	C:4- I	ID.	C1-:4 ID #		ening/Baseline
	Site I	ID:	Subject ID #.	Subject Initials	Week
Date:					
<u>Inclusio</u>	(mm/do n Criteria	a/yyyy)			
☐ Yes	□ No	1 Subject	is at least 18 years-of-age.		
□ Yes	_	2. Subject	has a DSM-IV diagnosis of co	ocaine dependence as	
☐ Yes	☐ No		ned by SCID.  is seeking treatment for coca	ine dependence.	
☐ Yes	□ No	4. Subject screening scheduled days, no days be	had at least 1 positive urine Eng/baseline period prior to ran ed samples tested, with no mo more than three specimens etween samples (including bet collected on Week 1, Day 1).	BE specimen (>300 ng/mL) ndomization with a minimum ore than two specimens co collected in one week, and	n of six of the 9 ollected on consecutive I no more than four
☐ Yes	□ No		has the ability to understand, d consent.	and having understood, ha	as provided written
☐ Yes	□ No	agree to	N/A Male e, be surgically sterile, 2 years o use an accepted method of nethod for at least 30 days aft	birth control as follows, and	d agree to continue us
		b) c)	barrier method with spermicionsteroidal contraceptive [oral, in conjunction with a barrier of Contraceptive patch used in contraceptive patch used in contracterine device [IUD]	Implanted, injected] used nethod	nethod
	any of Question Implete the fina		are answered "No" the subject is in	neligible. Please proceed to the	end of this form and
<u>Exclusio</u>	on Criteria				
☐ Yes	□ No	substan	has current dependence, defice other than cocaine, alcoholence on alcohol requiring med	ol, nicotine, or marijuana or	
☐ Yes	☐ No	2. Subject	is mandated by the court to c	obtain treatment for cocaine	-dependence.
☐ Yes	□ No		has been enrolled in an opiat done, LAAM, buprenorphine) v		ng.
☐ Yes	□ No		is someone who, in the opinion te the study protocol due to pr		
☐ Yes	□ No	disorde physici	ct has a psychiatric disorder, a er, brain disease, dementia or ian requires ongoing treatmer would make treatment compli	r any disorder that, in the on that would make study pa	pinion of the study

				S	Screening	/Baseline	
ı	Site ID	:	Subject ID #.	Subject Initia	ıls	Week	
				] [			
Date:	/mm/dd/	0.0.0					
☐ Yes	(mm/dd/y □ No 6		ct has had electroconvulsive ning.	therapy within the past	3 months	preceding	
☐ Yes	□ No 7	7. Subje	ct has a current suicidal idea SCID.	tion or plan (within the	past 30 da	ys) as asse	essed
☐ Yes	□ No 8	3. Subje	ct is pregnant or lactating.				
☐ Yes	□ No 9	9. Subje	ct has a serious medical illne	esses including, but not	limited to,		
		b)	uncontrolled hypertension, significant heart disease (in enrollment), or any clinically hepatic, renal or gastrointes significant alteration of metal potentially life-threatening of that may compromise subje	y significant cardiovascustinal disorders that cou abolism or excretion of or progressive medical il	ular abnorn Ild result in the study a Ilness othe	nality (ECG a clinically agent,	6), ′
☐ Yes	☐ No 1	-	ct has clinically significant ab nced in Appendix I.	onormal laboratory value	es, includir	ng those	
☐ Yes	☐ No 1	-	ct has AIDS according to the R 1999; 48 (No.RR-13:29-31		r AIDS		
☐ Yes	☐ No 1		ct has active syphilis that has nent for syphilis (see note bel		fuses		
☐ Yes	☐ No 1	I3. Subje x-ray)	ect has active tuberculosis (p.	ositive tuberculin test a	nd confirm	atory chest	t
☐ Yes	□ No 1	obstru the pa or oral	ct has a diagnosis of adult (i. uctive pulmonary disease (CC ast two years, or has current of liberal disease).	OPD), or has a history or recent (past 3 month	of acute ast is) treatme	thma within nt with inha	
☐ Yes	□ No 1	formal enhan A subj	ct is actively using albuterol of all diagnosis of asthma. (Inhance cocaine delivery to the luiject without respiratory diseancy be considered for inclusion	lers are sometimes use ngs). se who will consent to o	ed by cocai	ine addicts	to
☐ Yes	□ No 1		ct has received a drug with k m within 30 days prior to scre				
☐ Yes	□ No 1	admini	ed medication that could inte istration of study agent and o 3, or C, below:				
	ı	B) C)	) Five half lives of other medi ) Two weeks ) Interval recommended by o e protocol for a list of medicate	other medication's produ	uct labeling	-	

				Screen	ing/Baseline						
	Site ID:	: Sub	oject ID #.	Subject Initials	Week						
Date:											
☐ Yes	(mm/dd/y □ No 1	<ul><li>VYYY)</li><li>18. Subject has participal preceding screening.</li></ul>	ted in any experimer	ntal study within 2 mont	hs						
☐ Yes	☐ No 1	☐ No 19. Subject has a known or suspected hypersensitivity to Modafinil.									
☐ Yes	□ No 2	☐ 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.										
	<b>Notes on inclusion/exclusion criterion</b> : 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.										
		who are positive for syphilis by ve subjects must be treated for s.									
	hepatitis virus. Positi active liver disease. I the subject has active exclude a prospective	se panel for hepatitis is perform ive hepatitis results do not excilence. However, if liver function tests to hepatitis and should be excluse subject from participation, builded from participation.	lude a prospective subjec (e.g. ALT and AST) are c uded from the study (exclu	t from participation unless the over three times normal it is p usion criterion #10). A positive	ere is an indication of resumptive evidence that PPD result does not						
☐ Yes	□ No	Is the subject el	ligible for randomiz	ation based on the al	oove criteria?						
☐ Yes	☐ No	Was the subject	t randomized?								
	If "No", please indic	cate the reason on the End o	f Trial form:								
Physicia	an Signature:		Date	:							
				(mm/dd/yy)	y)						

## Form 2 - DEMOGRAPHY Screening/Baseline

	Site	e ID:		Subject	ID#.		Subject In	itials	ig/ <b>Dase</b> il Week
Date:	(mm/	/dd/yyyy)	]			L			
<u>General</u>									
1. Gender:		□Male		Female	7				
2. Date of E	Birth:								
		(mn	n/dd/yyy	ry)					
<u>Ethnicit</u>	y (regard	lless of race	)						
□Hispanic	or Latino								
		☐ Mexican, M☐ Puerto Ric☐ Cuban☐ South or C☐ Other, spe	an entral A		or Chicano				
☐ Not Hisp	anic or Latin	0							
<u>Race</u>									
		gle major race a			check all t	hat apply	·):		
☐ White ☐ Black or ☐ Asian	African Ame	erican							
L Asidii		(check all that Asian India Asian India Chinese Filipino Japanese Korean Vietnames Other, spe	an						
		laska Native							
∐ Native H	awaiian or C	Other Pacific Islan  (check all tha  Native Ha Guamania Samoan Other, spe	<i>t apply)</i> waiian ın or Ch	amorro					
Other, sp									

 $\square$  Participant chooses not to answer race/ethnicity question

## Form 2 - DEMOGRAPHY Screening/Baseline

	Site ID:	Subject ID #.	Subject Initials	Week		
<b>.</b>		<u>-</u>				
Date:						
	(mm/dd/yyyy)					
<u>Educati</u>	<u>on</u>					
1. Educati	on Completed (GED =	= 12 years):				
	years					
	months					
Employ		24				
EIIIDIOY	ment/Support Sta	atus				
1. C	urrent Employment Pa	attern (Past 30 Days)				
☐ Full Time (35+ hrs/wk)		Part time (regular hrs)	Part time (irregular hrs,day work)			
Student		☐ Military Service	Retired/Disabled			
Homema	aker	Unemployed	☐ In Controlled Environment			
2. Pa	ast Employment Patte	rn (Past 3 Years)				
☐ Full Time	e 5+ hrs/wk)	Part time (regular hrs)	Part time (irregular hrs,day work)			
Student		☐ Military Service	Retired/Disabled			
Homema	aker	Unemployed	☐ In Controlled Environment			
<u>Marital S</u>	<u>Status</u>					
Legally I	Married	☐ Living with Partner/ Cohabiting	☐Widowed			
Separate	ed	Divorced	☐ Never Married			

## Form 2 - DEMOGRAPHY Screening/Baseline

	Site ID:	Subject I	D#.	Subject Initials	_	Week
D.				L		
Date:						
Drug	(mm/dd/yyyy)					
<u>Drug/</u>	'Alcohol Use					
		# of Days in the Past 30	# of Years <u>Lifetime</u>	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.  $1 = Oral \ 2 = Nasal \ 3 = Smoking \ 4 = Non-IV Injection \ 5 = IV Injection$ 

Completed by (Initials):

# Form 2 - DEMOGRAPHY Screening/Raseline

			Screening	g/Basenne						
	Site ID:	Subject ID #.	Subject Initials	Week						
Date:										
	(mm/dd/yyyy)									
Accordin	According to the interviewer, which substance is the <u>major</u> problem?									
(	Check only one.									
	☐ No problem	Methamphetamines	Other Amphetamines							
	☐Heroin	☐ Methadone prescribed	☐ Methadone <i>illicit</i>							
	Opiates/analgesics	Barbiturates	Sedatives including Benzodiazepines							
	☐ Cocaine	Cannabis	Hallucinogens							
	Inhalants	□Nicotine								
	Alcohol Addiction	☐ Polydrug addiction								

				Screeni	ng/Baseli
	Site ID:		Subject ID #.	Subject Initials	Week
		$\overline{}$			
Date:					
	/mm/dd/vvv	24)			
	(mm/dd/yyy	<i>y)</i>			
Assia I Dis					
Axis I Dia	<u>AYIIOSIS</u> Plaasa list all	CUDDENTS	Substance Abuse or Denende	nce Diagnoses (Including DSM -IV o	rodo)
	riease iist aii	CORRENTS	abstance Abuse or Depender	nice Diagnoses (including DSW-IV C	.oue)
	Please list all	PAST Substa	ance Abuse or Dependence D	Diagnoses (Including DSM -IV code	)
			-		
					<u>_</u>
	Please	list all other	CURRENT Axis I Diagnoses (	Including DSM -IV code)	
					<del></del>
L	Please	list all other l	PAST Axis I Diagnoses (Inclu	dina DSM -IV code)	
		_	,	3	
Completed	d by (Initials):				

## Form 4 – MEDICAL HISTORY

101111 4 - 1111	EDICAL HISTORI
	Screening/Baseline

-	Site	e ID:			S	Subject ID	#.		Subject Initials	Week
Date:					A. Yes,	B. Yes,	C. No	D. Did	E. Specify or Describe	
	(mm/d	d/yyyy)		E	xcludes	Does Not Exclude	History Of	Not Evaluate	(Required if yes)	
1. Allergies,	, drug (specif	y) [								
2. Allergies	, other (speci	fy)								
	ty to study m		n		_					
or related	d compounds	i								
4. History o	of asthma									
5. HEENT [	Disorder									
6. Cardiova	scular Disor	der								
7. Renal Di	sorder									
8. Hepatic [	Disorder									
9. Pulmona	ry Disorder									
10. Gastroii	ntestinal Disc	order								
11. Musculo	oskeletal Dis	order								
12. Neurolo	ogic Disorder	:								
13. Psychia	atric Disorder									
14. Dermat	ologic Disord	ler								
15. Metabo	lic Disorder									
16. Hemato	ologic Disord	er								
17. Endocri	ine Disorder									
18. Genitou	ırinary Disor	der								
19. Reprod	uctive Syster	m								
20. Seizure										
21. Infectio	us Disease									
22. Other 1	(specify)									
23. Other 2	(specify)									
	_									

#### NIDA-MDS-Modaf-0001 Form 4 – MEDICAL HISTORY Screening/Baseline **Subject Initials** Site ID: Subject ID #. Week Date: (mm/dd/yyyy) **Surgical History** 24. Has patient ever had any major surgery? ☐ Yes No If 'Yes', list major surgeries below. Type of Surgery Date of Surgery Is Surgery Relevant to Study Participation? (mm/dd/yyyy) Yes. Yes, Does **Excludes** 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:	:	

## Form 5 PRIOR MEDICATIONS

					Screening/Baseline						
			Site	ID:	;	Subject ID #.		Subj	ect Initials	Week	
						-	$\neg$	_			
_											
Data											
Date:											
L	(mm	n/dd/yyy	v)								
Lloo the aubice				the DACT of		□Yes		□No	(If v.o.o.	nlagge complete	tabla)
Has the subjec	t taken al <b>Unit of M</b>			the PAST 3	J DAYS?	Frequency		□NO	(II yes	, please complete of Administration	тарте)
CAP = capsule	mg = mill		SUP = sup	pository	ONCE =	one dose QID = 4	imes/day		PO = oral		IA = intra-articula
g = gram	mĽ = milli		TSP = teas	spoon	QD = onc	e daily $QOD = \epsilon$	very other		TD = transdermal	VAG = vaginal	NAS = nasal
GR = grain	oz = ound		TBS = tabl		BID = twic		s needed		INH = inhaled	SQ = subcutaneous	
GTT = drop ug = microgram	PUF = pu		TAB = tabl UNK = unl		TID = 3 ti	mes/day			IM = intramuscula IV = intravenous	r SL = sublingual AUR = auricular	UNK = unknown
uL = microliter	01 1 – 3p	nay/squiit	ONIX - uni	CHOWII					IV = IIIIIaveilous	AON – auticulai	
					Route of				Continuing?		
Medication		Dose	Units	Frequency	Admini-	Start Date		Stop Date		Indication	
					stration				If yes)		
									] [ ]		
									]		
							<u> </u>				
							<u> </u>				
							<u> </u>				
							<u> </u>		_		
							<u> </u>				

							Scree	ning	/Baseline
	Site ID:			Subject ID #.		Subjec	et Initials		Week
			L		L				
Date:									
	/ / / / / /	,							
<u>Hepatiti</u>	(mm/dd/yyy •	'Y)							
<u>rrepatrit</u>	<u>s</u>						comments f	or	
Hepatitis E	B surface antigen	result		Negative		any pos	sitive value.		
·	J			Positive					
			Ħ	Positive, significant Indeterminate					
				Not assessed					
Hepatitis E	B surface antibody	result		Negative					
			P	Positive Positive, significant					
			፱	Indeterminate					
			Ш	Not assessed					
Hepatitis E	3 core antibody re	sult		Negative					
			H	Positive Positive, significant					
				Indeterminate					
			Ш	Not assessed					
Hepatitis C	C virus antibody re	esult		Negative					
			H	Positive Positive, significant					
			፱	Indeterminate					
			Ш	Not assessed					
<u>Purified</u>	Protein Deriv	ative (PPL	<b>)</b>	<u>Test</u>					
	ubject ever had a	positive PPD	tes						
	ed for TB? 'Yes', do not perform	PPD and leave	e the	$\square$ Yes e rest of the PPD section bl	lank, <u>h</u>	<u>owever</u> a	☐ No chest X -ray i	s <u>requ</u>	uired.
	administered:	Date				Time			
FFD (62) a	dummstered.	Dale L		(mm/dd/yyyy)		Tillie	(24-hour clock	k)	
DDD toot r	and:	Data				Time			
PPD test r	eau.	Date		(mm/dd/yyyy)		Time	(24-hour clock	(x)	
PPD test r	rocult:	Negative	П	Positive  Unkno	W/D	Птос	st not done		
				done, a chest X-ray is requ		□ 163	st flot dolle		
Comments	ş·								
	equired for any positi	ive value.							

