: The temperature must be higher than 90.0° F and lower than 100.0° F

Completed by (Initials): _____

Treatment Week 1 V2

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

Second Study Visit of Week ***Urine bar code sticker:*** _____

Date urine collected: _____ Urine not collected ☐
(mm/dd/yyyy)

Was urine temperature within expected range? ☐ Yes ☐ No

Franklin Cup: The temperature must be higher than 96.0° F and lower than 104.8° F On-Trak Cup: The temperature must be higher than 90.0 ° F and lower than 99.0° F Split Sample Cup: The temperature must be higher than 90.0 ° F and lower than 100.0° F

Completed by (Initials): _____

NIDA-MDS-Modaf-0001 **Form 23 – URINE BE SPECIMEN COLLECTION FORM**

Treatment Week 1 V3

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

Third Study Visit of Week ***Urine bar code sticker:*** _____

Date urine collected: _____ Urine not collected ☐
(mm/dd/yyyy)

Was urine temperature within expected range? ☐ Yes ☐ No

Franklin Cup: The temperature must be higher than 96.0 ° F and lower than 104.8 ° F On-Trak Cup: The temperature must be higher than 90.0 ° F and lower than 99.0 ° F Split Sample Cup: The temperature must be higher than 90.0 ° F and lower than 100.0 ° F

Completed by (Initials): _____

NIDA-MDS-Modaf-0001 **Form 24 – SUBSTANCE USE INVENTORY**

Treatment Week 1

Site ID: | Subject ID #. | Subject Initials | Week

Date: (mm/dd/yyyy)

Using timeline follow-back method, record whether subject has on each day since the last visit used any amount of the substances listed below, along with the most common route of administration for each drug. Begin with yesterday and work back to the last visit. Please be sure that days are continuous with last week's form.

Date of last visit: *(mm/dd/yyyy)*

Day of week							
Date							
	Used? ROA	**Used? ROA**	**Used? ROA**	**Used? ROA**	**Used? ROA**	**Used? ROA**	**Used? ROA**
Cocaine	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Alcohol	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Marijuana	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Amphetamines	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Opiates	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Barbiturates	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Benzodiazepines	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N

Route of administration (ROA) codes: 1 = oral, 2 = nasal, 3 = smoking, 4 = non-intravenous injection, 5 = intravenous injection

Completed by (Initials):

Treatment Week1

Site ID: | Subject ID #. | Subject Initials | Week

Date: (mm/dd/yyyy)

Cocaine

1. The intensity of my craving, that is, how much I desired cocaine in the past 24 hours was:

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

2. The frequency of my craving, that is, how often I desired cocaine in the past 24 hours was:

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

3. The length of time I spent craving for cocaine during the past 24 hours was:

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

4. Write in the number of times you think you had craving for cocaine during the past 24 hours:

☐

5. Write in the total time spent craving cocaine during the past 24 hours:

☐ hours ☐ minutes

6. The worst day: During the past week my most intense craving occurred on the following day:

☐ Sunday ☐ Monday ☐ Tuesday ☐ Wednesday
☐ Thursday ☐ Friday ☐ Saturday ☐ All days the same (go to Q. 8)

7. The date for that day was: ☐ *(mm/dd/yyyy)*

8. The intensity of my craving, that is, how much I desired cocaine on that worst day was:

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

Second Drug

9. A **2nd** craved drug during the past 24 hours was:
Mark only one of the following. If no 2nd craved drug, mark "None" and leave Questions 10-16 blank.

☐ None ☐ Downers or Sedatives (Barbiturates, etc.) ☐ Benzos (Valium, Xanax, etc.) ☐ Nicotine
☐ Alcohol ☐ Heroin or other Opiates (Morphine, etc.) ☐ Marijuana ☐ Other Specify ☐

10. The intensity of my craving, that is, how much I desired this **second** drug in the past 24 hours was:

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

Treatment Week1

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____ (mm/dd/yyyy)

11. The frequency of my craving, that is, how often I desired this **second** drug in the past 24 hours was:

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

12. The length of time I spent in craving for this **second** drug during the past 24 hours was:

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

Third Drug

13. A **3rd** craved drug during the past 24 hours was:
Mark only one of the following. If no 3rd craved drug, mark "None" and leave questions 14-16 blank.

☐ None ☐ Downers or Sedatives (Barbiturates, etc.) ☐ Benzos (Valium, Xanax, etc.) ☐ Nicotine

☐ Alcohol ☐ Heroin or other Opiates (Morphine, etc.) ☐ Marijuana ☐ Other Specify _____

14. The intensity of my craving, that is, how much I desired this **third** drug in the past 24 hours was:

☐ 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:

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

16. The length of time I spent in craving for this third drug during the past 24 hours was:

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

Completed by (Initials): _____

All questions except 4 and 5 are assessed by properly trained personnel. The subject is asked about each of the items in lay language and the response is recorded on a scale of 0-7 with 0 being normal or no symptoms. For question 4 and 5, the subject is asked to mark the appropriate place on the line (on page 3) that describes each of the questions. The rater then transcribes that as the response to those questions.

Date of last cocaine use: _____

Site ID: | Subject ID #. | Subject Initials | Week

Date: *(mm/dd/yyyy)*

(mm/dd/yyyy)

1. ***Hyperphagia***

0 = normal appetite
3-4 = eats a lot more than usual
7 = eats more than twice usual amount of food

2. Hypophagia

0 = normal appetite
3-4 = eats less than half of normal amount of food
7 = no appetite at all

3. Carbohydrate Craving

0 = no craving
3-4 = strong craving for sweets, cakes, and cookies half the time
7 = strong craving for sweets, cakes, and cookies all the time

4. Cocaine Craving Intensity

Please use subject intensity rating from pg. 3 of this form.

5. Cocaine Craving Frequency

Please use subject frequency rating from pg. 3 of this form.

6. Bradycardia

Please use scale below.

	0	1	2	3	4	5	6	7
Pulse (BPM)	>64	64-63	62-61	60-59	58-57	56-55	54-53	<53

7. Insomnia

0 = normal amount of sleep
3-4 = half of normal amount of sleep
7 = no sleep at all

8. Hypersomnia

0 = normal amount of sleep
3-4 = could sleep or does sleep half the day
7 = sleep or could sleep all the time

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____

(mm/dd/yyyy)

9. Anxiety ☐

0 = usually does not feel anxious
3-4 = feels anxious half the time
7 = feels anxious all the time

10. Energy Level ☐

0 = feels alert and has usual amount of energy
3-4 = feels tired half the time
7 = feels tired all the time

11. Activity Level ☐

0 = no change in usual activities
3-4 = participates in half of usual activities
7 = no participation in usual activities

12. Tension ☐

0-1 = rarely feel tense
3-4 = feels tense half the time
7 = feels tense most or all the time

13. Attention ☐

0 = able to concentrate on reading, conversation, tasks, and make plans without difficulty
3-4 = has difficulty with the above half the time
7 = has difficulty with the above all the time

14. Paranoid Ideation ☐

0 = no evidence of paranoid thoughts
3-4 = unable to trust anyone
5 = feels people are out to get him/her
7 = feels a specific person/group is plotting against him/her

15. Anhedonia ☐

0 = ability to enjoy themselves remains unchanged
3-4 = able to enjoy themselves half of the time
7 = unable to enjoy themselves at all

16. Depression ☐

0 = no feelings related to sadness or depression
3-4 = feels sad or depressed half the time
7 = feels depressed all of the time

17. Suicidality ☐

0 = does not think about being dead
3-4 = feels like life is not worth living
7 = feels like actually ending life

18. Irritability ☐

0 = feels that most things are not irritating
3-4 = feels that many things are irritating
7 = feels that mostly everything is irritating and upsetting

Completed by (Initials): _____

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

CSSA VISUAL ANALOG SCALE

Please do not mark on upright lines.

Please rate the highest intensity of the desire for cocaine you have felt in the last 24 hours:

|____|____|____|____|____|____|____|____|

No Desire at all ***Unable to Resist***

Please identify on the line below, how often you have felt the urge to use cocaine in the last 24 hours:

|____|____|____|____|____|____|____|____|

Never ***All the Time***

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

Cocaine Global Severity

At this time, how would you rate yourself overall for cocaine use and cocaine related problems?

- ☐ No problems
- ☐ Borderline problems
- ☐ Mild problems
- ☐ Moderate problems
- ☐ Marked problems
- ☐ Severe symptoms
- ☐ Most extreme problems possible

Global Improvement of Cocaine Dependence

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

- ☐ Not assessed
- ☐ Very much improved
- ☐ Much improved
- ☐ Minimally improved
- ☐ No change
- ☐ Minimally worse
- ☐ Much worse
- ☐ Very much worse

Completed by (Initials):

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____

(mm/dd/yyyy)

Current Severity

Please rate the subject's current severity in the eight specific problem areas below.

	None, Least Severe						**Most Severe**
Reported Cocaine Use: (frequency and amount of cocaine used)	1	2	3	4	5	6	7
Cocaine Seeking: (craving for cocaine, effort to stop, and drug seeking behavior)	1	2	3	4	5	6	7
Reported Use of Other Drugs: (frequency and amount of non-cocaine drug/alcohol use)	1	2	3	4	5	6	7
Observable Psychiatric Symptoms: (orientation, memory, comprehension, disorganized thinking, rapid/retarded speech, agitation, grooming, hostility, irritability, affective disturbance)	1	2	3	4	5	6	7
Reported Psychiatric Symptoms: (mood disturbance, depression, anxiety,inner restlessness, covert anger, somatic symptoms, energy level,motivation, sleep, appetite, libido, anhedonia)	1	2	3	4	5	6	7
Physical/Medical Problems: (those that have emerged or gotten worse after drug use)	1	2	3	4	5	6	7
Maladaptive Coping in the Family/Social area: (movement away from healthy relationships)	1	2	3	4	5	6	7
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

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____

(mm/dd/yyyy)

Global Severity of Cocaine Dependence

Considering your total clinical experience with the cocaine dependent population, how severe are this subject's cocaine dependence symptoms at this time?

- ☐ Normal, no symptoms
- ☐ Borderline symptoms
- ☐ Mild symptoms
- ☐ Moderate symptoms
- ☐ Marked symptoms
- ☐ Severe symptoms
- ☐ Most extreme symptoms possible

Global Improvement of Cocaine Dependence

Rate the total improvement in the participant's cocaine dependence symptoms whether or not, in your judgment, it is due entirely to drug treatment. Compared to the subject's admission to the project, how
much has the subject changed?

- ☐ Not assessed, first rating
- ☐ Very much improved
- ☐ Much improved
- ☐ Minimally improved
- ☐ No change
- ☐ Minimally worse
- ☐ Much worse
- ☐ Very much worse

Completed by (Initials): _____

Treatment Week 1

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

Date doses dispensed
Each dose is four tablets

(mm/dd/yyyy)

Kit Number:

Bottle Number:

Number of doses dispensed

Date unused doses returned

(mm/dd/yyyy)

Number of doses returned

Number of doses reported lost by subject

Doses taken:

Day of Week:	Date *(mm/dd/yyyy)*	Time Dose Taken	Dose Not Taken

Comments:

Completed by (Initials):

Treatment Week 1

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

Did subject receive standardized, manual-guided individual psychotherapy this week?

(If No, please comment below) ☐ Yes ☐ No

If yes, length of psychotherapy session _____ minutes

Did subject require emergency crisis management sessions this week? ☐ Yes ☐ No

If yes, how many? _____

Additional comments:

Completed by (Initials): _____

Treatment Week 2 V1

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

First Study Visit of Week

☐ Vital signs not assessed at this visit

Date _____ *(mm/dd/yyyy)* Time Vital Signs taken _____ *(24 hour clock)*

Temperature (oral) _____ (°F) NR: 94-100.4 CS ☐ NCS ☐

Comments for Temperature

Blood Pressure (sitting) _____ _____ (mm Hg) NR: 90-140/50-90 CS ☐ NCS ☐

Comments for Blood Pressure:

Pulse Rate (sitting) _____ (beats/min) NR: 50-120 CS ☐ NCS ☐

Comments for Pulse Rate:

Respiratory Rate (sitting) _____ (breaths/min) NR: 8-20 CS ☐ NCS ☐

Comments for Respiratory Rate:

Completed by (Initials): _____

Treatment Week 2 V2

Site ID: | Subject ID #. | Subject Initials | Week

Date: *(mm/dd/yyyy)*

Second Study Visit of Week

☐ Vital signs not assessed at this visit

Date *(mm/dd/yyyy)* Time Vital Signs taken *(24 hour clock)*

Temperature (oral) (°F) NR: 94-100.4 CS ☐ NCS ☐

Comments for Temperature

Blood Pressure (sitting) (mm Hg) NR: 90-140/50-90 CS ☐ NCS ☐

Comments for Blood Pressure:

Pulse Rate (sitting) (beats/min) NR: 50-120 CS ☐ NCS ☐

Comments for Pulse Rate:

Respiratory Rate (sitting) (breaths/min) NR: 8-20 CS ☐ NCS ☐

Comments for Respiratory Rate:

Completed by (Initials):

Treatment Week 2 V3

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

Third Study Visit of Week

☐ Vital signs not assessed at this visit

Date _____ *(mm/dd/yyyy)* Time Vital Signs taken _____ *(24 hour clock)*

Temperature (oral) _____ (°F) NR: 94-100.4 CS ☐ NCS ☐

Comments for Temperature

Blood Pressure (sitting) _____ _____ (mm Hg) NR: 90-140/50-90 CS ☐ NCS ☐

Comments for Blood Pressure:

Pulse Rate (sitting) _____ (beats/min) NR: 50-120 CS ☐ NCS ☐

Comments for Pulse Rate:

Respiratory Rate (sitting) _____ (breaths/min) NR: 8-20 CS ☐ NCS ☐

Comments for Respiratory Rate:

Completed by (Initials): _____

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

First Study Visit of Week ***Urine bar code sticker:*** _____

Date urine collected: _____
(mm/dd/yyyy)

Urine not collected ☐

Was urine temperature within expected range? ☐ Yes ☐ No

Franklin Cup: The temperature must be higher than 96.0° F and lower than 104.8° F On-Trak Cup: The temperature must be higher than 90.0° F and lower than 99.0° F Split Sample Cup: The temperature must be higher than 90.0° F and lower than 100.0° F

Completed by (Initials): _____

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

Second Study Visit of Week ***Urine bar code sticker:*** _____

Date urine collected: _____ Urine not collected ☐
(mm/dd/yyyy)

Was urine temperature within expected range? ☐ Yes ☐ No

Franklin Cup: The temperature must be higher than 96.0° F and lower than 104.8° F On-Trak Cup: The temperature must be higher than 90.0° F and lower than 99.0° F Split Sample Cup: The temperature must be higher than 90.0° F and lower than 100.0° F

Completed by (Initials): _____

Site ID: | Subject ID #. | Subject Initials | Week

Date: (mm/dd/yyyy)

Third Study Visit of Week ***Urine bar code sticker:***

Date urine collected: *(mm/dd/yyyy)* Urine not collected ☐

Was urine temperature within expected range? ☐ Yes ☐ No

Franklin Cup: The temperature must be higher than 96.0° F and lower than 104.8° F On-Trak Cup: The temperature must be higher than 90.0° F and lower than 99.0° F Split Sample Cup: The temperature must be higher than 90.0° F and lower than 100.0° F

Completed by (Initials):

NIDA-MDS-Modaf-0001 **Form 24 – SUBSTANCE USE INVENTORY**

Treatment Week 2

Site ID: | Subject ID #. | Subject Initials | Week

Date: (mm/dd/yyyy)

Using timeline follow-back method, record whether subject has on each day since the last visit used any amount of the substances listed below, along with the most common route of administration for each drug. Begin with yesterday and work back to the last visit. Please be sure that days are continuous with last week's form.

Date of last visit: *(mm/dd/yyyy)*

Day of week							
Date							
	Used? ROA	**Used? ROA**	**Used? ROA**	**Used? ROA**	**Used? ROA**	**Used? ROA**	**Used? ROA**
Cocaine	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Alcohol	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Marijuana	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Amphetamines	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Opiates	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Barbiturates	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Benzodiazepines	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N

Route of administration (ROA) codes: 1 = oral, 2 = nasal, 3 = smoking, 4 = non-intravenous injection, 5 = intravenous injection

Completed by (Initials):

Treatment Week 2

Site ID: | Subject ID #. | Subject Initials | Week

Date: (mm/dd/yyyy)

Cocaine

1. The intensity of my craving, that is, how much I desired cocaine in the past 24 hours was:

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

2. The frequency of my craving, that is, how often I desired cocaine in the past 24 hours was:

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

3. The length of time I spent craving for cocaine during the past 24 hours was:

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

4. Write in the number of times you think you had craving for cocaine during the past 24 hours:

☐

5. Write in the total time spent craving cocaine during the past 24 hours:

☐ hours ☐ minutes

6. The worst day: During the past week my most intense craving occurred on the following day:

☐ Sunday ☐ Monday ☐ Tuesday ☐ Wednesday
☐ Thursday ☐ Friday ☐ Saturday ☐ All days the same (go to Q. 8)

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

8. The intensity of my craving, that is, how much I desired cocaine on that worst day was:

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

Second Drug

9. A **2nd** craved drug during the past 24 hours was:
Mark only one of the following. If no 2nd craved drug, mark "None" and leave Questions 10-16 blank.

☐ None ☐ Downers or Sedatives (Barbiturates, etc.) ☐ Benzos (Valium, Xanax, etc.) ☐ Nicotine
☐ Alcohol ☐ Heroin or other Opiates (Morphine, etc.) ☐ Marijuana ☐ Other Specify ☐

10. The intensity of my craving, that is, how much I desired this **second** drug in the past 24 hours was:

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

Treatment Week 2

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____ (mm/dd/yyyy)

11. The frequency of my craving, that is, how often I desired this **second** drug in the past 24 hours was:

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

12. The length of time I spent in craving for this **second** drug during the past 24 hours was:

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

Third Drug

13. A **3rd** craved drug during the past 24 hours was:
Mark only one of the following. If no 3rd craved drug, mark "None" and leave questions 14-16 blank.

☐ None ☐ Downers or Sedatives (Barbiturates, etc.) ☐ Benzos (Valium, Xanax, etc.) ☐ Nicotine

☐ Alcohol ☐ Heroin or other Opiates (Morphine, etc.) ☐ Marijuana ☐ Other Specify _____

14. The intensity of my craving, that is, how much I desired this **third** drug in the past 24 hours was:

☐ 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:

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

16. The length of time I spent in craving for this third drug during the past 24 hours was:

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

Completed by (Initials): _____

All questions except 4 and 5 are assessed by properly trained personnel. The subject is asked about each of the items in lay language and the response is recorded on a scale of 0-7 with 0 being normal or no symptoms. For question 4 and 5, the subject is asked to mark the appropriate place on the line (on page 3) that describes each of the questions. The rater then transcribes that as the response to those questions.

_____

Treatment Week 2

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

Date of last cocaine use: _____
(mm/dd/yyyy)

1. Hyperphagia ☐

0 = normal appetite
3-4 = eats a lot more than usual
7 = eats more than twice usual amount of food

2. Hypophagia ☐

0 = normal appetite
3-4 = eats less than half of normal amount of food
7 = no appetite at all

3. Carbohydrate Craving ☐

0 = no craving
3-4 = strong craving for sweets, cakes, and cookies half the time
7 = strong craving for sweets, cakes, and cookies all the time

4. Cocaine Craving Intensity ☐ ***Please use subject intensity rating from pg. 3 of this form.***

5. Cocaine Craving Frequency ☐ ***Please use subject frequency rating from pg. 3 of this form.***

6. Bradycardia ☐ ***Please use scale below.***

	0	1	2	3	4	5	6	7
Pulse (BPM)	>64	64-63	62-61	60-59	58-57	56-55	54-53	<53

7. Insomnia ☐

0 = normal amount of sleep
3-4 = half of normal amount of sleep
7 = no sleep at all

8. Hypersomnia ☐

0 = normal amount of sleep
3-4 = could sleep or does sleep half the day
7 = sleep or could sleep all the time

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

9. Anxiety ☐

0 = usually does not feel anxious
3-4 = feels anxious half the time
7 = feels anxious all the time

10. Energy Level ☐

0 = feels alert and has usual amount of energy
3-4 = feels tired half the time
7 = feels tired all the time

11. Activity Level ☐

0 = no change in usual activities
3-4 = participates in half of usual activities
7 = no participation in usual activities

12. Tension ☐

0-1 = rarely feel tense
3-4 = feels tense half the time
7 = feels tense most or all the time

13. Attention ☐

0 = able to concentrate on reading, conversation, tasks, and make plans without difficulty
3-4 = has difficulty with the above half the time
7 = has difficulty with the above all the time

14. Paranoid Ideation ☐

0 = no evidence of paranoid thoughts
3-4 = unable to trust anyone
5 = feels people are out to get him/her
7 = feels a specific person/group is plotting against him/her

15. Anhedonia ☐

0 = ability to enjoy themselves remains unchanged
3-4 = able to enjoy themselves half of the time
7 = unable to enjoy themselves at all

16. Depression ☐

0 = no feelings related to sadness or depression
3-4 = feels sad or depressed half the time
7 = feels depressed all of the time

17. Suicidality ☐

0 = does not think about being dead
3-4 = feels like life is not worth living
7 = feels like actually ending life

18. Irritability ☐

0 = feels that most things are not irritating
3-4 = feels that many things are irritating
7 = feels that mostly everything is irritating and upsetting

Completed by (Initials): _____

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

CSSA VISUAL ANALOG SCALE

Please do not mark on upright lines.

Please rate the highest intensity of the desire for cocaine you have felt in the last 24 hours:

|_____|_____|_____|_____|_____|_____|_____|

No Desire at all ***Unable to Resist***

Please identify on the line below, how often you have felt the urge to use cocaine in the last 24 hours:

|_____|_____|_____|_____|_____|_____|_____|

Never ***All the Time***

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

Cocaine Global Severity

At this time, how would you rate yourself overall for cocaine use and cocaine related problems?

- ☐ No problems
- ☐ Borderline problems
- ☐ Mild problems
- ☐ Moderate problems
- ☐ Marked problems
- ☐ Severe symptoms
- ☐ Most extreme problems possible

Global Improvement of Cocaine Dependence

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

- ☐ Not assessed
- ☐ Very much improved
- ☐ Much improved
- ☐ Minimally improved
- ☐ No change
- ☐ Minimally worse
- ☐ Much worse
- ☐ Very much worse

Completed by (Initials): _____

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

Current Severity

Please rate the subject's current severity in the eight specific problem areas below.

	None, Least Severe						**Most Severe**
Reported Cocaine Use: (frequency and amount of cocaine used)	1	2	3	4	5	6	7
Cocaine Seeking: (craving for cocaine, effort to stop, and drug seeking behavior)	1	2	3	4	5	6	7
Reported Use of Other Drugs: (frequency and amount of non-cocaine drug/alcohol use)	1	2	3	4	5	6	7
Observable Psychiatric Symptoms: (orientation, memory, comprehension, disorganized thinking, rapid/retarded speech, agitation, grooming, hostility, irritability, affective disturbance)	1	2	3	4	5	6	7
Reported Psychiatric Symptoms: (mood disturbance, depression, anxiety,inner restlessness, covert anger, somatic symptoms, energy level,motivation, sleep, appetite, libido, anhedonia)	1	2	3	4	5	6	7
Physical/Medical Problems: (those that have emerged or gotten worse after drug use)	1	2	3	4	5	6	7
Maladaptive Coping in the Family/Social area: (movement away from healthy relationships)	1	2	3	4	5	6	7
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

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

Global Severity of Cocaine Dependence

Considering your total clinical experience with the cocaine dependent population, how severe are this subject's cocaine dependence symptoms at this time?

- ☐ Normal, no symptoms
- ☐ Borderline symptoms
- ☐ Mild symptoms
- ☐ Moderate symptoms
- ☐ Marked symptoms
- ☐ Severe symptoms
- ☐ Most extreme symptoms possible

Global Improvement of Cocaine Dependence

Rate the total improvement in the participant's cocaine dependence symptoms whether or not, in your judgment, it is due entirely to drug treatment. Compared to the subject's admission to the project, how
much has the subject changed?

- ☐ Not assessed, first rating
- ☐ Very much improved
- ☐ Much improved
- ☐ Minimally improved
- ☐ No change
- ☐ Minimally worse
- ☐ Much worse
- ☐ Very much worse

Completed by (Initials): _____

Treatment Week 2

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

Date doses dispensed _____
Each dose is four tablets
(mm/dd/yyyy)

Kit Number: _____

Bottle Number: _____

Number of doses dispensed _____

Date unused doses returned _____
(mm/dd/yyyy)

Number of doses returned _____

Number of doses reported lost by subject _____

Doses taken:

Day of Week:	Date *(mm/dd/yyyy)*	Time Dose Taken	Dose Not Taken

Comments: _____

Completed by (Initials): _____

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

Did subject receive standardized, manual-guided individual psychotherapy this week?

(If No, please comment below) ☐ Yes ☐ No

If yes, length of psychotherapy session _____ minutes

Did subject require emergency crisis management sessions this week? ☐ Yes ☐ No

If yes, how many? _____

Additional comments:

Completed by (Initials): _____

Treatment Week 2

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____

(mm/dd/yyyy)

This form is to be filled out for female subjects only. All female subjects must be tested at Screening/Baseline and have a negative pregnancy test in order to be eligible for this study.

What method of birth control is the participant currently using (prior to taking modafinil)?

- ☐ Oral contraceptive
- ☐ Barrier (diaphragm or condom plus spermicide)
- ☐ Levonorgestrel implant (Norplant)
- ☐ Intrauterine Contraceptive system (IUD)
- ☐ Medroxyprogesterone Acetate Contraceptive injection (Depo-Provera)
- ☐ Contraceptive patch
- ☐ Surgical Sterilization - Hysterectomy
- ☐ Surgical Sterilization - Tubal ligation

Unless surgically sterile or 2 years postmenopausal, does the subject agree to use an acceptable method of birth control during the study and 30 days after last dose of study drug?

☐ Yes ☐ No

If yes, mark below the acceptable method selected by the subject for use:

- ☐ barrier method with spermicide
- ☐ steroidal contraceptive [oral, Implanted, injected] used in conjunction with a barrier method
- ☐ Contraceptive patch used in conjunction with a barrier method
- ☐ Intrauterine device [IUD]

Was a pregnancy test performed? ☐ Yes ☐ No

If yes, date specimen collected _____

(mm/dd/yyyy)

Result: ☐ Negative ☐ Positive ☐ Unknown

If no, specify reason: _____

Is the subject lactating? ☐ Yes ☐ No

Comments: _____

Completed by (Initials): _____

Treatment Week 3 V1

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

First Study Visit of Week

☐ Vital signs not assessed at this visit

Date _____ *(mm/dd/yyyy)* Time Vital Signs taken _____ *(24 hour clock)*

Temperature (oral) _____ (°F) NR: 94-100.4 CS ☐ NCS ☐

Comments for Temperature

Blood Pressure (sitting) _____ / _____ (mm Hg) NR: 90-140/50-90 CS ☐ NCS ☐

Comments for Blood Pressure:

Pulse Rate (sitting) _____ (beats/min) NR: 50-120 CS ☐ NCS ☐

Comments for Pulse Rate:

Respiratory Rate (sitting) _____ (breaths/min) NR: 8-20 CS ☐ NCS ☐

Comments for Respiratory Rate:

Completed by (Initials): _____

Treatment Week 3 V2

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

Second Study Visit of Week

☐ Vital signs not assessed at this visit

Date _____ *(mm/dd/yyyy)* Time Vital Signs taken _____ *(24 hour clock)*

Temperature (oral) _____ (°F) NR: 94-100.4 CS ☐ NCS ☐

Comments for Temperature

Blood Pressure (sitting) _____ _____ (mm Hg) NR: 90-140/50-90 CS ☐ NCS ☐

Comments for Blood Pressure:

Pulse Rate (sitting) _____ (beats/min) NR: 50-120 CS ☐ NCS ☐

Comments for Pulse Rate:

Respiratory Rate (sitting) _____ (breaths/min) NR: 8-20 CS ☐ NCS ☐

Comments for Respiratory Rate:

Completed by (Initials): _____

Treatment Week 3 V3

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

Third Study Visit of Week

☐ Vital signs not assessed at this visit

Date _____ *(mm/dd/yyyy)* Time Vital Signs taken _____ *(24 hour clock)*

Temperature (oral) _____ (°F) NR: 94-100.4 CS ☐ NCS ☐

Comments for Temperature

Blood Pressure (sitting) _____ _____ (mm Hg) NR: 90-140/50-90 CS ☐ NCS ☐

Comments for Blood Pressure:

Pulse Rate (sitting) _____ (beats/min) NR: 50-120 CS ☐ NCS ☐

Comments for Pulse Rate:

Respiratory Rate (sitting) _____ (breaths/min) NR: 8-20 CS ☐ NCS ☐

Comments for Respiratory Rate:

Completed by (Initials): _____

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

First Study Visit of Week ***Urine bar code sticker:*** _____

Date urine collected: _____ Urine not collected ☐
(mm/dd/yyyy)

Was urine temperature within expected range? ☐ Yes ☐ No

Franklin Cup: The temperature must be higher than 96.0° F and lower than 104.8° F On-Trak Cup: The temperature must be higher than 90.0° F and lower than 99.0° F Split Sample Cup: The temperature must be higher than 90.0° F and lower than 100.0° F

Completed by (Initials): _____

Site ID: | Subject ID #. | Subject Initials | Week

Date: *(mm/dd/yyyy)*

Second Study Visit of Week ***Urine bar code sticker:***

Date urine collected: *(mm/dd/yyyy)* Urine not collected ☐

Was urine temperature within expected range? ☐ Yes ☐ No

Franklin Cup: The temperature must be higher than 96.0° F and lower than 104.8° F On-Trak Cup: The temperature must be higher than 90.0° F and lower than 99.0° F Split Sample Cup: The temperature must be higher than 90.0° F and lower than 100.0° F

Completed by (Initials):

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____

(mm/dd/yyyy)

Third Study Visit of Week ***Urine bar code sticker:*** _____

Date urine collected: _____ Urine not collected ☐

(mm/dd/yyyy)

Was urine temperature within expected range? ☐ Yes ☐ No

Franklin Cup: The temperature must be higher than 96.0° F and lower than 104.8° F On-Trak Cup: The temperature must be higher than 90.0 ° F and lower than 99.0° F Split Sample Cup: The temperature must be higher than 90.0 ° F and lower than 100.0 ° F

Completed by (Initials): _____

Treatment Week 3

Site ID: | Subject ID #. | Subject Initials | Week

Date: *(mm/dd/yyyy)*

Using timeline follow-back method, record whether subject has on each day since the last visit used any amount of the substances listed below, along with the most common route of administration for each drug. Begin with yesterday and work back to the last visit. Please be sure that days are continuous with last week's form.

Date of last visit: *(mm/dd/yyyy)*

Day of week

Date

	Used? ROA	Used? ROA	Used? ROA	Used? ROA	Used? ROA	Used? ROA	Used? ROA
Cocaine	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Alcohol	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Marijuana	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Amphetamines	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Opiates	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Barbiturates	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Benzodiazepines	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N

Route of administration (ROA) codes: 1 = oral, 2 = nasal, 3 = smoking, 4 = non-intravenous injection, 5 = intravenous injection

Completed by (Initials):

Treatment Week 3

Site ID: | Subject ID #. | Subject Initials | Week

Date: (mm/dd/yyyy)

Cocaine

1. The intensity of my craving, that is, how much I desired cocaine in the past 24 hours was:

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

2. The frequency of my craving, that is, how often I desired cocaine in the past 24 hours was:

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

3. The length of time I spent craving for cocaine during the past 24 hours was:

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

4. Write in the number of times you think you had craving for cocaine during the past 24 hours:

☐

5. Write in the total time spent craving cocaine during the past 24 hours:

☐ hours ☐ minutes

6. The worst day: During the past week my most intense craving occurred on the following day:

☐ Sunday ☐ Monday ☐ Tuesday ☐ Wednesday
☐ Thursday ☐ Friday ☐ Saturday ☐ All days the same (go to Q. 8)

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

8. The intensity of my craving, that is, how much I desired cocaine on that worst day was:

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

Second Drug

9. A **2nd** craved drug during the past 24 hours was:
Mark only one of the following. If no 2nd craved drug, mark "None" and leave Questions 10-16 blank.

☐ None ☐ Downers or Sedatives (Barbiturates, etc.) ☐ Benzos (Valium, Xanax, etc.) ☐ Nicotine
☐ Alcohol ☐ Heroin or other Opiates (Morphine, etc.) ☐ Marijuana ☐ Other Specify ☐

10. The intensity of my craving, that is, how much I desired this **second** drug in the past 24 hours was:

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

Treatment Week 3

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____

(mm/dd/yyyy)

11. The frequency of my craving, that is, how often I desired this **second** drug in the past 24 hours was:

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

12. The length of time I spent in craving for this **second** drug during the past 24 hours was:

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

Third Drug

13. A **3rd** craved drug during the past 24 hours was:
Mark only one of the following. If no 3rd craved drug, mark "None" and leave questions 14-16 blank.

☐ None ☐ Downers or Sedatives (Barbiturates, etc.) ☐ Benzos (Valium, Xanax, etc.) ☐ Nicotine

☐ Alcohol ☐ Heroin or other Opiates (Morphine, etc.) ☐ Marijuana ☐ Other Specify _____

14. The intensity of my craving, that is, how much I desired this **third** drug in the past 24 hours was:

☐ 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:

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

16. The length of time I spent in craving for this third drug during the past 24 hours was:

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

Completed by (Initials): _____

Site ID: | Subject ID #. | Subject Initials | Week

Date: *(mm/dd/yyyy)*

All questions except 4 and 5 are assessed by properly trained personnel. The subject is asked about each of the items in lay language and the response is recorded on a scale of 0-7 with 0 being normal or no symptoms. For question 4 and 5, the subject is asked to mark the appropriate place on the line (on page 3) that describes each of the questions. The rater then transcribes that as the response to those questions.

Date of last cocaine use: *(mm/dd/yyyy)*

1. Hyperphagia

0 = normal appetite
3-4 = eats a lot more than usual
7 = eats more than twice usual amount of food

2. Hypophagia

0 = normal appetite
3-4 = eats less than half of normal amount of food
7 = no appetite at all

3. Carbohydrate Craving

0 = no craving
3-4 = strong craving for sweets, cakes, and cookies half the time
7 = strong craving for sweets, cakes, and cookies all the time

4. Cocaine Craving Intensity

Please use subject intensity rating from pg. 3 of this form.

5. Cocaine Craving Frequency

Please use subject frequency rating from pg. 3 of this form.

6. Bradycardia

Please use scale below.

	0	1	2	3	4	5	6	7
Pulse (BPM)	>64	64-63	62-61	60-59	58-57	56-55	54-53	<53

7. Insomnia

0 = normal amount of sleep
3-4 = half of normal amount of sleep
7 = no sleep at all

8. Hypersomnia

0 = normal amount of sleep
3-4 = could sleep or does sleep half the day
7 = sleep or could sleep all the time

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

9. Anxiety

0 = usually does not feel anxious
3-4 = feels anxious half the time
7 = feels anxious all the time

10. Energy Level

0 = feels alert and has usual amount of energy
3-4 = feels tired half the time
7 = feels tired all the time

11. Activity Level

0 = no change in usual activities
3-4 = participates in half of usual activities
7 = no participation in usual activities

12. Tension

0-1 = rarely feel tense
3-4 = feels tense half the time
7 = feels tense most or all the time

13. Attention

0 = able to concentrate on reading, conversation, tasks, and make plans without difficulty
3-4 = has difficulty with the above half the time
7 = has difficulty with the above all the time

14. Paranoid Ideation

0 = no evidence of paranoid thoughts
3-4 = unable to trust anyone
5 = feels people are out to get him/her
7 = feels a specific person/group is plotting against him/her

15. Anhedonia

0 = ability to enjoy themselves remains unchanged
3-4 = able to enjoy themselves half of the time
7 = unable to enjoy themselves at all

16. Depression

0 = no feelings related to sadness or depression
3-4 = feels sad or depressed half the time
7 = feels depressed all of the time

17. Suicidality

0 = does not think about being dead
3-4 = feels like life is not worth living
7 = feels like actually ending life

18. Irritability

0 = feels that most things are not irritating
3-4 = feels that many things are irritating
7 = feels that mostly everything is irritating and upsetting

Completed by (Initials):

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

CSSA VISUAL ANALOG SCALE

Please do not mark on upright lines.

Please rate the highest intensity of the desire for cocaine you have felt in the last 24 hours:

|____|____|____|____|____|____|____|____|

No Desire at all ***Unable to Resist***

Please identify on the line below, how often you have felt the urge to use cocaine in the last 24 hours:

|____|____|____|____|____|____|____|____|

Never ***All the Time***

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____

(mm/dd/yyyy)

Cocaine Global Severity

At this time, how would you rate yourself overall for cocaine use and cocaine related problems?

- ☐ No problems
- ☐ Borderline problems
- ☐ Mild problems
- ☐ Moderate problems
- ☐ Marked problems
- ☐ Severe symptoms
- ☐ Most extreme problems possible

Global Improvement of Cocaine Dependence

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

- ☐ Not assessed
- ☐ Very much improved
- ☐ Much improved
- ☐ Minimally improved
- ☐ No change
- ☐ Minimally worse
- ☐ Much worse
- ☐ Very much worse

Completed by (Initials): _____

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

Current Severity

Please rate the subject's current severity in the eight specific problem areas below.

	None, Least Severe						**Most Severe**
Reported Cocaine Use: (frequency and amount of cocaine used)	1	2	3	4	5	6	7
Cocaine Seeking: (craving for cocaine, effort to stop, and drug seeking behavior)	1	2	3	4	5	6	7
Reported Use of Other Drugs: (frequency and amount of non-cocaine drug/alcohol use)	1	2	3	4	5	6	7
Observable Psychiatric Symptoms: (orientation, memory, comprehension, disorganized thinking, rapid/retarded speech, agitation, grooming, hostility, irritability, affective disturbance)	1	2	3	4	5	6	7
Reported Psychiatric Symptoms: (mood disturbance, depression, anxiety,inner restlessness, covert anger, somatic symptoms, energy level,motivation, sleep, appetite, libido, anhedonia)	1	2	3	4	5	6	7
Physical/Medical Problems: (those that have emerged or gotten worse after drug use)	1	2	3	4	5	6	7
Maladaptive Coping in the Family/Social area: (movement away from healthy relationships)	1	2	3	4	5	6	7
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

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

Global Severity of Cocaine Dependence

Considering your total clinical experience with the cocaine dependent population, how severe are this subject's cocaine dependence symptoms at this time?

- ☐ Normal, no symptoms
- ☐ Borderline symptoms
- ☐ Mild symptoms
- ☐ Moderate symptoms
- ☐ Marked symptoms
- ☐ Severe symptoms
- ☐ Most extreme symptoms possible

Global Improvement of Cocaine Dependence

Rate the total improvement in the participant's cocaine dependence symptoms whether or not, in your judgment, it is due entirely to drug treatment. Compared to the subject's admission to the project, how
much has the subject changed?

- ☐ Not assessed, first rating
- ☐ Very much improved
- ☐ Much improved
- ☐ Minimally improved
- ☐ No change
- ☐ Minimally worse
- ☐ Much worse
- ☐ Very much worse

Completed by (Initials): _____

Treatment Week 3

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____ *(mm/dd/yyyy)*

Date doses dispensed _____ *(mm/dd/yyyy)*
Each dose is four tablets

Kit Number: _____

Bottle Number: _____

Number of doses dispensed _____

Date unused doses returned _____ *(mm/dd/yyyy)*

Number of doses returned _____

Number of doses reported lost by subject _____

Doses taken:

Day of Week:	Date *(mm/dd/yyyy)*	Time Dose Taken	Dose Not Taken

Comments: _____

Completed by (Initials): _____

Treatment Week 3

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

Did subject receive standardized, manual-guided individual psychotherapy this week?

(If No, please comment below) ☐ Yes ☐ No

If yes, length of psychotherapy session _____ minutes

Did subject require emergency crisis management sessions this week? ☐ Yes ☐ No

If yes, how many? _____

Additional comments:

Completed by (Initials): _____

Treatment Week 4

Site ID: | Subject ID #. | Subject Initials | Week

Date: *(mm/dd/yyyy)*

Weekly Vital Signs

☐ Vital signs not assessed at this visit

Date *(mm/dd/yyyy)* Time Vital Signs taken *(24 hour clock)*

Temperature (oral) (°F) NR: 94-100.4 CS ☐ NCS ☐

Comments for Temperature

Blood Pressure (sitting) (mm Hg) NR: 90-140/50-90 CS ☐ NCS ☐

Comments for Blood Pressure:

Pulse Rate (sitting) (beats/min) NR: 50-120 CS ☐ NCS ☐

Comments for Pulse Rate:

Respiratory Rate (sitting) (breaths/min) NR: 8-20 CS ☐ NCS ☐

Comments for Respiratory Rate:

Completed by (Initials):

Form 23 – URINE BE SPECIMEN COLLECTION FORM

Treatment Week 4 V1

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____

(mm/dd/yyyy)

First Study Visit of Week ***Urine bar code sticker:*** _____

Date urine collected: _____ Urine not collected ☐

(mm/dd/yyyy)

Was urine temperature within expected range? ☐ Yes ☐ No

Franklin Cup: The temperature must be higher than 96.0 ° F and lower than 104.8 ° F On-Trak Cup: The temperature must be higher than 90.0 ° F and lower than 99.0 ° F Split Sample Cup: The temperature must be higher than 90.0 ° F and lower than 100.0 ° F

Completed by (Initials): _____

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____

(mm/dd/yyyy)

Second Study Visit of Week ***Urine bar code sticker:*** _____

Date urine collected: _____ Urine not collected ☐
(mm/dd/yyyy)

Was urine temperature within expected range? ☐ Yes ☐ No

Franklin Cup: The temperature must be higher than 96.0 ° F and lower than 104.8 ° F On-Trak Cup: The temperature must be higher than 90.0 ° F and lower than 99.0 ° F Split Sample Cup: The temperature must be higher than 90.0 ° F and lower than 100.0 ° F

Completed by (Initials): _____

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

Third Study Visit of Week ***Urine bar code sticker:***

Date urine collected:

(mm/dd/yyyy)

Urine not collected ☐

Was urine temperature within expected range? ☐ Yes ☐ No

Franklin Cup: The temperature must be higher than 96.0 ° F and lower than 104.8 ° F On-Trak Cup: The temperature must be higher than 90.0 ° F and lower than 99.0 ° F Split Sample Cup: The temperature must be higher than 90.0 ° F and lower than 100.0 ° F

Completed by (Initials):

NIDA-MDS-Modaf-0001 **Form 24 – SUBSTANCE USE INVENTORY**

Treatment Week 4

Site ID: | Subject ID #. | Subject Initials | Week

Date: *(mm/dd/yyyy)*

Using timeline follow-back method, record whether subject has on each day since the last visit used any amount of the substances listed below, along with the most common route of administration for each drug. Begin with yesterday and work back to the last visit. Please be sure that days are continuous with last week's form.

Date of last visit: *(mm/dd/yyyy)*

Day of week							
Date							
	Used? ROA	**Used? ROA**	**Used? ROA**	**Used? ROA**	**Used? ROA**	**Used? ROA**	**Used? ROA**
Cocaine	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Alcohol	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Marijuana	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Amphetamines	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Opiates	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Barbiturates	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Benzodiazepines	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N

Route of administration (ROA) codes: 1 = oral, 2 = nasal, 3 = smoking, 4 = non-intravenous injection, 5 = intravenous injection

Completed by (Initials):

Treatment Week 4

Site ID: | Subject ID #. | Subject Initials | Week

Date: *(mm/dd/yyyy)*

	Value	Normal	Abnormal*	Abnormal* Significant	Not Done	Comments (required for abnormal values)
1. Specific gravity		☐	☐	☐	☐	
2. pH		☐	☐	☐	☐	
3. Glucose		☐	☐	☐	☐	
4. Protein		☐	☐	☐	☐	
5. Ketones		☐	☐	☐	☐	
6. Occult Blood		☐	☐	☐	☐	
7. WBC		☐	☐	☐	☐	
8. RBC		☐	☐	☐	☐	
9. Epithelial Cells		☐	☐	☐	☐	

"Abnormal" is any value outside the normal laboratory range.

For Glucose, Protein, Ketones, and Occult Blood use the following scale to report Values:

-1 = Absent
0 = Trace
1
2
3
4

For WBC, RBC, and Epithelial Cells use the following scale to report Values:

1 = None (1 – 5)
2 = Few (6 – 10)
3 = Moderate (11 – 50)
4 = Heavy (>50)

☐ Check here if this form is completed for retest of previous lab tests.

Date of original lab tests: *(mm/dd/yyyy)*

Completed by (Initials):

Treatment Week 4

Site ID: | Subject ID #. | Subject Initials | Week

Date: *(mm/dd/yyyy)*

	Value		Normal	Abnormal*	Abnormal* Significant	Not Done	Comments (required for abnormal values)
1. Hemoglobin		g/dL	☐	☐	☐	☐	
2. Hematocrit		%	☐	☐	☐	☐	
3. RBC		M/uL	☐	☐	☐	☐	
4. Platelet count		K/uL	☐	☐	☐	☐	
5. WBC		K/uL	☐	☐	☐	☐	
6. Neutrophils		%	☐	☐	☐	☐	
7. Lymphocytes		%	☐	☐	☐	☐	
8. Monocytes		%	☐	☐	☐	☐	
9. Eosinophils		%	☐	☐	☐	☐	
10. Basophils		%	☐	☐	☐	☐	

Please refer to Appendix I of the protocol when determining the significance of abnormal values.

****"Abnormal" is any value outside the normal laboratory range.***

million/uL = mil/cumm = mill/mcl = M/cmm = x10^6/cumm

x 10^3/uL = thou/cumm = thou/mcl = K/cmm = 1000/uL = x 10^3/cumm

☐ Check here if results on this form are retests of previous lab tests.

Date of original lab tests: *(mm/dd/yyyy)*

Treatment Week 4

Site ID: | Subject ID #. | Subject Initials | Week

Date: (mm/dd/yyyy)

	Value		Normal	Abnormal*	Abnormal* Significant	Not Done	Comments (Required for Abnormal values)
1. Sodium		mmol/L	☐	☐	☐	☐	
2. Potassium		mmol/L	☐	☐	☐	☐	
3. Chloride		mmol/L	☐	☐	☐	☐	
4. CO2		mmol/L	☐	☐	☐	☐	
5. Glucose		mg/dL	☐	☐	☐	☐	
6. Creatinine		mg/dL	☐	☐	☐	☐	
7. Albumin		g/dL	☐	☐	☐	☐	
8. Total protein		g/dL	☐	☐	☐	☐	
9. SGOT/AST		U/L	☐	☐	☐	☐	
10. SGPT/ALT		U/L	☐	☐	☐	☐	
11. GGT		U/L	☐	☐	☐	☐	
12. Bilirubin		mg/dL	☐	☐	☐	☐	
13. BUN		mg/dL	☐	☐	☐	☐	

Please refer to Appendix I of the protocol when determining significance of abnormal values.

**** "Abnormal" is any value outside the normal laboratory range.***

mmol/L = mEq/L

☐ Check here if this form is completed for retest of previous lab tests.

Date of original lab tests (mm/dd/yyyy)

Treatment Week 4

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

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

If ECG is Normal please skip to Question C.

B. If ECG is abnormal, check below for all abnormalities.

	Abnormal	Abnormal Significant		Abnormal	Abnormal Significant
1. Increased QRS voltage	☐	☐	17. Supraventricular premature beat	☐	☐
2. Qtc prolongation	☐	☐	18. Ventricular premature beat	☐	☐
3. Left atrial hypertrophy	☐	☐	19. Supraventricular tachycardia	☐	☐
4. Right atrial hypertrophy	☐	☐	20. Ventricular tachycardia	☐	☐
5. Left ventricular hypertrophy	☐	☐	21. Atrial fibrillation	☐	☐
6. Right ventricular hypertrophy	☐	☐	22. Atrial flutter	☐	☐
7. Acute infarction	☐	☐	23. Other rhythm abnormalities	☐	☐
8. Subacute infarction	☐	☐	24. Implanted pacemaker	☐	☐
9. Old infarction	☐	☐	25. 1st degree A-V block	☐	☐
10. Myocardial ischemia	☐	☐	26. 2nd degree A-V block	☐	☐
11. Digitalis effect	☐	☐	27. 3rd degree A-V block	☐	☐
12. Symmetrical T-wave inversions	☐	☐	28. LBB block	☐	☐
13. Poor R-wave progression	☐	☐	29. RBB block	☐	☐
14. Other nonspecific ST/T	☐	☐	30. Pre-excitation syndrome	☐	☐
15. Sinus tachycardia	☐	☐	31. Other intraventricular condition	☐	☐
16. Sinus bradycardia	☐	☐	32. Other, specify _____	☐	☐

C. Ventricular rate (bpm) _____

D. PR (ms) _____

E. QRS (ms) _____

F. QTC (ms) _____

G. Are there any abnormalities noted above that preclude the subject from safe entry into or continuation in the study? ☐ **Yes** ☐ **No**

Treatment Week 4

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

Comments:

Treatment Week 4

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____

(mm/dd/yyyy

Cocaine

1. The intensity of my craving, that is, how much I desired cocaine in the past 24 hours was:

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

2. The frequency of my craving, that is, how often I desired cocaine in the past 24 hours was:

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

3. The length of time I spent craving for cocaine during the past 24 hours was:

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

4. Write in the number of times you think you had craving for cocaine during the past 24 hours:

_____

5. Write in the total time spent craving cocaine during the past 24 hours:

_____ hours _____ minutes

6. The worst day: During the past week my most intense craving occurred on the following day:

☐ Sunday ☐ Monday ☐ Tuesday ☐ Wednesday
☐ Thursday ☐ Friday ☐ Saturday ☐ All days the same (go to Q. 8)

7. The date for that day was: _____

(mm/dd/yyyy)

8. The intensity of my craving, that is, how much I desired cocaine on that worst day was:

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

Second Drug

9. A **2nd** craved drug during the past 24 hours was:
Mark only one of the following. If no 2nd craved drug, mark "None" and leave Questions 10-16 blank.

☐ None ☐ Downers or Sedatives (Barbiturates, etc.) ☐ Benzos (Valium, Xanax, etc.) ☐ Nicotine
☐ Alcohol ☐ Heroin or other Opiates (Morphine, etc.) ☐ Marijuana ☐ Other Specify _____

10. The intensity of my craving, that is, how much I desired this **second** drug in the past 24 hours was:

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

Treatment Week 4

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____

(mm/dd/yyyy

11. The frequency of my craving, that is, how often I desired this **second** drug in the past 24 hours was:

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

12. The length of time I spent in craving for this **second** drug during the past 24 hours was:

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

Third Drug

13. A **3rd** craved drug during the past 24 hours was:
Mark only one of the following. If no 3rd craved drug, mark "None" and leave questions 14-16 blank.

☐ None ☐ Downers or Sedatives (Barbiturates, etc.) ☐ Benzos (Valium, Xanax, etc.) ☐ Nicotine

☐ Alcohol ☐ Heroin or other Opiates (Morphine, etc.) ☐ Marijuana ☐ Other Specify _____

14. The intensity of my craving, that is, how much I desired this **third** drug in the past 24 hours was:

☐ 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:

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

16. The length of time I spent in craving for this third drug during the past 24 hours was:

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

Completed by (Initials): _____

Treatment Week 4

Site ID: | Subject ID #. | Subject Initials | Week

Date: *(mm/dd/yyyy)*

All questions except 4 and 5 are assessed by properly trained personnel. The subject is asked about each of the items in lay language and the response is recorded on a scale of 0-7 with 0 being normal or no symptoms. For question 4 and 5, the subject is asked to mark the appropriate place on the line (on page 3) that describes each of the questions. The rater then transcribes that as the response to those questions.

Date of last cocaine use: *(mm/dd/yyyy)*

1. Hyperphagia

0 = normal appetite
3-4 = eats a lot more than usual
7 = eats more than twice usual amount of food

2. Hypophagia

0 = normal appetite
3-4 = eats less than half of normal amount of food
7 = no appetite at all

3. Carbohydrate Craving

0 = no craving
3-4 = strong craving for sweets, cakes, and cookies half the time
7 = strong craving for sweets, cakes, and cookies all the time

4. Cocaine Craving Intensity

Please use subject intensity rating from pg. 3 of this form.

5. Cocaine Craving Frequency

Please use subject frequency rating from pg. 3 of this form.

6. Bradycardia

Please use scale below.

	0	1	2	3	4	5	6	7
Pulse (BPM)	>64	64-63	62-61	60-59	58-57	56-55	54-53	<53

7. Insomnia

0 = normal amount of sleep
3-4 = half of normal amount of sleep
7 = no sleep at all

8. Hypersomnia

0 = normal amount of sleep
3-4 = could sleep or does sleep half the day
7 = sleep or could sleep all the time

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

9. Anxiety _____

0 = usually does not feel anxious
3-4 = feels anxious half the time
7 = feels anxious all the time

10. Energy Level _____

0 = feels alert and has usual amount of energy
3-4 = feels tired half the time
7 = feels tired all the time

11. Activity Level _____

0 = no change in usual activities
3-4 = participates in half of usual activities
7 = no participation in usual activities

12. Tension _____

0-1 = rarely feel tense
3-4 = feels tense half the time
7 = feels tense most or all the time

13. Attention _____

0 = able to concentrate on reading, conversation, tasks, and make plans without difficulty
3-4 = has difficulty with the above half the time
7 = has difficulty with the above all the time

14. Paranoid Ideation _____

0 = no evidence of paranoid thoughts
3-4 = unable to trust anyone
5 = feels people are out to get him/her
7 = feels a specific person/group is plotting against him/her

15. Anhedonia _____

0 = ability to enjoy themselves remains unchanged
3-4 = able to enjoy themselves half of the time
7 = unable to enjoy themselves at all

16. Depression _____

0 = no feelings related to sadness or depression
3-4 = feels sad or depressed half the time
7 = feels depressed all of the time

17. Suicidality _____

0 = does not think about being dead
3-4 = feels like life is not worth living
7 = feels like actually ending life

18. Irritability _____

0 = feels that most things are not irritating
3-4 = feels that many things are irritating
7 = feels that mostly everything is irritating and upsetting

Completed by (Initials): _____

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

CSSA VISUAL ANALOG SCALE

Please do not mark on upright lines.

Please rate the highest intensity of the desire for cocaine you have felt in the last 24 hours:

|_____|_____|_____|_____|_____|_____|_____|

No Desire at all ***Unable to Resist***

Please identify on the line below, how often you have felt the urge to use cocaine in the last 24 hours:

|_____|_____|_____|_____|_____|_____|_____|

Never ***All the Time***

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

Cocaine Global Severity

At this time, how would you rate yourself overall for cocaine use and cocaine related problems?

- ☐ No problems
- ☐ Borderline problems
- ☐ Mild problems
- ☐ Moderate problems
- ☐ Marked problems
- ☐ Severe symptoms
- ☐ Most extreme problems possible

Global Improvement of Cocaine Dependence

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

- ☐ Not assessed
- ☐ Very much improved
- ☐ Much improved
- ☐ Minimally improved
- ☐ No change
- ☐ Minimally worse
- ☐ Much worse
- ☐ Very much worse

Completed by (Initials):

Treatment Week 4

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

Current Severity

Please rate the subject's current severity in the eight specific problem areas below.

	None, Least Severe						**Most Severe**
Reported Cocaine Use: (frequency and amount of cocaine used)	1	2	3	4	5	6	7
Cocaine Seeking: (craving for cocaine, effort to stop, and drug seeking behavior)	1	2	3	4	5	6	7
Reported Use of Other Drugs: (frequency and amount of non-cocaine drug/alcohol use)	1	2	3	4	5	6	7
Observable Psychiatric Symptoms: (orientation, memory, comprehension, disorganized thinking, rapid/retarded speech, agitation, grooming, hostility, irritability, affective disturbance)	1	2	3	4	5	6	7
Reported Psychiatric Symptoms: (mood disturbance, depression, anxiety,inner restlessness, covert anger, somatic symptoms, energy level,motivation, sleep, appetite, libido, anhedonia)	1	2	3	4	5	6	7
Physical/Medical Problems: (those that have emerged or gotten worse after drug use)	1	2	3	4	5	6	7
Maladaptive Coping in the Family/Social area: (movement away from healthy relationships)	1	2	3	4	5	6	7
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

Treatment Week 4

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

Global Severity of Cocaine Dependence

Considering your total clinical experience with the cocaine dependent population, how severe are this subject's cocaine dependence symptoms at this time?

- ☐ Normal, no symptoms
- ☐ Borderline symptoms
- ☐ Mild symptoms
- ☐ Moderate symptoms
- ☐ Marked symptoms
- ☐ Severe symptoms
- ☐ Most extreme symptoms possible

Global Improvement of Cocaine Dependence

Rate the total improvement in the participant's cocaine dependence symptoms whether or not, in your judgment, it is due entirely to drug treatment. Compared to the subject's admission to the project, how
much has the subject changed?

- ☐ Not assessed, first rating
- ☐ Very much improved
- ☐ Much improved
- ☐ Minimally improved
- ☐ No change
- ☐ Minimally worse
- ☐ Much worse
- ☐ Very much worse

Completed by (Initials):

NIDA-MDS-Modaf-0001 **Form 15 – HAMILTON DEPRESSION RATING SCALE**

Treatment Week 4

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

1. Depressed Mood

(sad, 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. Feelings of Guilt

- ☐ 0 = Absent
- ☐ 1 = Self-reproach, feels s/he 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. Suicide

- ☐ 0 = Absent
- ☐ 1 = Feels life is not worth living.
- ☐ 2 = Wishes s/he were dead or any thoughts of possible death to self.
- ☐ 3 = Suicide ideas or gesture.
- ☐ 4 = Attempts at suicide (any serious attempt rates 4).

4. Insomnia Early

- ☐ 0 = No difficulty falling asleep.
- ☐ 1 = Complains of occasional difficulty falling asleep. (i.e., more than ½ hour)
- ☐ 2 = Complains of nightly difficulty falling asleep.

5. 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. 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.

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

7. Work and 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 patient, or indirect in listlessness, indecision and vacillation *(feels s/he has to push self to work or activities).*
- ☐ 3 = Decrease in actual time spent in activities or decrease in productivity.
- ☐ 4 = Stopped working because of present illness.

8. 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. Agitation

- ☐ 0 = None
- ☐ 1 = Fidgetiness
- ☐ 2 = Playing with hands, hair, etc.
- ☐ 3 = Moving about, can't sit still
- ☐ 4 = Hand-wringing, nail-biting, hair-pulling, biting of lips

10. 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. Anxiety Somatic

(Physiological concomitants of anxiety such as: Gastrointestinal: dry mouth, wind, indigestion, diarrhea, cramps, belching. Cardiovascular: palpitations, headaches. Respiratory: hyperventilation, sighing. Urinary frequency. Sweating.)

- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Moderate
- ☐ 3 = Severe
- ☐ 4 = Incapacitating

12. Somatic Symptoms Gastrointestinal

- ☐ 0 = None
- ☐ 1 = Loss of appetite but eating without encouragement. Heavy feelings in abdomen.
- ☐ 2 = Difficulty eating without urging. Requests or requires laxatives or medication for bowels or medication for G.I. symptoms.

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

13. Somatic Symptoms General
- ☐ 0 = None
- ☐ 1 = Heaviness in limbs, back or head. Backaches, headache, muscle aches. Loss of energy and fatigability.
- ☐ 2 = Any clear-cut symptom rates 2.

14. Genital Symptoms
(such as loss of libido and menstrual disturbances)

- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Severe

15. Hypochondriasis

- ☐ 0 = Not present
- ☐ 1 = Self-absorption (bodily)
- ☐ 2 = Preoccupation with health
- ☐ 3 = Frequent complaints, requests for help, etc.
- ☐ 4 = Hypochondriacal delusions

16. Loss of Weight

- ☐ 0 = No weight loss
- ☐ 1 = Probable weight loss associated with present illness.
- ☐ 2 = Definite weight loss (according to subject)

17. 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

18. Diurnal Variation

- ☐ 0 = No variation
- ☐ 1 = (Mild) Doubtful or slight variation
- ☐ 2 = (Severe) Clear or marked variation

If answer is 1 or 2, note whether the symptoms are worse in: O A.M. O P.M.

19. Depersonalization and Derealization
(symptoms such as feelings of unreality and nihilistic ideas)

- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Moderate
- ☐ 3 = Severe
- ☐ 4 = Incapacitating

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

20. Paranoid Symptoms

- ☐ 0 = None
- ☐ 1 = Suspicious
- ☐ 2 = Ideas of reference
- ☐ 3 = Delusions of reference and persecution

21. Obsessive and Compulsive Symptoms

- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Severe

22. 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 chores or personal hygiene.
- ☐ 4 = Despite urging, does not perform necessary chores or personal hygiene.

23. 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. Worthlessness

(ranges from mild loss of self-esteem, feelings of inferiority, self-depreciation (loss of self-esteem) to delusion notions of 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 s/he is “no good,” “inferior,” etc.
- ☐ 4 = Expresses feelings of total worthlessness – e.g. “I am a heap of garbage” or equivalent

Completed by (Initials):

Treatment Week 4

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____

(mm/dd/yyyy)

Date doses dispensed _____
Each dose is four tablets *(mm/dd/yyyy)*

Kit Number: _____

Bottle Number: _____

Number of doses dispensed _____

Date unused doses returned _____
(mm/dd/yyyy)

Number of doses returned _____

Number of doses reported lost by subject _____

Doses taken:

Day of Week:	Date *(mm/dd/yyyy)*	Time Dose Taken	Dose Not Taken

Comments: _____

Completed by (Initials): _____

Treatment Week 4

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

Did subject receive standardized, manual-guided individual psychotherapy this week?