			Screening/Bas	Baseline	
Site ID:	Subject ID	#. Subje	ect Initials We		
Date:					
(mm/dd/yyy Chest X-Ray	y)				
Was a chest X-ray performe	d?	□ No			
Date chest x-ray performed:	(mm/dd/yyyy)				
Results of chest X-ray:	☐ Normal ☐ Abnormal, s ☐ Abnormal, s ☐ Indetermina ☐ Not assess	ate			
Provide comments for any a	bnormal finding:				
<u>HIV</u>					
Was a consent to perform a	n HIV test signed by the sub	ject?	□ No		
Was an HIV test performed?		☐ Yes	□ No		
What was the result of the H	IIV test? ☐ Positive	☐ Negative ☐ Ir	ndeterminate		

Completed by (Initials):

## Form 7 – SYPHILIS TEST

NIDA-MDS-Modal-0001		Sarooning/Rose
Site ID:	Subject ID #.	Subject Initials Weel
Date: (mm/dd/yyyy)		
apid plasma reagin (RPR) test re	esult: negative positive indeterminant not done	
RPR test is not done, state reas	son:	
If RPR test is positive, fluores RPR test is indeterminant, it n		FTA-abs) confirmatory test is required. If
AFA lest is indeterminant, it is	nust be repeated.	
Date FTA-abs test administered:		
	(mm/dd/yyyy)	
TA-abs test result:	<ul><li>negative</li><li>positive</li><li>indeterminant</li><li>not done</li></ul>	
FTA-abs test is not done, state r	reason:	
FTA-abs result is positive, is sub	bject willing to undergo treatment  Yes  No	for syphilis?
If the subject is unwilling to unresearch study.	undergo treatment for active syphilis, th	hey are ineligible to participate in this
treated, date of written proof of t	treatment: (mm/dd/yyyy)	
Comments:		

18. Breast

## Form 8 – PHYSICAL EXAM

	55 WIOUUI 0001					Screening/Baseline	
F	Site ID:	_	Subjec	t ID#.	1 6	Subject Initials Week	
Date:	(mm/dd/yyyy)	_ ]			] [		
1. Height 2. Weight	inch						
		A. Noi	B. mal Abnorr	C. mal Abnorma Significa		E. Comments (required for abnormal values)	
3. Oral (mou	uth)						
4. Head and	Neck						
5. Eyes, ear	s, nose/throat		] 🗆				
6. Cardiovas	scular						_
7. Chest							
8. Lungs			] 🗆				_
9. Abdomen	(include liver/spleen)		) 🗆				_
10. Extremiti	es						
11. Skin, hai	r, nails						
12. Neurops	ychiatric mental status						
13. Neurops	ychiatric sensory/motor						
14. Musculo	skeletal						_
15. General	appearance		] 🗆				
16. Rectal			] 🗆				_
17. Prostate			] 🗆				_

NIDA-MDS-Modaf-0001					Form 8 – PHYSICAL EXAM Screening/Baseline	
Site ID:	5	Subject l	ID#.	[	Subject Initials Week	
Date: (mm/dd/yyyy)						
	Normal	A. Abnorma	B. al Abnormal Significant	C. Not Done	D. E. Comments (required for abnormal values)	
19. Lymph						
20. Genital						_
21. Pelvic						
22. Other, specify						_

22. Other, specify

							Screen	ing/Baseline
	S	ite ID:		Subject	ID#.	_	Subject Initials	Week
Date:								
	(mr	n/dd/yyyy)						
		Value	Norn	nal Abnorm	nal* Abnorm Significar		Comments (required for abnormal	values)
1. Hemogl	obin	g/dL						
2. Hemato	ocrit	%						
3. RBC		M/uL						
4. Platelet	count	K/uL						
5. WBC		K/uL						
6. Neutrop	hils	%						
7. Lympho	ocytes	%						
8. Monocy	rtes	%						
9. Eosinop	ohils	%						
10. Basop	hils	%						
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 = $mil/cumm = mill/mcl = M/cmm = x10^6/cumm$ $x 10^3/uL = thou/cumm = thou/mcl = K/cmm = 1000/uL = x 10^3/cumm$								
☐ Checl	k here if re	esults on this f	orm are ret	ests of p	revious la	b tests.		
Date	of original	lab tests:		(mm/dc	<del>//yyyy)</del>			

							Scree	ening/Baseline
	Site ID:		Sı	ıbject ID	#		Subject Initials	Week
Date:								
	(mm/dd/yy	уу)						
	Value		Normal A	bnormal* A Si	.bnormal* gnificant		Comments (Required for Abnorn	nal 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 re	efer to Appen	dix I of the prot	ocol when	n determin	ing signif	icance o	f abnormal values.	
* "Abnor	mal" is any v	alue outside the	e normal l	aboratory	range.			
mmol/L :	= mEq/L							
☐ Check here	e if this form	is completed	for rete	st of prev	/ious lab	tests.		
Date of orig	inal lab test	s [				7		

G.	ID	a	1 '	> "		Screening/Baseline		
Sit	e ID:		ubject II	J #.	Γ	Subject Initials Week		
					L			
Date:								
(mm	/dd/yyyy)							
	Value	Normal A		Abnormal Significant		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	s any value outside th	e normal l	aborator	y range.				
For Glucose, P	rotein, Ketones, and	Occult Blo	ood use ti	he followii	ng scale	to report Values:		
	2 3							
For WBC, RBC	, and Epithelial Cells	use the fo	llowing s	cale to rep	oort Valu	es:		
1 = None (1 - 5) 2 = Few (6 - 10) 3 = Moderate (11 - 50) 4 = Heavy (>50)								
☐ Check here if thi	s form is complete	d for rete	est of pr	evious la	ab tests.			
Date of original I		m/dd/yyy	(V)					
Completed by (Initials		, , , ,	• /					

#### Form 14 – BIRTH CONTROL / PREGNANCY ASSESSMENT

			Sc	reening/Baseline					
	Site ID:	Subject ID #.	Subject Initials	_					
Doto	Г	$\neg$							
Date:									
	(mm/dd/yyyy)								
		emale subjects only. All fende subjects only. All fende in the second se							
What meth	hod of birth control is the	e participant currently using (	prior to taking modafinil)?	<b>?</b>					
	Oral contraceptive	<b>;</b>							
	Barrier (diaphragm or condom plus spermicide)								
	, , ,		•						
	_	aceptive system (IUD)							
	_	rone Acetate Contraceptive in	niection (Depo-Provera)						
	71 0	•							
	_ ' '	on - Hysterectomy							
	_	on - Tubal ligation							
	· ·	· ·							
		s postmenopausal, does the stated and 30 days after last of the state and 30 days after last of the stated and the stated are stated as the stated		cceptable					
If ves ma	rk below the acceptable	method selected by the subje	ect for use:						
yoo,a	_	•	50t 101 doc.						
		•	adl usad						
<u> </u>		ptive [oral, Implanted, injecten a barrier method	ay usea						
	Contraceptive pat	ch used in conjunction with a	a barrier method						
	Intrauterine device	; [IUD]							
Was a pre	egnancy test performed?	☐ Yes	□ No						
If	yes, date specimen colle	2cted							
"	yes, date specimen cont		mm/dd/yyyy)						
R	esult:	ve Desitive Dur	nknown						
If	no, specify reason:								
-	,,								
	<u> </u>								
Is the subj	ject lactating?	☐ Yes ☐	No						
Comments	s:								
Completed	d by (Initials):								

						Scr	eening/Baseline
ı	Site ID:			Subjec	t ID #. Subject I		Week
Date:							
	(mm/dd/yyy	y)					
A. ECG ov	erall results were:	=	mal .				
If E	ECG is Normal please		iormal ion C.				
B. If ECG i	s abnormal, check t	oelow for <u>all</u>	abnorm	alities.			
			Abnorm				Abnormal
		<u>Abnormal</u>	Significa	<u>ınt</u>	<u>At</u>	<u>onormal</u>	Significant
1. Increase	ed QRS voltage			17.	Supraventricular premature bea	t 🗆	
2. Qtc prole	ongation			18.	Ventricular premature beat		
3. Left atria	al hypertrophy			19.	Supraventricular tachycardia		
4. Right atı	rial hypertrophy			20.	Ventricular tachycardia		
5. Left vent	tricular hypertrophy			21.	Atrial fibrillation		
6. Right ve	ntricular hypertroph	у 🗆		22.	Atrial flutter		
7. Acute in	farction			23.	Other rhythm abnormalities		
8. Subacut	e infarction			24.	Implanted pacemaker		
9. Old infai	rction			25.	1 <sup>st</sup> degree A-V block		
10. Myoca	rdial ischemia			26.	2 <sup>nd</sup> degree A-V block		
11. Digitali	s effect			27.	3 <sup>rd</sup> degree A-V block		
12. Symme	etrical T-wave invers	sions 🗌		28.	LBB block		
13. Poor R	-wave progression			29.	RBB block		
14. Other r	nonspecific ST/T			30.	Pre-excitation syndrome		
15. Sinus t	achycardia			31.	Other intraventricular condition		
16. Sinus b	oradycardia			32.	Other, specify		
C. Ventricu	ular rate (bpm)			E.	QRS (ms)		
D. PR (ms	)			F.	QTC (ms)		
	nere any abnor ontinuation in t			bove	that preclude the subjec ☐ Yes ☐ No	t from	safe entry

#### Form 13 - ELECTROCARDIOGRAM

			Screen	ing/Baseline
	Site ID:	Subject ID #.	Subject Initials	Week
Date:	(mm/dd/yyyy)			
Comments:	( ()			

			Screenii	ng/Baseline
	Site ID:	Subject ID #.	Subject Initials	Week
Date:				
	(mm/dd/yyyy)			
	ssed Mood (sad, hopeless, helpless, worthle	ss)		
	<ul><li>2 = These feeling states</li><li>3 = Communicates feeling</li><li>posture, voice, and to</li></ul>	ally only these feeling states in	ally. rough facial expression,	
2. Feelin	gs of Guilt			
	<ul><li>2 = Ideas of guilt or rum</li><li>3 = Present illness is a  </li></ul>	s/he has let people down. ination over past errors or sinf punishment. Delusions of guilt r denunciatory voices and/or e		
3. Suicid	le			
	3 = Suicide ideas or ges	ead or any thoughts of possible	e death to self.	
4. Insom	nia Early			
	<ul> <li>□ 0 = No difficulty falling a</li> <li>□ 1 = Complains of occasi</li> <li>□ 2 = Complains of nightly</li> </ul>	ional difficulty falling asleep. (i	i.e., more than ½ hour)	
5. Insom	nia Middle			
		of being restless and disturbed ight – any getting out of bed ra		
6. Insom	inia Late			
		rs of the morning but goes bac again if gets out of bed.	ck to sleep.	

	Site ID:	Subject ID #.	Subject Initials	ing/Baseli Week
Date:				
7. Work an	(mm/dd/yyyy) nd Activities			
	<ul> <li>0 = No difficulty</li> <li>1 = Thoughts and feeling work or hobbies.</li> <li>2 = Loss of interest in a indirect in listlessne work or activities).</li> <li>3 = Decrease in actual</li> </ul>	ngs of incapacity, fatigue, or we activity; hobbies or work – eitherss, indecision and vacillation (for time spent in activities or decrease of present illness.	r directly reported by patien feels s/he has to push self	nt, or
8. Retarda		coduse of present limess.		
	owness of thought and speed  0 = Normal speech and the speech and the speech and the speech and the speech are speech and the speech and the speech and the speech and the speech are speech are speech are speech and the speech are speech are speech and the speech are speech and the speech are speech and the speech are speech are speech and the speech are speech and the speech are speech and the speech are speech are speech as the speech are speech are speech as the speech are speech as the speech are speech are speech are speech are speech are speech as the speech are spe	t interview	ecreased motor activity)	
9. Agitatior	า			
	<ul> <li>0 = None</li> <li>1 = Fidgetiness</li> <li>2 = Playing with hands</li> <li>3 = Moving about, can'</li> <li>4 = Hand-wringing, nail</li> </ul>		S	
10. Anxiety	y Psychic			
	<ul> <li>0 = No difficulty</li> <li>1 = Subjective tension</li> <li>2 = Worrying about mir</li> <li>3 = Apprehensive attitu</li> <li>4 = Fears expressed w</li> </ul>	nor matters ude apparent in face or speech		
cra	hysiological concomitants of	anxiety such as: Gastrointestinal: danxiety such as: Gastrointestinal: dans lance and		
	0 = Absent 1 = Mild 2 = Moderate 3 = Severe 4 = Incapacitating			
12. Somati	2 = Difficulty eating wit	tinal  It eating without encouragement  hout urging. Requests or requir  on for G.I. symptoms.	t. Heavy feelings in abdom es laxatives or medication	nen. for

			Screenin	g/Baselii
Γ	Site ID:	Subject ID #.	Subject Initials	Week
Date:	(mm/dd/yyyy)			
13. Somati	ic Symptoms General			
	0 = None 1 = Heaviness in limbs, energy and fatigabil 2 = Any clear-cut sympton	ity.	eadache, muscle aches. Loss	of
	l Symptoms uch as loss of libido and mens	trual disturbances)		
	0 = Absent 1 = Mild 2 = Severe			
15. Hypocl	hondriasis			
	0 = Not present 1 = Self-absorption (book 2 = Preoccupation with 3 = Frequent complaint 4 = Hypochondriacal de	health s, requests for help, etc.		
16. Loss of	f Weight			
	0 = No weight loss 1 = Probable weight los 2 = Definite weight loss	s associated with present illn (according to subject)	iess.	
17. Insight				
	<ul><li>0 = Acknowledges bein</li><li>1 = Acknowledges illne virus, need for rest,</li><li>2 = Denies being ill at a</li></ul>	ss but attributes cause to bac etc.	I food, climate, overwork,	
18. Diurna	I Variation			
	0 = No variation 1 = (Mild) Doubtful or sl 2 = (Severe) Clear or m If answer is 1 or 2,	narked variation	are worse in: O A.M. O P.M.	
	sonalization and Derealiza comptoms such as feelings of a			
	0 = Absent 1 = Mild 2 = Moderate 3 = Severe 4 = Incapacitating			

Completed by (Initials):

			Screening	ng/Baseline
	Site ID:	Subject ID #.	Subject Initials	Week
Date:				
Dute.	(mm/dd/yyyy)			
20. Parar	noid Symptoms			
[] [] []	0 = None 1 = Suspicious 2 = Ideas of reference 3 = Delusions of refer			
21. Obse	ssive and Compulsive Sy	rmptoms		
	0 = Absent 1 = Mild 2 = Severe			
22. Helpl	essness			
[] [] []	2 = Subject volunteer 3 = Requires urging, q personal hygiene.	s which are elicited only by inques his helpless feelings. Guidance and reassurance to access not perform necessary chor	ccomplish chores or	
23. Норе	lessness			
[ [ [ ]	2 = Consistently feels 3 = Expresses feeling which cannot be of	ots that "things will improve" but "hopeless" but accepts reassur is of discouragement, despair, p dispelled. d inappropriately perseverates,	rances. pessimism about future,	
		esteem, feelings of inferiority, self-d ness)	epreciation (loss of self-esteem)	to
	2 = Spontaneously ind 3 = Different from 2 by etc.	of worthlessness (loss of self edicates feelings of worthlessnessy degree: Subject volunteers that so of total worthlessness – e.g. "	ss (loss of self esteem). at s/he is "no good," "inferior	. ,9

G19

G20

											Screen	ning	/Baseli	ne
		Site I	D:	_	Sı	ıbject ID	#.	г	Su	bject In			Week	_
								L						
	Date	:												
		(mm/da	l/yyyy)											
	<u>Gene</u>	eral Informatio	<u>on</u>											
	G4. D	ate of admission												
	G8. C	Class	☐ Intal	ке			<i>(mm/dd/</i> w-up	<i>\yyyy)</i>						
	G9. C	Contact code	☐ In pe	erson		_	ohone			Mail				
	G10. G	Gender	Male			☐ Fema								
	G12. S	Special	☐ Tern	ninated		☐ Refu	sed			Unable	e to resp	ond		
		· low long have yo	u lived at	t your curi	ent ad	dress?		Years		_	nths			
		Date of birth:												
	0.0.2							(mm/da	l/yyyy)					
		Of what race do yo consider yourself?		☐ Black ☐ Ameri ☐ Alask	(not H can Ind an Nati					Hispar Hispar	nic - Mexi nic – Pue nic - Cuba nic - Othe	rto F an	Rican	
	G18. D	o you have a reli	gious pr	eference?	•	☐ Prote☐ Cath☐ Jewis				Islamio Other None				
G19	_ cont	e you been in a rolled environme last 30 days?	nt in	☐ No ☐ Jail ☐ Alcoh	ol/drug	treatmer	nt	☐ Ps		treatm ric trea	ent atment			
G20	How	v many days?												
	<u>MEDI</u>	ICAL STATUS	<u>i</u>											
M1*	How n	nany times in you	ır life hav	/e you be	en hos	pitalized	for me	dical pr	oblem	s?				
	M3. D	o you have any c	hronic m	nedical pro	oblem(s		continu			with y	our life?			
		If "Yes", please sp	ecify in '(	Comments'	•	∐ Yes		∐ No	)					
M4	Are y	you taking any pro				regular	basis fo	or a phy	ysical	proble	m?			
	-	If "Yes", please sp	pecify in '(	Comments'	•	□ Vec		□мс	`					

Date:    M5	Baseline/
M5	Week
M5	
M5	
M5 Do you receive a pension for a physical disability? (Exclude psychiatric disabilities.)    Yes	
Yes	
How many days have you experienced medical problems in the past 30 days?	
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	]
Confidence Ratings Is the above information significantly distorted by:  M10 Subject's misrepresentation?	
Is the above information significantly distorted by:  M10    Subject's misrepresentation?	
M11 Subject's inability to understand?	
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  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:	
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:	
E1* Education completed (GED = 12 years):  E2* Training or technical education completed:  Months  E4 Do you have a valid driver's license?  Do you have an automobile available for use?  Answer "no" if no valid driver's license.  E6. How long was your longest full-time job?  Years  No  Years  Months  Years  Months  Years  No  Years  Months	
E2* Training or technical education completed:  E4 Do you have a valid driver's license?  D5 Do you have an automobile available for use?  Answer "no" if no valid driver's license.  E6. How long was your longest full-time job?  E7 Usual (or last) occupation:	
E4 Do you have a valid driver's license?	
Do you have an automobile available for use?  Answer "no" if no valid driver's license.  E6. How long was your longest full-time job?  Years  Months  E7 Usual (or last) occupation:	
E5 Answer "no" if no valid driver's license.  E6. How long was your longest full-time job?  Years Months  E7 Usual (or last) occupation:	
E7 Usual (or last) occupation:	
Hollingshead occupational category:	

Site ID:	Subject ID #.		Subject			/ <b>Base</b> III Week
			L			
Date:						
E10. Usual employment pattern, past 3 y		_				
☐ 3 = part time (irregular ☐ 4 = student	r hours)				onme	nt
How many days were you paid for work	ing in the past 30 days	s?				
। How much money did you receive from th	e following sources in	the p	ast 30 days	?		
Employment (net income)		\$				
Unemployment compensation		\$				
1		Ψ				
] Welfare		\$				
Pension, benefits or social security		\$				
Mate, family or friends (money for perso	onal expenses)	\$				
Illegal		\$				
How many people depend on you for th	e majority of their food	d, she	lter, etc.?			
How many days have you experienced	employment problems	in the	e past 30 da	ays?		
- For Questions E20 and E21 please ask the subj	ect to use the subject rati	ng sca	le.			
				☐ 4 = Ex	ktremel	/
Confidence Ratings						
s the above information significantly disto	orted by:					
Subject's misrepresentation?	☐ Yes	5	☐ No			
Subject's inability to understand?	☐ Yes	3	☐ No			
Comments:						
	Date:    (mm/dd/yyyy)	Date:    (mm/dd/yyyy)	Date:    (mm/dd/yyyy)	Date:    (mm/dd/yyyy)    E10. Usual employment pattern, past 3 years.     1 = full time (35+ hrs/week)	Site ID: Subject ID #. Subject Initials    Date:	Date:

				Screen	ing/Baseline
	Site ID:	Subject ID #.		Subject Initials	Week
			<u> </u>		
	Date:				
	(mm/dd/yyyy) <b>Drug/Alcohol Abuse</b>				
	<u>Drug/Alconol Abuse</u>		time	Route of Administr	ation
	1	30 Days Ye	<u>ars</u>	(1 = oral, 2 = nasal, 3 = smoking, 4 = non iv	nj.
D1	Alcohol – any use at all			5 = iv inj.)	
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				
	Inhalants				
D12	<u> </u>  -		<u></u>		
D13	More than one substance per day (including alcohol)				
D17	How many times have you had alcoho	ol DTs?			
	How many times in your life have you be	en treated for:			
D19*	Alcohol abuse				
D20*	Drug abuse				
	How many times of these were detox on	ly?	<u>_</u>		
D21	Alcohol				
D22	Drugs				
I	- Enter "NN" if answers to Question D19	9 or D20 = "00"			
ŀ	How much money would you say you you	u spent in the past 3	0 days on:		
D23	Alcohol	\$			
D24	Drugs	\$			
	-			_	
D25	How many days have you been treate for alcohol or drugs in the past 30 day		A )		

							Screening	/Baseline
		Site ID:	Subje	ect ID #.	. —	Subject Ini	itials	Week
	Date:	(						
H		(mm/dd/yyyy) in the past 30 days	have you expe	rienced:				
D2		problems	, ,					
D2	Drug pro	oblems						
F		tions D28-31 please as bothered have you b						
D28	Alcohol probl		/ □ 2 = Mode	erately $\Box$	3 = Conside	erably $\Box$	4 = Extremely	,
D29	Drug problem ☐ 0 = No		/ □ 2 = Mode	erately 🗆	3 = Conside	erably $\square$	4 = Extremely	,
F	low important to	you now is treatme	nt for these:					
D30	Alcohol prob		/ □ 2 = Mode	erately	3 = Conside	erably 🔲	4 = Extremely	,
D31	Drug probler ☐ 0 = No	ns ot at all □ 1 = Slightly	/ □ 2 = Mode	erately 🗆	3 = Cons ide	erably 🔲	4 = Extremely	,
C	Confidence Ra	tings						
		ormation significantly	distorted by:					
D34	Subject's	s misrepresentation?	<b>?</b>	☐ Ye	es [	□ No		
D35	Subject's	s inability to understa	and?	☐ Ye	es [	No		
С	Comments:							
<u>L</u>	<u>egal Status</u>							_
L		mission prompted or je, probation/parole o		he criminal	· _	□ Yes	☐ No	
	Are you on p	probation or parole?				☐ Yes	☐ No	
F		in your life have yo	u been arrested	d and charge				
L3*	Shoplifting/va			. a.i.a oiiaigi				
L4*	1	tion violation(s)						
L5*	Drug charge	, ,						
L6*	Forgery	(J)						
		anco						
L7*	Weapons offe							
L8*		eny, breaking and e	ntering					
L9*	Robbery							

				ng/Baseline
	Site ID:	Subject ID #.	Subject Initials	Week
	Date:			
L10*	( <i>mm/dd/yyyy</i> )  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 be	en charged with the follow	ring:	
L18*	Disorderly conduct, vagrancy, public	intoxication?		
L19*	Driving while intoxicated?			
L20*	Major driving violations (reckless driv	ing, speeding, no license,	etc.)?	
L21*	How many months were you incarcer	rated in your life?	Months	
L24	Are you presently awaiting charges, t	rial or sentence?	☐ Yes ☐ No	
L25	What for?			
	If multiple charges, use the number of the m conduct, 19=driving while intoxicated, 20=m		6), or use the following codes:	18=disorderly
L26	How many days in the past 30 were yo	u detained or incarcerate	d?	
L27	How many days in the past 30 have yo	u engaged in illegal activi	ties for profit?	
	For Questions L28 and L29 please ask	the subject to use the subjec	ct rating scale.	
L28	How serious do you feel your present le □ 0 = Not at all □ 1 = Slightly		- Considerably ☐ 4 = Extren	nelv
L29	How important to you now is counselin	g or referral for these lega	·	,
	Confidence Ratings Is the above information significantly dist	orted by:		
L3	Subject's misrepresentation?	☐ Yes ☐	□ No	
L3	Subject's inability to understand?	☐ Yes ☐	□ No	
	Comments:			

										eeming	/Basenn
	_	Site I	D:		Sı	ıbject ID#.	Г	Subje	ct Initials	<b>—</b>	Week
	<u> </u>			<u></u>			L				
	D.										
	Date:	(mm/da	1/1/1/1/								
F	amily/So	ocial Rela		nins							
	-		_	<del></del>		_		_			
F1	Marital s	tatus		ried arated		<ul><li>☐ Remarried</li><li>☐ Divorced</li></ul>			dowed ver Marri	ed	
F3	Are you	satisfied wit	h this si	tuation?		☐ Yes ☐	No	□ Inc	lifferent		
F4*	Usual liv	ing arrange	ments (	oast three	e years)						
						with parents		alone			
		sexual partı children alo		e		with family with friends	_		led envird ble arrang		i
F6	•	atisfied with		•	angemen	its?	□ No		Indifferen	t	
F7	-	rrent alcoho				☐ Yes	□ No	1			
F8	Uses nor	n-prescribed	d drugs?	,		☐ Yes	□ No	1			
F9	With who	om do you s	pend m	ost of you	ur free tir	me?	☐ Fa	mily $\Box$	Friends		one
F10	Are vou	satisfied wi	th spen	dina vour	free tim	e this way?	ПΥ	s $\square$ N	o 🗌 Indi	fferent	
1 10	7 ll o you	oationoa wi	ит ороги	anig your	1100 1111	o tino way.		о <u> </u>	. <u> </u>	norone	
		ad any signi	ificant p	eriods in	which yo	ou have experie	enced se	erious pr	oblems g	etting	
al	long with:		In the	past 30 d	lave		ı	<u>_ifetime</u>			
					-						
			Yes	No	N/A		Yes	No	N/A		
F18	Mother										
F19	Father										
F20	Siblings										
F21	Sexual p Spo										
F00	Children		_						_		
F22	Criticiteri										
F23	Other signal										
	Plea	se specify if '	"Yes":								
F24	Close fr	riends									
F25	Neighbo	ors									
F26	Co-work	kers	П		П		П	П			

											Scree	ning	/Baseline
		Site I	D:	1	S	ubject ID	#.		Subje	ct Init	ials		Week
				J 								J	
	_												
	Date:	(mm/do	7/1000										
		·											
	Did anyone ab	ouse you?	•										
F2	Physically (c In the	caused yo past 30 c		harm) Yes		No		Lifetir	me		Yes		No
F2	Sexually (for	orced sex past 30 c		ces or s		acts) No		Lifetir	me		Yes		No
H	How many day	ys in the p	past 30 ha	ve you	had se	rious con	flicts?						
F30	] With v	our famil	٧٠.										
	- 1							<u> </u>					
F31	With c	other peop	ple exclud	ing fami	ily:								
	For Questions For How troubled (												
F32	Family pro □ 0 =	blems Not at all	☐ 1 = Slig	ghtly	☐ 2 = I	Moderately		3 = Cor	nsiderably		4 = Extr	emely	,
F33	Social prol	blems : Not at all	☐ 1 = Slig	ghtly	☐ 2 = I	Moderately		3 = Cor	nsiderably		4 = Extr	emely	,
H	How important	t to you n	ow is treat	ment or	r couns	eling for t	hese:						
F34	Family pro	oblems Not at all	☐ 1 = Slig	ghtly	□ 2 = I	Moderately		3 = Cor	nsiderably		4 = Extr	emely	,
F35	Social pro	blems Not at all	☐ 1 = Slig	ghtly	□ 2=I	Moderately		3 = Cor	nsiderably		4 = Extr	emely	,
<u>(</u>	Confidence	Rating	<u>1S</u>										
I	s the above ir	nformation	n significaı	ntly dist	orted b	y:							
F3	Subject's	misrepre	esentation	?		☐ Yes			lo				
F3	Subject's	s inability	to underst	and?		☐ Yes			lo				
	Comments:												
<u>.</u>	Psychiatric	Status	<b>:</b>										
	How many tim			reated	for any	psycholo	gical o	r emoti	onal prob	olem(s	s)?		
P1	In a hosp	oital or inp	atient sett	ing									
P2	As an ou	tpatient o	r private p	atient									
Р	Do you r	eceive a	pension fo	r a psyd	chiatric	disability	?		☐ Ye	es		] No	)

	Screen						
	Site ID:		Subject ID	#.	Subject Init	ials	Week
		L					
	Date:						
	(mm/dd/yyyy)	t w.o	a not a direc	rocult of drug	v/alaahal uaa) i	n which you	
	Have you had a significant period (tha have:	ιwa	S HOL A UHEC	result of drug	raiconoi use) i	ii wilicii you	
		<u>In</u>	the past 30 d	<u>ays</u>		<u>Lifetime</u>	
P4	Experienced serious depression (sadness,						
1 4	hopelessness, loss of						
	interest, difficulty with daily functioning)?	П	Yes	□ No	П	Yes	□ No
	Experienced serious		100		<u> —</u>	100	
P5	anxiety/tension (uptight,						
	unreasonably worried, inability to feel relaxed)?		Yes	□ No		Yes	☐ No
	Experienced hallucinations						
P6	(saw things or heard voices						
	that were not there)?		Yes	☐ No		Yes	☐ No
P7	Experienced trouble						
F /	understanding, concentrating, or remembering?		Yes	□ No		Yes	□ No
,	•		. (l !tl	- f - l l l / - l			
	For Questions P8-10, Subject can have been u Experienced trouble	inaei	tne influence (	ot aiconoi/drugs.	•		
P8	controlling violent behavior?		Yes	□ No		Yes	☐ No
P9	Experienced serious thoughts	_					
	of suicide?		Yes	∐ No		Yes	∐ No
P10	Attempted suicide?	Ш	Yes	□ No		Yes	∐ No
P11	Been prescribed medication						
	I for any psychological or emotional problem?		Yes	☐ No		Yes	☐ No
P12	How many days in the past 30 have you	ı exp	erienced thes	e psychological	or emotional pr	oblems?	
	For Questions P13 and P14 please a	sk th	e subject to us	e the subject rat	ing scale.		
	How much have you been troubled or bot	here	d by these psy	chological or er	motional probler	ns	J
P13	in the past 30 days?  □ 0 = Not at all □ 1 = Slightly		2 = Moderate	lv [	3 = Consider	ably □ 4 =	Extremely
	How important to you now is treatment fo			•	_ 0 = 00nsiden	аыу 🗀 +-	Lationicity
P14	☐ 0 = Not at all ☐ 1 = Slightly				3 = Consider	ably □ 4 =	Extremely
(	Confidence Ratings						
	s the above information significantly distorte	ed by	<i>r</i> :				
P22	Subject's misrepresentation?		Yes	□ No			
P23	Subject's inability to understand?		Yes	□ No			
F23	Comments:						
(	Completed by (Initials):						

			Screenir	ng/Baseline
	Site ID:	Subject ID #.	Subject Initials	Week
		j		
Date:				
	(mm/dd/yyyy)			
	(IIIII/dd/yyyy)			
	Ask subject to read each of the its	ems and choose only one answer for	r each question	
	Ask subject to read each of the ke	sing and one occorring one anower for	caon question	
Drug	l loo			
<u>Drug</u>	<u>ose</u>			
1 Low,	many timog have you hit up (i.e. ii	nigeted any drugs) in the last month	h2	
i. How i	I haven't hit up	njected any drugs) in the last montl	11 f	
		drugs in the last month, go to Quest	tion 7	
	Once a week or less	urugo iir aic iust monai, go to quest	1011 7 .	
	☐ More than once a week but	less than once a day		
	☐ Once a day	•		
	☐ 23 times a day			
	☐ More than three times a day			
		e you used a needle after someone	else had already	
used i				
	☐ No times			
	☐ One time			
	☐ Two times			
	☐ 3-5 times ☐ 6-10 times			
	☐ More than 10 times			
3 Howr		a needle before you in the past mo	unth?	
5. 1 10W 1	None	a needle belore you in the past mo	mu:	
	☐ One person			
	☐ Two people			
	☐ 3-5 people			
	6-10 people			
	☐ More than 10 people			
4. How r		someone used a needle after you?	?	
	☐ No times			
	One time			
	☐ Two times			
	☐ 3-5 times			
	☐ 6-10 times ☐ More than 10 times			
5 How		cleaned needles before re-using the	hem?	
J. 1 10W (	I do not re-use	cleaned needles before re-using ti	.ieiii:	
	Every time			
	☐ Often			
	Sometimes			
	☐ Rarely			
	☐ Never			
6. Befor	e using needles again, how often	in the past month did you use blea	ach to clean them?	
	☐ I do not re-use			
	Every time			
	Often			
	Sometimes			
	Rarely			
	☐ Never			

					ning/Baseline
	Site ID:	Subjec	t ID #.	Subject Initials	Week
Date:	(mm/dd/yyyy)				
<u>Sexual l</u>	<u>Behavior</u>				
	ny people, including clients None If you have not had s One	, have you had sex w			
	Two 3-5 people 6-10 people More than 10 people				
month?	n have you used condoms  No regular partner/no pe Every time Often Sometimes Rarely Never		th your regular part	ner(s) in the last	
	en have you used condoms No casual partner/no per Every time Often Sometimes Rarely Never		vith casual partners	?	
	ten have you used condom No paid partner/no pene Every time Often Sometimes Rarely Never		en paid for sex in th	e last month?	
	any times have you had an No times One time Two times 3-5 times 6-10 times More than 10 times	al sex in the last mor	nth?		
12. Have ye	veryone should answer Que ou had an HIV test come b Yes No Don't know	stion 12. ack positive?			

			Screen	ing/Baseline
	Site ID:	Subject ID #.	Subject Initials	Week
Date:				
2				
	(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 <u>RIGHT NOW</u> as you are filling out the questionnaire.

	Strongl <u>Disagre</u>	-					trongly <u>Agree</u>
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 t	:0						
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	e 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 cocain	ne. 1	2	3	4	5	6	7
18. Even if it were possible, I probably would not use cocaine	<b>:</b>						
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

										ening	/Baseline
	Site ID:	l i	Subject ID #.	1		Sul	oject	Initia	ıls	<b>-</b>	Week
Date:	(mm/dd/yyyy)			4						<b>-</b>	
	(IIIIII/GG/yyyy)		Sti	rongly	,				Str	ngly	
			<u>Di</u> :	sagre	<u>e</u>				<u>Ag</u>	<u>ree</u>	
21 I have	an urge for cocaine.			1	2	3	4	5	6	7	
	d not be able to control	now muc	ch cocaine I used if	•	_		·			•	
	some here.			1	2	3	4	5	6	7	
	g now, I could go withou	ut usina	cocaine for long time	. 1	2	3	4	5	6	7	
	d be less irritable now if	J	· ·	1	2	3	4	5	6	7	
	d feel energetic if I used			1	2	3	4	5	6	7	
	ant to use right now is c			1	2	3	4	5	6	7	
27. Using	cocaine would not shar	pen my o	concentration.	1	2	3	4	5	6	7	
28. I do no	ot need to use cocaine r	iow.		1	2	3	4	5	6	7	
29. It would	ld be difficult to turn dow	n cocair	ne this minute.	1	2	3	4	5	6	7	
30. If I use	e cocaine right now, I we	ould not	feel less restless.	1	2	3	4	5	6	7	
31. I will u	se cocaine as soon as I	get a ch	nance.	1	2	3	4	5	6	7	
32. Using	cocaine now would mal	ke things	seem just perfect.	1	2	3	4	5	6	7	
33. I want	to use cocaine so bad	that I car	n almost taste it.	1	2	3	4	5	6	7	
34. Nothin	g would be better than	using "co	oke" right now.	1	2	3	4	5	6	7	
35 If Luse	ed cocaine, my anger w	ould not	decrease	1	2	3	4	5	6	7	
	ld be easy to pass up th			1	2	3	4	5	6	7	
	oing to use cocaine as			1	2	3	4	5	6	7	
· ·	no desire for cocaine ri		•	1	2	3	4	5	6	7	
	I not stop myself from u	_									
here no		Ü		1	2	3	4	5	6	7	
40. Using	"coke" right now would	make me	e feel less tired.	1	2	3	4	5	6	7	
41. Using	cocaine would not be ve	ery satist	fying right now.	1	2	3	4	5	6	7	
42. If I trie	d a little "coke" now, I w	ould not	be able to stop using	l							
more o	of it.			1	2	3	4	5	6	7	
43. I would	d not feel less anxious if	I used "	coke".	1	2	3	4	5	6	7	
44. I am n	ot missing using cocain	e now.		1	2	3	4	5	6	7	
45. If I had	d some "coke" with me r	ight now	, I probably would no	t							
use it.				1	2	3	4	5	6	7	

### Form 35 – TREATMENT COMPLIANCE – HIV Counseling

				Screen	ning/Baseline			
	Site ID:	Subject 1	ID#.	Subject Initials	Week			
Date:	(mm/dd/yyyy)							
Did Subject receive HIV Counseling during Screening?								
(If No, ple	ase comment below)	☐ Yes	□ No					
Additional	comments:							
Complete	d by (Initials):							
Completed	a by (Illitiais).							