(If No, please comment below) ☐ Yes ☐ No

If yes, length of psychotherapy session ____ minutes

Did subject require emergency crisis management sessions this week? ☐ Yes ☐ No

If yes, how many? ____

Additional comments:

Completed by (Initials): ____

Treatment Week 4

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

This form is to be filled out for female subjects only. All female subjects must be tested at Screening/Baseline and have a negative pregnancy test in order to be eligible for this study.

What method of birth control is the participant currently using (prior to taking modafinil)?

- ☐ Oral contraceptive
- ☐ Barrier (diaphragm or condom plus spermicide)
- ☐ Levonorgestrel implant (Norplant)
- ☐ Intrauterine Contraceptive system (IUD)
- ☐ Medroxyprogesterone Acetate Contraceptive injection (Depo-Provera)
- ☐ Surgical Sterilization - Hysterectomy
- ☐ Surgical Sterilization - Tubal ligation

Unless surgically sterile or 2 years postmenopausal, does the subject agree to use an acceptable method of birth control during the study and 30 days after last dose of study drug?

☐ Yes ☐ No

If yes, mark below the acceptable method selected by the subject for use:

- ☐ barrier method with spermicide
- ☐ steroidal contraceptive [oral, Implanted, injected] used in conjunction with a barrier method
- ☐ Contraceptive patch used in conjunction with a barrier method
- ☐ Intrauterine device [IUD]

Was a pregnancy test performed? ☐ Yes ☐ No

If yes, date specimen collected

(mm/dd/yyyy)

Result: ☐ Negative ☐ Positive ☐ Unknown

If no, specify reason:

Is the subject lactating? ☐ Yes ☐ No

Comments:

Completed by (Initials):

Treatment Week 5

Site ID: | Subject ID #. | Subject Initials | Week

Date: *(mm/dd/yyyy)*

Weekly Vital Signs

☐ Vital signs not assessed at this visit

Date *(mm/dd/yyyy)* Time Vital Signs taken *(24 hour clock)*

Temperature (oral) (°F) NR: 94-100.4 CS ☐ NCS ☐

Comments for Temperature

Blood Pressure (sitting) (mm Hg) NR: 90-140/50-90 CS ☐ NCS ☐

Comments for Blood Pressure:

Pulse Rate (sitting) (beats/min) NR: 50-120 CS ☐ NCS ☐

Comments for Pulse Rate:

Respiratory Rate (sitting) (breaths/min) NR: 8-20 CS ☐ NCS ☐

Comments for Respiratory Rate:

Completed by (Initials):

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

First Study Visit of Week ***Urine bar code sticker:***

Date urine collected:

(mm/dd/yyyy)

Urine not collected ☐

Was urine temperature within expected range? ☐ Yes ☐ No

Franklin Cup: The temperature must be higher than 96.0° F and lower than 104.8° F On-Trak Cup: The temperature must be higher than 90.0 ° F and lower than 99.0° F Split Sample Cup: The temperature must be higher than 90.0° F and lower than 100.0° F

Completed by (Initials):

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

Second Study Visit of Week ***Urine bar code sticker:***

Date urine collected:
(mm/dd/yyyy)

Urine not collected ☐

Was urine temperature within expected range? ☐ Yes ☐ No

Franklin Cup: The temperature must be higher than 96.0 ° F and lower than 104.8 ° F On-Trak Cup: The temperature must be higher than 90.0 ° F and lower than 99.0 ° F Split Sample Cup: The temperature must be higher than 90.0 ° F and lower than 100.0 ° F

Completed by (Initials):

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

Third Study Visit of Week ***Urine bar code sticker:***

Date urine collected:

(mm/dd/yyyy)

Urine not collected ☐

Was urine temperature within expected range? ☐ Yes ☐ No

Franklin Cup: The temperature must be higher than 96.0 ° F and lower than 104.8 ° F On-Trak Cup: The temperature must be higher than 90.0 ° F and lower than 99.0 ° F Split Sample Cup: The temperature must be higher than 90.0 ° F and lower than 100.0 ° F

Completed by (Initials):

NIDA-MDS-Modaf-0001 **Form 24 – SUBSTANCE USE INVENTORY**

Treatment Week 5

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

Using timeline follow-back method, record whether subject has on each day since the last visit used any amount of the substances listed below, along with the most common route of administration for each drug. Begin with yesterday and work back to the last visit. Please be sure that days are continuous with last week's form.

Date of last visit:

(mm/dd/yyyy)

Day of week							
Date							
	Used? ROA	**Used? ROA**	**Used? ROA**	**Used? ROA**	**Used? ROA**	**Used? ROA**	**Used? ROA**
Cocaine	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Alcohol	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Marijuana	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Amphetamines	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Opiates	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Barbiturates	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Benzodiazepines	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N

Route of administration (ROA) codes: 1 = oral, 2 = nasal, 3 = smoking, 4 = non-intravenous injection, 5 = intravenous injection

Completed by (Initials):

Treatment Week 5

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

Cocaine

1. The intensity of my craving, that is, how much I desired cocaine in the past 24 hours was:

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

2. The frequency of my craving, that is, how often I desired cocaine in the past 24 hours was:

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

3. The length of time I spent craving for cocaine during the past 24 hours was:

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

4. Write in the number of times you think you had craving for cocaine during the past 24 hours:

5. Write in the total time spent craving cocaine during the past 24 hours:

hours minutes

6. The worst day: During the past week my most intense craving occurred on the following day:

☐ Sunday ☐ Monday ☐ Tuesday ☐ Wednesday
☐ Thursday ☐ Friday ☐ Saturday ☐ All days the same (go to Q. 8)

7. The date for that day was:

(mm/dd/yyyy)

8. The intensity of my craving, that is, how much I desired cocaine on that worst day was:

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

Second Drug

9. A **2nd** craved drug during the past 24 hours was:
Mark only one of the following. If no 2nd craved drug, mark "None" and leave Questions 10-16 blank.

☐ None ☐ Downers or Sedatives (Barbiturates, etc.) ☐ Benzos (Valium, Xanax, etc.) ☐ Nicotine
☐ Alcohol ☐ Heroin or other Opiates (Morphine, etc.) ☐ Marijuana ☐ Other Specify

10. The intensity of my craving, that is, how much I desired this **second** drug in the past 24 hours was:

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

Treatment Week 5

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____

(mm/dd/yyyy)

11. The frequency of my craving, that is, how often I desired this **second** drug in the past 24 hours was:

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

12. The length of time I spent in craving for this **second** drug during the past 24 hours was:

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

Third Drug

13. A **3rd** craved drug during the past 24 hours was:
Mark only one of the following. If no 3rd craved drug, mark "None" and leave questions 14-16 blank.

☐ None ☐ Downers or Sedatives (Barbiturates, etc.) ☐ Benzos (Valium, Xanax, etc.) ☐ Nicotine

☐ Alcohol ☐ Heroin or other Opiates (Morphine, etc.) ☐ Marijuana ☐ Other Specify _____

14. The intensity of my craving, that is, how much I desired this **third** drug in the past 24 hours was:

☐ 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:

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

16. The length of time I spent in craving for this third drug during the past 24 hours was:

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

Completed by (Initials): _____

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

All questions except 4 and 5 are assessed by properly trained personnel. The subject is asked about each of the items in lay language and the response is recorded on a scale of 0-7 with 0 being normal or no symptoms. For question 4 and 5, the subject is asked to mark the appropriate place on the line (on page 3) that describes each of the questions. The rater then transcribes that as the response to those questions.

Date of last cocaine use:

(mm/dd/yyyy)

1. Hyperphagia

0 = normal appetite
3-4 = eats a lot more than usual
7 = eats more than twice usual amount of food

2. Hypophagia

0 = normal appetite
3-4 = eats less than half of normal amount of food
7 = no appetite at all

3. Carbohydrate Craving

0 = no craving
3-4 = strong craving for sweets, cakes, and cookies half the time
7 = strong craving for sweets, cakes, and cookies all the time

4. Cocaine Craving Intensity

Please use subject intensity rating from pg. 3 of this form.

5. Cocaine Craving Frequency

Please use subject frequency rating from pg. 3 of this form.

6. Bradycardia

Please use scale below.

	0	1	2	3	4	5	6	7
Pulse (BPM)	>64	64-63	62-61	60-59	58-57	56-55	54-53	<53

7. Insomnia

0 = normal amount of sleep
3-4 = half of normal amount of sleep
7 = no sleep at all

8. Hypersomnia

0 = normal amount of sleep
3-4 = could sleep or does sleep half the day
7 = sleep or could sleep all the time

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

9. Anxiety

0 = usually does not feel anxious
3-4 = feels anxious half the time
7 = feels anxious all the time

10. Energy Level

0 = feels alert and has usual amount of energy
3-4 = feels tired half the time
7 = feels tired all the time

11. Activity Level

0 = no change in usual activities
3-4 = participates in half of usual activities
7 = no participation in usual activities

12. Tension

0-1 = rarely feel tense
3-4 = feels tense half the time
7 = feels tense most or all the time

13. Attention

0 = able to concentrate on reading, conversation, tasks, and make plans without difficulty
3-4 = has difficulty with the above half the time
7 = has difficulty with the above all the time

14. Paranoid Ideation

0 = no evidence of paranoid thoughts
3-4 = unable to trust anyone
5 = feels people are out to get him/her
7 = feels a specific person/group is plotting against him/her

15. Anhedonia

0 = ability to enjoy themselves remains unchanged
3-4 = able to enjoy themselves half of the time
7 = unable to enjoy themselves at all

16. Depression

0 = no feelings related to sadness or depression
3-4 = feels sad or depressed half the time
7 = feels depressed all of the time

17. Suicidality

0 = does not think about being dead
3-4 = feels like life is not worth living
7 = feels like actually ending life

18. Irritability

0 = feels that most things are not irritating
3-4 = feels that many things are irritating
7 = feels that mostly everything is irritating and upsetting

Completed by (Initials):

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

CSSA VISUAL ANALOG SCALE

Please do not mark on upright lines.

Please rate the highest intensity of the desire for cocaine you have felt in the last 24 hours:

|____|____|____|____|____|____|____|____|

No Desire at all ***Unable to Resist***

Please identify on the line below, how often you have felt the urge to use cocaine in the last 24 hours:

|____|____|____|____|____|____|____|____|

Never ***All the Time***

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

Cocaine Global Severity

At this time, how would you rate yourself overall for cocaine use and cocaine related problems?

- ☐ No problems
- ☐ Borderline problems
- ☐ Mild problems
- ☐ Moderate problems
- ☐ Marked problems
- ☐ Severe symptoms
- ☐ Most extreme problems possible

Global Improvement of Cocaine Dependence

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

- ☐ Not assessed
- ☐ Very much improved
- ☐ Much improved
- ☐ Minimally improved
- ☐ No change
- ☐ Minimally worse
- ☐ Much worse
- ☐ Very much worse

Completed by (Initials):

Treatment Week 5

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

Current Severity

Please rate the subject's current severity in the eight specific problem areas below.

	None, Least Severe						**Most Severe**
Reported Cocaine Use: (frequency and amount of cocaine used)	1	2	3	4	5	6	7
Cocaine Seeking: (craving for cocaine, effort to stop, and drug seeking behavior)	1	2	3	4	5	6	7
Reported Use of Other Drugs: (frequency and amount of non-cocaine drug/alcohol use)	1	2	3	4	5	6	7
Observable Psychiatric Symptoms: (orientation, memory, comprehension, disorganized thinking, rapid/retarded speech, agitation, grooming, hostility, irritability, affective disturbance)	1	2	3	4	5	6	7
Reported Psychiatric Symptoms: (mood disturbance, depression, anxiety,inner restlessness, covert anger, somatic symptoms, energy level,motivation, sleep, appetite, libido, anhedonia)	1	2	3	4	5	6	7
Physical/Medical Problems: (those that have emerged or gotten worse after drug use)	1	2	3	4	5	6	7
Maladaptive Coping in the Family/Social area: (movement away from healthy relationships)	1	2	3	4	5	6	7
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

Treatment Week 5

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

Global Severity of Cocaine Dependence

Considering your total clinical experience with the cocaine dependent population, how severe are this subject's cocaine dependence symptoms at this time?

- ☐ Normal, no symptoms
- ☐ Borderline symptoms
- ☐ Mild symptoms
- ☐ Moderate symptoms
- ☐ Marked symptoms
- ☐ Severe symptoms
- ☐ Most extreme symptoms possible

Global Improvement of Cocaine Dependence

Rate the total improvement in the participant's cocaine dependence symptoms whether or not, in your judgment, it is due entirely to drug treatment. Compared to the subject's admission to the project, how
much has the subject changed?

- ☐ Not assessed, first rating
- ☐ Very much improved
- ☐ Much improved
- ☐ Minimally improved
- ☐ No change
- ☐ Minimally worse
- ☐ Much worse
- ☐ Very much worse

Completed by (Initials):

Treatment Week 5

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

Date doses dispensed *(mm/dd/yyyy)*

Each dose is four tablets

Kit Number:

Bottle Number:

Number of doses dispensed

Date unused doses returned *(mm/dd/yyyy)*

Number of doses returned

Number of doses reported lost by subject

Doses taken:

Day of Week:	Date *(mm/dd/yyyy)*	Time Dose Taken	Dose Not Taken

Comments:

Completed by (Initials):

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

Did subject receive standardized, manual-guided individual psychotherapy this week?

(If No, please comment below) ☐ Yes ☐ No

If yes, length of psychotherapy session ____ minutes

Did subject require emergency crisis management sessions this week? ☐ Yes ☐ No

If yes, how many? ____

Additional comments:

Completed by (Initials): ____

Treatment Week 6

Site ID: | Subject ID #. | Subject Initials | Week

Date: *(mm/dd/yyyy)*

Weekly Vital Signs

☐ Vital signs not assessed at this visit

Date (mm/dd/yyyy) Time Vital Signs taken (24 hour clock)

Temperature (oral) (°F) NR: 94-100.4 CS ☐ NCS ☐

Comments for Temperature

Blood Pressure (sitting) (mm Hg) NR: 90-140/50-90 CS ☐ NCS ☐

Comments for Blood Pressure:

Pulse Rate (sitting) (beats/min) NR: 50-120 CS ☐ NCS ☐

Comments for Pulse Rate:

Respiratory Rate (sitting) (breaths/min) NR: 8-20 CS ☐ NCS ☐

Comments for Respiratory Rate:

Completed by (Initials):

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

First Study Visit of Week ***Urine bar code sticker:***

Date urine collected:

(mm/dd/yyyy)

Urine not collected ☐

Was urine temperature within expected range? ☐ Yes ☐ No

Franklin Cup: The temperature must be higher than 96.0 ° F and lower than 104.8 ° F On-Trak Cup: The temperature must be higher than 90.0 ° F and lower than 99.0 ° F Split Sample Cup: The temperature must be higher than 90.0 ° F and lower than 100.0 ° F

Completed by (Initials):

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

Second Study Visit of Week ***Urine bar code sticker:***

Date urine collected:
(mm/dd/yyyy)

Urine not collected ☐

Was urine temperature within expected range? ☐ Yes ☐ No

Franklin Cup: The temperature must be higher than 96.0 ° F and lower than 104.8 ° F On-Trak Cup: The temperature must be higher than 90.0 ° F and lower than 99.0 ° F Split Sample Cup: The temperature must be higher than 90.0 ° F and lower than 100.0 ° F

Completed by (Initials):

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

Third Study Visit of Week ***Urine bar code sticker:***

Date urine collected:

(mm/dd/yyyy)

Urine not collected ☐

Was urine temperature within expected range? ☐ Yes ☐ No

Franklin Cup: The temperature must be higher than 96.0 ° F and lower than 104.8 ° F On-Trak Cup: The temperature must be higher than 90.0 ° F and lower than 99.0 ° F Split Sample Cup: The temperature must be higher than 90.0 ° F and lower than 100.0 ° F

Completed by (Initials):

NIDA-MDS-Modaf-0001 **Form 24 – SUBSTANCE USE INVENTORY**

Treatment Week 6

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

Using timeline follow-back method, record whether subject has on each day since the last visit used any amount of the substances listed below, along with the most common route of administration for each drug. Begin with yesterday and work back to the last visit. Please be sure that days are continuous with last week's form.

Date of last visit:

(mm/dd/yyyy)

Day of week							
Date							
	Used? ROA	**Used? ROA**	**Used? ROA**	**Used? ROA**	**Used? ROA**	**Used? ROA**	**Used? ROA**
Cocaine	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Alcohol	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Marijuana	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Amphetamines	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Opiates	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Barbiturates	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Benzodiazepines	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N

Route of administration (ROA) codes: 1 = oral, 2 = nasal, 3 = smoking, 4 = non-intravenous injection, 5 = intravenous injection

Completed by (Initials):

Treatment Week 6

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

Cocaine

1. The intensity of my craving, that is, how much I desired cocaine in the past 24 hours was:

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

2. The frequency of my craving, that is, how often I desired cocaine in the past 24 hours was:

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

3. The length of time I spent craving for cocaine during the past 24 hours was:

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

4. Write in the number of times you think you had craving for cocaine during the past 24 hours:

5. Write in the total time spent craving cocaine during the past 24 hours:

hours minutes

6. The worst day: During the past week my most intense craving occurred on the following day:

☐ Sunday ☐ Monday ☐ Tuesday ☐ Wednesday
☐ Thursday ☐ Friday ☐ Saturday ☐ All days the same (go to Q. 8)

7. The date for that day was:

(mm/dd/yyyy)

8. The intensity of my craving, that is, how much I desired cocaine on that worst day was:

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

Second Drug

9. A **2nd** craved drug during the past 24 hours was:
Mark only one of the following. If no 2nd craved drug, mark "None" and leave Questions 10-16 blank.

☐ None ☐ Downers or Sedatives (Barbiturates, etc.) ☐ Benzos (Valium, Xanax, etc.) ☐ Nicotine
☐ Alcohol ☐ Heroin or other Opiates (Morphine, etc.) ☐ Marijuana ☐ Other Specify

10. The intensity of my craving, that is, how much I desired this **second** drug in the past 24 hours was:

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

Treatment Week 6

Site ID: | Subject ID #. | Subject Initials | Week

Date: *(mm/dd/yyyy)*

11. The frequency of my craving, that is, how often I desired this **second** drug in the past 24 hours was:

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

12. The length of time I spent in craving for this **second** drug during the past 24 hours was:

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

Third Drug

13. A **3rd** craved drug during the past 24 hours was:
Mark only one of the following. If no 3rd craved drug, mark "None" and leave questions 14-16 blank.

☐ None ☐ Downers or Sedatives (Barbiturates, etc.) ☐ Benzos (Valium, Xanax, etc.) ☐ Nicotine

☐ Alcohol ☐ Heroin or other Opiates (Morphine, etc.) ☐ Marijuana ☐ Other Specify

14. The intensity of my craving, that is, how much I desired this **third** drug in the past 24 hours was:

☐ 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:

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

16. The length of time I spent in craving for this third drug during the past 24 hours was:

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

Completed by (Initials):

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

All questions except 4 and 5 are assessed by properly trained personnel. The subject is asked about each of the items in lay language and the response is recorded on a scale of 0-7 with 0 being normal or no symptoms. For question 4 and 5, the subject is asked to mark the appropriate place on the line (on page 3) that describes each of the questions. The rater then transcribes that as the response to those questions.

Date of last cocaine use:

(mm/dd/yyyy)

1. Hyperphagia

0 = normal appetite
3-4 = eats a lot more than usual
7 = eats more than twice usual amount of food

2. Hypophagia

0 = normal appetite
3-4 = eats less than half of normal amount of food
7 = no appetite at all

3. Carbohydrate Craving

0 = no craving
3-4 = strong craving for sweets, cakes, and cookies half the time
7 = strong craving for sweets, cakes, and cookies all the time

4. Cocaine Craving Intensity

Please use subject intensity rating from pg. 3 of this form.

5. Cocaine Craving Frequency

Please use subject frequency rating from pg. 3 of this form.

6. Bradycardia

Please use scale below.

	0	1	2	3	4	5	6	7
Pulse (BPM)	>64	64-63	62-61	60-59	58-57	56-55	54-53	<53

7. Insomnia

0 = normal amount of sleep
3-4 = half of normal amount of sleep
7 = no sleep at all

8. Hypersomnia

0 = normal amount of sleep
3-4 = could sleep or does sleep half the day
7 = sleep or could sleep all the time

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

9. Anxiety

0 = usually does not feel anxious
3-4 = feels anxious half the time
7 = feels anxious all the time

10. Energy Level

0 = feels alert and has usual amount of energy
3-4 = feels tired half the time
7 = feels tired all the time

11. Activity Level

0 = no change in usual activities
3-4 = participates in half of usual activities
7 = no participation in usual activities

12. Tension

0-1 = rarely feel tense
3-4 = feels tense half the time
7 = feels tense most or all the time

13. Attention

0 = able to concentrate on reading, conversation, tasks, and make plans without difficulty
3-4 = has difficulty with the above half the time
7 = has difficulty with the above all the time

14. Paranoid Ideation

0 = no evidence of paranoid thoughts
3-4 = unable to trust anyone
5 = feels people are out to get him/her
7 = feels a specific person/group is plotting against him/her

15. Anhedonia

0 = ability to enjoy themselves remains unchanged
3-4 = able to enjoy themselves half of the time
7 = unable to enjoy themselves at all

16. Depression

0 = no feelings related to sadness or depression
3-4 = feels sad or depressed half the time
7 = feels depressed all of the time

17. Suicidality

0 = does not think about being dead
3-4 = feels like life is not worth living
7 = feels like actually ending life

18. Irritability

0 = feels that most things are not irritating
3-4 = feels that many things are irritating
7 = feels that mostly everything is irritating and upsetting

Completed by (Initials):

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

CSSA VISUAL ANALOG SCALE

Please do not mark on upright lines.

Please rate the highest intensity of the desire for cocaine you have felt in the last 24 hours:

|____|____|____|____|____|____|____|____|

No Desire at all ***Unable to Resist***

Please identify on the line below, how often you have felt the urge to use cocaine in the last 24 hours:

|____|____|____|____|____|____|____|____|

Never ***All the Time***

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

Cocaine Global Severity

At this time, how would you rate yourself overall for cocaine use and cocaine related problems?

- ☐ No problems
- ☐ Borderline problems
- ☐ Mild problems
- ☐ Moderate problems
- ☐ Marked problems
- ☐ Severe symptoms
- ☐ Most extreme problems possible

Global Improvement of Cocaine Dependence

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

- ☐ Not assessed
- ☐ Very much improved
- ☐ Much improved
- ☐ Minimally improved
- ☐ No change
- ☐ Minimally worse
- ☐ Much worse
- ☐ Very much worse

Completed by (Initials):

Treatment Week 6

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

Current Severity

Please rate the subject's current severity in the eight specific problem areas below.

	None, Least Severe						**Most Severe**
Reported Cocaine Use: (frequency and amount of cocaine used)	1	2	3	4	5	6	7
Cocaine Seeking: (craving for cocaine, effort to stop, and drug seeking behavior)	1	2	3	4	5	6	7
Reported Use of Other Drugs: (frequency and amount of non-cocaine drug/alcohol use)	1	2	3	4	5	6	7
Observable Psychiatric Symptoms: (orientation, memory, comprehension, disorganized thinking, rapid/retarded speech, agitation, grooming, hostility, irritability, affective disturbance)	1	2	3	4	5	6	7
Reported Psychiatric Symptoms: (mood disturbance, depression, anxiety,inner restlessness, covert anger, somatic symptoms, energy level,motivation, sleep, appetite, libido, anhedonia)	1	2	3	4	5	6	7
Physical/Medical Problems: (those that have emerged or gotten worse after drug use)	1	2	3	4	5	6	7
Maladaptive Coping in the Family/Social area: (movement away from healthy relationships)	1	2	3	4	5	6	7
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

Treatment Week 6

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

Global Severity of Cocaine Dependence

Considering your total clinical experience with the cocaine dependent population, how severe are this subject's cocaine dependence symptoms at this time?

- ☐ Normal, no symptoms
- ☐ Borderline symptoms
- ☐ Mild symptoms
- ☐ Moderate symptoms
- ☐ Marked symptoms
- ☐ Severe symptoms
- ☐ Most extreme symptoms possible

Global Improvement of Cocaine Dependence

Rate the total improvement in the participant's cocaine dependence symptoms whether or not, in your judgment, it is due entirely to drug treatment. Compared to the subject's admission to the project, how
much has the subject changed?

- ☐ Not assessed, first rating
- ☐ Very much improved
- ☐ Much improved
- ☐ Minimally improved
- ☐ No change
- ☐ Minimally worse
- ☐ Much worse
- ☐ Very much worse

Completed by (Initials):

Treatment Week 6

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____

(mm/dd/yyyy)

Date doses dispensed _____
Each dose is four tablets *(mm/dd/yyyy)*

Kit Number: _____

Bottle Number: _____

Number of doses dispensed _____

Date unused doses returned _____
(mm/dd/yyyy)

Number of doses returned _____

Number of doses reported lost by subject _____

Doses taken:

Day of Week:	Date *(mm/dd/yyyy)*	Time Dose Taken	Dose Not Taken

Comments: _____

Completed by (Initials): _____

Treatment Week 6

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

Did subject receive standardized, manual-guided individual psychotherapy this week?

(If No, please comment below) ☐ Yes ☐ No

If yes, length of psychotherapy session ____ minutes

Did subject require emergency crisis management sessions this week? ☐ Yes ☐ No

If yes, how many? ____

Additional comments:

Completed by (Initials): ____

Treatment Week 6

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

This form is to be filled out for female subjects only. All female subjects must be tested at Screening/Baseline and have a negative pregnancy test in order to be eligible for this study.

What method of birth control is the participant currently using (prior to taking modafinil)?

- ☐ Oral contraceptive
- ☐ Barrier (diaphragm or condom plus spermicide)
- ☐ Levonorgestrel implant (Norplant)
- ☐ Intrauterine Contraceptive system (IUD)
- ☐ Medroxyprogesterone Acetate Contraceptive injection (Depo-Provera)
- ☐ Contraceptive patch
- ☐ Surgical Sterilization - Hysterectomy
- ☐ Surgical Sterilization - Tubal ligation

Unless surgically sterile or 2 years postmenopausal, does the subject agree to use an acceptable method of birth control during the study and 30 days after last dose of study drug?

☐ Yes ☐ No

If yes, mark below the acceptable method selected by the subject for use:

- ☐ barrier method with spermicide
- ☐ steroidal contraceptive [oral, Implanted, injected] used in conjunction with a barrier method
- ☐ Contraceptive patch used in conjunction with a barrier method
- ☐ Intrauterine device [IUD]

Was a pregnancy test performed? ☐ Yes ☐ No

If yes, date specimen collected

(mm/dd/yyyy)

Result: ☐ Negative ☐ Positive ☐ Unknown

If no, specify reason:

Is the subject lactating? ☐ Yes ☐ No

Comments:

Completed by (Initials):

Treatment Week 7

Site ID: | Subject ID #. | Subject Initials | Week

Date: *(mm/dd/yyyy)*

Weekly Vital Signs

☐ Vital signs not assessed at this visit

Date (mm/dd/yyyy) Time Vital Signs taken (24 hour clock)

Temperature (oral) (°F) NR: 94-100.4 CS ☐ NCS ☐

Comments for Temperature

Blood Pressure (sitting) (mm Hg) NR: 90-140/50-90 CS ☐ NCS ☐

Comments for Blood Pressure:

Pulse Rate (sitting) (beats/min) NR: 50-120 CS ☐ NCS ☐

Comments for Pulse Rate:

Respiratory Rate (sitting) (breaths/min) NR: 8-20 CS ☐ NCS ☐

Comments for Respiratory Rate:

Completed by (Initials):

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

First Study Visit of Week ***Urine bar code sticker:***

Date urine collected:
(mm/dd/yyyy)

Urine not collected ☐

Was urine temperature within expected range? ☐ Yes ☐ No

Franklin Cup: The temperature must be higher than 96.0 ° F and lower than 104.8 ° F
On-Trak Cup: The temperature must be higher than 90.0 ° F and lower than 99.0 ° F Split
Sample Cup: The temperature must be higher than 90.0 ° F and lower than 100.0 ° F

Completed by (Initials):

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

Second Study Visit of Week ***Urine bar code sticker:***

Date urine collected: *(mm/dd/yyyy)* Urine not collected ☐

Was urine temperature within expected range? ☐ Yes ☐ No

Franklin Cup: The temperature must be higher than 96.0 ° F and lower than 104.8 ° F On-Trak Cup: The temperature must be higher than 90.0 ° F and lower than 99.0 ° F Split Sample Cup: The temperature must be higher than 90.0 ° F and lower than 100.0 ° F

Completed by (Initials):

Treatment Week 7 V3

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____

(mm/dd/yyyy)

Third Study Visit of Week ***Urine bar code sticker:*** _____

Date urine collected: _____ *(mm/dd/yyyy)*

Urine not collected ☐

Was urine temperature within expected range? ☐ Yes ☐ No

Franklin Cup: The temperature must be higher than 96.0 ° F and lower than 104.8 ° F On-Trak Cup: The temperature must be higher than 90.0 ° F and lower than 99.0 ° F Split Sample Cup: The temperature must be higher than 90.0 ° F and lower than 100.0 ° F

Completed by (Initials): _____

NIDA-MDS-Modaf-0001 **Form 24 – SUBSTANCE USE INVENTORY**

Treatment Week 7

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

Using timeline follow-back method, record whether subject has on each day since the last visit used any amount of the substances listed below, along with the most common route of administration for each drug. Begin with yesterday and work back to the last visit. Please be sure that days are continuous with last week's form.

Date of last visit:

(mm/dd/yyyy)

Day of week							
Date							
	Used? ROA	**Used? ROA**	**Used? ROA**	**Used? ROA**	**Used? ROA**	**Used? ROA**	**Used? ROA**
Cocaine	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Alcohol	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Marijuana	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Amphetamines	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Opiates	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Barbiturates	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Benzodiazepines	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N

Route of administration (ROA) codes: 1 = oral, 2 = nasal, 3 = smoking, 4 = non-intravenous injection, 5 = intravenous injection

Completed by (Initials):

Treatment Week 7

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

Cocaine

1. The intensity of my craving, that is, how much I desired cocaine in the past 24 hours was:

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

2. The frequency of my craving, that is, how often I desired cocaine in the past 24 hours was:

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

3. The length of time I spent craving for cocaine during the past 24 hours was:

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

4. Write in the number of times you think you had craving for cocaine during the past 24 hours:

5. Write in the total time spent craving cocaine during the past 24 hours:

hours minutes

6. The worst day: During the past week my most intense craving occurred on the following day:

☐ Sunday ☐ Monday ☐ Tuesday ☐ Wednesday
☐ Thursday ☐ Friday ☐ Saturday ☐ All days the same (go to Q. 8)

7. The date for that day was:

(mm/dd/yyyy)

8. The intensity of my craving, that is, how much I desired cocaine on that worst day was:

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

Second Drug

9. A **2nd** craved drug during the past 24 hours was:
Mark only one of the following. If no 2nd craved drug, mark "None" and leave Questions 10-16 blank.

☐ None ☐ Downers or Sedatives (Barbiturates, etc.) ☐ Benzos (Valium, Xanax, etc.) ☐ Nicotine
☐ Alcohol ☐ Heroin or other Opiates (Morphine, etc.) ☐ Marijuana ☐ Other Specify

10. The intensity of my craving, that is, how much I desired this **second** drug in the past 24 hours was:

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

Treatment Week 7

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____

(mm/dd/yyyy)

11. The frequency of my craving, that is, how often I desired this **second** drug in the past 24 hours was:

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

12. The length of time I spent in craving for this **second** drug during the past 24 hours was:

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

Third Drug

13. A **3rd** craved drug during the past 24 hours was:
Mark only one of the following. If no 3rd craved drug, mark "None" and leave questions 14-16 blank.

☐ None ☐ Downers or Sedatives (Barbiturates, etc.) ☐ Benzos (Valium, Xanax, etc.) ☐ Nicotine

☐ Alcohol ☐ Heroin or other Opiates (Morphine, etc.) ☐ Marijuana ☐ Other Specify _____

14. The intensity of my craving, that is, how much I desired this **third** drug in the past 24 hours was:

☐ 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:

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

16. The length of time I spent in craving for this third drug during the past 24 hours was:

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

Completed by (Initials): _____

Treatment Week 7

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

All questions except 4 and 5 are assessed by properly trained personnel. The subject is asked about each of the items in lay language and the response is recorded on a scale of 0-7 with 0 being normal or no symptoms. For question 4 and 5, the subject is asked to mark the appropriate place on the line (on page 3) that describes each of the questions. The rater then transcribes that as the response to those questions.

Date of last cocaine use:

(mm/dd/yyyy)

1. Hyperphagia

0 = normal appetite
3-4 = eats a lot more than usual
7 = eats more than twice usual amount of food

2. Hypophagia

0 = normal appetite
3-4 = eats less than half of normal amount of food
7 = no appetite at all

3. Carbohydrate Craving

0 = no craving
3-4 = strong craving for sweets, cakes, and cookies half the time
7 = strong craving for sweets, cakes, and cookies all the time

4. Cocaine Craving Intensity

Please use subject intensity rating from pg. 3 of this form.

5. Cocaine Craving Frequency

Please use subject frequency rating from pg. 3 of this form.

6. Bradycardia

Please use scale below.

	0	1	2	3	4	5	6	7
Pulse (BPM)	>64	64-63	62-61	60-59	58-57	56-55	54-53	<53

7. Insomnia

0 = normal amount of sleep
3-4 = half of normal amount of sleep
7 = no sleep at all

8. Hypersomnia

0 = normal amount of sleep
3-4 = could sleep or does sleep half the day
7 = sleep or could sleep all the time

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

9. Anxiety

0 = usually does not feel anxious
3-4 = feels anxious half the time
7 = feels anxious all the time

10. Energy Level

0 = feels alert and has usual amount of energy
3-4 = feels tired half the time
7 = feels tired all the time

11. Activity Level

0 = no change in usual activities
3-4 = participates in half of usual activities
7 = no participation in usual activities

12. Tension

0-1 = rarely feel tense
3-4 = feels tense half the time
7 = feels tense most or all the time

13. Attention

0 = able to concentrate on reading, conversation, tasks, and make plans without difficulty
3-4 = has difficulty with the above half the time
7 = has difficulty with the above all the time

14. Paranoid Ideation

0 = no evidence of paranoid thoughts
3-4 = unable to trust anyone
5 = feels people are out to get him/her
7 = feels a specific person/group is plotting against him/her

15. Anhedonia

0 = ability to enjoy themselves remains unchanged
3-4 = able to enjoy themselves half of the time
7 = unable to enjoy themselves at all

16. Depression

0 = no feelings related to sadness or depression
3-4 = feels sad or depressed half the time
7 = feels depressed all of the time

17. Suicidality

0 = does not think about being dead
3-4 = feels like life is not worth living
7 = feels like actually ending life

18. Irritability

0 = feels that most things are not irritating
3-4 = feels that many things are irritating
7 = feels that mostly everything is irritating and upsetting

Completed by (Initials):

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

CSSA VISUAL ANALOG SCALE

Please do not mark on upright lines.

Please rate the highest intensity of the desire for cocaine you have felt in the last 24 hours:

|____|____|____|____|____|____|____|

No Desire at all ***Unable to Resist***

Please identify on the line below, how often you have felt the urge to use cocaine in the last 24 hours:

|____|____|____|____|____|____|____|

Never ***All the Time***

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

Cocaine Global Severity

At this time, how would you rate yourself overall for cocaine use and cocaine related problems?

- ☐ No problems
- ☐ Borderline problems
- ☐ Mild problems
- ☐ Moderate problems
- ☐ Marked problems
- ☐ Severe symptoms
- ☐ Most extreme problems possible

Global Improvement of Cocaine Dependence

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

- ☐ Not assessed
- ☐ Very much improved
- ☐ Much improved
- ☐ Minimally improved
- ☐ No change
- ☐ Minimally worse
- ☐ Much worse
- ☐ Very much worse

Completed by (Initials):

Treatment Week 7

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

Current Severity

Please rate the subject's current severity in the eight specific problem areas below.

	None, Least Severe						**Most Severe**
Reported Cocaine Use: (frequency and amount of cocaine used)	1	2	3	4	5	6	7
Cocaine Seeking: (craving for cocaine, effort to stop, and drug seeking behavior)	1	2	3	4	5	6	7
Reported Use of Other Drugs: (frequency and amount of non-cocaine drug/alcohol use)	1	2	3	4	5	6	7
Observable Psychiatric Symptoms: (orientation, memory, comprehension, disorganized thinking, rapid/retarded speech, agitation, grooming, hostility, irritability, affective disturbance)	1	2	3	4	5	6	7
Reported Psychiatric Symptoms: (mood disturbance, depression, anxiety,inner restlessness, covert anger, somatic symptoms, energy level,motivation, sleep, appetite, libido, anhedonia)	1	2	3	4	5	6	7
Physical/Medical Problems: (those that have emerged or gotten worse after drug use)	1	2	3	4	5	6	7
Maladaptive Coping in the Family/Social area: (movement away from healthy relationships)	1	2	3	4	5	6	7
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

Treatment Week 7

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

Global Severity of Cocaine Dependence

Considering your total clinical experience with the cocaine dependent population, how severe are this subject's cocaine dependence symptoms at this time?

- ☐ Normal, no symptoms
- ☐ Borderline symptoms
- ☐ Mild symptoms
- ☐ Moderate symptoms
- ☐ Marked symptoms
- ☐ Severe symptoms
- ☐ Most extreme symptoms possible

Global Improvement of Cocaine Dependence

Rate the total improvement in the participant's cocaine dependence symptoms whether or not, in your judgment, it is due entirely to drug treatment. Compared to the subject's admission to the project, how
much has the subject changed?

- ☐ Not assessed, first rating
- ☐ Very much improved
- ☐ Much improved
- ☐ Minimally improved
- ☐ No change
- ☐ Minimally worse
- ☐ Much worse
- ☐ Very much worse

Completed by (Initials):

Treatment Week 7

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

Date doses dispensed

Each dose is four tablets

(mm/dd/yyyy)

Kit Number:

Bottle Number:

Number of doses dispensed

Date unused doses returned

(mm/dd/yyyy)

Number of doses returned

Number of doses reported lost by subject

Doses taken:

Day of Week:	Date *(mm/dd/yyyy)*	Time Dose Taken	Dose Not Taken

Comments:

Completed by (Initials):

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

Did subject receive standardized, manual-guided individual psychotherapy this week?

(If No, please comment below) ☐ Yes ☐ No

If yes, length of psychotherapy session ____ minutes

Did subject require emergency crisis management sessions this week? ☐ Yes ☐ No

If yes, how many? ____

Additional comments:

Completed by (Initials): ____

Treatment Week 8

Site ID: | Subject ID #. | Subject Initials | Week

Date: *(mm/dd/yyyy)*

Weekly Vital Signs

☐ Vital signs not assessed at this visit

Date (mm/dd/yyyy) Time Vital Signs taken (24 hour clock)

Temperature (oral) (°F) NR: 94-100.4 CS ☐ NCS ☐

Comments for Temperature

Blood Pressure (sitting) (mm Hg) NR: 90-140/50-90 CS ☐ NCS ☐

Comments for Blood Pressure:

Pulse Rate (sitting) (beats/min) NR: 50-120 CS ☐ NCS ☐

Comments for Pulse Rate:

Respiratory Rate (sitting) (breaths/min) NR: 8-20 CS ☐ NCS ☐

Comments for Respiratory Rate:

Completed by (Initials):

Site ID:	Subject ID #.	Subject Initials	Week

Date:

First Study Visit of Week ***Urine bar code sticker:***

Date urine collected: *(mm/dd/yyyy)*

Urine not collected ☐

Was urine temperature within expected range? ☐ Yes ☐ No

Franklin Cup: The temperature must be higher than 96.0 ° F and lower than 104.8 ° F On-Trak Cup: The temperature must be higher than 90.0 ° F and lower than 99.0 ° F Split Sample Cup: The temperature must be higher than 90.0 ° F and lower than 100.0 ° F

Completed by (Initials):

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

Second Study Visit of Week ***Urine bar code sticker:***

Date urine collected: *(mm/dd/yyyy)* Urine not collected ☐

Was urine temperature within expected range? ☐ Yes ☐ No

Franklin Cup: The temperature must be higher than 96.0 ° F and lower than 104.8 ° F On-Trak Cup: The temperature must be higher than 90.0 ° F and lower than 99.0 ° F Split Sample Cup: The temperature must be higher than 90.0 ° F and lower than 100.0 ° F

Completed by (Initials):

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

Third Study Visit of Week ***Urine bar code sticker:***

Date urine collected:

(mm/dd/yyyy)

Urine not collected ☐

Was urine temperature within expected range? ☐ Yes ☐ No

Franklin Cup: The temperature must be higher than 96.0 ° F and lower than 104.8 ° F On-Trak Cup: The temperature must be higher than 90.0 ° F and lower than 99.0 ° F Split Sample Cup: The temperature must be higher than 90.0 ° F and lower than 100.0 ° F

Completed by (Initials):

NIDA-MDS-Modaf-0001 **Form 24 – SUBSTANCE USE INVENTORY**

Treatment Week 8

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

Using timeline follow-back method, record whether subject has on each day since the last visit used any amount of the substances listed below, along with the most common route of administration for each drug. Begin with yesterday and work back to the last visit. Please be sure that days are continuous with last week's form.

Date of last visit:

(mm/dd/yyyy)

Day of week							
Date							
	Used? ROA	**Used? ROA**	**Used? ROA**	**Used? ROA**	**Used? ROA**	**Used? ROA**	**Used? ROA**
Cocaine	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Alcohol	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Marijuana	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Amphetamines	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Opiates	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Barbiturates	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Benzodiazepines	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N

Route of administration (ROA) codes: 1 = oral, 2 = nasal, 3 = smoking, 4 = non-intravenous injection, 5 = intravenous injection

Completed by (Initials):

Treatment Week 8

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

	Value	Normal	Abnormal*	Abnormal* Significant	Not Done	Comments (required for abnormal values)
1. Specific gravity		☐	☐	☐	☐	
2. pH		☐	☐	☐	☐	
3. Glucose		☐	☐	☐	☐	
4. Protein		☐	☐	☐	☐	
5. Ketones		☐	☐	☐	☐	
6. Occult Blood		☐	☐	☐	☐	
7. WBC		☐	☐	☐	☐	
8. RBC		☐	☐	☐	☐	
9. Epithelial Cells		☐	☐	☐	☐	

"Abnormal" is any value outside the normal laboratory range.

For Glucose, Protein, Ketones, and Occult Blood use the following scale to report Values:

-1 = Absent
0 = Trace
1
2
3
4

For WBC, RBC, and Epithelial Cells use the following scale to report Values:

1 = None (1 – 5)
2 = Few (6 – 10)
3 = Moderate (11 – 50)
4 = Heavy (>50)

☐ Check here if this form is completed for retest of previous lab tests.

Date of original lab tests

(mm/dd/yyyy)

Completed by (Initials):

Treatment Week 8

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

	Value		Normal	Abnormal*	Abnormal* Significant	Not Done	Comments (required for abnormal values)
1. Hemoglobin		g/dL	☐	☐	☐	☐	
2. Hematocrit		%	☐	☐	☐	☐	
3. RBC		M/uL	☐	☐	☐	☐	
4. Platelet count		K/uL	☐	☐	☐	☐	
5. WBC		K/uL	☐	☐	☐	☐	
6. Neutrophils		%	☐	☐	☐	☐	
7. Lymphocytes		%	☐	☐	☐	☐	
8. Monocytes		%	☐	☐	☐	☐	
9. Eosinophils		%	☐	☐	☐	☐	
10. Basophils		%	☐	☐	☐	☐	

Please refer to Appendix I of the protocol when determining the significance of abnormal values.

****"Abnormal" is any value outside the normal laboratory range.***

million/uL = mil/cumm = mill/mcl = M/cmm = x10^6/cumm

x 10^3/uL = thou/cumm = thou/mcl = K/cmm = 1000/uL = x 10^3/cumm

☐ Check here if results on this form are retests of previous lab tests.

Date of original lab tests

(mm/dd/yyyy)

Treatment Week 8

Site ID: | Subject ID #. | Subject Initials | Week

Date: *(mm/dd/yyyy)*

	Value		Normal	Abnormal*	Abnormal* Significant	Not Done	Comments (Required for Abnormal values)
1. Sodium		mmol/L	☐	☐	☐	☐	
2. Potassium		mmol/L	☐	☐	☐	☐	
3. Chloride		mmol/L	☐	☐	☐	☐	
4. CO2		mmol/L	☐	☐	☐	☐	
5. Glucose		mg/dL	☐	☐	☐	☐	
6. Creatinine		mg/dL	☐	☐	☐	☐	
7. Albumin		g/dL	☐	☐	☐	☐	
8. Total protein		g/dL	☐	☐	☐	☐	
9. SGOT/AST		U/L	☐	☐	☐	☐	
10. SGPT/ALT		U/L	☐	☐	☐	☐	
11. GGT		U/L	☐	☐	☐	☐	
12. Bilirubin		mg/dL	☐	☐	☐	☐	
13. BUN		mg/dL	☐	☐	☐	☐	

Please refer to Appendix I of the protocol when determining significance of abnormal values.

**** "Abnormal" is any value outside the normal laboratory range.***

mmol/L = mEq/L

☐ Check here if this form is completed for retest of previous lab tests.

Date of original lab tests *(mm/dd/yyyy)*

Treatment Week 8

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

Cocaine

1. The intensity of my craving, that is, how much I desired cocaine in the past 24 hours was:

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

2. The frequency of my craving, that is, how often I desired cocaine in the past 24 hours was:

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

3. The length of time I spent craving for cocaine during the past 24 hours was:

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

4. Write in the number of times you think you had craving for cocaine during the past 24 hours:

5. Write in the total time spent craving cocaine during the past 24 hours:

hours minutes

6. The worst day: During the past week my most intense craving occurred on the following day:

☐ Sunday ☐ Monday ☐ Tuesday ☐ Wednesday
☐ Thursday ☐ Friday ☐ Saturday ☐ All days the same (go to Q. 8)

7. The date for that day was:

(mm/dd/yyyy)

8. The intensity of my craving, that is, how much I desired cocaine on that worst day was:

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

Second Drug

9. A **2nd** craved drug during the past 24 hours was:
Mark only one of the following. If no 2nd craved drug, mark "None" and leave Questions 10-16 blank.

☐ None ☐ Downers or Sedatives (Barbiturates, etc.) ☐ Benzos (Valium, Xanax, etc.) ☐ Nicotine
☐ Alcohol ☐ Heroin or other Opiates (Morphine, etc.) ☐ Marijuana ☐ Other Specify

10. The intensity of my craving, that is, how much I desired this **second** drug in the past 24 hours was:

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

Treatment Week 8

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____

(mm/dd/yyyy)

11. The frequency of my craving, that is, how often I desired this **second** drug in the past 24 hours was:

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

12. The length of time I spent in craving for this **second** drug during the past 24 hours was:

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

Third Drug

13. A **3rd** craved drug during the past 24 hours was:
Mark only one of the following. If no 3rd craved drug, mark "None" and leave questions 14-16 blank.

☐ None ☐ Downers or Sedatives (Barbiturates, etc .) ☐ Benzos (Valium, Xanax, etc.) ☐ Nicotine

☐ Alcohol ☐ Heroin or other Opiates (Morphine, etc.) ☐ Marijuana ☐ Other Specify _____

14. The intensity of my craving, that is, how much I desired this **third** drug in the past 24 hours was:

☐ 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:

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

16. The length of time I spent in craving for this third drug during the past 24 hours was:

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

Completed by (Initials): _____

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

All questions except 4 and 5 are assessed by properly trained personnel. The subject is asked about each of the items in lay language and the response is recorded on a scale of 0-7 with 0 being normal or no symptoms. For question 4 and 5, the subject is asked to mark the appropriate place on the line (on page 3) that describes each of the questions. The rater then transcribes that as the response to those questions.

Date of last cocaine use:

(mm/dd/yyyy)

1. Hyperphagia

0 = normal appetite
3-4 = eats a lot more than usual
7 = eats more than twice usual amount of food

2. Hypophagia

0 = normal appetite
3-4 = eats less than half of normal amount of food
7 = no appetite at all

3. Carbohydrate Craving

0 = no craving
3-4 = strong craving for sweets, cakes, and cookies half the time
7 = strong craving for sweets, cakes, and cookies all the time

4. Cocaine Craving Intensity

Please use subject intensity rating from pg. 3 of this form.

5. Cocaine Craving Frequency

Please use subject frequency rating from pg. 3 of this form.

6. Bradycardia

Please use scale below.

	0	1	2	3	4	5	6	7
Pulse (BPM)	>64	64-63	62-61	60-59	58-57	56-55	54-53	<53

7. Insomnia

0 = normal amount of sleep
3-4 = half of normal amount of sleep
7 = no sleep at all

8. Hypersomnia

0 = normal amount of sleep
3-4 = could sleep or does sleep half the day
7 = sleep or could sleep all the time

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

9. Anxiety

0 = usually does not feel anxious
3-4 = feels anxious half the time
7 = feels anxious all the time

10. Energy Level

0 = feels alert and has usual amount of energy
3-4 = feels tired half the time
7 = feels tired all the time

11. Activity Level

0 = no change in usual activities
3-4 = participates in half of usual activities
7 = no participation in usual activities

12. Tension

0-1 = rarely feel tense
3-4 = feels tense half the time
7 = feels tense most or all the time

13. Attention

0 = able to concentrate on reading, conversation, tasks, and make plans without difficulty
3-4 = has difficulty with the above half the time
7 = has difficulty with the above all the time

14. Paranoid Ideation

0 = no evidence of paranoid thoughts
3-4 = unable to trust anyone
5 = feels people are out to get him/her
7 = feels a specific person/group is plotting against him/her

15. Anhedonia

0 = ability to enjoy themselves remains unchanged
3-4 = able to enjoy themselves half of the time
7 = unable to enjoy themselves at all

16. Depression

0 = no feelings related to sadness or depression
3-4 = feels sad or depressed half the time
7 = feels depressed all of the time

17. Suicidality

0 = does not think about being dead
3-4 = feels like life is not worth living
7 = feels like actually ending life

18. Irritability

0 = feels that most things are not irritating
3-4 = feels that many things are irritating
7 = feels that mostly everything is irritating and upsetting

Completed by (Initials):

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

CSSA VISUAL ANALOG SCALE

Please do not mark on upright lines.

Please rate the highest intensity of the desire for cocaine you have felt in the last 24 hours:

|____|____|____|____|____|____|____|____|

No Desire at all ***Unable to Resist***

Please identify on the line below, how often you have felt the urge to use cocaine in the last 24 hours:

|____|____|____|____|____|____|____|____|

Never ***All the Time***

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

Cocaine Global Severity

At this time, how would you rate yourself overall for cocaine use and cocaine related problems?

- ☐ No problems
- ☐ Borderline problems
- ☐ Mild problems
- ☐ Moderate problems
- ☐ Marked problems
- ☐ Severe symptoms
- ☐ Most extreme problems possible

Global Improvement of Cocaine Dependence

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

- ☐ Not assessed
- ☐ Very much improved
- ☐ Much improved
- ☐ Minimally improved
- ☐ No change
- ☐ Minimally worse
- ☐ Much worse
- ☐ Very much worse

Completed by (Initials):

Treatment Week 8

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

Current Severity

Please rate the subject's current severity in the eight specific problem areas below.

	None, Least Severe						**Most Severe**
Reported Cocaine Use: (frequency and amount of cocaine used)	1	2	3	4	5	6	7
Cocaine Seeking: (craving for cocaine, effort to stop, and drug seeking behavior)	1	2	3	4	5	6	7
Reported Use of Other Drugs: (frequency and amount of non-cocaine drug/alcohol use)	1	2	3	4	5	6	7
Observable Psychiatric Symptoms: (orientation, memory, comprehension, disorganized thinking, rapid/retarded speech, agitation, grooming, hostility, irritability, affective disturbance)	1	2	3	4	5	6	7
Reported Psychiatric Symptoms: (mood disturbance, depression, anxiety,inner restlessness, covert anger, somatic symptoms, energy level,motivation, sleep, appetite, libido, anhedonia)	1	2	3	4	5	6	7
Physical/Medical Problems: (those that have emerged or gotten worse after drug use)	1	2	3	4	5	6	7
Maladaptive Coping in the Family/Social area: (movement away from healthy relationships)	1	2	3	4	5	6	7
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

Treatment Week 8

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

Global Severity of Cocaine Dependence

Considering your total clinical experience with the cocaine dependent population, how severe are this subject's cocaine dependence symptoms at this time?

- ☐ Normal, no symptoms
- ☐ Borderline symptoms
- ☐ Mild symptoms
- ☐ Moderate symptoms
- ☐ Marked symptoms
- ☐ Severe symptoms
- ☐ Most extreme symptoms possible

Global Improvement of Cocaine Dependence

Rate the total improvement in the participant's cocaine dependence symptoms whether or not, in your judgment, it is due entirely to drug treatment. Compared to the subject's admission to the project, how
much has the subject changed?

- ☐ Not assessed, first rating
- ☐ Very much improved
- ☐ Much improved
- ☐ Minimally improved
- ☐ No change
- ☐ Minimally worse
- ☐ Much worse
- ☐ Very much worse

Completed by (Initials):

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

1. Depressed Mood

(sad, 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. Feelings of Guilt

- ☐ 0 = Absent
- ☐ 1 = Self-reproach, feels s/he 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. Suicide

- ☐ 0 = Absent
- ☐ 1 = Feels life is not worth living.
- ☐ 2 = Wishes s/he were dead or any thoughts of possible death to self.
- ☐ 3 = Suicide ideas or gesture.
- ☐ 4 = Attempts at suicide (any serious attempt rates 4).

4. Insomnia Early

- ☐ 0 = No difficulty falling asleep.
- ☐ 1 = Complains of occasional difficulty falling asleep. (i.e., more than ½ hour)
- ☐ 2 = Complains of nightly difficulty falling asleep.

5. 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. 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.

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

7. Work and 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 patient, or indirect in listlessness, indecision and vacillation *(feels s/he has to push self to work or activities).*
- ☐ 3 = Decrease in actual time spent in activities or decrease in productivity.
- ☐ 4 = Stopped working because of present illness.

8. 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. Agitation

- ☐ 0 = None
- ☐ 1 = Fidgetiness
- ☐ 2 = Playing with hands, hair, etc.
- ☐ 3 = Moving about, can't sit still
- ☐ 4 = Hand-wringing, nail-biting, hair-pulling, biting of lips

10. 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. Anxiety Somatic

(Physiological concomitants of anxiety such as: Gastrointestinal: dry mouth, wind, indigestion, diarrhea, cramps, belching. Cardiovascular: palpitations, headaches. Respiratory: hyperventilation, sighing. Urinary frequency. Sweating.)

- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Moderate
- ☐ 3 = Severe
- ☐ 4 = Incapacitating

12. Somatic Symptoms Gastrointestinal

- ☐ 0 = None
- ☐ 1 = Loss of appetite but eating without encouragement. Heavy feelings in abdomen.
- ☐ 2 = Difficulty eating without urging. Requests or requires laxatives or medication for bowels or medication for G.I. symptoms.

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

13. Somatic Symptoms General
- ☐ 0 = None
- ☐ 1 = Heaviness in limbs, back or head. Backaches, headache, muscle aches. Loss of energy and fatigability.
- ☐ 2 = Any clear-cut symptom rates 2.

14. Genital Symptoms
(such as loss of libido and menstrual disturbances)

- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Severe

15. Hypochondriasis

- ☐ 0 = Not present
- ☐ 1 = Self-absorption (bodily)
- ☐ 2 = Preoccupation with health
- ☐ 3 = Frequent complaints, requests for help, etc.
- ☐ 4 = Hypochondriacal delusions

16. Loss of Weight

- ☐ 0 = No weight loss
- ☐ 1 = Probable weight loss associated with present illness.
- ☐ 2 = Definite weight loss (according to subject)

17. 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

18. Diurnal Variation

- ☐ 0 = No variation
- ☐ 1 = (Mild) Doubtful or slight variation
- ☐ 2 = (Severe) Clear or marked variation

If answer is 1 or 2, note whether the symptoms are worse in: O A.M. O P.M.

19. Depersonalization and Derealization
(symptoms such as feelings of unreality and nihilistic ideas)

- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Moderate
- ☐ 3 = Severe
- ☐ 4 = Incapacitating

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

20. Paranoid Symptoms

- ☐ 0 = None
- ☐ 1 = Suspicious
- ☐ 2 = Ideas of reference
- ☐ 3 = Delusions of reference and persecution

21. Obsessive and Compulsive Symptoms

- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Severe

22. 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 chores or personal hygiene.
- ☐ 4 = Despite urging, does not perform necessary chores or personal hygiene.

23. 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. Worthlessness

(ranges from mild loss of self-esteem, feelings of inferiority, self-depreciation (loss of self-esteem) to delusion notions of 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 s/he is “no good,” “inferior,” etc.
- ☐ 4 = Expresses feelings of total worthlessness – e.g. “I am a heap of garbage” or equivalent

Completed by (Initials):

Treatment Week 8

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____

(mm/dd/yyyy)

Date doses dispensed _____
Each dose is four tablets *(mm/dd/yyyy)*

Kit Number: _____

Bottle Number: _____

Number of doses dispensed _____

Date unused doses returned _____
(mm/dd/yyyy)

Number of doses returned _____

Number of doses reported lost by subject _____

Doses taken:

Day of Week:	Date *(mm/dd/yyyy)*	Time Dose Taken	Dose Not Taken

Comments: _____

Completed by (Initials): _____

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

Did subject receive standardized, manual-guided individual psychotherapy this week?

(If No, please comment below) ☐ Yes ☐ No

If yes, length of psychotherapy session ☐ minutes

Did subject require emergency crisis management sessions this week? ☐ Yes ☐ No

If yes, how many? ☐

Additional comments:

Completed by (Initials): ☐

Treatment Week 8

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

This form is to be filled out for female subjects only. All female subjects must be tested at Screening/Baseline and have a negative pregnancy test in order to be eligible for this study.

What method of birth control is the participant currently using (prior to taking modafinil)?

- ☐ Oral contraceptive
- ☐ Barrier (diaphragm or condom plus spermicide)
- ☐ Levonorgestrel implant (Norplant)
- ☐ Intrauterine Contraceptive system (IUD)
- ☐ Medroxyprogesterone Acetate Contraceptive injection (Depo-Provera)
- ☐ Contraceptive patch
- ☐ Surgical Sterilization - Hysterectomy
- ☐ Surgical Sterilization - Tubal ligation

Unless surgically sterile or 2 years postmenopausal, does the subject agree to use an acceptable method of birth control during the study and 30 days after last dose of study drug?

☐ Yes ☐ No

If yes, mark below the acceptable method selected by the subject for use:

- ☐ barrier method with spermicide
- ☐ steroidal contraceptive [oral, Implanted, injected] used in conjunction with a barrier method
- ☐ Contraceptive patch used in conjunction with a barrier method
- ☐ Intrauterine device [IUD]

Was a pregnancy test performed? ☐ Yes ☐ No

If yes, date specimen collected

(mm/dd/yyyy)

Result: ☐ Negative ☐ Positive ☐ Unknown

If no, specify reason:

Is the subject lactating? ☐ Yes ☐ No

Comments:

Completed by (Initials):

Treatment Week 9

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

Weekly Vital Signs

☐ Vital signs not assessed at this visit

Date (mm/dd/yyyy) Time Vital Signs taken (24 hour clock)

Temperature (oral) (°F) NR: 94-100.4 CS ☐ NCS ☐

Comments for Temperature

Blood Pressure (sitting) (mm Hg) NR: 90-140/50-90 CS ☐ NCS ☐

Comments for Blood Pressure:

Pulse Rate (sitting) (beats/min) NR: 50-120 CS ☐ NCS ☐

Comments for Pulse Rate:

Respiratory Rate (sitting) (breaths/min) NR: 8-20 CS ☐ NCS ☐

Comments for Respiratory Rate:

Completed by (Initials):

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

First Study Visit of Week ***Urine bar code sticker:***

Date urine collected:
(mm/dd/yyyy)

Urine not collected ☐

Was urine temperature within expected range? ☐ Yes ☐ No

Franklin Cup: The temperature must be higher than 96.0 ° F and lower than 104.8 ° F On-Trak Cup: The temperature must be higher than 90.0 ° F and lower than 99.0 ° F Split Sample Cup: The temperature must be higher than 90.0 ° F and lower than 100.0 ° F

Completed by (Initials):

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

Second Study Visit of Week ***Urine bar code sticker:***

Date urine collected: *(mm/dd/yyyy)* Urine not collected ☐

Was urine temperature within expected range? ☐ Yes ☐ No

Franklin Cup: The temperature must be higher than 96.0 ° F and lower than 104.8 ° F On-Trak Cup: The temperature must be higher than 90.0 ° F and lower than 99.0 ° F Split Sample Cup: The temperature must be higher than 90.0 ° F and lower than 100.0 ° F

Completed by (Initials):

Treatment Week 9 V3

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____

(mm/dd/yyyy)

Third Study Visit of Week ***Urine bar code sticker:*** _____

Date urine collected: _____ *(mm/dd/yyyy)* Urine not collected ☐

Was urine temperature within expected range? ☐ Yes ☐ No

Franklin Cup: The temperature must be higher than 96.0 ° F and lower than 104.8 ° F On-Trak Cup: The temperature must be higher than 90.0 ° F and lower than 99.0 ° F Split Sample Cup: The temperature must be higher than 90.0 ° F and lower than 100.0 ° F

Completed by (Initials): _____

NIDA-MDS-Modaf-0001 **Form 24 – SUBSTANCE USE INVENTORY**

Treatment Week 9

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

Using timeline follow-back method, record whether subject has on each day since the last visit used any amount of the substances listed below, along with the most common route of administration for each drug. Begin with yesterday and work back to the last visit. Please be sure that days are continuous with last week's form.