Site ID: Sub		ng/Baseline Week -3 V1 et Initials Week
Date:		
First Study Visit of Week		
Date Vital signs not assessed at this visit	Time Vital Signs taken	(24 hour clock)
Temperature (oral) Comments for Temperature	NR: 94-100.4	CS NCS
Blood Pressure (sitting) (mm Hg) Comments for Blood Pressure:	NR: 90-140/50-90	CS□ NCS□
Pulse Rate (sitting) (beats/min)  Comments for Pulse Rate:	NR: 50-120	CS NCS
Respiratory Rate (sitting) (breaths/min) Comments for Respiratory Rate:	NR: 8-20	CS NCS
Completed by (Initials):		

	Site ID:	Subject ID #.		Screening/Baseline Subject Initials		
	Site ID.	Subject ID #.	Subjec	t illitiais	Week	
Date:						
	(mm/dd/yyyy)					
<u>Second</u>	Study Visit of Week					
☐ Vital s	igns not assessed at this visit					
Date	(mm/dd/yyyy)	Time	Vital Signs taken	(24 hour clock)		
Temperatu	ure (oral)	NR:	94-100.4	CS □ NCS		
Comments	s for Temperature					
		7				
Blood Pres	ssure (sitting)	(mm Hg) NR:	90-140/50-90	CS □ NCS		
Comments	s for Blood Pressure:					
Dulce Pet	(heats/m	io) ND:	 50-120	CS□ NCS		
Pulse Rate Comments	e (sitting) (beats/m s for Pulse Rate:	iiii) NK.	50-120	CS LI NCS		
			0.00	00 🗆 100		
		aths/min) NR:	8-20	CS □ NCS		
	d by (Initials):					

	Site ID:	Subjo	ect ID#.	Screening/Baseline Wee			ek -3 V3 Week
	Site ID.	Subje	жит <i>р</i> #.	Subjec	t Illitiais		WCCK
Date:							
	(mm/dd/yyyy)						
Third St	tudy Visit of Wee	<u>ek</u>					
☐ Vital s	signs not assessed a	t this visit					
Date	(mm/dd/yyyy)		Time Vital S	igns taken	(24 hour	clock)	
Temperati	ure (oral)		NR: 94-100.	4	cs □	NCS □	
Comment	s for Temperature						7
	ssure (sitting) s for Blood Pressure	(mm Hg)	NR: 90-140/	50-90	cs 🗆	NCS 🗆	
Pulse Rat	e (sitting)	(beats/min)	NR: 50-120		cs 🗆	NCS □	_
Comment	s for Pulse Rate:						
Respirato	ry Rate (sitting)	(breaths/min)	NR: 8-20		cs □	NCS □	
Comment	s for Respiratory Rat	e:					
Complete	d by (Initials):						

# Form 22 – URINE BE and TOX. SPECIMEN COLLECTION

			Screening/Bas	seline Week -3 V1
	Site ID:	Subject ID	)#. Subject Initia	ls Week
Date:	(mm/dd/yyyy)			
First St	tudy Visit of Wee	<b>ek</b> Urine b	ar code sticker:	
Date urin	e collected	(mm/dd/yyyy)	Urine not collected	
F	On-Trak Cup: The tempe	rature must be <u>higher</u> than 96.	0° Fand <u>lower</u> than 99.0° F Split	□ No
☐ Amph ☐ Benzo ☐ Barbit ☐ Opiate	ne Positive etamine Positive odiazepine Positive urates Positive es Positive	Cocaine Negative Amphetamine Negat Benzodiazepine Neg Barbiturates Negative Opiates Negative	gative   Not Completed	

# Form 22 – URINE BE and TOX. SPECIMEN COLLECTION

			Screening/Baseli	ne Week –3 V2
	Site ID:	Subject ID #.	Subject Initials	Week
Date:	(mm/dd/yyyy)			
<u>Second</u>	Study Visit of W	<b>'eek</b> Urine bar co	ode sticker:	
Date urine	e collected (n	nm/dd/yyyy)	Urine not collected	
Fr Tr	rak Cup: The temperature	expected range? hture must be <u>higher</u> than 96.0° Fa e must be <u>higher</u> than 90.0° Fand <u>i</u> ture must be <u>higher</u> than 90.0° Fa	and <u>lower</u> than 104.8° F On- lower than 99.0° F Split	No
☐ Amphe	ne Positive etamine Positive diazepine Positive urates Positive s Positive	☐ Cocaine Negative ☐ Amphetamine Negative ☐ Benzodiazepine Negative ☐ Barbiturates Negative ☐ Opiates Negative	□ Not Completed e □ Not Completed □ Not Completed □ Not Completed	
Completed	d by (Initials):			

# Form 22 – URINE BE and TOX. SPECIMEN COLLECTION

				Scre	eening/Baseline	Week –3 V3
	Site I	D:	Subject ID #.		Subject Initials	Week
Date:	(mm/do	d/yyyy)				
Third S	tudy Visit o	of Week	Urine bar c	ode sticker:		
Date urine	e collected	(mm/dd/yy	(y)	Urine not	collected	
Fr Tr	ranklin Cup: The rak Cup: The ten	nperature must b	d range? st be <u>higher</u> than 96.0° F e <u>higher</u> than 90.0° F and t be <u>higher</u> than 90.0° F a	and <u>lower</u> than 1 <u>lower</u> than 99.0°	° F Split	
☐ Amphe	ne Positive etamine Positive diazepine Positive urates Positive s Positive	ve	ocaine Negative hphetamine Negative enzodiazepine Negative hrbiturates Negative biates Negative	e 🔲 Not C Not C	ompleted ompleted ompleted ompleted	
Complete	d by (Initials):					

### Form 24 – SUBSTANCE USE INVENTORY

Site	ID:	Subject II	D#.	Screening/B Subject Initials	Week Week	-3		
Date: (mm/d	d/yyyy)					1		
Using timeline follow-back of administration for each Date of last v	drug. Begin with y	hether subject has vesterday and work	on each day since t back to the last vis	the last visit used a it. Please be sure tl	ny amount of the su hat days are contin	ubstances listed be uous with last weel	low, along with the k's form.	e most common route
Date of last v		ld/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 adminis	tration (ROA) code	s: 1 = oral, 2 = nasa	l, 3 = smoking, 4 = l	non-intravenous in	jection, 5 = intraver	nous injection		
Completed by (Initials):								

					Screening/Basel	
	Site	ID:	Subject ID	#.	Subject Initials	Week
						,
Date:						
	(mm/c	dd/yyyy)				
Coca	<u>ine</u>					
1. The	intensity of my	craving, that is, he	ow much I desire	ed cocaine in the p	oast 24 hours was:	
	☐ None at all	☐ Slight	☐ Moderate	☐ Considerat	ole □ Extrem	e
2. The	<u>frequency</u> of m	y craving, that is,	how often I desir	ed cocaine in the	past 24 hours was	s:
	☐ Never	☐ Almost never	☐ Several t	imes 🔲 Reg	ularly	ost constantly
3. The	<u>length</u> of time I	spent craving for	cocaine during the	he past 24 hours v	was:	
	☐ None at all	☐ Very shor	t Short	☐ Somewhat	long	long
4. Writ	e in the <u>number</u>	of times you think	k you had cravinç	g for cocaine durir	ng the past 24 hou	rs:
5. Writ	e in the total <u>tim</u>	ne spent craving c	ocaine during the	e past 24 hours:		
6. The			my most intense	e craving occurred	d on the following o	day:
	Sunday Thursday	☐ Monday ☐ Friday	☐ Tuesday ☐ Saturday	☐ Wednesday ☐ All days the same	e (go to Q. 8)	
7 The	data for that da					
7. The	date for that da	y was. L	(mm/dd/yyyy)			
8. The	intensity of my	craving, that is, h	ow much I desire	d cocaine on that	worst day was:	
	☐ None at all	☐ Slight	☐ Moderate	☐ Considerat	ole 🗆 Extrem	ıe
<u>Seco</u>	nd Drug					
9. A <b>2</b> '	nd craved drug d Mark <u>only one</u> o	luring the past 24 of the following. If no	hours was: o 2 <sup>nd</sup> craved drug, m	ark "None" and leave	e Questions 10-16 bla	nnk.
	☐ None		ners or Sedatives iturates, etc.)	Benzos	☐ Nicotine	
	Alcohol	☐ Hero	oiturates, etc.) oin or other Opiates ohine, etc.)	(Valium, Xanax, et	Other Specify	
	e <u>intensity</u> of my urs was:	y craving, that is,	how much I desir	red this <b>second</b> di	rug in the past 24	_
	☐ None at all	☐ Slight	☐ Moderate	☐ Considerat	ole 🗆 Extrem	ıe

	Site	ID:	Subject ID	#.	Subject	Screening/B Initials	Week
Date:	(mm/c	dd/yyyy)					
	•	ny craving, that is, h	now often I desi	red this <b>seco</b>	<b>nd</b> drug in t	the past 24	
I	☐ Never	☐ Almost never	☐ Several tir	mes $\square$	Regularly	☐ Almost o	constantly
12. The <u> </u>	length of time	I spent in craving for	or this <b>second</b> o	lrug during th	e past 24 h	ours was:	
I	☐ None at all	☐ Very short	☐ Short	☐ Some	what long	☐ Very Ion	g
<i>Third I</i>	d craved drug	during the past 24 h	nours was: <sup>rd</sup> craved drug, mal	rk "None" and l	eave questio	ns 14-16 blank.	
1	☐ None	(Barbitu ☐ Heroin	ors or Sedatives irates, etc.) or other Opiates ne, etc.)	☐ Benzos (Valium, Xana ☐ Marijuana	ax, etc.)	☐ Nicotine ☐ Other Specify	
	intensity of my s was:	craving, that is, ho	ow much I desire	ed this <b>third</b> o	Irug in the p	oast 24	
I	☐ None at all	☐ Slight	☐ Moderate	☐ Consid	erable	☐ Extreme	
	<u>frequency</u> of n s was:	ny craving, that is, I	now often I desi	red this <b>third</b>	drug in the	past 24	
l	☐ Never	☐ Almost never	☐ Several tir	mes $\square$	Regularly	☐ Almost o	constantly
16. The <u>l</u>	length of time	I spent in craving for	or this third drug	during the pa	ast 24 hour	s was:	
[	☐ None at all	☐ Very short	☐ Short	☐ Some\	what long	☐ Very Ion	g
Complet	ed by (Initials)						

# NIDA-MDS-Modaf-0001 Form 30 - COCAINE SELECTIVE SEVERITY ASSESSMENT Screening/Baseline Week -3 Subject ID #. **Subject Initials** Site ID: Week

Da	ate:	
	(mm/dd/yyyy)	
ite	questions except 4 and 5 are assesse ms in lay language and the response is estion 4 and 5, the subject is asked to b	od by properly trained personnel. The subject is asked about each of the seconded on a scale of 0-7 with 0 being normal or no symptoms. For mark the appropriate place on the line (on page 3) that describes each of transcribes that as the response to those questions.
Da	ate of last cocaine use:	
		(mm/dd/yyyy)
1.	Hyperphagia	
	0 = normal appetite 3-4 = eats a lot more than usua 7 = eats more than twice usua	
2.	Hypophagia	
	0 = normal appetite 3-4 = eats less than half of nor 7 = no appetite at all	rmal amount of food
3.	Carbohydrate Craving	
		s, cakes, and cookies half the time 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 Pulse (BPM) >64	
7.	Insomnia	
	0 = normal amount of sleep 3-4 = half of normal amount of 7 = no sleep at all	f sleep
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

### Form 30 - COCAINE SELECTIVE SEVERITY ASSESSMENT

Screening/Baseline Week -3

	Site ID:	Subject ID #.	Subject Initials	Week
			J	
Dat	e:			
	(mm/dd/nnn/)			
o	(mm/dd/yyyy) Anxiety			
<b>3.</b> 1	•			
	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 3-4 = feels tired half the time 7 = feels tired all the time	energy		
11.	Activity Level			
	<ul><li>0 = no change in usual activities</li><li>3-4 = participates in half of usual activities</li><li>7 = no participation in usual activities</li></ul>	ies		
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, con 3-4 = has difficulty with the above half t 7 = has difficulty with the above all the	the time	make plans without difficulty	
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 plot	tting against him/her		
15.	Anhedonia			
	0 = ability to enjoy themselves remains 3-4 = able to enjoy themselves half of the 7 = unable to enjoy themselves at all			
16.	Depression			
	0 = no feelings related to sadness or de 3-4 = feels sad or depressed half the tir 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 irritati 3-4 = feels that many things are irritatin 7 = feels that mostly everything is irritati	ng		
Cor	npleted by (Initials):			

NIDA-M	DS-Modaf-0001	Form 30 - COCA	AINE SEL	ECTIVE SEVERITY AS	SSESSMENT
	Site ID:	Subject ID #.	<b>-</b>	Screening/Baselin Subject Initials	week -3
Date:	(mm/dd/yyyy)				
	ISUAL ANALOG SCA	<u>LE</u>			
Please rate	e the highest intensity of the               No Desire  at all	e desire for cocaine you	u have felt <u>l</u> <i>Unable t</i> o		
Please ide hours:	entify on the line below, how	often you have felt the	urge to u	se cocaine in the last 24	1

# Form 28 - CLINICAL GLOBAL IMPRESSION - SELF NIDA-MDS-Modaf-0001 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?

# ☐ Moderate problem ☐ Marked problems ☐ Severe symptoms ☐ Most extreme problems possible

### **Global Improvement of Cocaine Dependence**

,	ou rate yourself for changes in cocaine use and cocaine ems since the beginning of this study?
	Not assessed Very much improved Much improved

Minimally improved No change Minimally worse Much worse Very much worse

No problems Borderline problems

Moderate problems

☐ Mild problems

Completed by (Initials):	

(mm/dd/yyyy)

### $Form\ 29-CLINICAL\ GLOBAL\ IMPRESSION\ \textbf{-}\ OBSERVER$

			Screening/Bas	eline Week -3
Site ID:	Subject ID #.		Subject Initials	Week
		1 [		
		_		_

## **Current Severity**

Date:

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

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

NIDA-MI	OS-Modaf-0001	Form 29 - CLINICAI	L GLOBAL IMPRESSION - OBSE	
	Site ID:	Subject ID #.	Screening/Baseline We	eek -3
Date:	(mm/dd/yyyy)			
Global S	everity of Cocaine De	<u>ependence</u>		
Considering this subject	g your total clinical experier 's cocaine dependence syr	nce with the cocaine depending mptoms at this time?	ent population, how severe are	
	Normal, no symptoms Borderline symptoms Mild symptoms Moderate symptoms Marked symptoms Severe symptoms Most extreme symptoms	possible		
Global In	nprovement of Cocai	ne Dependence		
your judgmo project, how	ent, it is due entirely to dru		e symptoms whether or not, in ne subject's admission to the	
	Not assessed, first rating Very much improved Much improved Minimally improved No change Minimally worse Much worse Very much worse			

	Site ID:	Subject ID #.		g/Baseline v Initials	week –2 VI Week
Date:					
First St	udy Visit of Week				
☐ Vital s	signs not assessed at this visit				
Date	(mm/dd/yyyy)	Time Vital S	Signs taken	(24 hour clock)	
Temperat	, , ,	NR: 94-100	.4	CS□ NCS	
Comment	s for Temperature				
		ND 00440	/50.00		
	ssure (sitting) (ı s for Blood Pressure:	mm Hg) NR: 90-140	/50-90	CS NCS	
Pulse Rat	e (sitting) (beats/min)	NR: 50-120		CS □ NCS	
Comment	s for Pulse Rate:				
	ry Rate (sitting) (breath: s for Respiratory Rate:	s/min) NR: 8-20		CS NCS	
	To recognition, reaction				
Complete	d by (Initials):				

	Site ID:	Subject		ng/Baseline wee ct Initials	<b>k –2 V2</b> Week
Date:		]			
<u>Second</u>	Study Visit of Wee	<u>k</u>			
☐ Vital si	igns not assessed at this (mm/dd/yyyy)	s visit	Time Vital Signs taken	(24 hour clock)	
Temperatu	ure (oral)	(°F)	NR: 94-100.4	CS□ NCS□	
	ssure (sitting)	(mm Hg)	NR: 90-140/50-90	CS   NCS	
Pulse Rate	e (sitting) (be	eats/min)	NR: 50-120	CS □ NCS □	
	s for Pulse Rate:		ND 0.00	00 [] 1120 []	
	y Rate (sitting) s for Respiratory Rate:	(breaths/min)	NR: 8-20	CS □ NCS □	
	d by (Initials):				

	Site ID:	Subject ID #.	Screening/Base Subject Initials	line week –2 V3 Week
	Site ID.	Subject ID #.	Subject illitials	Week
Date:				
Third S	tudy Visit of Week			
_	igns not assessed at this visit			
Date	(mm/dd/yyyy)	Time Vital S	igns taken (24 hour	· clock)
Temperati	ure (oral) (°F)	NR: 94-100.	4 CS □	NCS □
	ssure (sitting) (mm	Hg) NR: 90-140/	50-90 CS □	NCS
Pulse Rat	e (sitting) (beats/min)	NR: 50-120	cs □	NCS □
	s for Pulse Rate:			
	ry Rate (sitting) (breaths/mi	n) NR: 8-20	CS □	NCS □
	d by (Initials):			

# NIDA-MDS-Modaf-0001 Form 22 – URINE BE and TOX. SPECIMEN COLLECTION FORM Screening/Baseline Week -2 V1 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?  Franklin Cup: The temperature must be <u>higher</u> than 96.0° F and <u>lower</u> Trak Cup: The temperature must be <u>higher</u> than 90.0° F and <u>lower</u> Sample Cup: The temperature must be <u>higher</u> than 90.0° F and <u>lower</u>	than 99.0° F Split
Results:  Cocaine Positive Amphetamine Positive Benzodiazepine Positive Barbiturates Positive Opiates Positive Opiates Positive Completed by (Initials):	<ul> <li>□ Not Completed</li> <li>□ Not Completed</li> <li>□ Not Completed</li> <li>□ Not Completed</li> </ul>

### NIDA-MDS-Modaf-0001 Form 22 - URINE BE and TOX. SPECIMEN COLLECTION **FORM** Screening/Baseline Week -2 V2 Subject Initials Site ID: Subject ID #. Week Date: (mm/dd/yyyy) Second Study Visit of Week Urine bar code sticker: Date urine collected: Urine not collected (mm/dd/yyyy) ☐ Yes ☐ No Was urine temperature within expected range? 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

☐ Cocaine Negative

☐ Opiates Negative

☐ Amphetamine Negative

☐ Barbiturates Negative

☐ Benzodiazepine Negative

☐ Not Completed☐ Not Completed

☐ Not Completed

☐ Not Completed

Results:

☐ Cocaine Positive

☐ Opiates Positive

☐ Amphetamine Positive

☐ Barbiturates Positive

Completed by (Initials):

☐ Benzodiazepine Positive

### NIDA-MDS-Modaf-0001 Form 22 - URINE BE and TOX. SPECIMEN COLLECTION **FORM** Screening/Baseline Week -2 V3 Subject Initials Site ID: Subject ID #. Week Date: (mm/dd/yyyy) Third Study Visit of Week Urine bar code sticker: Date urine collected Urine not collected (mm/dd/yyyy) ☐ No Was urine temperature within expected range? ☐ Yes 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 Negative

☐ Barbiturates Negative

☐ Opiates Negative

☐ Benzodiazepine Positive

☐ Barbiturates Positive

Completed by (Initials):

☐ Opiates Positive

☐ Not Completed

☐ Not Completed

■ Not Completed

### Form 24 – SUBSTANCE USE INVENTORY

Site	ID:	Subject II	) #	Screening/B Subject Initials	aseline Week Week	-2		
						J		
Date:								
(mm/c Using timeline follow-bac of administration for each	dd/yyyy) k method, record wl drug. Begin with y	hether subject has resterday and work	on each day since t back to the last vis	the last visit used a it. Please be sure ti	ny amount of the si hat days are contin	ubstances listed be uous with last weel	low, along with the k's form.	most common route
Date of last v		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 adminis	stration (ROA) code:	s: 1 = oral, 2 = nasa	l, 3 = smoking, 4 = 1	non-intravenous in	jection, 5 = intraver	nous injection		
Completed by (Initials)	:							

	Site ID:		Subject ID	<b>\</b> #		<b>ening/Baseline</b> et Initials	Week -
	Site iD.		Subject in	ν π.	Subjec	t mitais	WCCK
Date:	(mm/dd/y	<i>yyy)</i>					
<u>Cocain</u>	<u>e</u>						
1. The <u>in</u> t	tensity of my crav	ving, that is, ho	ow much I desire	ed cocaine in	the past 24	hours was:	
	☐ None at all	☐ Slight	☐ Moderate	☐ Consi	derable	☐ Extreme	
2. The fre	equency of my cr	aving, that is,	how often I desi	red cocaine ir	the past 2	4 hours was:	
	☐ Never ☐	Almost never	☐ Several t	imes $\square$	Regularly	☐ Almost c	onstantly
3. The <u>le</u>	ngth of time I spe	ent craving for	cocaine during t	he past 24 ho	ours was:		
	☐ None at all	☐ Very short	t 🗌 Short	☐ Some	ewhat long	☐ Very long	3
	n the <u>number</u> of t	·		_	-	past 24 hours:	
6. The <u>w</u>	hours  brst day: During  Sunday	minutes the past week Monday	my most intens	e craving occ		e following day:	
	Thursday	Friday	Saturday		e same (go to	Q. 8)	
7. The da	ate for that day w		m/dd/yyyy)				
8. The <u>int</u>	tensity of my crav	ving, that is, ho	ow much I desire	ed cocaine on	that worst	day was:	
	☐ None at all	☐ Slight	☐ Moderate	☐ Consi	derable	☐ Extreme	
Secono	d Drug						
	craved drug durin Mark <u>only one</u> of the			nark "None" and	l leave Quest	ions 10-16 blank.	
	None		ners or Sedatives	Benzos		☐ Nicotine	
	Alcohol	Hero	iturates, etc.) in or other Opiates phine, etc.)	(Valium, Xar ☐ Marijuana	nax, etc.)	Other Specify	
	ntensity of my crass was:		. ,	red this <b>seco</b>	<b>nd</b> drug in f		<u> </u>
	☐ None at all	☐ Slight	☐ Moderate	☐ Consi	derable	☐ Extreme	

	Site	ID:	Subject ID	<b>)</b> #		ning/Basel Initials	ine Week -2 Week
Date:	(mm/c	ld/yyyy)			,		
	e <u>frequency</u> of n urs was:	ny craving, that is,	how often I des	sired this <b>sec</b> o	ond drug in	the past 24	
	☐ Never	☐ Almost never	☐ Several t	times $\square$	Regularly	☐ Almo	st constantly
12. The	e <u>length</u> of time	I spent in craving for	or this <b>second</b>	drug during tl	ne past 24 h	nours was:	
	☐ None at all	☐ Very short	☐ Short	☐ Some	what long	☐ Very	ong
<u>Thiro</u>	l Drug						
13. A 3	3 <sup>rd</sup> craved drug o Mark <u>only one</u> o	during the past 24 h	nours was: r <sup>d</sup> craved drug, m	ark "None" and	leave questic	ons 14-16 blan	k.
	☐ None		ers or Sedatives urates, etc.)	☐ Benzos (Valium, Xar	nax etc)	☐ Nicotine	
	Alcohol	Heroin	or other Opiates ne, etc.)	☐ Marijuana	iax, cic.j	Other Specify	
	e <u>intensity</u> of my urs was:	craving, that is, ho	ow much I desi	red this <b>third</b>	drug in the	past 24	
	☐ None at all	☐ Slight	☐ Moderate	☐ Consi	derable	☐ Extreme	<b>:</b>
	e <u>frequency</u> of n urs was:	ny craving, that is,	how often I des	sired this <b>thirc</b>	<b>I</b> drug in the	past 24	
	☐ Never	☐ Almost never	☐ Several t	times $\square$	Regularly	☐ Almo	st constantly
16. The	e <u>length</u> of time	I spent in craving for	or this third dru	g during the p	oast 24 hou	rs was:	
	☐ None at all	☐ Very short	☐ Short	☐ Some	what long	□ Very	ong
Compl	eted by (Initials)	:					

Form 30 - COCAINE SELECTIVE SEVERITY ASSESSMENT NIDA-MDS-Modaf-0001 Screening/Baseline Week -2 **Subject Initials** Site ID: Subject ID #. 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 craving3-4 = 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. 3 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

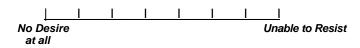
### Form 30 - COCAINE SELECTIVE SEVERITY ASSESSMENT

Screening/Baseline Week -2

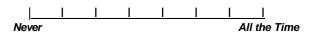
		Site ID:		Subject ID #.	_	Subject Initials	Week
Dat	te:						
		(mm/dd/yyyy)					
<b>9.</b> .	Anxiet						
	3-	= usually does not fee 4 = feels anxious half = feels anxious all the	the time				
10.	Energ	gy Level					
	3-	= feels alert and has u 4 = feels tired half the = feels tired all the tim	time	of energy			
11.	Activ	ity Level					
	3-	= no change in usual a 4 = participates in hall = no participation in us	fof usual acti				
12.	Tens	ion					
	3-	1 = rarely feel tense 4 = feels tense half th = feels tense most or a					
13.	Atte	ntion					
	3-	= able to concentrate of 4 = has difficulty with the has difficulty with the	the above ha		d make pl	ans without difficulty	
14.	Parai	noid Ideation					
	3- 5-	<ul><li>no evidence of paral</li><li>4 = unable to trust any</li><li>feels people are out</li><li>feels a specific pers</li></ul>	one to get him/h				
15.	Anhe	edonia					
	3-	= ability to enjoy them: 4 = able to enjoy them = unable to enjoy ther	nselves half c	of the time			
16.	Depr	ession					
	0 3-	= no feelings related to 4 = feels sad or depre = feels depressed all	ssed half the				
17.	Suici	dality					
	0 : 3-	= does not think about 4 = feels like life is no = feels like actually en	t worth living				
18.	Irrital	bility					
	3-	= feels that most thing 4 = feels that many th = feels that mostly eve	ings are irrita	ating			
Cor	npleted	d by (Initials):					

NIDA-M	IDS-Modaf-0001	Form 30 - COCAINE S	SELECTIVE SEVERITY A	
	Site ID:	Subject ID #.	Screening/Basel Subject Initials	ine Week -2 Week
Date:	(mm/dd/yyyy)			
CSSA V	ISUAL ANALOG SC	<u>ALE</u>		
Please do r	not mark on upright lines.			

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



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



# Form 28 - CLINICAL GLOBAL IMPRESSION - SELF NIDA-MDS-Modaf-0001 **Screening/Baseline Week -2 Subject Initials** Week Site ID: Subject ID #. 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

### Form 29 – CLINICAL GLOBAL IMPRESSION - OBSERVER

Screening/Baselin	ne Week -2
C 1 1 1 1 1 1	337 1

	Site ID:	S	ubject 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 <u>Severe</u>					-	Most Severe
Report	ed Cocaine Use: (frequency and amount of cocaine used)	1	2	3	4	5	6	7
Cocain	e Seeking: (craving for cocaine, effort to stop, and drug seeking behavior)	1	2	3	4	5	6	7
Report	ed Use of Other Drugs: (frequency and amount of non-cocaine drug/alcohol use)	1	2	3	4	5	6	7
Observ	vable Psychiatric Symptoms: (orientation, memory, comprehension, disorganized thinking, rapid/retarded speech, agitation, grooming, hostility, irritability, affective disturbance)	1	2	3	4	5	6	7
Report	ed Psychiatric Symptoms: (mood disturbance, depression, anxiety,inner restlessness, covert anger, somatic symptoms energy level,motivation, sleep, appetite, libido, anhedonia)	s, 1	2	3	4	5	6	7
Physic	al/Medical Problems: (those that have emerged or gotten worse after drug use)	1	2	3	4	5	6	7
Malada	aptive Coping in the Family/Social area: (movement away from healthy relationships)	1	2	3	4	5	6	7
Malada	aptive 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

NIDA-MDS-Modaf-0001		Form 29 - CLINICAL	GLOBAL IMPRESSION - OBSERVE
			Screening/Baseline Week -
Г	Site ID:	Subject ID #.	Subject Initials Week
Date:			
_	(mm/dd/yyyy)		
Global S	everity of Cocaine D	<u>ependence</u>	
	's cocaine dependence sy	nce with the cocaine depender mptoms at this time?	nt population, how severe are
	Normal, no symptoms Borderline symptoms Mild symptoms Moderate symptoms		
	Marked symptoms Severe symptoms	pagaible	
	Most extreme symptoms		
Global In	nprovement of Coca	<u>ine Dependence</u>	
your judgment project, how	ent, it is due entirely to dru	ticipant's cocaine dependence ug treatment. Compared to the	
	Not assessed, first rating Very much improved Much improved Minimally improved No change Minimally worse Much worse Very much worse		

	Site ID:	Subject ID #.		g/Baseli Initials	ne Week -1 V1 Week
	Site 15.	Subject ID II.	Subject	muus	T WEEK
Date:	(mm/dd/yyyy)				
_	udy Visit of Week				
Date	igns not assessed at this visit  (mm/dd/yyyy)	Time Vita	l Signs taken	(24 hour c	lock)
Temperat	ure (oral) (°F) s for Temperature	NR: 94-10	00.4	CS □ 1	vcs □
	ssure (sitting) (s for Blood Pressure:	(mm Hg) NR: 90-14	40/50-90	cs 🗆 ı	NCS
Pulse Rat Comment	e (sitting) (beats/min s for Pulse Rate:	) NR: 50-12	20	cs□ r	NCS
	ry Rate (sitting) (breath s for Respiratory Rate:	ns/min) NR: 8-20		CS□ 1	NCS
Complete	d by (Initials):				

	Site ID:	Subject ID #.	Screening/Base Subject Initials	line Week -1 V2 Week
Date:	(mm/dd/yyyy)			
<u>Second</u>	Study Visit of Week			
☐ Vital s	igns not assessed at this visit (mm/dd/yyyy)	Time Vital	Signs taken (24 hour	r clock)
Temperati	ure (oral) (°F s for Temperature	NR: 94-10	0.4 CS □	NCS □
	ssure (sitting) s for Blood Pressure:	(mm Hg) NR: 90-14	0/50-90 CS □	NCS
Pulse Rat	e (sitting) (beats/mi s for Pulse Rate:	n) NR: 50-12	0 CS 🗆	NCS 🗆
	ry Rate (sitting) (breat s for Respiratory Rate:	ths/min) NR: 8-20	cs□	NCS
Complete	d by (Initials):			

# Form 9 - VITAL SIGNS NIDA-MDS-Modaf-0001 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 Time Vital Signs taken (mm/dd/yyyy) (24 hour clock) (°F) Temperature (oral) CS ☐ NCS ☐ NR: 94-100.4 Comments for Temperature CS ☐ NCS ☐ Blood Pressure (sitting) (mm Hg) NR: 90-140/50-90 Comments for Blood Pressure: CS ☐ NCS ☐ Pulse Rate (sitting) (beats/min) NR: 50-120 Comments for Pulse Rate:

(breaths/min)

NR: 8-20

Respiratory Rate (sitting)

Completed by (Initials):

Comments for Respiratory Rate:

CS ☐ NCS ☐

# Form 22 – URINE BE and TOX. SPECIMEN COLLECTION FORM

Site ID:	Subject ID	9	eline Week -1 V1  Week  Week
(mm/dd/yyy)	<u>'</u>		
First Study Visit of V	<b>Veek</b> Urine bar code st	icker:	
Date urine collected:	(mm/dd/yyyy)	Urine not collected	
Trak Cup: The tempe	thin expected range? mperature must be <u>higher</u> than 96.0 erature must be <u>higher</u> than 90.0 ° F mperature must be <u>higher</u> than 90.0	and <u>lower</u> than 99.0° F Split	] No
Results:  Cocaine Positive Amphetamine Positive Benzodiazepine Positive Barbiturates Positive Opiates Positive Completed by (Initials):	Cocaine Negative Amphetamine Negative Benzodiazepine Neg Barbiturates Negative Opiates Negative	ative   Not Completed	

### NIDA-MDS-Modaf-0001 Form 22 - URINE BE and TOX. SPECIMEN COLLECTION **FORM** Screening/Baseline Week -1 V2 Subject Initials Site ID: Subject ID #. 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 Negative

☐ Opiates Negative

☐ Amphetamine Negative

☐ Barbiturates Negative

☐ Benzodiazepine Negative

□ Not Completed□ Not Completed□ Not Completed

☐ Not Completed

☐ Cocaine Positive

☐ Opiates Positive

☐ Amphetamine Positive

☐ Barbiturates Positive

Completed by (Initials):

☐ Benzodiazepine Positive

#### NIDA-MDS-Modaf-0001 Form 22 - URINE BE and TOX. SPECIMEN COLLECTION **FORM** Screening/Baseline Week -1 V3 Subject Initials Site ID: Subject ID #. Week Date: (mm/dd/yyyy) **Third Study Visit of Week** Urine bar code sticker: Date urine collected Urine not collected (mm/dd/yyyy) ☐ Yes ☐ No Was urine temperature within expected range? 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 ☐ Not Completed☐ Not Completed ☐ Amphetamine Positive ☐ Amphetamine Negative ☐ Benzodiazepine Positive ☐ Benzodiazepine Negative

☐ Barbiturates Negative

☐ Opiates Negative

☐ Barbiturates Positive

Completed by (Initials):

☐ Opiates Positive

☐ Not Completed

☐ Not Completed

#### Form 24 – SUBSTANCE USE INVENTORY

				_	aseline Week	-1		
Site	ID:	Subject ID	)#. 	Subject Initials	Week	1		
Date:	d/yyyy)							
Using timeline follow-back	Jsing 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 v	isit:		(mm/dd/yy)	vy)				
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):	

			a 11		Screening/Baseline			
	Site ID:	<del></del>	Subject ID	) #. 	Subject Init	ials	Week	
Date:								
	(mm/old/u	(a a d)						
	(mm/dd/y	<i>(</i> yy)						
<u>Cocaine</u>	<u>e</u>							
	<u>ensity</u> of my crav ] None at all	ring, that is, ho □ Slight	w much I desire	ed cocaine in the Consider		rs was: Extreme		
		· ·						
	<u>quency</u> of my cra ] Never □	aving, that is, h Almost never	now often I desir Several t		ne past 24 ho egularly	urs was:	constantly	
	<u>igth</u> of time I spe ] None at all	nt craving for o	•	he past 24 hour ☐ Somewh		☐ Very lone	g	
4. Write in	the <u>number</u> of t	imes you think	you had craving	g for cocaine du	ring the past	24 hours:		
5. Write ir	the total <u>time</u> sp	pent craving co	ocaine during the	e past 24 hours:	:			
6. The <u>wo</u>	rst day: During	the past week	my most intense	e craving occurr	ed on the fol	lowing day:		
	Sunday [	] Monday ] Friday	☐ Tuesday ☐ Saturday	☐ Wednesday ☐ All days the sa	ame (go to Q. 8)			
7. The da	te for that day wa		m/dd/yyyy)					
8. The <u>inte</u>	ensity of my crav	ring, that is, ho	w much I desire	ed cocaine on th	at worst day	was:		
	None at all	☐ Slight	☐ Moderate	☐ Consider	rable	Extreme		
Secono	l Drug							
9. A <b>2<sup>nd</sup></b> c	raved drug durin lark <u>only one</u> of the	g the past 24 h	nours was: <b>2<sup>nd</sup> craved drug, m</b>	ark "None" and le	ave Questions	10-16 blank.		
	None		ers or Sedatives	Benzos		Nicotine		
	Alcohol	Heroi	turates, etc.) n or other Opiates hine, etc.)	(Valium, Xanax Marijuana		Other Specify		
10. The <u>in</u> hours	itensity of my cra was:	aving, that is, h	now much I desir	red this <b>second</b>	drug in the p	ast 24		
	None at all	☐ Slight	☐ Moderate	☐ Consider	rable $\Box$	Extreme		

	Q:	ID.	C,-1-:/ TF	<b>\</b> #		ning/Basel	
	Site	ועו:	Subject II	J #.	Subject	t Initials	Week
Date:							
	(mm/c	ld/yyyy)					
	·						
11. The <u>fr</u> hours		ny craving, that is,	how often I des	sired this s	second drug in	the past 24	
	Never	☐ Almost never	☐ Several	times	☐ Regularly	☐ Almo	st constantly
12. The <u>le</u>	ength of time	I spent in craving	for this <b>second</b>	drug duri	ng the past 24 l	nours was:	
	None at all	☐ Very short	☐ Short	□s	omewhat long	☐ Very	long
<u>Third D</u>	<u>Prug</u>						
13. A <b>3<sup>rd</sup> (</b>	crave d drug o lark <u>only one</u> o	during the past 24 fthe following. If no	hours was: 3 <sup>rd</sup> craved drug, m	ark "None"	and leave questic	ons 14-16 blan	k.
	None		ers or Sedatives urates, etc.)	Benzo	s , Xanax, etc.)	☐ Nicotine	
	Alcohol	Heroir	n or other Opiates nine, etc.)	(Vallum ☐ Marijua		Other Specify	
14. The <u>ir</u> hours		$\prime$ craving, that is, h	ow much I desi	red this <b>th</b>	ird drug in the	past 24	
	None at all	☐ Slight	☐ Moderate	□ C	onsiderable	☐ Extreme	)
15. The <u>fr</u> hours		ny craving, that is,	how often I des	sired this <b>t</b>	hird drug in the	past 24	
	Never	☐ Almost never	☐ Several	times	☐ Regularly	☐ Almo	st constantly
16. The <u>le</u>	ength of time	I spent in craving	for this third dru	ıg during t	he past 24 hou	rs was:	
	None at all	☐ Very short	☐ Short	□s	omewhat long	☐ Very	long
Complete	d 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 asthe response to those questions.

N	IDA-MDS-Modaf-0001	For	rm 30 – C	OCAIN	E SELE	CTIVE S	SEVERI	TY ASS	ESSMENT
						Scree	ening/B	aselin	e Week -1
	Site ID:	5	Subject ID	#.		Subjec	t Initials		Week
Da	ate: (mm/dd/yyyy)								
Da	ate of last cocaine use:								
1.	Hyperphagia		(mm/dd/)	vyyy)					
	0 = normal appetite 3-4 = eats a lot more than usua 7 = eats more than twice usual		ood						
2.	Hypophagia								
	0 = normal appetite 3-4 = eats less than half of norm 7 = no appetite at all	mal amount	of food						
3.	Carbohydrate Craving								
	0 = no craving 3-4 = strong craving for sweets 7 = strong craving for sweets, or				me				
4.	Cocaine Craving Intensity	Please	use subje	ct intensi	ty rating f	rom pg. 3	of this fo	rm.	
5.	Cocaine Craving Frequency	Please	use subje	ct frequer	ncy rating	from pg.	3 of this f	orm.	
6.	Bradycardia	Please	use scale	below.					
	0 Pulse (BPM) >64	1 64-63	2 62-61	3 60-59	4 58-57	5 56-55	6 54-53	7 <53	
7.	Insomnia								
	0 = normal amount of sleep 3-4 = half of normal amount of 7 = no sleep at all	sleep							

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

#### Form 30 - COCAINE SELECTIVE SEVERITY ASSESSMENT

Screening/Baseline Week -1

	Site ID:	Subject ID #.	Subject Initials	Week
Dat	e: (mm/dd/yyyy)			
0	Anxiety			
<b>9.</b> 1	0 = usually does not feel anx	ious		
	3-4 = feels anxious half the t 7 = feels anxious all the time	ime		
10.	Energy Level			
	0 = feels alert and has usual 3-4 = feels tired half the time 7 = feels tired all the time			
11.	Activity Level			
	0 = no change in usual activi 3-4 = participates in half of u 7 = no participation in usual a	sual activities		
12.	Tension			
	0-1 = rarely feel tense 3-4 = feels tense half the tim 7 = feels tense most or all the			
13.	Attention			
	0 = able to concentrate on re 3-4 = has difficulty with the a 7 = has difficulty with the abo		ce plans without difficulty	
14.	Paranoid Ideation			
	0 = no evidence of paranoid of 3-4 = unable to trust anyone 5 = feels people are out to go 7 = feels a specific person/gr	-		
15.	Anhedonia			
	0 = ability to enjoy themselve 3-4 = able to enjoy themselve 7 = unable to enjoy themselve	es half of the time		
16.	Depression			
	0 = no feelings related to sac 3-4 = feels sad or depressed 7 = feels depressed all of the	I half the time		
17.	Suicidality			
	0 = does not think about beir 3-4 = feels like life is not wor 7 = feels like actually ending	th living		
18.	Irritability			
	0 = feels that most things are 3-4 = feels that many things 7 = feels that mostly everythi	are irritating		
Cor	npleted by (Initials):			

NIDA-MDS-Modaf-0001		Form 30 - COCAINE SELECTIVE SEVERITY ASSESSMENT				
1 (12 11 1/12 S 1/12 WW )	~~ <u>-</u>			Screening/Base	line Week -1	
Site II	):	Subject ID #.		Subject Initials	Week	
Date: (mm/dd/	(4444)					
CSSA VISUAL ANA						
Please do not mark on uprig	ht lines.					
Please rate the highest i	ntensity of the des	ire for cocaine you	have felt in	the last 24 hours:		
No D at a		<u> </u>	 Unable to Re	sist		
Please identify on the lin	e below, how ofter	n you have felt the	urge to use	cocaine in the last	24	

hours:

# NIDA-MDS-Modaf-0001 Form 28 - CLINICAL GLOBAL IMPRESSION - SELF **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

# **Global Improvement of Cocaine Dependence**

Most extreme problems possible

you rate yourself for changes in cocaine use and cocaine lems 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 (	(Initiala).	
Completed by (	milliais).	
Completed by	(IIIIIIIIIII).	

#### Form 29 - CLINICAL GLOBAL IMPRESSION - OBSERVER

		Screening/Base	line Week -1
Subject ID #.	<u></u>	Subject Initials	Week

Date:	
	(mm/dd/yyyy)

Site ID:

# **Current Severity**

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

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

NIDA-MDS-Modaf-0001		Form 29 - CLINICAL	GLOBAL IMPRESSION - OBSERVER
	Site ID:	Subject ID #.	Screening/Baseline Week -1 Subject Initials Week
Date:	(mm/dd/yyyy)		
Global S	everity of Cocaine	<u>Dependence</u>	
	g your total clinical exper 's cocaine dependence s	ience with the cocaine depende symptoms at this time?	nt population, how severe are
	Normal, no symptoms Borderline symptoms Mild symptoms Moderate symptoms Marked symptoms Severe symptoms Most extreme symptom	ns possible	
Global In	mprovement of Coc	aine Dependence	
your judgm project, how	ent, it is due entirely to d	articipant's cocaine dependence rug treatment. Compared to the	
	Not assessed, first ratir Very much improved Much improved Minimally improved No change Minimally worse Much worse Very much worse	ng	

	Site ID:		Subject ID #.	[	Screening/Baselin Subject Initials	e Week -1 Week
Date:	(mm/dd/yyyy)					
Did subject recei	ve standardized, manu	al-gı	uided individual psy	chother	apy this week?	
(If No, please co	mment below)		Yes	No		
If yes, length of p	osychotherapy session		minu	tes		
	ire emergency crisis ssions this week?		Yes 🗆	No		
If yes, how many	/?					
Additional comm	ents:					_
						_

				R	andomization
	Site ID:	Subject II	D #.	Subject Initials	Week
Date:					
	(mm/dd/yyyy)				
<u>Eligibili</u>	<u>ty for Randomization</u>				
				_	
1. Is the s	ubject eligible for randomiz	ation?	☐ Yes	∐ No	
Obtain this	information from Page 3 of Ent	ry Criteria CRF (Form	19)		
Randon	<u>mization Information</u>				
	ime the informed consent to ays of cocaine use in the pa		as signed, indi	cate the number of se	lf-reported
۵.	ayo or occamo dec in the po	iot oo aayo .			
Obtain this	information from Demographic	s CRF, Drug and Alco	hol Use section (	Form2).	
3. Gender	☐ Male	☐ Female			
A 61					
	itering the above info omization, and Kit Nu		andomizatio	on system, pieas	e record Date
Oi rana	omization, and the Na	mber below.			
Randon	nization				
Nariuur	<u>IIIZAUOII</u>				
3. D	ate of randomization				
О. В	ate of fandomization		(mm/dd/yyyy)		
5. Treatm	ent kit number assigned				
	is assumed that the first dose v Study Day 1.	vill be received on the	same day as ran	domization. Therefore, L	ay of Randomization

	Site II	Site ID: Subject ID #.		Treatment Wee			ek 1 V1 Week	
ſ	510 11		Subjec		Busjee	t mittais	$\neg$ $\lceil$	- Treek
Date:	(mm/dd,	/уууу)						
<u>First Stu</u>	ıdy Visit of	<u>Week</u>						
☐ Vital sig	gns not asses	sed at this	visit T					
Date	(mm/c	ld/yyyy)	]	Time Vital Si	gns taken	(24 hour	clock)	
Temperatu	re (oral)		](°F)	NR: 94-100.4	1	cs□	NCS □	
Comments	for Tempera	ture						
	sure (sitting) for Blood Pre	essure:	(mm Hg)	NR: 90-140/5	50-90	cs 🗆	NCS 🗆	
Pulse Rate	(sitting) for Pulse Rat		ts/min)	NR: 50-120		cs 🗆	NCS □	
	/ Rate (sitting for Respirato		breaths/min)	NR: 8-20		cs 🗆	NCS 🗆	
Completed	by (Initials):							<u> </u>

a. TD		C1.:4	ID# Cubic	Treatment Week		
ſ	Site ID:	Subject	1D#. Subject	t Initials Wee	K	
Date:						
	(mm/dd/yyyy)					
<u>Second</u>	Study Visit of We	<u>eek</u>				
☐ Vital si	gns not assessed at t	his visit				
Date	(mm/dd/yyyy)		Time Vital Signs taken	(24 hour clock)		
Temperatu		(°F)	NR: 94-100.4	CS □ NCS □		
Comments	for Temperature					
Blood Pres	ssure (sitting)	(mm Hg)	NR: 90-140/50-90	CS □ NCS □		
Comments	for Blood Pressure:					
Pulse Rate	e (sitting)	(beats/min)	NR: 50-120	CS   NCS		
	for Pulse Rate:	,				
Pospirator	y Rate (sitting)	(breaths/min)	NR: 8-20	CS NCS		
	for Respiratory Rate:		NIX. 0-20			
Completed	by (Initials):					

						Treatm		<b>k 1 V3</b> Veek
ı	Site ID:		Subjec	Subjec	Subject Initials			
_								
Date:			•					
			ı					
Third St	tudy Visit o	f Wook						
_	-							
	igns not asses	ssed at this	visit					
Date	(mm/c	dd/yyyy)		Time Vital Si	gns taken	(24 hour d	clock)	
Temperatu			(°F)	NR: 94-100.4	1	CS 🗆 I		
	s for Tempera	ture	( · /		•			
	<u>·</u>							
Blood Pres	ssure (sitting)		(mm Hg)	NR: 90-140/5	50-90	cs □ ı	NCS 🗆	
	s for Blood Pre	essure:	, σ,					
Pulse Rate			ats/min)	NR: 50-120		CS □ I	NCS 🗆	
Comments	s for Pulse Ra	te:						_
Respirator	y Rate (sitting	1)	(breaths/min)	NR: 8-20		CS □ I	NCS 🗆	
	s for Respirato		(breatis/iiii)	W. 0 20		ОО 🗀 .	1100	
	- Tor recopilate	ory reaco.						7
Completed	d by (Initials):							

Date:

# Form 23 – URINE BE SPECIMEN COLLECTION FORM

# Site ID: Subject ID #. Subject Initials Week (mm/dd/yyyy)

	(mm/dd	//уууу)						
First Stud	<u>ly Visit of</u>	<sup>r</sup> Week	Urine bar	code sticker:				
Date urine co	ollected:	(mm/dd/yy	vyy)	U	rine not collected			
Was urine temperature within expected range?  Franklin Cup: The temperature must be <u>higher</u> than 96.0° F and <u>lower</u> than 104.8° F  On-Trak Cup: The temperature must be <u>higher</u> than 90.0° F and <u>lower</u> than 99.0° F Split  Sample Cup: The temperature must be <u>higher</u> than 90.0° F and <u>lower</u> than 100.0° F								
Completed b	y (Initials):							

#### Form 23 – URINE BE SPECIMEN COLLECTION FORM

**Treatment Week 1 V2** 

				11 camicii	I VICCE I V
Site	ID:	Subject ID	#.	Subject Initials	Week
Date: (mm/a	dd/yyyy)				
<u>Second Study Vis</u>	sit of Week	Urine bar code	e sticker:		
Date urine collected:	(mm/dd/yyy	<i>ly)</i>	Urine	e not collected	
Trak Cup: The te	ne temperature mus emperature must be	d range? st be <u>higher</u> than 96.0 e <u>higher</u> than 90.0°F t be <u>higher</u> than 90.0	and lower than	99.0° F Split	
Completed by (Initials)	:				

NIDA-M	DS-Modaf-0001	Form 23 – URINE BE SPECIMEN COLLECTION FORM Treatment Week 1 V3						
	Site ID:	Subject ID #.	Subject Initials	Week				
Date:	(mm/dd/yyyy)							
<u>Third St</u>	tudy Visit of Week	Urine bar code sticke	r:					
Date urine	collected: (mm/dd/y	<i>yyyy)</i>	Urine not collected	]				
Fr Tr	temperature within expect anklin Cup: The temperature m ak Cup: The temperature must ample Cup: The temperature m	ust be <u>higher</u> than 96.0°F and <u>l</u> be <u>higher</u> than 90.0°F and <u>lowe</u>	er than 99.0° F Split					
Completed	d by (Initials):							

#### Form 24 – SUBSTANCE USE INVENTORY

			Treatment Week I					
Site I	D:	Subject II	) #.	Subject Initials	Week	■		
Date:								
(mm/dd Using timeline follow-back of administration for each of	method, record wh	ether subject has desterday and work	on each day since t back to the last vis	he last visit used a it. Please be sure tl	ny amount of the su hat days are contine	ıbstances listed be uous with last weel	elow, along with the k	most common route
Date of last vi								
	(mm/do	1/уууу)						
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 administ	tration (ROA) codes	s: 1 = oral, 2 = nasal	l, 3 = smoking, 4 = l	non-intravenous in	jection, 5 = intraver	nous injection		
Completed by (Initials):								

	Site II	<b>)</b> :	Subject ID	#. Sul	Treatment Week Subject Initials Week		
					J. C.		
Date:	(mm/dd/	уууу)					
<u>Cocain</u>	<u>ıe</u>						
1. The <u>in</u>	tensity of my cra	aving, that is, h	now much I desire	d cocaine in the past	24 hours was:		
	☐ None at all	☐ Slight	☐ Moderate	☐ Considerable	☐ Extreme	)	
_		craving, that is Almost never	, how often I desir □ Several ti	ed cocaine in the pas mes		st constantly	
	ngth of time I sp ☐ None at all	pent craving fo	_	ne past 24 hours was		long	
4. Write i	n the <u>number</u> of	times you thin	nk you had craving	for cocaine during t	he past 24 hour	s:	
5. Write i	in the total <u>time</u>	spent craving minutes	cocaine during the	e past 24 hours:			
6. The <u>w</u>	orst day: During	g the past wee	k my most intense	craving occurred on	the following d	ау:	
[	Sunday Thursday	☐ Monday ☐ Friday	☐ Tuesday ☐ Saturday	☐ Wednesday ☐ All days the same (go	o to Q. 8)		
7. The da	ate for that day	was:	(mm/dd/yyyy)				
8. The <u>in</u>	tensity of my cra	aving, that is, h	now much I desire	d cocaine on that wo	rst day was:		
[	☐ None at all	☐ Slight	☐ Moderate	☐ Considerable	☐ Extreme	)	
<u>Secon</u>	d Drug						
	craved drug dur Mark <u>only one</u> of th			ark "None" and leave Qu	estions 10-16 blar	ık.	
[	None		vners or Sedatives	Benzos	☐ Nicotine		
[	Alcohol	Her	biturates, etc.) oin or other Opiates rphine, etc.)	(Valium, Xanax, etc.)  Marijuana	Other Specify		
	<u>ntensity</u> of my c s was:	raving, that is,	how much I desir	ed this <b>second</b> drug	in the past 24		
[	☐ None at all	☐ Slight	☐ Moderate	☐ Considerable	☐ Extreme	)	

Date of last cocaine use:

							ment Week1
	Site	ID:	Subject II	) #. 	Subject	Initials	Week
Date:							
	(mm/c	ld/yyyy)					
	frequency of rs was:	my craving, that is	, how often I des	sired this <b>sec</b> o	ond drug in	the past 24	
	☐ Never	☐ Almost never	☐ Several	times $\square$	Regularly	☐ Almo	ost constantly
12. The	length of time	I spent in craving	for this second	drug during t	he past 24 h	nours was:	
	☐ None at all	☐ Very shor	t 🗆 Short	☐ Some	ewhat long	☐ Very	long
Third I	Drug						
13. A <b>3</b> <sup>rc</sup>	d craved drug <i>Mark <u>only</u> one</i> c	during the past 24 of the following. If no	4 hours was: o 3 <sup>d</sup> craved drug, m	ark "None" and	leave questic	ons 14-16 blar	nk.
	None		ners or Sedatives	☐ Benzos (Valium, Xar	nav etc)	☐ Nicotine	
	Alcohol	☐ Hero	oin or other Opiates ohine, etc.)	Marijuana	iax, etc.)	Other Specify	
	intensity of m	y craving, that is,	how much I desi	red this <b>third</b>	drug in the	past 24	
	☐ None at all	☐ Slight	☐ Moderate	☐ Consi	derable	☐ Extrem	е
	frequency of rs was:	my craving, that is	s, how often I des	sired this <b>thirc</b>	d drug in the	past 24	
	☐ Never	☐ Almost never	☐ Several	times $\square$	Regularly	☐ Almo	ost constantly
16. The	<u>length</u> of time	I spent in craving	for this third dru	ıg during the μ	oast 24 hou	rs was:	
	☐ None at all	☐ Very shor	t 🔲 Short	☐ Some	ewhat long	☐ Very	long
Complet	ed by (Initials)	):					
items in la question	ay language and 4 and 5, the sub	d 5 are assessed by I the response is rec ject is asked to marl The rater then transc	orded on a scale of the appropriate pl	f 0-7 with 0 bein lace on the line (	g normal or n (on page 3) th	o symptoms.	For

#### Form 30 - COCAINE SELECTIVE SEVERITY ASSESSMENT

k 1

								Tre	eatmer	nt Weel
	Site ID:		5	Subject II	) #.	_	Subjec	t Initials		Week
						L				
D	rate:									
	(mm/dd/yyyy)									
				(mm/dd/	'yyyy)					
1.	Hyperphagia									
	0 = normal appetite 3-4 = eats a lot more tha 7 = eats more than twice		ınt of fo	ood						
2.	Hypophagia									
	0 = normal appetite 3-4 = eats less than half 7 = no appetite at all	of normal ar	mount o	of food						
3.	Carbohydrate Craving									
	0 = no craving 3-4 = strong craving for 7 = strong craving for sw									
4.	Cocaine Craving Intensit		Please	use subje	ct intensi	ity rating	from pg. 3	of this fo	rm.	
5.	Cocaine Craving Frequer		Please	use subje	ct frequei	ncy ratin	g from pg.	3 of this f	orm.	
6.	Bradycardia									
	•		Please	use scale	below.					
	Pulse (BPM)	0 >64	1 64-63	2 62-61	3 60-59	4 58-57	5 56-55	6 54-53	7 <53	
7.	Insomnia									
	0 = normal amount of slo 3-4 = half of normal amo 7 = no sleep at all									
8.	Hypersomnia									
	0 = normal amount of slo 3-4 = could sleep or doe 7 = sleep or could sleep	s sleep half	the day	y						

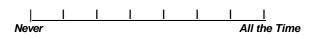
#### Form 30 - COCAINE SELECTIVE SEVERITY ASSESSMENT

**Treatment Week 1** 

	Site ID:	Subject ID #.	Subject Initials	Weel
Dat	te:			
	(mm/dd/yyyy)			
9.	Anxiety			
	0 = usually does not feel anx 3-4 = feels anxious half the f 7 = feels anxious all the time	ime		
10.	Energy Level			
	0 = feels alert and has usual 3-4 = feels tired half the time 7 = feels tired all the time			
11.	Activity Level			
	0 = no change in usual activi 3-4 = participates in half of u 7 = no participation in usual	sual activities		
12.	Tension			
	0-1 = rarely feel tense 3-4 = feels tense half the tim 7 = feels tense most or all th			
13.	Attention			
	0 = able to concentrate on re 3-4 = has difficulty with the a 7 = has difficulty with the ab		ake plans without difficulty	
14.	Paranoid Ideation			
	0 = no evidence of paranoid 3-4 = unable to trust anyone 5 = feels people are out to g 7 = feels a specific person/g	-		
15.	Anhedonia			
	0 = ability to enjoy themselve 3-4 = able to enjoy themselv 7 = unable to enjoy themselv	es half of the time		
16.	Depression			
	0 = no feelings related to sa 3-4 = feels sad or depressed 7 = feels depressed all of the	I half the time		
17.	Suicidality			
	0 = does not think about beir 3-4 = feels like life is not wor 7 = feels like actually ending	th living		
18.	Irritability			
	0 = feels that most things are 3-4 = feels that many things 7 = feels that mostly everythi	are irritating		
Cor	mpleted by (Initials):	$\neg$		

NIDA-MDS-Modaf-0001		Form 30 - COCAIN	Form 30 - COCAINE SELECTIVE SEVERITY ASSESSMENT						
Г	Site ID:	Subject ID #.	Subject Initials	ment Week 1 Week					
Date:									
	(mm/dd/yyyy)  UAL ANALOG SCA  nark on upright lines.	<u>LE</u>							
Please rate tl	he highest intensity of the	e desire for cocaine you ha	ve felt in the last 24 hours:						
	No Desire at all	l I I I Un	l able to Resist						

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



# NIDA-MDS-Modaf-0001 Form 28 – CLINICAL GLOBAL IMPRESSION - SELF Treatment Week 1 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

# $Form\ 29-CLINICAL\ GLOBAL\ IMPRESSION\ -\ OBSERVER$

Trea	tment	Wee	ek 1	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 <u>Severe</u>					-	Most Severe
Report	ed Cocaine Use: (frequency and amount of cocaine used)	1	2	3	4	5	6	7
Cocain	ne Seeking: (craving for cocaine, effort to stop, and drug seeking behavior)	1	2	3	4	5	6	7
Report	ed Use of Other Drugs: (frequency and amount of non-cocaine drug/alcohol use)	1	2	3	4	5	6	7
Observ	vable Psychiatric Symptoms: (orientation, memory, comprehension, disorganized thinking, rapid/retarded speech, agitation, grooming, hostility, irritability, affective disturbance)	1	2	3	4	5	6	7
Report	ted 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
Physic	al/Medical Problems: (those that have emerged or gotten worse after drug use)	1	2	3	4	5	6	7
Malada	aptive Coping in the Family/Social area: (movement away from healthy relationships)	1	2	3	4	5	6	7
Malada	aptive 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

NIDA-M	IDS-Modaf-0001	Form 29 – CL	INICAL GLO	OBAL IMPRESSIO	
				Treat	tment Week 1
	Site ID:	Subject ID #.		Subject Initials	Week
Date:					
	(mm/dd/yyyy)				
Global S	Severity of Cocaine D	<u>ependence</u>			
	-	<del>-</del>			
Considerir	ng your total clinical experie	ence with the cocaine	dependent po	opulation, how seve	ere are
	ct's cocaine dependence sy			,	
•	·	•			
	Normal, no symptoms				
	Borderline symptoms				
	Mild symptoms				
	Moderate symptoms				
	Marked symptoms				
	<ul><li>Severe symptoms</li><li>Most extreme symptoms</li></ul>	s nocciblo			
<u> </u>	i wost extreme symptoms	s hossinie			
Global	Improvement of Coca	ine Dependence			
<u>Giobai i</u>	inprovement or coca	ine Dependence			
Rate the t	otal improvement in the pa	rticinant's cocaine den	endence sym	ontoms whether or	not in
	ment, it is due entirely to dr				
project, ho		3		,	
	the subject changed?				
	_				
	Not assessed, first rating	g			
	Very much improved				
L	Much improved				
	Minimally improved				
	No change				
	Minimally worse Much worse				
	Very much worse				
	J VEIY IIIUUII WUISE				

			Treatn	nent Week 1
	Site ID:	Subject ID #.	Subject Initials	Week
Date:				
Date doses <i>Eac</i>	(mm/dd/yyyy) dispensed h dose is four tablets	(mm/dd/yyyy)		
Kit Number:				
Bottle Numb	er:			
Number of c	loses dispensed			
Date unused	d doses returned	(mm/dd/yyyy)		
Number of c	loses returned			
Number of c	loses reported lost by subject	t		
Doses taken	:			
	Day of Week:	<u>Date</u>	Time Dose	Dose Not
		(mm/dd/yyyy)	Taken	Taken
Comments:				
Completed b	by (Initials):			

	Site ID:		Subject ID	#.		Treatn Subject Initials	week 1
Date:	(mm/dd/yyyy)						
Did subjec	t receive standardized, manu	ıal-gu	uided individu	ıal psyd	chothe	erapy this week?	
(If No, plea	ase comment below)		Yes		No		
If yes, leng	yth of psychotherapy session			minut	es		
	et require emergency crisis ent sessions this week?		Yes		No		
If yes, hov	v many?						
Additional	comments:						

V1

				Treatment Week 2
	Site ID:	Subject	ID#. Subje	ct Initials Wee
Date:	(mm/dd/yyyy)			
First St	udy Visit of Wee	<u>k</u>		
☐ Vital s	igns not assessed at	this visit		
Date	(mm/dd/yyyy)		Time Vital Signs taken	(24 hour clock)
Temperati	ure (oral)	(°F)	NR: 94-100.4	CS □ NCS □
Comment	s for Temperature			
	ssure (sitting) s for Blood Pressure:	(mm Hg)	NR: 90-140/50-90	CS   NCS
Pulse Rat	e (sitting)	(beats/min)	NR: 50-120	CS NCS
	ry Rate (sitting) s for Respiratory Rate	(breaths/min) e:	NR: 8-20	CS   NCS
Complete	d by (Initials):			

				Treatment Week 2 V		
	Site ID:	Subject I	D#. Sub	Subject Initials W		
Date:	(mm/dd/yyyy)					
Second	Study Visit of Week					
☐ Vital s	signs not assessed at this v	isit				
Date	(mm/dd/yyyy)		Time Vital Signs tak	en (24 hour clock)		
Temperat	ure (oral)	(°F)	NR: 94-100.4	CS □ NCS		
Comment	s for Temperature					
	essure (sitting)	(mm Hg)	NR: 90-140/50-90	CS□ NCS		
	s for Blood Pressure:	- ()	ND, 50 400			
	te (sitting) (beat ts for Pulse Rate:	s/min)	NR: 50-120	CS ☐ NCS		
Respirato		oreaths/min)	NR: 8-20	CS□ NCS		
	d by (Initials):					

	C:4- ID.	C1-:4	ID # C1.	Treatment Wed	
	Site ID:	Subject	1D#. 500	ject Initials	Week
Date:	(mm/dd/yyyy)				
Third S	tudy Visit of Week				
☐ Vital_s	igns not assessed at this	visit			
Date	(mm/dd/yyyy)		Time Vital Signs take	en (24 hour clock)	
Temperati	ure (oral)	(°F)	NR: 94-100.4	CS□ NCS□	
Comment	s for Temperature				
	ssure (sitting)	(mm Hg)	NR: 90-140/50-90	CS ☐ NCS ☐	
Comment	s for Blood Pressure:				
Pulse Rate (sitting) (beats/min)			NR: 50-120	CS □ NCS □	
Comments	s for Pulse Rate:				
Respirato	ry Rate (sitting)	(breaths/min)	NR: 8-20	CS □ NCS □	
Comment	s for Respiratory Rate:				
Complete	d by (Initials):				

Completed by (Initials):

#### Form 23 - URINE BE SPECIMEN COLLECTION FORM

**Treatment 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 <u>higher</u> than 90.0 ° F and <u>lower</u> than 99.0 ° F Split Sample Cup: The temperature must be <u>higher</u> than 90.0 ° F and <u>lower</u> than 100.0 ° F

Site ID:

### Form 23 – URINE BE SPECIMEN COLLECTION FORM

Subject ID #. Subject Initials Week

Subject Initials Week

Date:	(mm/dd	/уууу)						
<u>Second</u>	Study Visi	<u>it of Week</u>	Urine bar	code sticker:				
Date urine	collected:	(mm/dd/yyy	у)	Uı	ine not collected			
Fra Tra	Vas urine temperature within expected range?							
Completed	by (Initials):							

#### Form 23 – URINE BE SPECIMEN COLLECTION FORM

**Treatment Week 2 V3** 

				11 Catilici	it vvcck 2 v
	Site ID:	Subject ID	#	Subject Initials	Week
Date:	nm/dd/yyyy)				
Third Study V	isit of Week	Urine bar code	sticker:		
Date urine collecte	ed: (mm/dd/yy	<i>yy)</i>	Urine	not collected	]
Franklin Cu Trak Cup: 1	ature within expecte up: The temperature mu The temperature must b p: The temperature must	st be <u>higher</u> than 96.0 e <u>higher</u> than 90.0 ° F a	and <u>lower</u> than 9	9.0° F Split	
Completed by (Init	tials):				

#### Form 24 – SUBSTANCE USE INVENTORY

					Treatment Week 2					
Sit	e ID:	Subject II	) #.	Subject Initials	Week	•				
Date:	/44/									
(mm/ Using timeline follow-ba	/dd/yyyy)	ether suhject has i	on each day since i	the last visit used a	ny amount of the su	ihstances listed he	low along with the r	nost common roi		
of administration for each	ch drug. Begin with ye	esterday and work	back to the last vis	it. Please be sure ti	hat days are continu	ous with last week	c's form.	iost common roc		
Date of last	visit:									
	(mm/d	d/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					
Alcohol			□Y/□N	□Y/□N	□Y/□N	□Y/□N	□Y/ □N			
Marijuana	□Y/ □N		□Y/□N							
Amphetamines	□Y/ □N		□Y/ □N	□Y/□N ☐	□Y/□N ☐		□Y/ □N			
Opiates	□Y/ □N	□Y/ □N	□Y/ □N	□Y/ □N	$\square$ Y/ $\square$ N $\square$	□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			
Pouto of admin	nistration (POA) codes	· 1 – oral 2 – nasa	l 2 – smokina 1 –	non-intravonous in	ioction 5 - intravor	ous injection				

Completed by (Initials):	

	Site	ID.	Subject II	<b>)</b> #	Subje	<b>Treatm</b> ct Initials	nent Week 2 Week
	Site	ш.	Subject II	<i>σ</i> π.	Subje	et initials	WCCK
Date:	(mm/d	d/yyyy)					
<u>Cocain</u>	<u>e</u>						
1. The <u>int</u>	ensity of my	craving, that is,	how much I desir	ed cocaine in	the past 24	4 hours was:	
	None at all	☐ Slight	☐ Moderate	☐ Cons	siderable	☐ Extreme	•
2. The fre	equency of m	y craving, that i	s, how often I desi	red cocaine i	n the past 2	24 hours was	:
	Never	☐ Almost neve	r 🗌 Several	times [	Regularly	☐ Almo	ost constantly
3. The <u>ler</u>	ngth of time I	spent craving f	or cocaine during	the past 24 h	ours was:		
Ε	None at all	☐ Very sh	ort	☐ Som	ewhat long	☐ Very	long
4. Write in	n the <u>number</u>	of times you th	ink you had cravir	ng for cocaine	e during the	past 24 hour	S:
5. Write in	n the total <u>tim</u>	ne spent cravino	g cocaine during th	ne past 24 ho	urs:		
6. The <u>wo</u>	orst day: Dur	ing the past we	ek my most intens	e craving oc	curred on th	ne following d	ay:
	Sunday Thursday	☐ Monday ☐ Friday	☐ Tuesday ☐ Saturday	☐ Wednesda	ay ne same (go to	Q. 8)	
7. The da	ite for that da	y was:	(mm/dd/yyyy)				
8. The <u>int</u>	ensity of my	craving, that is,	how much I desir	ed cocaine o	n that worst	day was:	
	None at all	☐ Slight	☐ Moderate	☐ Cons	siderable	☐ Extreme	Э
<u>Second</u>	d Drug						
9. A <b>2<sup>nd</sup></b> o	craved drug d Mark <u>only one</u> o	uring the past 2 f the following. If	24 hours was: no 2 <sup>nd</sup> craved drug, n	nark "None" an	d leave Ques	tions 10-16 blaı	nk.
	None		owners or Sedatives arbiturates, etc.)	☐ Benzos (Valium, Xa	anav etc )	☐ Nicotine	
	Alcohol	□н	eroin or other Opiates orphine, etc.)	☐ Marijuana	ux, 010.j	Other Specify	
10. The <u>ir</u> hours		craving, that is	s, how much I des	ired this seco	ond drug in	the past 24	
Γ	None at all	☐ Slight	☐ Moderate	☐ Cons	siderable	☐ Extreme	Э

						Treatr	nent Week	2
	Site	ID:	Subject ID #.		Subjec	ct Initials	Week	
								J
Date:								
Dutc.	(mm/c	ld/yyyy)						
	<u>frequency</u> of r s was:	my craving, that is, l	now often I desired	this <b>seco</b> ı	<b>1d</b> drug in	the past 24		
	☐ Never	☐ Almost never	☐ Several time	s 🗆 F	Regularly	☐ Alm	ost constantly	/
12. The	length of time	I spent in craving for	or this <b>second</b> dru	g during the	e past 24	hours was:		
	☐ None at all	☐ Very short	☐ Short	☐ Somew	hat long	☐ Very	long	
Third I	Drug							
	<del>_</del>							
13. A <b>3</b> <sup>r</sup>	<sup>d</sup> craved drug <i>Mark <u>only one</u> o</i>	during the past 24 h	nours was: <sup>rd</sup> craved drug, mark '	'None" and le	eave questi	ons 14-16 blai	nk.	
	None	☐ Downe	rs or Sedatives	Benzos		☐ Nicotine		
	Alcohol	`		(Valium, Xana Marijuana	x, etc.)	Other _		
	LI Alcohol		ne, etc.)	iviarijuaria		Specify		
	intensity of mys	y craving, that is, ho	ow much I desired	this <b>third</b> d	rug in the	past 24		
	☐ None at all	☐ Slight	☐ Moderate	☐ Conside	erable	☐ Extrem	ne	
	<u>frequency</u> of r 's was:	my craving, that is,	now often I desired	d this <b>third</b>	drug in the	e past 24		
	☐ Never	☐ Almost never	☐ Several time	s □ F	Regularly	☐ Alm	ost constantly	/
16. The	length of time	I spent in craving for	or this third drug d	uring the pa	ast 24 hou	ırs was:		
	☐ None at all	☐ Very short	☐ Short	☐ Somew		☐ Very	/ long	
		_ vory crion	_ Grien		mat long	,	10.19	
Complet	ted 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.

### Form 30 - COCAINE SELECTIVE SEVERITY ASSESSMENT

ek 2

									Tre	eatmer	nt Wee
		Site ID:			Subject II	) #.	_	Subjec	t Initials		Weel
			<u></u>				L				
Da	ate:										
D۵	ate of la	(mm/dd/yyyy) st cocaine use:									
٥	ate of ia	ot cocame asc.			(mm/dd/	<i>(yyyy</i> )					
1.	Hyper	phagia		]							
	3-	= normal appetite -4 = eats a lot more tha = eats more than twice		unt of fo	ood						
2.	Нурор	ohagia									
	3-	= normal appetite -4 = eats less than half = no appetite at all	of normal a	mount (	of food						
3.	Carbo	hydrate Craving									
	3-	= no craving -4 = strong craving for s = strong craving for sw					me				
4.	Cocaii	ne Craving Intensity		Please	use subje	ct intensi	ty rating	from pg. 3	of this fo	rm.	
5.	Cocai	ne Craving Frequen		Please	use subje	ct freque	ncy ratin	g from pg.	3 of this f	orm.	
6.	Brady	cardia		Please	use scale	below.					
		Pulse (BPM)	0 >64	1 64-63	2 62-61	3 60-59	4 58-57	5 56-55	6 54-53	7 <53	
7.	Insom	nia									
	3-	= normal amount of sle -4 = half of normal amo = no sleep at all		)							
8.	Hyper	somnia									
	3-	= normal amount of sle -4 = could sleep or doe: = sleep or could sleep	s sleep half	the day	y						

### Form 30 - COCAINE SELECTIVE SEVERITY ASSESSMENT

**Treatment Week 2** 

		Site ID:		Subject ID #.	-	Subject Initials	Week
			<u>-</u>		1		
Dat	e:						
		(mm/dd/yyyy)					
9	Anxie	ty					
	3-	= usually does not feel ar 4 = feels anxious half the = feels anxious all the tir	time				
10.	Ener	gy Level					
	3-	<ul><li>feels alert and has usu</li><li>4 = feels tired half the tir</li><li>feels tired all the time</li></ul>		ergy			
11.	Activ	ity Level					
	3-	= no change in usual act 4 = participates in half of = no participation in usua	usual activities				
12.	Tens	ion					
	3-	1 = rarely feel tense 4 = feels tense half the t = feels tense most or all					
13.	Atte	ntion					
	3-	<ul><li>able to concentrate on</li><li>4 = has difficulty with the</li><li>has difficulty with the a</li></ul>	above half the t	ime	make pl	ans without difficulty	
14.	Parai	noid Ideation					
	3- 5	<ul><li>no evidence of paranoi</li><li>4 = unable to trust anyor</li><li>feels people are out to</li><li>feels a specific person</li></ul>	e get him/her	against him/her			
15.	Anhe	edonia					
	3-	<ul><li>ability to enjoy themsel</li><li>4 = able to enjoy themse</li><li>unable to enjoy themse</li></ul>	lves half of the ti				
16.	Depr	ession					
	3-	= no feelings related to s 4 = feels sad or depress = feels depressed all of t	ed half the time	ssion			
17.	Suici	dality					
	3-	<ul><li>does not think about be</li><li>4 = feels like life is not w</li><li>feels like actually endir</li></ul>	orth living				
18.	Irrita	bility					
	3-	= feels that most things a 4 = feels that many thing = feels that mostly every	s are irritating	and upsetting			
Con	nplete	d by (Initials):					

N	NID	Λ_	M	DC	_N/I	ha	of_	ΛΛ	Λ1
Τ.	ענו	А-	TVL	כט	-171	ou	aı-	w	V I

#### Form 30 – COCAINE SELECTIVE SEVERITY ASSESSMENT

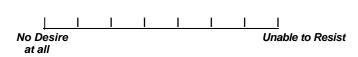
Treatment Week 2

				Ticat		IL VICCIN 2
	Site ID:	Subject ID #.	_	Subject Initials	_	Week
Date:						
	(mm/dd/yyyy)					

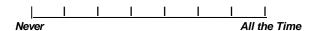
#### CSSA VISUAL ANALOG SCALE

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:



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



Treatment	Woolz	1

NIDA-MDS-Modaf-0001		Form 28 – CLIN	Form 28 - CLINICAL GLOBAL IMPRESSION - SEI				
	Site ID:	Subject ID #.	Treatm Subject Initials	ent Week Week			
	Site 15.	Subject ID #.	Subject mitals	Week			
Date:	(mm/dd/yyyy)						
Cocaine	Global Severity						
	, how would you rate you e related problems?	self overall for cocaine use					
	No problems Borderline problems Mild problems Moderate problems Marked problems Severe symptoms Most extreme problems	possible					
Global In	nprovement of Coca	<u>ine Dependence</u>					
	you rate yourself for char blems since the beginning	nges in cocaine use and cocaine of this study?	<b>;</b>				
	Not assessed Very much improved Much improved Minimally improved No change Minimally worse Much worse Very much worse						

## Form 29 - CLINICAL GLOBAL IMPRESSION - OBSERVER

Trea	tme	nt \	W۵	ρk	2

	Site ID:		Subject ID #.	Subject Initials	Week	
Data						
Date:	(mm/dd/yyyy)					

## **Current Severity**

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

		None, Least <u>Severe</u>						Most <u>Severe</u>
Reported Cocaine and amoun	Use: (frequency t of cocaine used)	1	2	3	4	5	6	7
	(craving for ffort to stop, and ing behavior)	1	2	3	4	5	6	7
	Other Drugs:  of and amount of the drug/alcohol use)	1	2	3	4	5	6	7
comprehe thinking, ra agitation, g	iatric Symptoms: n, memory, nsion, disorganized apid/retarded speech, grooming, hostility, affective disturbance)	1	2	3	4	5	6	7
anxiety,inr covert ang energy lev	tric Symptoms: turbance, depression, ner restlessness, ger, somatic symptome rel,motivation, sleep, bido, anhedonia)	s, 1	2	3	4	5	6	7
	Problems: t have emerged or rse after drug use)	1	2	3	4	5	6	7
area: (mo	ig in the Family/Socia vement away from ationships)	l 1	2	3	4	5	6	7
housing, e	g in Other areas: loyment, legal, tc. movement away em solving in those	1	2	3	4	5	6	7

NIDA-MDS-Modaf-0001		Form 29 – CLINIC.	AL GLOBAL IMPRESSION - OB	
			Treatment	
_	Site ID:	Subject ID #.	Subject Initials	Week
Date:	(mm/dd/yyyy)			
<u>Global S</u>	Severity of Cocaine Depe	<u>ndence</u>		
	g your total clinical experience to the community of the contract of the community of the c		ndent population, how severe are	
	Normal, no symptoms Borderline symptoms Mild symptoms Moderate symptoms Marked symptoms Severe symptoms Most extreme symptoms poss	sible		
Global In	mprovement of Cocaine	<u>Dependence</u>		
your judgm project, how	ent, it is due entirely to drug tre		nce symptoms whether or not, in the subject's admission to the	
	Not assessed, first rating Very much improved Much improved Minimally improved No change Minimally worse Much worse Very much worse			

			Treatn	nent Week 2
-	Site ID:	Subject ID #.	Subject Initials	Week
Date:	(mm/dd/yyyy)			
Date dose:	s dispensed och dose is four tablets	(mm/dd/yyyy)		
Kit Numbe	r:			
Bottle Num	ber:			
Number of	doses dispensed			
Date unus	ed doses returned	(mm/dd/yyyy)		
Number of	doses returned			
Number of	doses reported lost by subject			
Doses take	en:			
	Day of Week:	<u>Date</u>	Time Dose	Dose Not
		(mm/dd/yyyy)	Taken	Taken
Comments				
Comments				
Completed	by (Initials):			

## Form 34 - TREATMENT COMPLIANCE - PSYCHOTHERAPY

ek 2

1(11)/1-1(1	1D5-1110uar-0001	•				Treatm	ent Wee
	Site ID:	_	Subject ID	#.	ī	Subject Initials	Week
Date:	(mm/dd/yyyy)				·		
Did subject	ct receive standardized, mar	nual-gı	uided individu	ual psyd	chothe	rapy this week?	
(If No, ple	ase comment below)		Yes		No		
If yes, leng	gth of psychotherapy sessio	n		minu	tes		
	ct require emergency crisis ent sessions this week?		Yes		No		
If yes, how	w many?						
Additional	comments:						
							_

				Treat	ment Week 2
	Site ID:	Subje	ct ID#.	Subject Initials	Week
		╝, └──			
Date:					
	(mm/dd/yyyy)				
This form		or female subiects o	onlv. All female s	subjects must be test	ted at
				to be eligible for this	
What metl	hod of birth control is	the participant currer	ntly using (prior to	taking modafinil)?	
	Oral contracep	tive			
	Barrier (diaphr	agm or condom plus	spermicide)		
	Levonorgestre	l implant (Norplant)			
	Intrauterine Co	ntraceptive system (I	UD)		
	] Medroxyproge:	sterone Acetate Cont	raceptive injection	n (Depo-Provera)	
	Contraceptive	patch			
	Surgical Steriliz	zation - Hysterectomy	/		
	Surgical Steriliz	zation - Tubal ligation			
		ars postmenopausal, he study and 30 days		agree to use an accept study drug?	otable
	] Yes	□ No		, -	
If yes, ma	rk below the acceptal	ole method selected b	by the subject for	use:	
	barrier method	with spermicide			
		aceptive [oral, Implan with a barrier method	•	d	
	Contraceptive	patch used in conjund	ction with a barrie	er method	
	Intrauterine de	vice [IUD]			
Was a pre	egnancy test performe	ed?	Yes	□ No	
If	yes, date specimen o	collected			
			(mm/dd/yyy	<i>y)</i>	
R	esult:	gative	☐ Unknown	1	
If	no, specify reason:				
Is the sub	ject lactating?	☐ Yes	□ No		
Comment	s:				
Completed	d by (Initials):				

	G': ID	0.11	TD #	<b>Treatment Week 3</b>	
	Site ID:	Subject	Subjection Subjection	et Initials Wee	k
_					
Date:	(mm/dd/ssss				
	(mm/dd/yyyy	)			
First St	udy Visit of We	e <u>k</u>			
☐ Vital_s	signs not assessed	at this visit			
Date	(mm/dd/yyyy	<u>'</u> )	Time Vital Signs taken	(24 hour clock)	
Temperat	ure (oral)	(°F)	NR: 94-100.4	CS □ NCS □	
Comment	s for Temperature				
Blood Pre	ssure (sitting)	(mm Hg)	NR: 90-140/50-90	CS ☐ NCS ☐	
Comment	s for Blood Pressur	e:			
Pulse Rat	re (sitting)	(beats/min)	NR: 50-120	CS   NCS	
	s for Pulse Rate:		1411. 00 120	00 L 1100 L	
Respirato	ry Rate (sitting)	(breaths/min)	NR: 8-20	CS ☐ NCS ☐	
Comment	s for Respiratory Ra	ate:			
Complete	d by (Initiala)				
Complete	d by (Initials):				

	Site I	D:	Subject	ID#.	Subjec	Treatn t Initials	nent We	eek 3 V2 Week
Date:	(mm/dc	d/yyyy)						
<u>Second</u>	Study Visi	it of Week	[					
☐ Vital s	signs not asse	ssed at this	visit					
Date	(mm/	(dd/yyyy)		Time Vital Siç	gns taken	(24 hou	r clock)	
Temperati	ure (oral) s for Tempera	ature	(°F)	NR: 94-100.4		cs 🗆	NCS □	
	ssure (sitting) s for Blood Pr	essure:	(mm Hg)	NR: 90-140/5	0-90	cs 🗆	NCS 🗆	
Pulse Rat	e (sitting)	(bea	ats/min)	NR: 50-120		cs □	NCS □	
Respirato	s for Pulse Ra ry Rate (sitting s for Respirate	g)	(breaths/min)	NR: 8-20		cs 🗆	NCS 🗆	
Completed	d by (Initials):							

	a	a 11		<b>Treatment Week 3 V3</b>
	Site ID:	Subject	Subject Subject	et Initials Week
Date:	(mm/dd/yyyy)			
Third S	tudy Visit of Wee	<u>k</u>		
☐ Vital s	signs not assessed at	this visit		
Date	(mm/dd/yyyy)		Time Vital Signs taken	(24 hour clock)
Temperat	ure (oral)	(°F)	NR: 94-100.4	CS □ NCS □
Comment	s for Temperature			
	ssure (sitting)	(mm Hg)	NR: 90-140/50-90	CS   NCS
Pulse Rat	e (sitting)	(beats/min)	NR: 50-120	CS □ NCS □
Comment	s for Pulse Rate:			
Respirato	ry Rate (sitting)	(breaths/min)	NR: 8-20	CS □ NCS □
	s for Respiratory Rate	»: 		
Complete	d by (Initials):			

### Form 23 – URINE BE SPECIMEN COLLECTION FORM

**Treatment Week 3 V1** 

ſ	Site II	): 	Subjec	et ID#.	Subject Initial	ls Week
Date:	(mm/dd/	/уууу)				
<u>First Stu</u>	ıdy Visit of	<u>Week</u>	Urine bar o	code sticker:		
Date urine	collected:	(mm/dd/y	yyy)	Ur	ine not collected	
Fra Tra	ak Cup: The tem	temperature m perature must l	ust be <u>higher</u> thar be <u>higher</u> than 90.	n 96.0° F and <u>lowe</u> 0° F and <u>lower</u> th 90.0° F and <u>lower</u>		□ No
Completed	by (Initials):					

### Form 23 – URINE BE SPECIMEN COLLECTION FORM

Treatment Week 3 V2

			1 reaument	week 5 v
Site	ID:	Subject ID #.	Subject Initials	Week
Date: (mm/o	ld/yyyy)			
Second Study Vis	sit of Week u	Irine bar code sticker:		
Date urine collected:	(mm/dd/yyyy)	Uri	ine not collected	
Trak Cup: The te	e temperature must be mperature must be <u>hig</u> l	nge? <u>higher</u> than 96.0°F and <u>lowe</u> her than 90.0°F and <u>lower</u> tha her than 90.0°F and <u>lower</u> tha	an 99.0° F Split Sa	
Completed by (Initials)				

### Form 23 – URINE BE SPECIMEN COLLECTION FORM

**Treatment Week 3 V3** 

Site	ID:	Subject ID #	<u>.</u>	Subject Initials	s	Week
Date:						
(mm/c	dd/yyyy)					
Third Study Visit	of Week	Urine bar code	sticker:			
Date urine collected:	(mm/dd/yyyy	<i>'</i> )	Urine	not collected		
Trak Cup: The te	he temperature must emperature must be	range? be <u>higher</u> than 96.0° <u>higher</u> than 90.0°F a be <u>higher</u> than 90.0°	nd <u>lower</u> than 9	9.0° F Split	] No	
Completed by (Initials)	:					

#### Form 24 – SUBSTANCE USE INVENTORY

				Tre	eatment Week	3		
Sit	te ID:	Subject II	) #.	Subject Initials	Week	-		
						]		
Date:								
(mm	n/dd/yyyy)							
Using timeline follow-ba of administration for each	ack method, record wi	hether subject has o	on each day since t	the last visit used a	ny amount of the su	ubstances listed be	low, along with the r	nost common route
Date of last		cotorday and nork	buon to the last vio	ni i icado de sare a	nat days are contin	uouo marriuot neer	o Tomi.	
Date of last		dd/yyyy)						
Day of week	,							
Day of week								
Date								
	Used? ROA	Used? ROA	Used? ROA	Used? ROA	Used? ROA	Used? ROA	Used? ROA	
Cocaine	□Y/ □N	□Y/ □N	$\square$ Y/ $\square$ N $\square$	□Y/ □N	□Y/ □N	$\square$ Y/ $\square$ N	□Y/ □N	
Alcohol	□Y/ □N	□Y/ □N	□Y/ □N	□Y/ □N	□Y/ □N	□Y/ □N	□Y/ □N	
Marijuana	□Y/ □N	□Y/ □N	$\square$ Y/ $\square$ N $\square$	□Y/ □N	□Y/ □N	$\square$ Y/ $\square$ N	□Y/ □N	
Amphetamines	□Y/ □N	□Y/ □N	$\square$ Y/ $\square$ N	□Y/ □N	□Y/ □N	$\square$ Y/ $\square$ N $\square$	□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 admir	nistration (ROA) code	s: 1 = oral, 2 = nasa	l, 3 = smoking, 4 = 1	non-intravenous in	jection, 5 = intraver	nous injection	_	
Completed by (Initials	s):							

						tment Week
	Site	ID:	Subject ID	<u>#.</u>	Subject Initials	Week
Date:						
	(mm/d	ld/yyyy)				
Cocain	۵					
	<del>-</del> -	craving, that is, h	ow much I desire	d cocaine in the p	ast 24 hours was	s:
	None at all	☐ Slight	☐ Moderate	☐ Considerab	le 🗌 Extre	me
2. The fre	quency of my	/ craving, that is,	how often I desire	ed cocaine in the	past 24 hours wa	as:
	] Never	☐ Almost never	☐ Several ti			most constantly
3. The <u>ler</u>	ngth of time I None at all	spent craving for Very shor		ne past 24 hours v		ry long
4. Write ir	the <u>number</u>	of times you thin	k you had craving	for cocaine durin	g the past 24 ho	urs:
5. Write ir	the total tim	e spent craving o	ocaine during the	past 24 hours:		
	hours	minutes				
6. The <u>wo</u>	<u>rst</u> day: Duri	ng the past week	my most intense	craving occurred	on the following	day:
	Sunday Thursday	☐ Monday ☐ Friday	☐ Tuesday ☐ Saturday	☐ Wednesday ☐ All days the same	e (go to Q. 8)	
7 Thodo	to for that day					
7. THE da	te for that day	•	nm/dd/yyyy)			
8. The <u>int</u>	ensity of my o	craving, that is, h	ow much I desire	d cocaine on that	worst day was:	
	None at all	☐ Slight	☐ Moderate	☐ Considerab	-	me
Second	l Drug					
9. A <b>2<sup>nd</sup></b> c	raved drug dı	uring the past 24 fthe following. If no	hours was: o 2 <sup>nd</sup> craved drug, ma	ark "None