Date of last visit:

(mm/dd/yyyy)

Day of week							
Date							
	Used? ROA	**Used? ROA**	**Used? ROA**	**Used? ROA**	**Used? ROA**	**Used? ROA**	**Used? ROA**
Cocaine	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Alcohol	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Marijuana	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Amphetamines	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Opiates	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Barbiturates	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Benzodiazepines	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N

Route of administration (ROA) codes: 1 = oral, 2 = nasal, 3 = smoking, 4 = non-intravenous injection, 5 = intravenous injection

Completed by (Initials):

Treatment Week 9

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

Cocaine

1. The intensity of my craving, that is, how much I desired cocaine in the past 24 hours was:

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

2. The frequency of my craving, that is, how often I desired cocaine in the past 24 hours was:

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

3. The length of time I spent craving for cocaine during the past 24 hours was:

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

4. Write in the number of times you think you had craving for cocaine during the past 24 hours:

5. Write in the total time spent craving cocaine during the past 24 hours:

hours minutes

6. The worst day: During the past week my most intense craving occurred on the following day:

☐ Sunday ☐ Monday ☐ Tuesday ☐ Wednesday
☐ Thursday ☐ Friday ☐ Saturday ☐ All days the same (go to Q. 8)

7. The date for that day was:

(mm/dd/yyyy)

8. The intensity of my craving, that is, how much I desired cocaine on that worst day was:

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

Second Drug

9. A **2nd** craved drug during the past 24 hours was:
Mark only one of the following. If no 2nd craved drug, mark "None" and leave Questions 10-16 blank.

☐ None ☐ Downers or Sedatives (Barbiturates, etc.) ☐ Benzos (Valium, Xanax, etc.) ☐ Nicotine
☐ Alcohol ☐ Heroin or other Opiates (Morphine, etc.) ☐ Marijuana ☐ Other Specify

10. The intensity of my craving, that is, how much I desired this **second** drug in the past 24 hours was:

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

Treatment Week 9

Site ID: | Subject ID #. | Subject Initials | Week

Date: *(mm/dd/yyyy)*

11. The frequency of my craving, that is, how often I desired this **second** drug in the past 24 hours was:

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

12. The length of time I spent in craving for this **second** drug during the past 24 hours was:

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

Third Drug

13. A **3rd** craved drug during the past 24 hours was:
Mark only one of the following. If no 3rd craved drug, mark "None" and leave questions 14-16 blank.

☐ None ☐ Downers or Sedatives (Barbiturates, etc.) ☐ Benzos (Valium, Xanax, etc.) ☐ Nicotine

☐ Alcohol ☐ Heroin or other Opiates (Morphine, etc.) ☐ Marijuana ☐ Other Specify

14. The intensity of my craving, that is, how much I desired this **third** drug in the past 24 hours was:

☐ 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:

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

16. The length of time I spent in craving for this third drug during the past 24 hours was:

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

Completed by (Initials):

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

All questions except 4 and 5 are assessed by properly trained personnel. The subject is asked about each of the items in lay language and the response is recorded on a scale of 0-7 with 0 being normal or no symptoms. For question 4 and 5, the subject is asked to mark the appropriate place on the line (on page 3) that describes each of the questions. The rater then transcribes that as the response to those questions.

Date of last cocaine use:

(mm/dd/yyyy)

1. Hyperphagia

0 = normal appetite
3-4 = eats a lot more than usual
7 = eats more than twice usual amount of food

2. Hypophagia

0 = normal appetite
3-4 = eats less than half of normal amount of food
7 = no appetite at all

3. Carbohydrate Craving

0 = no craving
3-4 = strong craving for sweets, cakes, and cookies half the time
7 = strong craving for sweets, cakes, and cookies all the time

4. Cocaine Craving Intensity

Please use subject intensity rating from pg. 3 of this form.

5. Cocaine Craving Frequency

Please use subject frequency rating from pg. 3 of this form.

6. Bradycardia

Please use scale below.

	0	1	2	3	4	5	6	7
Pulse (BPM)	>64	64-63	62-61	60-59	58-57	56-55	54-53	<53

7. Insomnia

0 = normal amount of sleep
3-4 = half of normal amount of sleep
7 = no sleep at all

8. Hypersomnia

0 = normal amount of sleep
3-4 = could sleep or does sleep half the day
7 = sleep or could sleep all the time

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

9. Anxiety

0 = usually does not feel anxious
3-4 = feels anxious half the time
7 = feels anxious all the time

10. Energy Level

0 = feels alert and has usual amount of energy
3-4 = feels tired half the time
7 = feels tired all the time

11. Activity Level

0 = no change in usual activities
3-4 = participates in half of usual activities
7 = no participation in usual activities

12. Tension

0-1 = rarely feel tense
3-4 = feels tense half the time
7 = feels tense most or all the time

13. Attention

0 = able to concentrate on reading, conversation, tasks, and make plans without difficulty
3-4 = has difficulty with the above half the time
7 = has difficulty with the above all the time

14. Paranoid Ideation

0 = no evidence of paranoid thoughts
3-4 = unable to trust anyone
5 = feels people are out to get him/her
7 = feels a specific person/group is plotting against him/her

15. Anhedonia

0 = ability to enjoy themselves remains unchanged
3-4 = able to enjoy themselves half of the time
7 = unable to enjoy themselves at all

16. Depression

0 = no feelings related to sadness or depression
3-4 = feels sad or depressed half the time
7 = feels depressed all of the time

17. Suicidality

0 = does not think about being dead
3-4 = feels like life is not worth living
7 = feels like actually ending life

18. Irritability

0 = feels that most things are not irritating
3-4 = feels that many things are irritating
7 = feels that mostly everything is irritating and upsetting

Completed by (Initials):

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

CSSA VISUAL ANALOG SCALE

Please do not mark on upright lines.

Please rate the highest intensity of the desire for cocaine you have felt in the last 24 hours:

|____|____|____|____|____|____|____|____|

No Desire at all ***Unable to Resist***

Please identify on the line below, how often you have felt the urge to use cocaine in the last 24 hours:

|____|____|____|____|____|____|____|____|

Never ***All the Time***

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

Cocaine Global Severity

At this time, how would you rate yourself overall for cocaine use and cocaine related problems?

- ☐ No problems
- ☐ Borderline problems
- ☐ Mild problems
- ☐ Moderate problems
- ☐ Marked problems
- ☐ Severe symptoms
- ☐ Most extreme problems possible

Global Improvement of Cocaine Dependence

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

- ☐ Not assessed
- ☐ Very much improved
- ☐ Much improved
- ☐ Minimally improved
- ☐ No change
- ☐ Minimally worse
- ☐ Much worse
- ☐ Very much worse

Completed by (Initials):

Treatment Week 9

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

Current Severity

Please rate the subject's current severity in the eight specific problem areas below.

	None, Least Severe						**Most Severe**
Reported Cocaine Use: (frequency and amount of cocaine used)	1	2	3	4	5	6	7
Cocaine Seeking: (craving for cocaine, effort to stop, and drug seeking behavior)	1	2	3	4	5	6	7
Reported Use of Other Drugs: (frequency and amount of non-cocaine drug/alcohol use)	1	2	3	4	5	6	7
Observable Psychiatric Symptoms: (orientation, memory, comprehension, disorganized thinking, rapid/retarded speech, agitation, grooming, hostility, irritability, affective disturbance)	1	2	3	4	5	6	7
Reported Psychiatric Symptoms: (mood disturbance, depression, anxiety,inner restlessness, covert anger, somatic symptoms, energy level,motivation, sleep, appetite, libido, anhedonia)	1	2	3	4	5	6	7
Physical/Medical Problems: (those that have emerged or gotten worse after drug use)	1	2	3	4	5	6	7
Maladaptive Coping in the Family/Social area: (movement away from healthy relationships)	1	2	3	4	5	6	7
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

Treatment Week 9

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

Global Severity of Cocaine Dependence

Considering your total clinical experience with the cocaine dependent population, how severe are this subject's cocaine dependence symptoms at this time?

- ☐ Normal, no symptoms
- ☐ Borderline symptoms
- ☐ Mild symptoms
- ☐ Moderate symptoms
- ☐ Marked symptoms
- ☐ Severe symptoms
- ☐ Most extreme symptoms possible

Global Improvement of Cocaine Dependence

Rate the total improvement in the participant's cocaine dependence symptoms whether or not, in your judgment, it is due entirely to drug treatment. Compared to the subject's admission to the project, how
much has the subject changed?

- ☐ Not assessed, first rating
- ☐ Very much improved
- ☐ Much improved
- ☐ Minimally improved
- ☐ No change
- ☐ Minimally worse
- ☐ Much worse
- ☐ Very much worse

Completed by (Initials):

Treatment Week 9

Site ID: | Subject ID #. | Subject Initials | Week

Date: *(mm/dd/yyyy)*

Date doses dispensed *(mm/dd/yyyy)*
Each dose is four tablets

Kit Number:

Bottle Number:

Number of doses dispensed

Date unused doses returned *(mm/dd/yyyy)*

Number of doses returned

Number of doses reported lost by subject

Doses taken:

Day of Week:	Date *(mm/dd/yyyy)*	Time Dose Taken	Dose Not Taken

Comments:

Completed by (Initials):

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

Did subject receive standardized, manual-guided individual psychotherapy this week?

(If No, please comment below) ☐ Yes ☐ No

If yes, length of psychotherapy session ____ minutes

Did subject require emergency crisis management sessions this week? ☐ Yes ☐ No

If yes, how many? ____

Additional comments:

Completed by (Initials): ____

Treatment Week 10

Site ID:	Subject ID #.	Subject Initials	Week

Date:

Weekly Vital Signs

☐ Vital signs not assessed at this visit

Date _____ (mm/dd/yyyy) Time Vital Signs taken _____ (24 hour clock)

Temperature (oral) _____ (°F) NR: 94-100.4 CS ☐ NCS ☐

Comments for Temperature

Blood Pressure (sitting) _____ _____ (mm Hg) NR: 90-140/50-90 CS ☐ NCS ☐

Comments for Blood Pressure:

Pulse Rate (sitting) _____ (beats/min) NR: 50-120 CS ☐ NCS ☐

Comments for Pulse Rate:

Respiratory Rate (sitting) _____ (breaths/min) NR: 8-20 CS ☐ NCS ☐

Comments for Respiratory Rate:

Completed by (Initials): _____

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

First Study Visit of Week ***Urine bar code sticker:***

Date urine collected:
(mm/dd/yyyy)

Urine not collected ☐

Was urine temperature within expected range? ☐ Yes ☐ No

Franklin Cup: The temperature must be higher than 96.0 ° F and lower than 104.8 ° F On-Trak Cup: The temperature must be higher than 90.0 ° F and lower than 99.0 ° F Split Sample Cup: The temperature must be higher than 90.0 ° F and lower than 100.0 ° F

Completed by (Initials):

Treatment Week 10 V2

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____

(mm/dd/yyyy)

Second Study Visit of Week ***Urine bar code sticker:*** _____

Date urine collected: _____ *(mm/dd/yyyy)* Urine not collected ☐

Was urine temperature within expected range? ☐ Yes ☐ No

Franklin Cup: The temperature must be higher than 96.0 ° F and lower than 104.8 ° F On-Trak Cup: The temperature must be higher than 90.0 ° F and lower than 99.0 ° F Split Sample Cup: The temperature must be higher than 90.0 ° F and lower than 100.0 ° F

Completed by (Initials): _____

NIDA-MDS-Modaf-0001 **Form 23 – URINE BE SPECIMEN COLLECTION FORM**

Treatment Week 10 V3

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____

(mm/dd/yyyy)

Third Study Visit of Week ***Urine bar code sticker:*** _____

Date urine collected: _____ Urine not collected ☐

(mm/dd/yyyy)

Was urine temperature within expected range? ☐ Yes ☐ No

Franklin Cup: The temperature must be higher than 96.0 ° F and lower than 104.8 ° F On-Trak Cup: The temperature must be higher than 90.0 ° F and lower than 99.0 ° F Split Sample Cup: The temperature must be higher than 90.0 ° F and lower than 100.0 ° F

Completed by (Initials): _____

NIDA-MDS-Modaf-0001 **Form 24 – SUBSTANCE USE INVENTORY**

Treatment Week 10

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

Using timeline follow-back method, record whether subject has on each day since the last visit used any amount of the substances listed below, along with the most common route of administration for each drug. Begin with yesterday and work back to the last visit. Please be sure that days are continuous with last week's form.

Date of last visit:

(mm/dd/yyyy)

Day of week							
Date							
	Used? ROA	**Used? ROA**	**Used? ROA**	**Used? ROA**	**Used? ROA**	**Used? ROA**	**Used? ROA**
Cocaine	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Alcohol	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Marijuana	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Amphetamines	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Opiates	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Barbiturates	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Benzodiazepines	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N

Route of administration (ROA) codes: 1 = oral, 2 = nasal, 3 = smoking, 4 = non-intravenous injection, 5 = intravenous injection

Completed by (Initials):

Treatment Week 10

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

Cocaine

1. The intensity of my craving, that is, how much I desired cocaine in the past 24 hours was:

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

2. The frequency of my craving, that is, how often I desired cocaine in the past 24 hours was:

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

3. The length of time I spent craving for cocaine during the past 24 hours was:

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

4. Write in the number of times you think you had craving for cocaine during the past 24 hours:

5. Write in the total time spent craving cocaine during the past 24 hours:

hours minutes

6. The worst day: During the past week my most intense craving occurred on the following day:

☐ Sunday ☐ Monday ☐ Tuesday ☐ Wednesday
☐ Thursday ☐ Friday ☐ Saturday ☐ All days the same (go to Q. 8)

7. The date for that day was:

(mm/dd/yyyy)

8. The intensity of my craving, that is, how much I desired cocaine on that worst day was:

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

Second Drug

9. A **2nd** craved drug during the past 24 hours was:
Mark only one of the following. If no 2nd craved drug, mark "None" and leave Questions 10-16 blank.

☐ None
☐ Alcohol
☐ Downers or Sedatives (Barbiturates, etc.)
☐ Heroin or other Opiates (Morphine, etc.)
☐ Benzos (Valium, Xanax, etc.)
☐ Marijuana
☐ Nicotine
☐ Other Specify

10. The intensity of my craving, that is, how much I desired this **second** drug in the past 24 hours was:

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

Treatment Week 10

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____

(mm/dd/yyyy)

11. The frequency of my craving, that is, how often I desired this **second** drug in the past 24 hours was:

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

12. The length of time I spent in craving for this **second** drug during the past 24 hours was:

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

Third Drug

13. A **3rd** craved drug during the past 24 hours was:
Mark only one of the following. If no 3rd craved drug, mark "None" and leave questions 14-16 blank.

☐ None ☐ Downers or Sedatives (Barbiturates, etc.) ☐ Benzos (Valium, Xanax, etc.) ☐ Nicotine

☐ Alcohol ☐ Heroin or other Opiates (Morphine, etc.) ☐ Marijuana ☐ Other Specify _____

14. The intensity of my craving, that is, how much I desired this **third** drug in the past 24 hours was:

☐ 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:

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

16. The length of time I spent in craving for this third drug during the past 24 hours was:

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

Completed by (Initials): _____

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

All questions except 4 and 5 are assessed by properly trained personnel. The subject is asked about each of the items in lay language and the response is recorded on a scale of 0-7 with 0 being normal or no symptoms. For question 4 and 5, the subject is asked to mark the appropriate place on the line (on page 3) that describes each of the questions. The rater then transcribes that as the response to those questions.

Date of last cocaine use:

(mm/dd/yyyy)

1. Hyperphagia

0 = normal appetite
3-4 = eats a lot more than usual
7 = eats more than twice usual amount of food

2. Hypophagia

0 = normal appetite
3-4 = eats less than half of normal amount of food
7 = no appetite at all

3. Carbohydrate Craving

0 = no craving
3-4 = strong craving for sweets, cakes, and cookies half the time
7 = strong craving for sweets, cakes, and cookies all the time

4. Cocaine Craving Intensity

Please use subject intensity rating from pg. 3 of this form.

5. Cocaine Craving Frequency

Please use subject frequency rating from pg. 3 of this form.

6. Bradycardia

Please use scale below.

	0	1	2	3	4	5	6	7
Pulse (BPM)	>64	64-63	62-61	60-59	58-57	56-55	54-53	<53

7. Insomnia

0 = normal amount of sleep
3-4 = half of normal amount of sleep
7 = no sleep at all

8. Hypersomnia

0 = normal amount of sleep
3-4 = could sleep or does sleep half the day
7 = sleep or could sleep all the time

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

9. Anxiety

0 = usually does not feel anxious
3-4 = feels anxious half the time
7 = feels anxious all the time

10. Energy Level

0 = feels alert and has usual amount of energy
3-4 = feels tired half the time
7 = feels tired all the time

11. Activity Level

0 = no change in usual activities
3-4 = participates in half of usual activities
7 = no participation in usual activities

12. Tension

0-1 = rarely feel tense
3-4 = feels tense half the time
7 = feels tense most or all the time

13. Attention

0 = able to concentrate on reading, conversation, tasks, and make plans without difficulty
3-4 = has difficulty with the above half the time
7 = has difficulty with the above all the time

14. Paranoid Ideation

0 = no evidence of paranoid thoughts
3-4 = unable to trust anyone
5 = feels people are out to get him/her
7 = feels a specific person/group is plotting against him/her

15. Anhedonia

0 = ability to enjoy themselves remains unchanged
3-4 = able to enjoy themselves half of the time
7 = unable to enjoy themselves at all

16. Depression

0 = no feelings related to sadness or depression
3-4 = feels sad or depressed half the time
7 = feels depressed all of the time

17. Suicidality

0 = does not think about being dead
3-4 = feels like life is not worth living
7 = feels like actually ending life

18. Irritability

0 = feels that most things are not irritating
3-4 = feels that many things are irritating
7 = feels that mostly everything is irritating and upsetting

Completed by (Initials):

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

CSSA VISUAL ANALOG SCALE

Please do not mark on upright lines.

Please rate the highest intensity of the desire for cocaine you have felt in the last 24 hours:

|____|____|____|____|____|____|____|____|

No Desire at all ***Unable to Resist***

Please identify on the line below, how often you have felt the urge to use cocaine in the last 24 hours:

|____|____|____|____|____|____|____|____|

Never ***All the Time***

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

Cocaine Global Severity

At this time, how would you rate yourself overall for cocaine use and cocaine related problems?

- ☐ No problems
- ☐ Borderline problems
- ☐ Mild problems
- ☐ Moderate problems
- ☐ Marked problems
- ☐ Severe symptoms
- ☐ Most extreme problems possible

Global Improvement of Cocaine Dependence

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

- ☐ Not assessed
- ☐ Very much improved
- ☐ Much improved
- ☐ Minimally improved
- ☐ No change
- ☐ Minimally worse
- ☐ Much worse
- ☐ Very much worse

Completed by (Initials):

Screening/Baseline Week -3

Site ID:	Subject ID #.	Subject Initials	Week

Date:

Current Severity

Please rate the subject's current severity in the eight specific problem areas below.

	None, Least Severe						**Most Severe**
Reported Cocaine Use: (frequency and amount of cocaine used)	1	2	3	4	5	6	7
Cocaine Seeking: (craving for cocaine, effort to stop, and drug seeking behavior)	1	2	3	4	5	6	7
Reported Use of Other Drugs: (frequency and amount of non-cocaine drug/alcohol use)	1	2	3	4	5	6	7
Observable Psychiatric Symptoms: (orientation, memory, comprehension, disorganized thinking, rapid/retarded speech, agitation, grooming, hostility, irritability, affective disturbance)	1	2	3	4	5	6	7
Reported Psychiatric Symptoms: (mood disturbance, depression, anxiety,inner restlessness, covert anger, somatic symptoms, energy level,motivation, sleep, appetite, libido, anhedonia)	1	2	3	4	5	6	7
Physical/Medical Problems: (those that have emerged or gotten worse after drug use)	1	2	3	4	5	6	7
Maladaptive Coping in the Family/Social area: (movement away from healthy relationships)	1	2	3	4	5	6	7
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

Treatment Week 10

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

Global Severity of Cocaine Dependence

Considering your total clinical experience with the cocaine dependent population, how severe are this subject's cocaine dependence symptoms at this time?

- ☐ Normal, no symptoms
- ☐ Borderline symptoms
- ☐ Mild symptoms
- ☐ Moderate symptoms
- ☐ Marked symptoms
- ☐ Severe symptoms
- ☐ Most extreme symptoms possible

Global Improvement of Cocaine Dependence

Rate the total improvement in the participant's cocaine dependence symptoms whether or not, in your judgment, it is due entirely to drug treatment. Compared to the subject's admission to the project, how
much has the subject changed?

- ☐ Not assessed, first rating
- ☐ Very much improved
- ☐ Much improved
- ☐ Minimally improved
- ☐ No change
- ☐ Minimally worse
- ☐ Much worse
- ☐ Very much worse

Completed by (Initials):

Treatment Week 10

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

Date doses dispensed
Each dose is four tablets

(mm/dd/yyyy)

Kit Number:

Bottle Number:

Number of doses dispensed

Date unused doses returned

(mm/dd/yyyy)

Number of doses returned

Number of doses reported lost by subject

Doses taken:

Day of Week:	Date (*mm/dd/yyyy*)	Time Dose Taken	Dose Not Taken

Comments:

Completed by (Initials):

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

Did subject receive standardized, manual-guided individual psychotherapy this week?

(If No, please comment below) ☐ Yes ☐ No

If yes, length of psychotherapy session ____ minutes

Did subject require emergency crisis management sessions this week? ☐ Yes ☐ No

If yes, how many? ____

Additional comments:

Completed by (Initials): ____

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

This form is to be filled out for female subjects only. All female subjects must be tested at Screening/Baseline and have a negative pregnancy test in order to be eligible for this study.

What method of birth control is the participant currently using (prior to taking modafinil)?

- ☐ Oral contraceptive
- ☐ Barrier (diaphragm or condom plus spermicide)
- ☐ Levonorgestrel implant (Norplant)
- ☐ Intrauterine Contraceptive system (IUD)
- ☐ Medroxyprogesterone Acetate Contraceptive injection (Depo-Provera)
- ☐ Contraceptive patch
- ☐ Surgical Sterilization - Hysterectomy
- ☐ Surgical Sterilization - Tubal ligation

Unless surgically sterile or 2 years postmenopausal, does the subject agree to use an acceptable method of birth control during the study and 30 days after last dose of study drug?

☐ Yes ☐ No

If yes, mark below the acceptable method selected by the subject for use:

- ☐ barrier method with spermicide
- ☐ steroidal contraceptive [oral, Implanted, injected] used in conjunction with a barrier method
- ☐ Contraceptive patch used in conjunction with a barrier method
- ☐ Intrauterine device [IUD]

Was a pregnancy test performed? ☐ Yes ☐ No

If yes, date specimen collected

(mm/dd/yyyy)

Result: ☐ Negative ☐ Positive ☐ Unknown

If no, specify reason:

Is the subject lactating? ☐ Yes ☐ No

Comments:

Completed by (Initials):

Treatment Week 10

Site ID: | Subject ID #. | Subject Initials | Week

Date: (mm/dd/yyyy)

Weekly Vital Signs

☐ Vital signs not assessed at this visit

Date (mm/dd/yyyy) Time Vital Signs taken (24 hour clock)

Temperature (oral) (°F) NR: 94-100.4 CS ☐ NCS ☐

Comments for Temperature

Blood Pressure (sitting) (mm Hg) NR: 90-140/50-90 CS ☐ NCS ☐

Comments for Blood Pressure:

Pulse Rate (sitting) (beats/min) NR: 50-120 CS ☐ NCS ☐

Comments for Pulse Rate:

Respiratory Rate (sitting) (breaths/min) NR: 8-20 CS ☐ NCS ☐

Comments for Respiratory Rate:

Completed by (Initials):

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

First Study Visit of Week ***Urine bar code sticker:***

Date urine collected:

(mm/dd/yyyy)

Urine not collected ☐

Was urine temperature within expected range? ☐ Yes ☐ No

Franklin Cup: The temperature must be higher than 96.0 ° F and lower than 104.8 ° F On-Trak Cup: The temperature must be higher than 90.0 ° F and lower than 99.0 ° F Split Sample Cup: The temperature must be higher than 90.0 ° F and lower than 100.0 ° F

Completed by (Initials):

Form 23 – URINE BE SPECIMEN COLLECTION FORM

Treatment Week 11 V2

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____

(mm/dd/yyyy)

Second Study Visit of Week ***Urine bar code sticker:*** _____

Date urine collected: _____ *(mm/dd/yyyy)*

Urine not collected ☐

Was urine temperature within expected range? ☐ Yes ☐ No

Franklin Cup: The temperature must be higher than 96.0 ° F and lower than 104.8 ° F On-Trak Cup: The temperature must be higher than 90.0 ° F and lower than 99.0 ° F Split Sample Cup: The temperature must be higher than 90.0 ° F and lower than 100.0 ° F

Completed by (Initials): _____

Form 23 – URINE BE SPECIMEN COLLECTION FORM

Treatment Week 11 V3

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____

(mm/dd/yyyy)

Third Study Visit of Week ***Urine bar code sticker:*** _____

Date urine collected: _____ *(mm/dd/yyyy)*

Urine not collected ☐

Was urine temperature within expected range? ☐ Yes ☐ No

Franklin Cup: The temperature must be higher than 96.0 ° F and lower than 104.8 ° F On-Trak Cup: The temperature must be higher than 90.0 ° F and lower than 99.0 ° F Split Sample Cup: The temperature must be higher than 90.0 ° F and lower than 100.0 ° F

Completed by (Initials): _____

NIDA-MDS-Modaf-0001 **Form 24 – SUBSTANCE USE INVENTORY**

Treatment Week 11

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

Using timeline follow-back method, record whether subject has on each day since the last visit used any amount of the substances listed below, along with the most common route of administration for each drug. Begin with yesterday and work back to the last visit. Please be sure that days are continuous with last week's form.

Date of last visit:

(mm/dd/yyyy)

Day of week							
Date							
	Used? ROA	**Used? ROA**	**Used? ROA**	**Used? ROA**	**Used? ROA**	**Used? ROA**	**Used? ROA**
Cocaine	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Alcohol	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Marijuana	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Amphetamines	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Opiates	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Barbiturates	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Benzodiazepines	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N

Route of administration (ROA) codes: 1 = oral, 2 = nasal, 3 = smoking, 4 = non-intravenous injection, 5 = intravenous injection

Completed by (Initials):

Treatment Week 11

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

Cocaine

1. The intensity of my craving, that is, how much I desired cocaine in the past 24 hours was:

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

2. The frequency of my craving, that is, how often I desired cocaine in the past 24 hours was:

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

3. The length of time I spent craving for cocaine during the past 24 hours was:

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

4. Write in the number of times you think you had craving for cocaine during the past 24 hours:

5. Write in the total time spent craving cocaine during the past 24 hours:

hours minutes

6. The worst day: During the past week my most intense craving occurred on the following day:

☐ Sunday ☐ Monday ☐ Tuesday ☐ Wednesday
☐ Thursday ☐ Friday ☐ Saturday ☐ All days the same (go to Q. 8)

7. The date for that day was:

(mm/dd/yyyy)

8. The intensity of my craving, that is, how much I desired cocaine on that worst day was:

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

Second Drug

9. A **2nd** craved drug during the past 24 hours was:
Mark only one of the following. If no 2nd craved drug, mark "None" and leave Questions 10-16 blank.

☐ None ☐ Downers or Sedatives (Barbiturates, etc.) ☐ Benzos (Valium, Xanax, etc.) ☐ Nicotine
☐ Alcohol ☐ Heroin or other Opiates (Morphine, etc.) ☐ Marijuana ☐ Other Specify

10. The intensity of my craving, that is, how much I desired this **second** drug in the past 24 hours was:

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

Treatment Week 11

Site ID: | Subject ID #. | Subject Initials | Week

Date: *(mm/dd/yyyy)*

11. The frequency of my craving, that is, how often I desired this **second** drug in the past 24 hours was:

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

12. The length of time I spent in craving for this **second** drug during the past 24 hours was:

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

Third Drug

13. A **3rd** craved drug during the past 24 hours was:
Mark only one of the following. If no 3rd craved drug, mark "None" and leave questions 14-16 blank.

☐ None ☐ Downers or Sedatives (Barbiturates, etc.) ☐ Benzos (Valium, Xanax, etc.) ☐ Nicotine

☐ Alcohol ☐ Heroin or other Opiates (Morphine, etc.) ☐ Marijuana ☐ Other Specify

14. The intensity of my craving, that is, how much I desired this **third** drug in the past 24 hours was:

☐ 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:

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

16. The length of time I spent in craving for this third drug during the past 24 hours was:

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

Completed by (Initials):

Treatment Week 11

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

All questions except 4 and 5 are assessed by properly trained personnel. The subject is asked about each of the items in lay language and the response is recorded on a scale of 0-7 with 0 being normal or no symptoms. For question 4 and 5, the subject is asked to mark the appropriate place on the line (on page 3) that describes each of the questions. The rater then transcribes that as the response to those questions.

Date of last cocaine use:

(mm/dd/yyyy)

1. Hyperphagia

0 = normal appetite
3-4 = eats a lot more than usual
7 = eats more than twice usual amount of food

2. Hypophagia

0 = normal appetite
3-4 = eats less than half of normal amount of food
7 = no appetite at all

3. Carbohydrate Craving

0 = no craving
3-4 = strong craving for sweets, cakes, and cookies half the time
7 = strong craving for sweets, cakes, and cookies all the time

4. Cocaine Craving Intensity

Please use subject intensity rating from pg. 3 of this form.

5. Cocaine Craving Frequency

Please use subject frequency rating from pg. 3 of this form.

6. Bradycardia

Please use scale below.

	0	1	2	3	4	5	6	7
Pulse (BPM)	>64	64-63	62-61	60-59	58-57	56-55	54-53	<53

7. Insomnia

0 = normal amount of sleep
3-4 = half of normal amount of sleep
7 = no sleep at all

8. Hypersomnia

0 = normal amount of sleep
3-4 = could sleep or does sleep half the day
7 = sleep or could sleep all the time

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

9. Anxiety

0 = usually does not feel anxious
3-4 = feels anxious half the time
7 = feels anxious all the time

10. Energy Level

0 = feels alert and has usual amount of energy
3-4 = feels tired half the time
7 = feels tired all the time

11. Activity Level

0 = no change in usual activities
3-4 = participates in half of usual activities
7 = no participation in usual activities

12. Tension

0-1 = rarely feel tense
3-4 = feels tense half the time
7 = feels tense most or all the time

13. Attention

0 = able to concentrate on reading, conversation, tasks, and make plans without difficulty
3-4 = has difficulty with the above half the time
7 = has difficulty with the above all the time

14. Paranoid Ideation

0 = no evidence of paranoid thoughts
3-4 = unable to trust anyone
5 = feels people are out to get him/her
7 = feels a specific person/group is plotting against him/her

15. Anhedonia

0 = ability to enjoy themselves remains unchanged
3-4 = able to enjoy themselves half of the time
7 = unable to enjoy themselves at all

16. Depression

0 = no feelings related to sadness or depression
3-4 = feels sad or depressed half the time
7 = feels depressed all of the time

17. Suicidality

0 = does not think about being dead
3-4 = feels like life is not worth living
7 = feels like actually ending life

18. Irritability

0 = feels that most things are not irritating
3-4 = feels that many things are irritating
7 = feels that mostly everything is irritating and upsetting

Completed by (Initials):

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

CSSA VISUAL ANALOG SCALE

Please do not mark on upright lines.

Please rate the highest intensity of the desire for cocaine you have felt in the last 24 hours:

|____|____|____|____|____|____|____|

No Desire at all ***Unable to Resist***

Please identify on the line below, how often you have felt the urge to use cocaine in the last 24 hours:

|____|____|____|____|____|____|____|

Never ***All the Time***

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

Cocaine Global Severity

At this time, how would you rate yourself overall for cocaine use and cocaine related problems?

- ☐ No problems
- ☐ Borderline problems
- ☐ Mild problems
- ☐ Moderate problems
- ☐ Marked problems
- ☐ Severe symptoms
- ☐ Most extreme problems possible

Global Improvement of Cocaine Dependence

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

- ☐ Not assessed
- ☐ Very much improved
- ☐ Much improved
- ☐ Minimally improved
- ☐ No change
- ☐ Minimally worse
- ☐ Much worse
- ☐ Very much worse

Completed by (Initials):

Treatment Week 11

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

Current Severity

Please rate the subject's current severity in the eight specific problem areas below.

	None, Least Severe						**Most Severe**
Reported Cocaine Use: (frequency and amount of cocaine used)	1	2	3	4	5	6	7
Cocaine Seeking: (craving for cocaine, effort to stop, and drug seeking behavior)	1	2	3	4	5	6	7
Reported Use of Other Drugs: (frequency and amount of non-cocaine drug/alcohol use)	1	2	3	4	5	6	7
Observable Psychiatric Symptoms: (orientation, memory, comprehension, disorganized thinking, rapid/retarded speech, agitation, grooming, hostility, irritability, affective disturbance)	1	2	3	4	5	6	7
Reported Psychiatric Symptoms: (mood disturbance, depression, anxiety,inner restlessness, covert anger, somatic symptoms, energy level,motivation, sleep, appetite, libido, anhedonia)	1	2	3	4	5	6	7
Physical/Medical Problems: (those that have emerged or gotten worse after drug use)	1	2	3	4	5	6	7
Maladaptive Coping in the Family/Social area: (movement away from healthy relationships)	1	2	3	4	5	6	7
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

Treatment Week 11

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

Global Severity of Cocaine Dependence

Considering your total clinical experience with the cocaine dependent population, how severe are this subject's cocaine dependence symptoms at this time?

- ☐ Normal, no symptoms
- ☐ Borderline symptoms
- ☐ Mild symptoms
- ☐ Moderate symptoms
- ☐ Marked symptoms
- ☐ Severe symptoms
- ☐ Most extreme symptoms possible

Global Improvement of Cocaine Dependence

Rate the total improvement in the participant's cocaine dependence symptoms whether or not, in your judgment, it is due entirely to drug treatment. Compared to the subject's admission to the project, how
much has the subject changed?

- ☐ Not assessed, first rating
- ☐ Very much improved
- ☐ Much improved
- ☐ Minimally improved
- ☐ No change
- ☐ Minimally worse
- ☐ Much worse
- ☐ Very much worse

Completed by (Initials):

Treatment Week 11

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____

(mm/dd/yyyy)

Date doses dispensed _____
Each dose is four tablets *(mm/dd/yyyy)*

Kit Number: _____

Bottle Number: _____

Number of doses dispensed _____

Date unused doses returned _____
(mm/dd/yyyy)

Number of doses returned _____

Number of doses reported lost by subject _____

Doses taken:

Day of Week:	Date *(mm/dd/yyyy)*	Time Dose Taken	Dose Not Taken

Comments: _____

Completed by (Initials): _____

Treatment Week 11

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____

(mm/dd/yyyy)

Did subject receive standardized, manual-guided individual psychotherapy this week?

(If No, please comment below) ☐ Yes ☐ No

If yes, length of psychotherapy session _____ minutes

Did subject require emergency crisis management sessions this week? ☐ Yes ☐ No

If yes, how many? _____

Additional comments:

Completed by (Initials): _____

Treatment Week 12

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

Weekly Vital Signs

☐ Vital signs not assessed at this visit

Date (mm/dd/yyyy) Time Vital Signs taken (24 hour clock)

Temperature (oral) (°F) NR: 94-100.4 CS ☐ NCS ☐

Comments for Temperature

Blood Pressure (sitting) (mm Hg) NR: 90-140/50-90 CS ☐ NCS ☐

Comments for Blood Pressure:

Pulse Rate (sitting) (beats/min) NR: 50-120 CS ☐ NCS ☐

Comments for Pulse Rate:

Respiratory Rate (sitting) (breaths/min) NR: 8-20 CS ☐ NCS ☐

Comments for Respiratory Rate:

Completed by (Initials):

Form 23 – URINE BE SPECIMEN COLLECTION FORM

Treatment Week 12 V1

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____

(mm/dd/yyyy)

First Study Visit of Week ***Urine bar code sticker:*** _____

Date urine collected: _____ *(mm/dd/yyyy)* Urine not collected ☐

Was urine temperature within expected range? ☐ Yes ☐ No

Franklin Cup: The temperature must be higher than 96.0 ° F and lower than 104.8 ° F On-Trak Cup: The temperature must be higher than 90.0 ° F and lower than 99.0 ° F Split Sample Cup: The temperature must be higher than 90.0 ° F and lower than 100.0 ° F

Completed by (Initials): _____

Treatment Week 12 V2

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____

(mm/dd/yyyy)

Second Study Visit of Week ***Urine bar code sticker:*** _____

Date urine collected: _____ *(mm/dd/yyyy)* Urine not collected ☐

Was urine temperature within expected range? ☐ Yes ☐ No

Franklin Cup: The temperature must be higher than 96.0 ° F and lower than 104.8 ° F On-Trak Cup: The temperature must be higher than 90.0 ° F and lower than 99.0 ° F Split Sample Cup: The temperature must be higher than 90.0 ° F and lower than 100.0 ° F

Completed by (Initials): _____

Form 23 – URINE BE SPECIMEN COLLECTION FORM

Treatment Week 12 V3

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____

(mm/dd/yyyy)

Third Study Visit of Week ***Urine bar code sticker:*** _____

Date urine collected: _____ *(mm/dd/yyyy)*

Urine not collected ☐

Was urine temperature within expected range? ☐ Yes ☐ No

Franklin Cup: The temperature must be higher than 96.0 ° F and lower than 104.8 ° F On-Trak Cup: The temperature must be higher than 90.0 ° F and lower than 99.0 ° F Split Sample Cup: The temperature must be higher than 90.0 ° F and lower than 100.0 ° F

Completed by (Initials): _____

NIDA-MDS-Modaf-0001 **Form 24 – SUBSTANCE USE INVENTORY**

Treatment Week 12

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

Using timeline follow-back method, record whether subject has on each day since the last visit used any amount of the substances listed below, along with the most common route of administration for each drug. Begin with yesterday and work back to the last visit. Please be sure that days are continuous with last week's form.

Date of last visit:

(mm/dd/yyyy)

Day of week							
Date							
	Used? ROA	**Used? ROA**	**Used? ROA**	**Used? ROA**	**Used? ROA**	**Used? ROA**	**Used? ROA**
Cocaine	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Alcohol	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Marijuana	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Amphetamines	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Opiates	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Barbiturates	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Benzodiazepines	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N

Route of administration (ROA) codes: 1 = oral, 2 = nasal, 3 = smoking, 4 = non-intravenous injection, 5 = intravenous injection

Completed by (Initials):

Treatment Week 12

Site ID: | Subject ID #. | Subject Initials | Week

Date: *(mm/dd/yyyy)*

	Value	Normal	Abnormal*	Abnormal* Significant	Not Done	Comments (required for abnormal values)
1. Specific gravity		☐	☐	☐	☐	
2. pH		☐	☐	☐	☐	
3. Glucose		☐	☐	☐	☐	
4. Protein		☐	☐	☐	☐	
5. Ketones		☐	☐	☐	☐	
6. Occult Blood		☐	☐	☐	☐	
7. WBC		☐	☐	☐	☐	
8. RBC		☐	☐	☐	☐	
9. Epithelial Cells		☐	☐	☐	☐	

"Abnormal" is any value outside the normal laboratory range.

For Glucose, Protein, Ketones, and Occult Blood use the following scale to report Values:

-1 = Absent
0 = Trace
1
2
3
4

For WBC, RBC, and Epithelial Cells use the following scale to report Values:

1 = None (1 – 5)
2 = Few (6 – 10)
3 = Moderate (11 – 50)
4 = Heavy (>50)

☐ Check here if this form is completed for retest of previous lab tests.

Date of original lab tests *(mm/dd/yyyy)*

Completed by (Initials):

Treatment Week 12

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

	Value		Normal	Abnormal*	Abnormal* Significant	Not Done	Comments (required for abnormal values)
1. Hemoglobin		g/dL	☐	☐	☐	☐	
2. Hematocrit		%	☐	☐	☐	☐	
3. RBC		M/uL	☐	☐	☐	☐	
4. Platelet count		K/uL	☐	☐	☐	☐	
5. WBC		K/uL	☐	☐	☐	☐	
6. Neutrophils		%	☐	☐	☐	☐	
7. Lymphocytes		%	☐	☐	☐	☐	
8. Monocytes		%	☐	☐	☐	☐	
9. Eosinophils		%	☐	☐	☐	☐	
10. Basophils		%	☐	☐	☐	☐	

Please refer to Appendix I of the protocol when determining the significance of abnormal values.

****"Abnormal" is any value outside the normal laboratory range.***

million/uL = mil/cumm = mill/mcl = M/cmm = x10^6/cumm

x 10^3/uL = thou/cumm = thou/mcl = K/cmm = 1000/uL = x 10^3/cumm

☐ Check here if results on this form are retests of previous lab tests.

Date of original lab tests

(mm/dd/yyyy)

Treatment Week 12

Site ID: | Subject ID #. | Subject Initials | Week

Date: *(mm/dd/yyyy)*

	Value		Normal	Abnormal*	Abnormal* Significant	Not Done	Comments (Required for Abnormal values)
1. Sodium		mmol/L	☐	☐	☐	☐	
2. Potassium		mmol/L	☐	☐	☐	☐	
3. Chloride		mmol/L	☐	☐	☐	☐	
4. CO2		mmol/L	☐	☐	☐	☐	
5. Glucose		mg/dL	☐	☐	☐	☐	
6. Creatinine		mg/dL	☐	☐	☐	☐	
7. Albumin		g/dL	☐	☐	☐	☐	
8. Total protein		g/dL	☐	☐	☐	☐	
9. SGOT/AST		U/L	☐	☐	☐	☐	
10. SGPT/ALT		U/L	☐	☐	☐	☐	
11. GGT		U/L	☐	☐	☐	☐	
12. Bilirubin		mg/dL	☐	☐	☐	☐	
13. BUN		mg/dL	☐	☐	☐	☐	

Please refer to Appendix I of the protocol when determining significance of abnormal values.
**** "Abnormal" is any value outside the normal laboratory range.***

mmol/L = mEq/L

☐ Check here if this form is completed for retest of previous lab tests.

Date of original lab tests *(mm/dd/yyyy)*

Treatment Week 12

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____

(mm/dd/yyyy)

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

If ECG is Normal please skip to Question C.

B. If ECG is abnormal, check below for all abnormalities.

	Abnormal	Abnormal Significant		Abnormal	Abnormal Significant
1. Increased QRS voltage	☐	☐	17. Supraventricular premature beat	☐	☐
2. Qtc prolongation	☐	☐	18. Ventricular premature beat	☐	☐
3. Left atrial hypertrophy	☐	☐	19. Supraventricular tachycardia	☐	☐
4. Right atrial hypertrophy	☐	☐	20. Ventricular tachycardia	☐	☐
5. Left ventricular hypertrophy	☐	☐	21. Atrial fibrillation	☐	☐
6. Right ventricular hypertrophy	☐	☐	22. Atrial flutter	☐	☐
7. Acute infarction	☐	☐	23. Other rhythm abnormalities	☐	☐
8. Subacute infarction	☐	☐	24. Implanted pacemaker	☐	☐
9. Old infarction	☐	☐	25. 1st degree A-V block	☐	☐
10. Myocardial ischemia	☐	☐	26. 2nd degree A-V block	☐	☐
11. Digitalis effect	☐	☐	27. 3rd degree A-V block	☐	☐
12. Symmetrical T-wave inversions	☐	☐	28. LBB block	☐	☐
13. Poor R-wave progression	☐	☐	29. RBB block	☐	☐
14. Other nonspecific ST/T	☐	☐	30. Pre-excitation syndrome	☐	☐
15. Sinus tachycardia	☐	☐	31. Other intraventricular condition	☐	☐
16. Sinus bradycardia	☐	☐	32. Other, specify _____	☐	☐

C. Ventricular rate (bpm) _____

D. PR (ms) _____

E. QRS (ms) _____

F. QTC (ms) _____

G. Are there any abnormalities noted above that preclude the subject from safe entry into or continuation in the study? ☐ **Yes** ☐ **No**

Treatment Week 12

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

Comments:

Treatment Week 12

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

1. Height ☐ inches

2. Weight ☐ pounds

	A. Normal	B. Abnormal	C. Abnormal Significant	D. Not Done	E. Comments (required for abnormal values)
3. Oral (mouth)	☐	☐	☐	☐	
4. Head and Neck	☐	☐	☐	☐	
5. Eyes, ears, nose/throat	☐	☐	☐	☐	
6. Cardiovascular	☐	☐	☐	☐	
7. Chest	☐	☐	☐	☐	
8. Lungs	☐	☐	☐	☐	
9. Abdomen (include liver/spleen)	☐	☐	☐	☐	
10. Extremities	☐	☐	☐	☐	
11. Skin, hair, nails	☐	☐	☐	☐	
12. Neuropsychiatric mental status	☐	☐	☐	☐	
13. Neuropsychiatric sensory/motor	☐	☐	☐	☐	
14. Musculoskeletal	☐	☐	☐	☐	
15. General appearance	☐	☐	☐	☐	
16. Rectal	☐	☐	☐	☐	
17. Prostate	☐	☐	☐	☐	
18. Breast	☐	☐	☐	☐	

Treatment Week 12

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

	A. Normal	B. Abnormal	C. Abnormal Significant	D. Not Done	E. Comments (required for abnormal values)
19. Lymph	☐	☐	☐	☐	
20. Genital	☐	☐	☐	☐	
21. Pelvic	☐	☐	☐	☐	
22. Other, specify	☐	☐	☐	☐	
22. Other, specify	☐	☐	☐	☐	

Treatment Week 12

Site ID: | Subject ID #. | Subject Initials | Week

Date: *(mm/dd/yyyy)*

Cocaine

1. The intensity of my craving, that is, how much I desired cocaine in the past 24 hours was:

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

2. The frequency of my craving, that is, how often I desired cocaine in the past 24 hours was:

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

3. The length of time I spent craving for cocaine during the past 24 hours was:

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

4. Write in the number of times you think you had craving for cocaine during the past 24 hours:

☐

5. Write in the total time spent craving cocaine during the past 24 hours:

☐ hours ☐ minutes

6. The worst day: During the past week my most intense craving occurred on the following day:

☐ Sunday ☐ Monday ☐ Tuesday ☐ Wednesday
☐ Thursday ☐ Friday ☐ Saturday ☐ All days the same (go to Q. 8)

7. The date for that day was: ☐ *(mm/dd/yyyy)*

8. The intensity of my craving, that is, how much I desired cocaine on that worst day was:

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

Second Drug

9. A **2nd** craved drug during the past 24 hours was:
Mark only one of the following. If no 2nd craved drug, mark "None" and leave Questions 10-16 blank.

☐ None ☐ Downers or Sedatives (Barbiturates, etc.) ☐ Benzos (Valium, Xanax, etc.) ☐ Nicotine
☐ Alcohol ☐ Heroin or other Opiates (Morphine, etc.) ☐ Marijuana ☐ Other Specify ☐

10. The intensity of my craving, that is, how much I desired this **second** drug in the past 24 hours was:

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

Treatment Week 12

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____

(mm/dd/yyyy)

11. The frequency of my craving, that is, how often I desired this **second** drug in the past 24 hours was:

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

12. The length of time I spent in craving for this **second** drug during the past 24 hours was:

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

Third Drug

13. A **3rd** craved drug during the past 24 hours was:
Mark only one of the following. If no 3rd craved drug, mark "None" and leave questions 14-16 blank.

☐ None ☐ Downers or Sedatives (Barbiturates, etc.) ☐ Benzos (Valium, Xanax, etc.) ☐ Nicotine

☐ Alcohol ☐ Heroin or other Opiates (Morphine, etc.) ☐ Marijuana ☐ Other Specify _____

14. The intensity of my craving, that is, how much I desired this **third** drug in the past 24 hours was:

☐ 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:

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

16. The length of time I spent in craving for this third drug during the past 24 hours was:

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

Completed by (Initials): _____

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

All questions except 4 and 5 are assessed by properly trained personnel. The subject is asked about each of the items in lay language and the response is recorded on a scale of 0-7 with 0 being normal or no symptoms. For question 4 and 5, the subject is asked to mark the appropriate place on the line (on page 3) that describes each of the questions. The rater then transcribes that as the response to those questions.

Date of last cocaine use:

(mm/dd/yyyy)

1. Hyperphagia

0 = normal appetite
3-4 = eats a lot more than usual
7 = eats more than twice usual amount of food

2. Hypophagia

0 = normal appetite
3-4 = eats less than half of normal amount of food
7 = no appetite at all

3. Carbohydrate Craving

0 = no craving
3-4 = strong craving for sweets, cakes, and cookies half the time
7 = strong craving for sweets, cakes, and cookies all the time

4. Cocaine Craving Intensity

Please use subject intensity rating from pg. 3 of this form.

5. Cocaine Craving Frequency

Please use subject frequency rating from pg. 3 of this form.

6. Bradycardia

Please use scale below.

	0	1	2	3	4	5	6	7
Pulse (BPM)	>64	64-63	62-61	60-59	58-57	56-55	54-53	<53

7. Insomnia

0 = normal amount of sleep
3-4 = half of normal amount of sleep
7 = no sleep at all

8. Hypersomnia

0 = normal amount of sleep
3-4 = could sleep or does sleep half the day
7 = sleep or could sleep all the time

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

9. Anxiety

0 = usually does not feel anxious
3-4 = feels anxious half the time
7 = feels anxious all the time

10. Energy Level

0 = feels alert and has usual amount of energy
3-4 = feels tired half the time
7 = feels tired all the time

11. Activity Level

0 = no change in usual activities
3-4 = participates in half of usual activities
7 = no participation in usual activities

12. Tension

0-1 = rarely feel tense
3-4 = feels tense half the time
7 = feels tense most or all the time

13. Attention

0 = able to concentrate on reading, conversation, tasks, and make plans without difficulty
3-4 = has difficulty with the above half the time
7 = has difficulty with the above all the time

14. Paranoid Ideation

0 = no evidence of paranoid thoughts
3-4 = unable to trust anyone
5 = feels people are out to get him/her
7 = feels a specific person/group is plotting against him/her

15. Anhedonia

0 = ability to enjoy themselves remains unchanged
3-4 = able to enjoy themselves half of the time
7 = unable to enjoy themselves at all

16. Depression

0 = no feelings related to sadness or depression
3-4 = feels sad or depressed half the time
7 = feels depressed all of the time

17. Suicidality

0 = does not think about being dead
3-4 = feels like life is not worth living
7 = feels like actually ending life

18. Irritability

0 = feels that most things are not irritating
3-4 = feels that many things are irritating
7 = feels that mostly everything is irritating and upsetting

Completed by (Initials):

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

CSSA VISUAL ANALOG SCALE

Please do not mark on upright lines.

Please rate the highest intensity of the desire for cocaine you have felt in the last 24 hours:

|____|____|____|____|____|____|____|____|

No Desire at all ***Unable to Resist***

Please identify on the line below, how often you have felt the urge to use cocaine in the last 24 hours:

|____|____|____|____|____|____|____|____|

Never ***All the Time***

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

Cocaine Global Severity

At this time, how would you rate yourself overall for cocaine use and cocaine related problems?

- ☐ No problems
- ☐ Borderline problems
- ☐ Mild problems
- ☐ Moderate problems
- ☐ Marked problems
- ☐ Severe symptoms
- ☐ Most extreme problems possible

Global Improvement of Cocaine Dependence

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

- ☐ Not assessed
- ☐ Very much improved
- ☐ Much improved
- ☐ Minimally improved
- ☐ No change
- ☐ Minimally worse
- ☐ Much worse
- ☐ Very much worse

Completed by (Initials):

Treatment Week 12

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

Current Severity

Please rate the subject's current severity in the eight specific problem areas below.

	None, Least Severe						**Most Severe**
Reported Cocaine Use: (frequency and amount of cocaine used)	1	2	3	4	5	6	7
Cocaine Seeking: (craving for cocaine, effort to stop, and drug seeking behavior)	1	2	3	4	5	6	7
Reported Use of Other Drugs: (frequency and amount of non-cocaine drug/alcohol use)	1	2	3	4	5	6	7
Observable Psychiatric Symptoms: (orientation, memory, comprehension, disorganized thinking, rapid/retarded speech, agitation, grooming, hostility, irritability, affective disturbance)	1	2	3	4	5	6	7
Reported Psychiatric Symptoms: (mood disturbance, depression, anxiety,inner restlessness, covert anger, somatic symptoms, energy level,motivation, sleep, appetite, libido, anhedonia)	1	2	3	4	5	6	7
Physical/Medical Problems: (those that have emerged or gotten worse after drug use)	1	2	3	4	5	6	7
Maladaptive Coping in the Family/Social area: (movement away from healthy relationships)	1	2	3	4	5	6	7
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

Treatment Week 12

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

Global Severity of Cocaine Dependence

Considering your total clinical experience with the cocaine dependent population, how severe are this subject's cocaine dependence symptoms at this time?

- ☐ Normal, no symptoms
- ☐ Borderline symptoms
- ☐ Mild symptoms
- ☐ Moderate symptoms
- ☐ Marked symptoms
- ☐ Severe symptoms
- ☐ Most extreme symptoms possible

Global Improvement of Cocaine Dependence

Rate the total improvement in the participant's cocaine dependence symptoms whether or not, in your judgment, it is due entirely to drug treatment. Compared to the subject's admission to the project, how
much has the subject changed?

- ☐ Not assessed, first rating
- ☐ Very much improved
- ☐ Much improved
- ☐ Minimally improved
- ☐ No change
- ☐ Minimally worse
- ☐ Much worse
- ☐ Very much worse

Completed by (Initials):

Treatment Week 12

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

Indicate how much you agree or disagree with each of the following statements by circling the number which best shows how you feel. The lower the number, the more you disagree; the higher the number, the more you agree with the statement. Please complete every item. We are interested in how you are thinking or feeling RIGHT NOW as you are filling out the questionnaire.

	Strongly Disagree						**Strongly Agree**
1. If I were using cocaine, I could think more clearly.	1	2	3	4	5	6	7
2. Right now I am not making plans to use “coke.”	1	2	3	4	5	6	7
3. My desire to use cocaine seems overpowering.	1	2	3	4	5	6	7
4. I am thinking of ways to get cocaine.	1	2	3	4	5	6	7
5. I don’t want to use “coke”.	1	2	3	4	5	6	7
6. If I were offered some “coke”, I would use it immediately.	1	2	3	4	5	6	7
7. Using cocaine would make me feel less depressed.	1	2	3	4	5	6	7
8. I could easily control how much cocaine I use right now.	1	2	3	4	5	6	7
9. I crave “coke” right now.	1	2	3	4	5	6	7
10. Using cocaine would make me feel powerful.	1	2	3	4	5	6	7
11. If there were cocaine in front of me, it would be hard not to use it.	1	2	3	4	5	6	7
12. Using cocaine would not help me calm down right now.	1	2	3	4	5	6	7
13. I would feel very alert if I used cocaine right now.	1	2	3	4	5	6	7
14. If I had the chance to use “coke”, I don’t think I would use it.	1	2	3	4	5	6	7
15. I would not enjoy using cocaine right now.	1	2	3	4	5	6	7
16. I would do almost anything for cocaine right now.	1	2	3	4	5	6	7
17. I could control things better right now if I could use cocaine.	1	2	3	4	5	6	7
18. Even if it were possible, I probably would not use cocaine right now.	1	2	3	4	5	6	7
19. Using “coke” would not be pleasant.	1	2	3	4	5	6	7
20. I think that I could resist using “coke” right now.	1	2	3	4	5	6	7

Treatment Week 12

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

	Strongly Disagree						Strongly Agree
21. I have an urge for cocaine.	1	2	3	4	5	6	7
22. I would not be able to control how much cocaine I used if I had some here.	1	2	3	4	5	6	7
23. Starting now, I could go without using cocaine for long time.	1	2	3	4	5	6	7
24. I would be less irritable now if I could use cocaine.	1	2	3	4	5	6	7
25. I would feel energetic if I used cocaine.	1	2	3	4	5	6	7
26. All I want to use right now is cocaine.	1	2	3	4	5	6	7
27. Using cocaine would not sharpen my concentration.	1	2	3	4	5	6	7
28. I do not need to use cocaine now.	1	2	3	4	5	6	7
29. It would be difficult to turn down cocaine this minute.	1	2	3	4	5	6	7
30. If I use cocaine right now, I would not feel less restless.	1	2	3	4	5	6	7
31. I will use cocaine as soon as I get a chance.	1	2	3	4	5	6	7
32. Using cocaine now would make things seem just perfect.	1	2	3	4	5	6	7
33. I want to use cocaine so bad that I can almost taste it.	1	2	3	4	5	6	7
34. Nothing would be better than using “coke” right now.	1	2	3	4	5	6	7
35. If I used cocaine, my anger would not decrease.	1	2	3	4	5	6	7
36. It would be easy to pass up the chance to use cocaine.	1	2	3	4	5	6	7
37. I am going to use cocaine as soon as possible.	1	2	3	4	5	6	7
38. I have no desire for cocaine right now.	1	2	3	4	5	6	7
39. I could not stop myself from using cocaine if I had some here now.	1	2	3	4	5	6	7
40. Using “coke” right now would make me feel less tired.	1	2	3	4	5	6	7
41. Using cocaine would not be very satisfying right now.	1	2	3	4	5	6	7
42. If I tried a little “coke” now, I would not be able to stop using more of it.	1	2	3	4	5	6	7
43. I would not feel less anxious if I used “coke”.	1	2	3	4	5	6	7
44. I am not missing using cocaine now.	1	2	3	4	5	6	7
45. If I had some “coke” with me right now, I probably would not use it.	1	2	3	4	5	6	7

Completed by (Initials):

Treatment Week 12

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

1. Depressed Mood
(sad, 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. Feelings of Guilt

- ☐ 0 = Absent
- ☐ 1 = Self-reproach, feels s/he 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. Suicide

- ☐ 0 = Absent
- ☐ 1 = Feels life is not worth living.
- ☐ 2 = Wishes s/he were dead or any thoughts of possible death to self.
- ☐ 3 = Suicide ideas or gesture.
- ☐ 4 = Attempts at suicide (any serious attempt rates 4).

4. Insomnia Early

- ☐ 0 = No difficulty falling asleep.
- ☐ 1 = Complains of occasional difficulty falling asleep. (i.e., more than ½ hour)
- ☐ 2 = Complains of nightly difficulty falling asleep.

5. 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. 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.

Treatment Week 12

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

7. Work and 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 patient, or indirect in listlessness, indecision and vacillation *(feels s/he has to push self to work or activities).*
- ☐ 3 = Decrease in actual time spent in activities or decrease in productivity.
- ☐ 4 = Stopped working because of present illness.

8. 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. Agitation

- ☐ 0 = None
- ☐ 1 = Fidgetiness
- ☐ 2 = Playing with hands, hair, etc.
- ☐ 3 = Moving about, can't sit still
- ☐ 4 = Hand-wringing, nail-biting, hair-pulling, biting of lips

10. 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. Anxiety Somatic

(Physiological concomitants of anxiety such as: Gastrointestinal: dry mouth, wind, indigestion, diarrhea, cramps, belching. Cardiovascular: palpitations, headaches. Respiratory: hyperventilation, sighing. Urinary frequency. Sweating.)

- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Moderate
- ☐ 3 = Severe
- ☐ 4 = Incapacitating

12. Somatic Symptoms Gastrointestinal

- ☐ 0 = None
- ☐ 1 = Loss of appetite but eating without encouragement. Heavy feelings in abdomen.
- ☐ 2 = Difficulty eating without urging. Requests or requires laxatives or medication for

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bowels or medication for G.I. symptoms.

13. Somatic Symptoms General

- ☐ 0 = None
- ☐ 1 = Heaviness in limbs, back or head. Backaches, headache, muscle aches. Loss of energy and fatigability.
- ☐ 2 = Any clear-cut symptom rates 2.

14. Genital Symptoms
(such as loss of libido and menstrual disturbances)

- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Severe

15. Hypochondriasis

- ☐ 0 = Not present
- ☐ 1 = Self-absorption (bodily)
- ☐ 2 = Preoccupation with health
- ☐ 3 = Frequent complaints, requests for help, etc.
- ☐ 4 = Hypochondriacal delusions

16. Loss of Weight

- ☐ 0 = No weight loss
- ☐ 1 = Probable weight loss associated with present illness.
- ☐ 2 = Definite weight loss (according to subject)

17. 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

18. Diurnal Variation

- ☐ 0 = No variation
- ☐ 1 = (Mild) Doubtful or slight variation
- ☐ 2 = (Severe) Clear or marked variation

If answer is 1 or 2, note whether the symptoms are worse in: O A.M. O P.M.

19. Depersonalization and Derealization
(symptoms such as feelings of unreality and nihilistic ideas)

- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Moderate
- ☐ 3 = Severe
- ☐ 4 = Incapacitating

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20. Paranoid Symptoms

- ☐ 0 = None
- ☐ 1 = Suspicious
- ☐ 2 = Ideas of reference
- ☐ 3 = Delusions of reference and persecution

21. Obsessive and Compulsive Symptoms

- ☐ 0 = Absent
- ☐ 1 = Mild
- ☐ 2 = Severe

22. 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 chores or personal hygiene.
- ☐ 4 = Despite urging, does not perform necessary chores or personal hygiene.

23. 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. Worthlessness

(ranges from mild loss of self-esteem, feelings of inferiority, self-depreciation (loss of self-esteem) to delusion notions of 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 s/he is “no good,” “inferior,” etc.
- ☐ 4 = Expresses feelings of total worthlessness – e.g. “I am a heap of garbage” or equivalent

Completed by (Initials):

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General Information

G4. Date of admission *(mm/dd/yyyy)*

G8. Class ☐ Intake ☐ Follow-up

G9. Contact code ☐ In person ☐ Telephone ☐ Mail

G10. Gender ☐ Male ☐ Female

G12. Special ☐ Terminated ☐ Refused ☐ Unable to respond

G14. How long have you lived at your current address? Years Months

G16. Date of birth: *(mm/dd/yyyy)*

G17. Of what race do you consider yourself?
☐ White (not Hispanic)
☐ Black (not Hispanic)
☐ American Indian
☐ Alaskan Native
☐ Asian/Pacific Islander
☐ Hispanic - Mexican
☐ Hispanic – Puerto Rican
☐ Hispanic - Cuban
☐ Hispanic - Other

G18. Do you have a religious preference?
☐ Protestant
☐ Catholic
☐ Jewish
☐ Islamic
☐ Other
☐ None

G Have you been in a controlled environment in the last 30 days?
☐ No
☐ Jail
☐ Alcohol/drug treatment
☐ Medical treatment
☐ Psychiatric treatment
☐ Other

G How many days?

MEDICAL STATUS

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

M3. Do you have any chronic medical problem(s) which continue to interfere with your life? ☐ Yes ☐ No

If "Yes", please specify in 'Comments'.

Are you taking any prescribed medication on a regular basis for a physical problem? ☐ Yes ☐ No

If "Yes", please specify in 'Comments'.

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Do you receive a pension for a physical disability? (Exclude psychiatric disabilities.) ☐ Yes ☐ No

If yes to #M5, please specify in Comments section below.

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

For #M7 and M8 please ask the subject to use the subject rating scale.

How troubled or bothered have you been by these medical problems in the past 30 days?
☐ 0 = Not at all ☐ 1 = Slightly ☐ 2 = Moderately ☐ 3 = Considerably ☐ 4 = Extremely

How important to you now is treatment for these medical problems?
☐ 0 = Not at all ☐ 1 = Slightly ☐ 2 = Moderately ☐ 3 = Considerably ☐ 4 = Extremely

Confidence Ratings

Is the above information significantly distorted by:

Subject's misrepresentation? ☐ Yes ☐ No

Subject's inability to understand? ☐ Yes ☐ No

Comments:

Employment/Support Status

Education completed (GED = 12 years): Years Months

Training or technical education completed: Months

Do you have a valid driver's license? ☐ Yes ☐ No

Do you have an automobile available for use? ☐ Yes ☐ No
Answer "no" if no valid driver's license.

E6. How long was your longest full-time job? Years Months

Usual (or last) occupation:

Hollingshead occupational category: ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9

1 = Higher execs, major professionals, owners of large businesses
2 = Managers of medium sized businesses, nurses, opticians, pharmacists, social workers, teachers
3 = Administrative personnel, managers, owners/proprietors of small businesses (bakery, car dealership, engraving business, florist, decorator, actor, reporter, travel agent)
4 = Clerical and sales, technicians, bank teller, bookkeeper, clerk, draftsperson, timekeeper, secretary
5 = Skilled manual – usually having had training (baker, barber, brakeperson, chef, electrician, fireperson, lineperson, machinist, mechanic, paperhanger, painter, repairperson, tailor, welder, policeperson, 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)
8 = Homemaker
9 = Student, disabled, no occupation

Does someone contribute the majority of your support? ☐ Yes ☐ No

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E10. Usual employment pattern, past 3 years.

- ☐ 1 = full time (35+ hrs/week)
- ☐ 2 = part time (regular hours)
- ☐ 3 = part time (irregular hours)
- ☐ 4 = student
- ☐ 5 = military service
- ☐ 6 = retired/disabled
- ☐ 7 = unemployed
- ☐ 8 = in controlled environment

E11 How many days were you paid for working in the past 30 days?

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

	Employment (net income)	$
	Unemployment compensation	$
	Welfare	$
	Pension, benefits or social security	$
	Mate, family or friends (money for personal expenses)	$
	Illegal	$

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

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

For Questions E20 and E21 please ask the subject to use the subject rating scale.

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

☐ 0 = Not at all ☐ 1 = Slightly ☐ 2 = Moderately ☐ 3 = Considerably ☐ 4 = Extremely

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

☐ 0 = Not at all ☐ 1 = Slightly ☐ 2 = Moderately ☐ 3 = Considerably ☐ 4 = Extremely

Confidence Ratings

Is the above information significantly distorted by:

Subject's misrepresentation? ☐ Yes ☐ No

Subject's inability to understand? ☐ Yes ☐ No

Comments:

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Drug/Alcohol Abuse

		Days in Past 30 Days	Lifetime Years	Route of Administration (1 = oral, 2 = nasal, 3 = smoking, 4 = non iv inj. 5 = iv inj.)
	Alcohol – any use at all			
	Alcohol – to intoxication			
	Heroin			
	Methadone			
	Other opiates/analgesics			
	Barbiturates			
	Other sedatives/hypnotics/tranquilizers			
	Cocaine			
	Amphetamines			
	Cannabis			
	Hallucinogens			
	Inhalants			
	More than one substance per day (including alcohol)			
D17	How many times have you had alcohol DTs?			

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

D19*	Alcohol abuse	
D20*	Drug abuse	

How many times of these were detox only?

D21	Alcohol	
D22	Drugs	

Enter "NN" if answers to Question D19 or D20 = "00"

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

	Alcohol	$
	Drugs	$

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

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

Alcohol problems

Drug problems

For Questions D28-31 please ask the subject to use the subject rating scale.

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

Alcohol problems
☐ 0 = Not at all ☐ 1 = Slightly ☐ 2 = Moderately ☐ 3 = Considerably ☐ 4 = Extremely

Drug problems
☐ 0 = Not at all ☐ 1 = Slightly ☐ 2 = Moderately ☐ 3 = Considerably ☐ 4 = Extremely

How important to you now is treatment for these:

Alcohol problems
☐ 0 = Not at all ☐ 1 = Slightly ☐ 2 = Moderately ☐ 3 = Considerably ☐ 4 = Extremely

Drug problems
☐ 0 = Not at all ☐ 1 = Slightly ☐ 2 = Moderately ☐ 3 = Considerably ☐ 4 = Extremely

Confidence Ratings

Is the above information significantly distorted by:

Subject's misrepresentation? ☐ Yes ☐ No

Subject's inability to understand? ☐ Yes ☐ No

Comments:

Legal Status

L1. Was this admission prompted or suggested by the criminal justice system (judge, probation/parole officer, etc.)? ☐ Yes ☐ No

Are you on probation or parole? ☐ Yes ☐ No

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

Shoplifting/vandalism

Parole/probation violation(s)

Drug charge(s)

Forgery

Weapons offense

Burglary, larceny, breaking and entering

Robbery

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	Assault	
	Arson	
	Rape	
	Homicide, manslaughter	
	Prostitution	
	Contempt of court	
	Other, specify:	
	How many of these charges resulted in conviction?	

Enter "NN" if no arrests or charges.

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

	Disorderly conduct, vagrancy, public intoxication?	
	Driving while intoxicated?	
	Major driving violations (reckless driving, speeding, no license, etc.)?	
L21*	How many months were you incarcerated in your life?	Months
	Are you presently awaiting charges, trial or sentence? ☐ Yes ☐ No	
	What for?	

If multiple charges, use the number of the most severe from above(L3-L16), or use the following codes: 18=disorderly conduct, 19=driving while intoxicated, 20=major driving violation.

L26	How many days in the past 30 were you detained or incarcerated?	
	How many days in the past 30 have you engaged in illegal activities for profit?	

For Questions L28 and L29 please ask the subject to use the subject rating scale.

L28 How serious do you feel your present legal problems are?
☐ 0 = Not at all ☐ 1 = Slightly ☐ 2 = Moderately ☐ 3 = Considerably ☐ 4 = Extremely

How important to you now is counseling or referral for these legal problems?
☐ 0 = Not at all ☐ 1 = Slightly ☐ 2 = Moderately ☐ 3 = Considerably ☐ 4 = Extremely

Confidence Ratings

Is the above information significantly distorted by:

	Subject's misrepresentation?	☐ Yes	☐ No
	Subject's inability to understand?	☐ Yes	☐ No

Comments:

Treatment Week 12

Site ID: | Subject ID #. | Subject Initials | Week

Date: *(mm/dd/yyyy)*

Family/Social Relationships

Marital status ☐ Married ☐ Remarried ☐ Widowed ☐ Separated ☐ Divorced ☐ Never Married

Are you satisfied with this situation? ☐ Yes ☐ No ☐ Indifferent

Usual living arrangements (past three years)

☐ 1 = with sexual partner and children ☐ 4 = with parents ☐ 7 = alone
☐ 2 = with sexual partner alone ☐ 5 = with family ☐ 8 = controlled environment
☐ 3 = with children alone ☐ 6 = with friends ☐ 9 = no stable arrangements

Are you satisfied with these living arrangements? ☐ Yes ☐ No ☐ Indifferent

Do you live with anyone who:

Has a current alcohol problem? ☐ Yes ☐ No

Uses non-prescribed drugs? ☐ Yes ☐ No

With whom do you spend most of your free time? ☐ Family ☐ Friends ☐ Alone

Are you satisfied with spending your free time this way? ☐ Yes ☐ No ☐ Indifferent

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

	In the past 30 days			Lifetime		
	Yes	No	N/A	Yes	No	N/A
Mother	☐	☐	☐	☐	☐	☐
Father	☐	☐	☐	☐	☐	☐
Siblings	☐	☐	☐	☐	☐	☐
Sexual partner/ Spouse	☐	☐	☐	☐	☐	☐
Children	☐	☐	☐	☐	☐	☐
Other significant family	☐	☐	☐	☐	☐	☐

Please specify if "Yes":

Close friends	☐	☐	☐	☐	☐	☐
Neighbors	☐	☐	☐	☐	☐	☐
Co-workers	☐	☐	☐	☐	☐	☐

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Did anyone abuse you?

Physically (caused you physical harm)
In the past 30 days ☐ Yes ☐ No Lifetime ☐ Yes ☐ No

Sexually (forced sexual advances or sexual acts)
In the past 30 days ☐ Yes ☐ No Lifetime ☐ Yes ☐ No

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

With your family:

With other people excluding family:

For Questions F32-35 please ask the subject to use the subject rating scale.
How troubled or bothered have you been in the past 30 days by these:

Family problems
☐ 0 = Not at all ☐ 1 = Slightly ☐ 2 = Moderately ☐ 3 = Considerably ☐ 4 = Extremely

Social problems
☐ 0 = Not at all ☐ 1 = Slightly ☐ 2 = Moderately ☐ 3 = Considerably ☐ 4 = Extremely

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

Family problems
☐ 0 = Not at all ☐ 1 = Slightly ☐ 2 = Moderately ☐ 3 = Considerably ☐ 4 = Extremely

Social problems
☐ 0 = Not at all ☐ 1 = Slightly ☐ 2 = Moderately ☐ 3 = Considerably ☐ 4 = Extremely

Confidence Ratings

Is the above information significantly distorted by:

Subject's misrepresentation? ☐ Yes ☐ No

Subject's inability to understand? ☐ Yes ☐ No

Comments:

Psychiatric Status

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

In a hospital or inpatient setting

As an outpatient or private patient

Do you receive a pension for a psychiatric disability? ☐ Yes ☐ No

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

		In the past 30 days		Lifetime	
P4	Experienced serious depression (sadness, hopelessness, loss of interest, difficulty with daily functioning)?	☐ Yes	☐ No	☐ Yes	☐ No
P5	Experienced serious anxiety/tension (uptight, unreasonably worried, inability to feel relaxed)?	☐ Yes	☐ No	☐ Yes	☐ No
P6	Experienced hallucinations (saw things or heard voices that were not there)?	☐ Yes	☐ No	☐ Yes	☐ No
P7	Experienced trouble understanding, concentrating, or remembering?	☐ Yes	☐ No	☐ Yes	☐ No

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

P8	Experienced trouble controlling violent behavior?	☐ Yes	☐ No	☐ Yes	☐ No
P9	Experienced serious thoughts of suicide?	☐ Yes	☐ No	☐ Yes	☐ No
P10	Attempted suicide?	☐ Yes	☐ No	☐ Yes	☐ No
P11	Been prescribed medication for any psychological or emotional problem?	☐ Yes	☐ No	☐ Yes	☐ No

P12 How many days in the past 30 have you experienced these psychological or emotional problems?

For Questions P13 and P14 please ask the subject to use the subject rating scale.

P13 How much have you been troubled or bothered by these psychological or emotional problems in the past 30 days?

☐ 0 = Not at all ☐ 1 = Slightly ☐ 2 = Moderately ☐ 3 = Considerably ☐ 4 = Extremely

P14 How important to you now is treatment for these psychological problems?

☐ 0 = Not at all ☐ 1 = Slightly ☐ 2 = Moderately ☐ 3 = Considerably ☐ 4 = Extremely

Confidence Ratings

Is the above information significantly distorted by:

P22	Subject's misrepresentation?	☐ Yes	☐ No
P23	Subject's inability to understand?	☐ Yes	☐ No

Comments:

Completed by (Initials:

Treatment Week 12

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Date:

(mm/dd/yyyy)

Ask subject to read each of the items and choose only one answer for each question

Drug Use

1. How many times have you hit up (i.e. injected any drugs) in the last month?
   - ☐ I haven't hit up

     If you have not injected drugs in the last month, go to Question 7.
   - ☐ Once a week or less
   - ☐ More than once a week but less than once a day
   - ☐ Once a day
   - ☐ 2--3 times a day
   - ☐ More than three times a day
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 past month?
   - ☐ None
   - ☐ One person
   - ☐ Two people
   - ☐ 3-5 people
   - ☐ 6-10 people
   - ☐ More than 10 people
4. How many times in the last month has someone used a needle after you?
   - ☐ 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?
   - ☐ I do not re-use
   - ☐ Every time
   - ☐ Often
   - ☐ Sometimes
   - ☐ Rarely
   - ☐ Never
6. Before using needles again, how often in the past month did you use bleach to clean them?
   - ☐ I do not re-use
   - ☐ Every time
   - ☐ Often
   - ☐ Sometimes
   - ☐ Rarely
   - ☐ Never

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Date:

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Sexual Behavior

7. How many people, including clients, have you had sex with in the last month?
   - ☐ None

   If you have not had sex in the last month, skip to Question 12.
   - ☐ One
   - ☐ Two
   - ☐ 3-5 people
   - ☐ 6-10 people
   - ☐ More than 10 people

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

9. How often have you used condoms when you had sex with casual partners?
   - ☐ No casual partner/no penetrative sex
   - ☐ Every time
   - ☐ Often
   - ☐ Sometimes
   - ☐ Rarely
   - ☐ Never

10. How often have you used condoms when you have been paid for sex in the last month?
   - ☐ No paid partner/no penetrative sex
   - ☐ Every time
   - ☐ Often
   - ☐ Sometimes
   - ☐ Rarely
   - ☐ Never

11. How many times have you had anal sex in the last month?
   - ☐ No times
   - ☐ One time
   - ☐ Two times
   - ☐ 3-5 times
   - ☐ 6-10 times
   - ☐ More than 10 times

   Everyone should answer Question 12.

12. Have you had an HIV test come back positive?
   - ☐ Yes
   - ☐ No
   - ☐ Don't know

Completed by (Initials):

Treatment Week 12

Site ID: | Subject ID #. | Subject Initials | Week

Date: *(mm/dd/yyyy)*

Date doses dispensed *(mm/dd/yyyy)*
Each dose is four tablets

Kit Number:

Bottle Number:

Number of doses dispensed

Date unused doses returned *(mm/dd/yyyy)*

Number of doses returned

Number of doses reported lost by subject

Doses taken:

Day of Week:	Date *(mm/dd/yyyy)*	Time Dose Taken	Dose Not Taken

Comments:

Completed by (Initials):

Treatment Week 12

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

Did subject receive standardized, manual-guided individual psychotherapy this week?

(If No, please comment below) ☐ Yes ☐ No

If yes, length of psychotherapy session minutes

Did subject require emergency crisis management sessions this week? ☐ Yes ☐ No

If yes, how many?

Additional comments:

Completed by (Initials):

Treatment Week 12

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____

(mm/dd/yyyy)

This form is to be filled out for <u>female subjects only</u>. All female subjects must be tested at Screening/Baseline and have a negative pregnancy test in order to be eligible for this study.

What method of birth control is the participant currently using (prior to taking modafinil)?

- ☐ Oral contraceptive
- ☐ Barrier (diaphragm or condom plus spermicide)
- ☐ Levonorgestrel implant (Norplant)
- ☐ Intrauterine Contraceptive system (IUD)
- ☐ Medroxyprogesterone Acetate Contraceptive injection (Depo-Provera)
- ☐ Contraceptive patch
- ☐ Surgical Sterilization - Hysterectomy
- ☐ Surgical Sterilization - Tubal ligation

Unless surgically sterile or 2 years postmenopausal, does the subject agree to use an acceptable method of birth control during the study and 30 days after last dose of study drug?

☐ Yes ☐ No

If yes, mark below the acceptable method selected by the subject for use:

- ☐ barrier method with spermicide
- ☐ steroidal contraceptive [oral, Implanted, injected] used in conjunction with a barrier method
- ☐ Contraceptive patch used in conjunction with a barrier method
- ☐ Intrauterine device [IUD]

Was a pregnancy test performed? ☐ Yes ☐ No

If yes, date specimen collected _____

(mm/dd/yyyy)

Result: ☐ Negative ☐ Positive ☐ Unknown

If no, specify reason: _____

Is the subject lactating? ☐ Yes ☐ No

Comments: _____

Completed by (Initials): _____

Treatment Week 12

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

Did Subject receive HIV Counseling at Week 12?

(If No, please comment below) ☐ Yes ☐ No

Additional comments:

Completed by (Initials):

Treatment Week 16

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____

(mm/dd/yyyy)

Weekly Study Visit ***Urine bar code sticker:*** _____

Date urine collected: _____ Urine not collected ☐

(mm/dd/yyyy)

Was urine temperature within expected range? ☐ Yes ☐ No

Franklin Cup: The temperature must be higher than 96.0 ° F and lower than 104.8 ° F On-Trak Cup: The temperature must be higher than 90.0 ° F and lower than 99.0 ° F Split Sample Cup: The temperature must be higher than 90.0 ° F and lower than 100.0 ° F

Completed by (Initials): _____

NIDA-MDS-Modaf-0001 **Form 24 – SUBSTANCE USE INVENTORY**

Treatment Week 13

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

Using timeline follow-back method, record whether subject has on each day since the last visit used any amount of the substances listed below, along with the most common route of administration for each drug. Begin with yesterday and work back to the last visit. Please be sure that days are continuous with last week's form.

Date of last visit:

(mm/dd/yyyy)

Day of week							
Date							
	Used? ROA	**Used? ROA**	**Used? ROA**	**Used? ROA**	**Used? ROA**	**Used? ROA**	**Used? ROA**
Cocaine	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Alcohol	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Marijuana	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Amphetamines	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Opiates	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Barbiturates	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Benzodiazepines	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N

Route of administration (ROA) codes: 1 = oral, 2 = nasal, 3 = smoking, 4 = non-intravenous injection, 5 = intravenous injection

Completed by (Initials):

NIDA-MDS-Modaf-0001 **Form 24 – SUBSTANCE USE INVENTORY**

Treatment Week 14

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

Using timeline follow-back method, record whether subject has on each day since the last visit used any amount of the substances listed below, along with the most common route of administration for each drug. Begin with yesterday and work back to the last visit. Please be sure that days are continuous with last week's form.

Date of last visit:

(mm/dd/yyyy)

Day of week							
Date							
	Used? ROA	**Used? ROA**	**Used? ROA**	**Used? ROA**	**Used? ROA**	**Used? ROA**	**Used? ROA**
Cocaine	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Alcohol	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Marijuana	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Amphetamines	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Opiates	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Barbiturates	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Benzodiazepines	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N

Route of administration (ROA) codes: 1 = oral, 2 = nasal, 3 = smoking, 4 = non-intravenous injection, 5 = intravenous injection

Completed by (Initials):

NIDA-MDS-Modaf-0001 **Form 24 – SUBSTANCE USE INVENTORY**

Treatment Week 15

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

Using timeline follow-back method, record whether subject has on each day since the last visit used any amount of the substances listed below, along with the most common route of administration for each drug. Begin with yesterday and work back to the last visit. Please be sure that days are continuous with last week's form.

Date of last visit:

(mm/dd/yyyy)

Day of week							
Date							
	Used? ROA	**Used? ROA**	**Used? ROA**	**Used? ROA**	**Used? ROA**	**Used? ROA**	**Used? ROA**
Cocaine	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Alcohol	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Marijuana	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Amphetamines	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Opiates	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Barbiturates	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Benzodiazepines	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N

Route of administration (ROA) codes: 1 = oral, 2 = nasal, 3 = smoking, 4 = non-intravenous injection, 5 = intravenous injection

Completed by (Initials):

NIDA-MDS-Modaf-0001 **Form 24 – SUBSTANCE USE INVENTORY**

Treatment Week 16

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

Using timeline follow-back method, record whether subject ha s on each day since the last visit used any amount of the substances listed below, along with the most common route of administration for each drug. Begin with yesterday and work back to the last visit. Please be sure that days are continuous with last week's form.

Date of last visit:

(mm/dd/yyyy)

Day of week							
Date							
	Used? ROA	**Used? ROA**	**Used? ROA**	**Used? ROA**	**Used? ROA**	**Used? ROA**	**Used? ROA**
Cocaine	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Alcohol	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Marijuana	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Amphetamines	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Opiates	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Barbiturates	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N
Benzodiazepines	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N	☐Y/☐N

Route of administration (ROA) codes: 1 = oral, 2 = nasal, 3 = smoking, 4 = non-intravenous injection, 5 = intravenous injection

Completed by (Initials):

Treatment Week 16

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

Ask subject to read each of the items and choose only one answer for each question

Drug Use

1. How many times have you hit up (i.e. injected any drugs) in the last month?
   - ☐ I haven't hit up
     If you have not injected drugs in the last month, go to Question 7.
   - ☐ Once a week or less
   - ☐ More than once a week but less than once a day
   - ☐ Once a day
   - ☐ 2--3 times a day
   - ☐ More than three times a day
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 past month?
   - ☐ None
   - ☐ One person
   - ☐ Two people
   - ☐ 3-5 people
   - ☐ 6-10 people
   - ☐ More than 10 people
4. How many times in the last month has someone used a needle after you?
   - ☐ 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?
   - ☐ I do not re-use
   - ☐ Every time
   - ☐ Often
   - ☐ Sometimes
   - ☐ Rarely
   - ☐ Never
6. Before using needles again, how often in the past month did you use bleach to clean them?
   - ☐ I do not re-use
   - ☐ Every time
   - ☐ Often
   - ☐ Sometimes
   - ☐ Rarely
   - ☐ Never

Treatment Week 16

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

Sexual Behavior

7. How many people, including clients, have you had sex with in the last month?
   - ☐ None

   If you have not had sex in the last month, skip to Question 12.
   - ☐ One
   - ☐ Two
   - ☐ 3-5 people
   - ☐ 6-10 people
   - ☐ More than 10 people

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

9. How often have you used condoms when you had sex with casual partners?
   - ☐ No casual partner/no penetrative sex
   - ☐ Every time
   - ☐ Often
   - ☐ Sometimes
   - ☐ Rarely
   - ☐ Never

10. How often have you used condoms when you have been paid for sex in the last month?
   - ☐ No paid partner/no penetrative sex
   - ☐ Every time
   - ☐ Often
   - ☐ Sometimes
   - ☐ Rarely
   - ☐ Never

11. How many times have you had anal sex in the last month?
   - ☐ No times
   - ☐ One time
   - ☐ Two times
   - ☐ 3-5 times
   - ☐ 6-10 times
   - ☐ More than 10 times

   Everyone should answer Question 12.

12. Have you had an HIV test come back positive?
   - ☐ Yes
   - ☐ No
   - ☐ Don't know

Completed by (Initials):

Treatment Week 16

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

This form is to be filled out for female subjects only. All female subjects must be tested at Screening/Baseline and have a negative pregnancy test in order to be eligible for this study.

What method of birth control is the participant currently using (prior to taking modafinil)?

- ☐ Oral contraceptive
- ☐ Barrier (diaphragm or condom plus spermicide)
- ☐ Levonorgestrel implant (Norplant)
- ☐ Intrauterine Contraceptive system (IUD)
- ☐ Medroxyprogesterone Acetate Contraceptive injection (Depo-Provera)
- ☐ Contraceptive patch
- ☐ Surgical Sterilization - Hysterectomy
- ☐ Surgical Sterilization - Tubal ligation

Unless surgically sterile or 2 years postmenopausal, does the subject agree to use an acceptable method of birth control during the study and 30 days after last dose of study drug?

☐ Yes ☐ No

If yes, mark below the acceptable method selected by the subject for use:

- ☐ barrier method with spermicide
- ☐ steroidal contraceptive [oral, Implanted, injected] used in conjunction with a barrier method
- ☐ Contraceptive patch used in conjunction with a barrier method
- ☐ Intrauterine device [IUD]

Was a pregnancy test performed? ☐ Yes ☐ No

If yes, date specimen collected

(mm/dd/yyyy)

Result: ☐ Negative ☐ Positive ☐ Unknown

If no, specify reason:

Is the subject lactating? ☐ Yes ☐ No

Comments:

Completed by (Initials):

Treatment Week 16

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

Did Subject receive HIV Counseling at Follow up?

(If No, please comment below) ☐ Yes ☐ No

Additional comments:

Completed by (Initials):

NIDA-MDS-Modaf-0001 **Form 37 – FOLLOW UP**
Treatment Week 16

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

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

If Yes, date of contact: *(mm/dd/yyyy)* If No, skip to question #7.

2. Does the subject report currently receiving treatment for drug or alcohol abuse/dependence? ☐ Yes ☐ No
3. Does the subject report that s/he would take the study drug again if it were generally available for substance abuse treatment? ☐ Yes ☐ No ☐ Unknown
4. Have any adverse events occurred? ☐ Yes ☐ No
   If 'Yes', an Adverse Event CRF form must be completed.
5. Have any serious adverse events occurred? ☐ Yes ☐ No
   If 'Yes', a Serious Adverse Event report must be filed.
6. If subject does not complete the SUI, ask about use of any of the following and if so, for how many days since last clinic visit? (Select all that apply.)

	Days Used
☐ Cocaine	
☐ Methamphetamines	
☐ Amphetamines	
☐ Benzodiazepines	
☐ Alcohol	
☐ Marijuana	
☐ Sedatives	
☐ Nicotine	
☐ Opiates	
☐ Barbiturates	
☐ None	
☐ Other	

If unable to make contact with the subject, please complete the following:

7. Has contact been made with someone who can verify his/her status? ☐ Yes ☐ No
   If yes, according to the contact:
8. Is the subject living? ☐ Yes ☐ No ☐ Unknown
   If the subject has died, a Serious Adverse Event report must be filed.
9. Is the subject currently using Cocaine? ☐ Yes ☐ No ☐ Unknown
10. Additional comments:

Completed by (Initials):

End of Trial

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

This form must be completed for every consented subject.

1. Date of last clinic visit *(mm/dd/yyyy)*

2. Date of last study drug dispensed *(mm/dd/yyyy)*

3. Was the subject randomized? ☐ Yes ☐ No

If "No", indicate below reason(s) not randomized.

If "Yes", indicate below reason(s) subject is no longer in study.

Reason(s) subject's participation has ended:

Mark all that apply.

☐ Subject completed study.

☐ Subject failed to meet Inclusion/Exclusion criteria. ***Entry Criteria form must indicate which criteria were/were not met.***

☐ Subject declined to participate (during Screening).

☐ Subject requested to withdraw from study

☐ Subject reports drug not working ☐ Other ***Please specify below.***

☐ Subject developed sensitivity to study drug or 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. Please specify which Adverse Event(s) is(are) involved.

☐ Subject terminated for administrative reasons . ***Include protocol non-compliance in this Category. Provide comments.***

☐ Subject transferred to another treatment program (select type)

☐ Methadone ☐ LAAM ☐ Drug Free ☐ Inpatient Detox or Treatment

☐ Therapeutic Community ☐ Other, specify

☐ Subject became pregnant.
☐ Subject moved from area.
☐ Subject died.
☐ Subject did not return to study/clinic
☐ Subject is in a controlled environment
☐ Other ***Provide comments***

4. Comments:

I, by signing and dating this form, indicate my assurance that with my supervision and management, all data in the CRF have been reviewed and are correct.

Principal Investigator: ***Signature*** Date

(mm/dd/yyyy)

NIDA-MDS-Modaf-0001

Form 16 – ADVERSE EVENTS

All Visits

Site ID:	Subject ID #.	Subject Initials

Has the subject had any Adverse Events during the time period evaluated? ☐ Yes ☐ No ***(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?**
1 = Mild 2 = Moderate 3 = Severe	1 = Definitely 2 = Probably 3 = Possibly 4 = Remotely 5 = Definitely Not 6 = Unknown	1 = None 2 = Discontinued Perm. 3 = Discontinued Temp 4 = Reduced Dose 5 = Increased Dose 6 = Delayed Dose	1 = None 2 = Pharmacologic Therapy 3 = Nonpharm. Therapy 4 = Hospitalization	1 = Resolved, no sequelae 2 = Still present, no treatment 3 = Still present, being treated 4 = Residual effects, no treatment 5 = Residual effects, being treated 6 = Death 7 = Unknown	1 = Yes 0 = No *(If yes, complete SAE Form)*

A **Adverse Event**	B **Start Date**	C **Stop Date**	D **Severity**	E **Related**	F **Action**	G **Other Act.**	H **Outcome**	I **SAE?**

NIDA-MDS-Modaf-0001

Form 16 – ADVERSE EVENTS

All Visits

Site ID: | Subject ID #. | Subject Initials

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

D: Severity

1 = Mild
2 = Moderate
3 = Severe

E: Relationship

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

F: Action Taken Regarding Study Drug

1 = None
2 = Discontinued Perm.
3 = Discontinued Temp
4 = Reduced Dose
5 = Increased Dose
6 = Delayed Dose

G: Other Action Taken

1 = None
2 = Pharmacologic Therapy
3 = Nonpharm. Therapy
4 = Hospitalization

H: Outcome of AE

1 = Resolved, no sequelae
2 = Still present, no treatment
3 = Still present, being treated
4 = Residual effects, no treatment
5 = Residual effects, being treated
6 = Death
7 = Unknown

I: Serious?

1 = Yes
0 = No
(If yes, complete SAE Form)

A **Adverse Event**	B **Start Date**	C **Stop Date**	D **Severity**	E **Related**	F **Action**	G **Other Act.**	H **Outcome**	I **SAE?**

NIDA-MDS-Modaf-0001

Form 16 – ADVERSE EVENTS

All Visits

Site ID: | Subject ID #. | Subject Initials

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

D: Severity

1 = Mild
2 = Moderate
3 = Severe

E: Relationship

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2 = Probably
3 = Possibly
4 = Remotely
5 = Definitely Not
6 = Unknown

F: Action Taken Regarding Study Drug

1 = None
2 = Discontinued Perm.
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4 = Reduced Dose
5 = Increased Dose
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G: Other Action Taken

1 = None
2 = Pharmacologic Therapy
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4 = Hospitalization

H: Outcome of AE

1 = Resolved, no sequelae
2 = Still present, no treatment
3 = Still present, being treated
4 = Residual effects, no treatment
5 = Residual effects, being treated
6 = Death
7 = Unknown

I: Serious?

1 = Yes
0 = No
(If yes, complete SAE Form)

A **Adverse Event**	B **Start Date**	C **Stop Date**	D **Severity**	E **Related**	F **Action**	G **Other Act.**	H **Outcome**	I **SAE?**

All Visits

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

Demographic Information

Date of Consent: *(mm/dd/yyyy)* Gender: ☐ Male ☐ Female

Date of Birth: *(mm/dd/yyyy)* Height: in Weight: lb

Ethnicity (regardless of race):

☐ Hispanic or Latino
☐ Not Hispanic or Latino

Race (indicate which single major race applies):

☐ White ☐ Black or African American ☐ Asian
☐ American Indian or Alaska Native ☐ Native Hawaiian or Other Pacific Islander
☐ Other, specify ☐ Unknown

☐ Participant chooses not to answer race/ethnicity questions.

Serious Adverse Event

Type of event

☐ Death
☐ Immediately Life-threatening event
☐ Hospitalization/prolonged hospitalization
☐ Persistent/Significant Disability
☐ Congenital anomaly
☐ Other, specify

If patient died, Date of death *(mm/dd/yyyy)*

Cause of Death

Autopsy Report Requested? ☐ Yes ☐ No Reason:

Description of the Serious Adverse Event (make sure the description and date are consistent with the AE Form):

Onset date: *(mm/dd/yyyy)* Severity Grade: ☐ Mild ☐ Moderate ☐ Severe

Reported to IRB by: Date: *(mm/dd/yyyy)*

All Visits

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

Reported to Sponsor (NIDA) by: _____ Date: _____
(mm/dd/yyyy)

Type of Report: ☐ Initial Report ☐ Follow-up Report

Was the SAE related to the investigational agent?

☐ Definitely ☐ Probably ☐ Possibly ☐ Remotely ☐ Definitely Not ☐ Unknown

Action Taken regarding investigational agent:

☐ None ☐ Discontinued temporarily ☐ Increased dose
☐ Discontinued permanently ☐ Reduced dose ☐ Delayed dose

Other actions taken:

☐ None ☐ Remedial therapy – non-pharmacologic
☐ Remedial therapy – pharmacologic ☐ Hospitalization -new or prolonged

Outcome to date:

☐ Resolved; no sequelae ☐ Resulted in chronic condition, severe and/or permanent disability
☐ Not yet resolved, but improving ☐ Deceased
☐ Not yet resolved, no change ☐ Unknown
☐ Not yet resolved, worsening

Date of SAE Resolution: _____ ☐ continuing
(mm/dd/yyyy)

Concomitant medications: (both legal and illicit)

Relevant tests/laboratory data, including dates:

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

All Visits

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

Investigational Agent Administration

Is the investigational agent information known? ☐ Yes ☐ No

If yes, investigational agent name Lot number:

Expiration date:

(mm/dd/yyyy)

Quantity: Units: Frequency: Route of Administration:

Codes listed below.

Start date: Stop date:

(mm/dd/yyyy) *(mm/dd/yyyy)*

Comments:

Unit of Medication

CAP = capsule
g = gram
GR = grain
GTT = drop
ug = microgram
uL = microliter
mg = milligram
mL = milliliter
PCH = patch
oz = ounce
PUF = puff
SPY = spray/squirt
SUP = suppository
TSP = teaspoon
TBS = tablespoon
TAB = tablet
UNK = unknown

Frequency

ONCE = one dose
QD = once daily
BID = twice daily
TID = 3 times/day
QID = 4 times/day
QOD = every other day
PRN = as needed

Route of Administration

PO = oral
TD = transdermal
INH = inhaled
IM = intramuscular
IV = intravenous
REC = rectal
VAG = vaginal
SQ = subcutaneous
SL = sublingual
AUR = auricular
IA = intra-articular
NAS = nasal
IO = intraocular
UNK = unknown

All Visits

Site ID: | Subject ID #. | Subject Initials | Week

Date: *(mm/dd/yyyy)*

Demographic Information

Date of Consent: *(mm/dd/yyyy)* Gender: ☐ Male ☐ Female

Date of Birth: *(mm/dd/yyyy)* Height: in Weight: lb

Ethnicity (regardless of race):

☐ Hispanic or Latino
☐ Not Hispanic or Latino

Race (indicate which single major race applies):

☐ White ☐ Black or African American ☐ Asian
☐ American Indian or Alaska Native ☐ Native Hawaiian or Other Pacific Islander
☐ Other, specify ☐ Unknown

☐ Participant chooses not to answer race/ethnicity questions.

Serious Adverse Event

Type of event

☐ Death
☐ Immediately Life-threatening event
☐ Hospitalization/prolonged hospitalization
☐ Persistent/Significant Disability
☐ Congenital anomaly
☐ Other, specify

If patient died, Date of death *(mm/dd/yyyy)*

Cause of Death

Autopsy Report Requested? ☐ Yes ☐ No Reason:

Description of the Serious Adverse Event (make sure the description and date are consistent with the AE Form):

Onset date: *(mm/dd/yyyy)* Severity Grade: ☐ Mild ☐ Moderate ☐ Severe

Reported to IRB by: Date: *(mm/dd/yyyy)*

All Visits

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

Reported to Sponsor (NIDA) by: _____ Date: _____
(mm/dd/yyyy)

Type of Report: ☐ Initial Report ☐ Follow-up Report

Was the SAE related to the investigational agent?

☐ Definitely ☐ Probably ☐ Possibly ☐ Remotely ☐ Definitely Not ☐ Unknown

Action Taken regarding investigational agent:

☐ None ☐ Discontinued temporarily ☐ Increased dose
☐ Discontinued permanently ☐ Reduced dose ☐ Delayed dose

Other actions taken:

☐ None ☐ Remedial therapy – non-pharmacologic
☐ Remedial therapy – pharmacologic ☐ Hospitalization -new or prolonged

Outcome to date:

☐ Resolved; no sequelae ☐ Resulted in chronic condition, severe and/or permanent disability
☐ Not yet resolved, but improving ☐ Deceased
☐ Not yet resolved, no change ☐ Unknown
☐ Not yet resolved, worsening

Date of SAE Resolution: _____ ☐ continuing
(mm/dd/yyyy)

Concomitant medications: (both legal and illicit)

Relevant tests/laboratory data, including dates:

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

All Visits

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

Investigational Agent Administration

Is the investigational agent information known? ☐ Yes ☐ No

If yes, investigational agent name Lot number:

Expiration date:

(mm/dd/yyyy)

Quantity: Units: Frequency: Route of Administration:

Codes listed below.

Start date: *(mm/dd/yyyy)*

Stop date: *(mm/dd/yyyy)*

Comments:

Unit of Medication

CAP = capsule
g = gram
GR = grain
GTT = drop
ug = microgram
uL = microliter
mg = milligram
mL = milliliter
PCH = patch
oz = ounce
PUF = puff
SPY = spray/squirt
SUP = suppository
TSP = teaspoon
TBS = tablespoon
TAB = tablet
UNK = unknown

Frequency

ONCE = one dose
QD = once daily
BID = twice daily
TID = 3 times/day
QID = 4 times/day
QOD = every other day
PRN = as needed

Route of Administration

PO = oral
TD = transdermal
INH = inhaled
IM = intramuscular
IV = intravenous
REC = rectal
VAG = vaginal
SQ = subcutaneous
SL = sublingual
AUR = auricular
IA = intra-articular
NAS = nasal
IO = intraocular
UNK = unknown

All Visits

Site ID: | Subject ID #. | Subject Initials | Week

Date: *(mm/dd/yyyy)*

Demographic Information

Date of Consent: *(mm/dd/yyyy)* Gender: ☐ Male ☐ Female

Date of Birth: *(mm/dd/yyyy)* Height: in Weight: lb

Ethnicity (regardless of race):

☐ Hispanic or Latino
☐ Not Hispanic or Latino

Race (indicate which single major race applies):

☐ White ☐ Black or African American ☐ Asian
☐ American Indian or Alaska Native ☐ Native Hawaiian or Other Pacific Islander
☐ Other, specify ☐ Unknown

☐ Participant chooses not to answer race/ethnicity questions.

Serious Adverse Event

Type of event

☐ Death
☐ Immediately Life-threatening event
☐ Hospitalization/prolonged hospitalization
☐ Persistent/Significant Disability
☐ Congenital anomaly
☐ Other, specify

If patient died, Date of death *(mm/dd/yyyy)*

Cause of Death

Autopsy Report Requested? ☐ Yes ☐ No Reason:

Description of the Serious Adverse Event (make sure the description and date are consistent with the AE Form):

Onset date: *(mm/dd/yyyy)* Severity Grade: ☐ Mild ☐ Moderate ☐ Severe

Reported to IRB by: Date: *(mm/dd/yyyy)*

All Visits

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____
(mm/dd/yyyy)

Reported to Sponsor (NIDA) by: _____ Date: _____
(mm/dd/yyyy)

Type of Report: ☐ Initial Report ☐ Follow-up Report

Was the SAE related to the investigational agent?

☐ Definitely ☐ Probably ☐ Possibly ☐ Remotely ☐ Definitely Not ☐ Unknown

Action Taken regarding investigational agent:

☐ None ☐ Discontinued temporarily ☐ Increased dose
☐ Discontinued permanently ☐ Reduced dose ☐ Delayed dose

Other actions taken:

☐ None ☐ Remedial therapy – non-pharmacologic
☐ Remedial therapy – pharmacologic ☐ Hospitalization -new or prolonged

Outcome to date:

☐ Resolved; no sequelae ☐ Resulted in chronic condition, severe and/or permanent disability
☐ Not yet resolved, but improving
☐ Not yet resolved, no change ☐ Deceased
☐ Not yet resolved, worsening ☐ Unknown

Date of SAE Resolution: _____ ☐ continuing
(mm/dd/yyyy)

Concomitant medications: (both legal and illicit)

Relevant tests/laboratory data, including dates:

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

All Visits

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

Investigational Agent Administration

Is the investigational agent information known? ☐ Yes ☐ No

If yes, investigational agent name | Lot number:

Expiration date:

(mm/dd/yyyy)

Quantity: | Units: | Frequency: | Route of Administration:

Codes listed below.

Start date:

(mm/dd/yyyy)

Stop date:

(mm/dd/yyyy)

Comments:

Unit of Medication

CAP = capsule
g = gram
GR = grain
GTT = drop
ug = microgram
uL = microliter
mg = milligram
mL = milliliter
PCH = patch
oz = ounce
PUF = puff
SPY = spray/squirt
SUP = suppository
TSP = teaspoon
TBS = tablespoon
TAB = tablet
UNK = unknown

Frequency

ONCE = one dose
QD = once daily
BID = twice daily
TID = 3 times/day
QID = 4 times/day
QOD = every other day
PRN = as needed

Route of Administration

PO = oral
TD = transdermal
INH = inhaled
IM = intramuscular
IV = intravenous
REC = rectal
VAG = vaginal
SQ = subcutaneous
SL = sublingual
AUR = auricular
IA = intra-articular
NAS = nasal
IO = intraocular
UNK = unknown

All Visits

Site ID: | Subject ID #. | Subject Initials

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

Unit of Medication

CAP = capsule	mg = milligram	SUP = suppository
g = gram	mL = milliliter	TSP = teaspoon
GR = grain	oz = ounce	TBS = tablespoon
GTT = drop	PUF = puff	TAB = tablet
ug = microgram	SPY = spray/squirt	UNK = unknown
uL = microliter	PCH = Patch	

Frequency

ONCE = one dose	QID = 4 times/day
QD = once daily	QOD = every other day
BID = twice daily	PRN = as needed
TID = 3 times/day	

Route of Administration

PO = oral	REC = rectal	IA = intra-articular
TD = transdermal	VAG = vaginal	NAS = nasal
INH = inhaled	SQ = subcutaneous	IO = intraocular
IM = intramuscular	SL = sublingual	UNK = unknown
IV = intravenous	AUR = auricular	

Medication	Dose	Units	Frequency	Route of Administration	Start Date	Stop Date	Continuing? (check if yes)	Indication
							☐	
							☐	
							☐	
							☐	
							☐	
							☐	
							☐	
							☐	

NIDA-MDS-Modaf-0001 **Form 18 – CONCOMITANT MEDICATIONS**

All Visits

Site ID: | Subject ID #. | Subject Initials

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

Unit of Medication

CAP = capsule
g = gram
GR = grain
GTT = drop
ug = microgram
uL = microliter
mg = milligram
mL = milliliter
oz = ounce
PUF = puff
SPY = spray/squirt
PCH = Patch
SUP = suppository
TSP = teaspoon
TBS = tablespoon
TAB = tablet
UNK = unknown

Frequency

ONCE = one dose
QD = once daily
BID = twice daily
TID = 3 times/day
QID = 4 times/day
QOD = every other day
PRN = as needed

Route of Administration

PO = oral
TD = transdermal
INH = inhaled
IM = intramuscular
IV = intravenous
REC = rectal
VAG = vaginal
SQ = subcutaneous
SL = sublingual
AUR = auricular
IA = intra-articular
NAS = nasal
IO = intraocular
UNK = unknown

Medication	Dose	Units	Frequency	Route of Administration	Start Date	Stop Date	Continuing? (check if yes)	Indication
							☐	
							☐	
							☐	
							☐	
							☐	
							☐	
							☐	
							☐	

NIDA-MDS-Modaf-0001 **Form 18 – CONCOMITANT MEDICATIONS**

All Visits

Site ID: | Subject ID #. | Subject Initials

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

Unit of Medication

CAP = capsule
g = gram
GR = grain
GTT = drop
ug = microgram
uL = microliter
mg = milligram
mL = milliliter
oz = ounce
PUF = puff
SPY = spray/squirt
PCH = Patch
SUP = suppository
TSP = teaspoon
TBS = tablespoon
TAB = tablet
UNK = unknown

Frequency

ONCE = one dose
QD = once daily
BID = twice daily
TID = 3 times/day
QID = 4 times/day
QOD = every other day
PRN = as needed

Route of Administration

PO = oral
TD = transdermal
INH = inhaled
IM = intramuscular
IV = intravenous
REC = rectal
VAG = vaginal
SQ = subcutaneous
SL = sublingual
AUR = auricular
IA = intra-articular
NAS = nasal
IO = intraocular
UNK = unknown

Medication	Dose	Units	Frequency	Route of Administration	Start Date	Stop Date	Continuing? (check if yes)	Indication
							☐	
							☐	
							☐	
							☐	
							☐	
							☐	
							☐	
							☐	

Retest

Site ID:	Subject ID #.	Subject Initials	Week

Date:

Retest 1

Date (mm/dd/yyyy) Time Vital Signs taken (24 hour clock)

Temperature (oral) (°F) NR: 94-100.4 CS ☐ NCS ☐

Comments for Temperature

Blood Pressure (sitting) (mm Hg) NR: 90-140/50-90 CS ☐ NCS ☐

Comments for Blood Pressure:

Pulse Rate (sitting) (beats/min) NR: 50-120 CS ☐ NCS ☐

Comments for Pulse Rate:

Respiratory Rate (sitting) (breaths/min) NR: 8-20 CS ☐ NCS ☐

Comments for Respiratory Rate:

Completed by (Initials):

Retest

Site ID:	Subject ID #.	Subject Initials	Week

Date:

Retest 2

Date _____ (mm/dd/yyyy) Time Vital Signs taken _____ (24 hour clock)

Temperature (oral) _____ (°F) NR: 94-100.4 CS ☐ NCS ☐

Comments for Temperature

Blood Pressure (sitting) _____ / _____ (mm Hg) NR: 90-140/50-90 CS ☐ NCS ☐

Comments for Blood Pressure:

Pulse Rate (sitting) _____ (beats/min) NR: 50-120 CS ☐ NCS ☐

Comments for Pulse Rate:

Respiratory Rate (sitting) _____ (breaths/min) NR: 8-20 CS ☐ NCS ☐

Comments for Respiratory Rate:

Completed by (Initials): _____

Retest

Site ID:	Subject ID #.	Subject Initials	Week

Date:

Retest 3

Date (mm/dd/yyyy) Time Vital Signs taken (24 hour clock)

Temperature (oral) (°F) NR: 94-100.4 CS ☐ NCS ☐

Comments for Temperature

Blood Pressure (sitting) (mm Hg) NR: 90-140/50-90 CS ☐ NCS ☐

Comments for Blood Pressure:

Pulse Rate (sitting) (beats/min) NR: 50-120 CS ☐ NCS ☐

Comments for Pulse Rate:

Respiratory Rate (sitting) (breaths/min) NR: 8-20 CS ☐ NCS ☐

Comments for Respiratory Rate:

Completed by (Initials):

Retest

Site ID:	Subject ID #.	Subject Initials	Week

Date:

Retest 4

Date (mm/dd/yyyy) Time Vital Signs taken (24 hour clock)

Temperature (oral) (°F) NR: 94-100.4 CS ☐ NCS ☐

Comments for Temperature

Blood Pressure (sitting) (mm Hg) NR: 90-140/50-90 CS ☐ NCS ☐

Comments for Blood Pressure:

Pulse Rate (sitting) (beats/min) NR: 50-120 CS ☐ NCS ☐

Comments for Pulse Rate:

Respiratory Rate (sitting) (breaths/min) NR: 8-20 CS ☐ NCS ☐

Comments for Respiratory Rate:

Completed by (Initials):

Unscheduled

Site ID:	Subject ID #.	Subject Initials	Week

Date: _____

(mm/dd/yyyy)

This form is to be filled out for female subjects only. All female subjects must be tested at Screening/Baseline and have a negative pregnancy test in order to be eligible for this study.

What method of birth control is the participant currently using (prior to taking modafinil)?

- ☐ Oral contraceptive
- ☐ Barrier (diaphragm or condom plus spermicide)
- ☐ Levonorgestrel implant (Norplant)
- ☐ Intrauterine Contraceptive system (IUD)
- ☐ Medroxyprogesterone Acetate Contraceptive injection (Depo-Provera)
- ☐ Contraceptive patch
- ☐ Surgical Sterilization - Hysterectomy
- ☐ Surgical Sterilization - Tubal ligation

Unless surgically sterile or 2 years postmenopausal, does the subject agree to use an acceptable method of birth control during the study and 30 days after last dose of study drug?

☐ Yes ☐ No

If yes, mark below the acceptable method selected by the subject for use:

- ☐ barrier method with spermicide
- ☐ steroidal contraceptive [oral, Implanted, injected] used in conjunction with a barrier method
- ☐ Contraceptive patch used in conjunction with a barrier method
- ☐ Intrauterine device [IUD]

Was a pregnancy test performed? ☐ Yes ☐ No

If yes, date specimen collected _____

(mm/dd/yyyy)

Result: ☐ Negative ☐ Positive ☐ Unknown

If no, specify reason: _____

Is the subject lactating? ☐ Yes ☐ No

Comments: _____

Completed by (Initials): _____

Unscheduled 1

Site ID: | Subject ID #. | Subject Initials | Week

Date: (mm/dd/yyyy)

	Value		Normal	Abnormal*	Abnormal* Significant	Not Done	Comments (required for abnormal values)
1. Hemoglobin		g/dL	☐	☐	☐	☐	
2. Hematocrit		%	☐	☐	☐	☐	
3. RBC		M/uL	☐	☐	☐	☐	
4. Platelet count		K/uL	☐	☐	☐	☐	
5. WBC		K/uL	☐	☐	☐	☐	
6. Neutrophils		%	☐	☐	☐	☐	
7. Lymphocytes		%	☐	☐	☐	☐	
8. Monocytes		%	☐	☐	☐	☐	
9. Eosinophils		%	☐	☐	☐	☐	
10. Basophils		%	☐	☐	☐	☐	

Please refer to Appendix I of the protocol when determining the significance of abnormal values.

****"Abnormal" is any value outside the normal laboratory range.***

million/uL = mil/cumm = mill/mcl = M/cmm = x10^6/cumm

x 10^3/uL = thou/cumm = thou/mcl = K/cmm = 1000/uL = x 10^3/cumm

☐ Check here if results on this form are retests of previous lab tests.

Date of original lab tests (mm/dd/yyyy)

Unscheduled 2

Site ID: | Subject ID #. | Subject Initials | Week

Date: *(mm/dd/yyyy)*

	Value		Normal	Abnormal*	Abnormal* Significant	Not Done	Comments (required for abnormal values)
1. Hemoglobin		g/dL	☐	☐	☐	☐	
2. Hematocrit		%	☐	☐	☐	☐	
3. RBC		M/uL	☐	☐	☐	☐	
4. Platelet count		K/uL	☐	☐	☐	☐	
5. WBC		K/uL	☐	☐	☐	☐	
6. Neutrophils		%	☐	☐	☐	☐	
7. Lymphocytes		%	☐	☐	☐	☐	
8. Monocytes		%	☐	☐	☐	☐	
9. Eosinophils		%	☐	☐	☐	☐	
10. Basophils		%	☐	☐	☐	☐	

Please refer to Appendix I of the protocol when determining the significance of abnormal values.

****"Abnormal" is any value outside the normal laboratory range.***

million/uL = mil/cumm = mill/mcl = M/cmm = x10^6/cumm

x 10^3/uL = thou/cumm = thou/mcl = K/cmm = 1000/uL = x 10^3/cumm

☐ Check here if results on this form are retests of previous lab tests.

Date of original lab tests *(mm/dd/yyyy)*

Unscheduled 1

Site ID: | Subject ID #. | Subject Initials | Week

Date: (mm/dd/yyyy)

	Value		Normal	Abnormal*	Abnormal* Significant	Not Done	Comments (Required for Abnormal values)
1. Sodium		mmol/L	☐	☐	☐	☐	
2. Potassium		mmol/L	☐	☐	☐	☐	
3. Chloride		mmol/L	☐	☐	☐	☐	
4. CO2		mmol/L	☐	☐	☐	☐	
5. Glucose		mg/dL	☐	☐	☐	☐	
6. Creatinine		mg/dL	☐	☐	☐	☐	
7. Albumin		g/dL	☐	☐	☐	☐	
8. Total protein		g/dL	☐	☐	☐	☐	
9. SGOT/AST		U/L	☐	☐	☐	☐	
10. SGPT/ALT		U/L	☐	☐	☐	☐	
11. GGT		U/L	☐	☐	☐	☐	
12. Bilirubin		mg/dL	☐	☐	☐	☐	
13. BUN		mg/dL	☐	☐	☐	☐	

Please refer to Appendix I of the protocol when determining significance of abnormal values.

**** "Abnormal" is any value outside the normal laboratory range.***

mmol/L = mEq/L

☐ Check here if this form is completed for retest of previous lab tests.

Date of original lab tests _____ *(mm/dd/yyyy)*

Unscheduled 2

Site ID: | Subject ID #. | Subject Initials | Week

Date: *(mm/dd/yyyy)*

	Value		Normal	Abnormal*	Abnormal* Significant	Not Done	Comments (Required for Abnormal values)
1. Sodium		mmol/L	☐	☐	☐	☐	
2. Potassium		mmol/L	☐	☐	☐	☐	
3. Chloride		mmol/L	☐	☐	☐	☐	
4. CO2		mmol/L	☐	☐	☐	☐	
5. Glucose		mg/dL	☐	☐	☐	☐	
6. Creatinine		mg/dL	☐	☐	☐	☐	
7. Albumin		g/dL	☐	☐	☐	☐	
8. Total protein		g/dL	☐	☐	☐	☐	
9. SGOT/AST		U/L	☐	☐	☐	☐	
10. SGPT/ALT		U/L	☐	☐	☐	☐	
11. GGT		U/L	☐	☐	☐	☐	
12. Bilirubin		mg/dL	☐	☐	☐	☐	
13. BUN		mg/dL	☐	☐	☐	☐	

Please refer to Appendix I of the protocol when determining significance of abnormal values.

**** "Abnormal" is any value outside the normal laboratory range.***

mmol/L = mEq/L

☐ Check here if this form is completed for retest of previous lab tests.

Date of original lab tests *(mm/dd/yyyy)*

Unscheduled 1

Site ID: | Subject ID #. | Subject Initials | Week

Date: *(mm/dd/yyyy)*

	Value	Normal	Abnormal*	Abnormal* Significant	Not Done	Comments (required for abnormal values)
1. Specific gravity		☐	☐	☐	☐	
2. pH		☐	☐	☐	☐	
3. Glucose		☐	☐	☐	☐	
4. Protein		☐	☐	☐	☐	
5. Ketones		☐	☐	☐	☐	
6. Occult Blood		☐	☐	☐	☐	
7. WBC		☐	☐	☐	☐	
8. RBC		☐	☐	☐	☐	
9. Epithelial Cells		☐	☐	☐	☐	

"Abnormal" is any value outside the normal laboratory range.

For Glucose, Protein, Ketones, and Occult Blood use the following scale to report Values:

-1 = Absent
0 = Trace
1
2
3
4

For WBC, RBC, and Epithelial Cells use the following scale to report Values:

1 = None (1 – 5)
2 = Few (6 – 10)
3 = Moderate (11 – 50)
4 = Heavy (>50)

☐ Check here if this form is completed for retest of previous lab tests.

Date of original lab tests *(mm/dd/yyyy)*

Completed by (Initials):

Unscheduled 2

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

	Value	Normal	Abnormal*	Abnormal* Significant	Not Done	Comments (required for abnormal values)
1. Specific gravity		☐	☐	☐	☐	
2. pH		☐	☐	☐	☐	
3. Glucose		☐	☐	☐	☐	
4. Protein		☐	☐	☐	☐	
5. Ketones		☐	☐	☐	☐	
6. Occult Blood		☐	☐	☐	☐	
7. WBC		☐	☐	☐	☐	
8. RBC		☐	☐	☐	☐	
9. Epithelial Cells		☐	☐	☐	☐	

"Abnormal" is any value outside the normal laboratory range.

For Glucose, Protein, Ketones, and Occult Blood use the following scale to report Values:

-1 = Absent
0 = Trace
1
2
3
4

For WBC, RBC, and Epithelial Cells use the following scale to report Values:

1 = None (1 – 5)
2 = Few (6 – 10)
3 = Moderate (11 – 50)
4 = Heavy (>50)

☐ Check here if this form is completed for retest of previous lab tests.

Date of original lab tests

(mm/dd/yyyy)

Completed by (Initials):

Unscheduled 1

Site ID: | Subject ID #. | Subject Initials | Week

Date: *(mm/dd/yyyy)*

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

If ECG is Normal please skip to Question C.

B. If ECG is abnormal, check below for all abnormalities.

	Abnormal	Abnormal Significant		Abnormal	Abnormal Significant
1. Increased QRS voltage	☐	☐	17. Supraventricular premature beat	☐	☐
2. Qtc prolongation	☐	☐	18. Ventricular premature beat	☐	☐
3. Left atrial hypertrophy	☐	☐	19. Supraventricular tachycardia	☐	☐
4. Right atrial hypertrophy	☐	☐	20. Ventricular tachycardia	☐	☐
5. Left ventricular hypertrophy	☐	☐	21. Atrial fibrillation	☐	☐
6. Right ventricular hypertrophy	☐	☐	22. Atrial flutter	☐	☐
7. Acute infarction	☐	☐	23. Other rhythm abnormalities	☐	☐
8. Subacute infarction	☐	☐	24. Implanted pacemaker	☐	☐
9. Old infarction	☐	☐	25. 1st degree A-V block	☐	☐
10. Myocardial ischemia	☐	☐	26. 2nd degree A-V block	☐	☐
11. Digitalis effect	☐	☐	27. 3rd degree A-V block	☐	☐
12. Symmetrical T-wave inversions	☐	☐	28. LBB block	☐	☐
13. Poor R-wave progression	☐	☐	29. RBB block	☐	☐
14. Other nonspecific ST/T	☐	☐	30. Pre-excitation syndrome	☐	☐
15. Sinus tachycardia	☐	☐	31. Other intraventricular condition	☐	☐
16. Sinus bradycardia	☐	☐	32. Other, specify	☐	☐

C. Ventricular rate (bpm)

D. PR (ms)

E. QRS (ms)

F. QTC (ms)

G. Are there any abnormalities noted above that preclude the subject from safe entry into or continuation in the study? ☐ **Yes** ☐ **No**

Unscheduled 1

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

Comments:

Unscheduled 2

Site ID: | Subject ID #. | Subject Initials | Week

Date:

(mm/dd/yyyy)

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

If ECG is Normal please skip to Question C.

B. If ECG is abnormal, check below for all abnormalities.

	Abnormal	Abnormal Significant		Abnormal	Abnormal Significant
1. Increased QRS voltage	☐	☐	17. Supraventricular premature beat	☐	☐
2. Qtc prolongation	☐	☐	18. Ventricular premature beat	☐	☐
3. Left atrial hypertrophy	☐	☐	19. Supraventricular tachycardia	☐	☐
4. Right atrial hypertrophy	☐	☐	20. Ventricular tachycardia	☐	☐
5. Left ventricular hypertrophy	☐	☐	21. Atrial fibrillation	☐	☐
6. Right ventricular hypertrophy	☐	☐	22. Atrial flutter	☐	☐
7. Acute infarction	☐	☐	23. Other rhythm abnormalities	☐	☐
8. Subacute infarction	☐	☐	24. Implanted pacemaker	☐	☐
9. Old infarction	☐	☐	25. 1st degree A-V block	☐	☐
10. Myocardial ischemia	☐	☐	26. 2nd degree A-V block	☐	☐
11. Digitalis effect	☐	☐	27. 3rd degree A-V block	☐	☐
12. Symmetrical T-wave inversions	☐	☐	28. LBB block	☐	☐
13. Poor R-wave progression	☐	☐	29. RBB block	☐	☐
14. Other nonspecific ST/T	☐	☐	30. Pre-excitation syndrome	☐	☐
15. Sinus tachycardia	☐	☐	31. Other intraventricular condition	☐	☐
16. Sinus bradycardia	☐	☐	32. Other, specify	☐	☐

C. Ventricular rate (bpm)

D. PR (ms)

E. QRS (ms)

F. QTC (ms)

G. Are there any abnormalities noted above that preclude the subject from safe entry into or continuation in the study? ☐ **Yes** ☐ **No**

Unscheduled 2

Site ID:	Subject ID #.	Subject Initials	Week

Date:

(mm/dd/yyyy)

Comments: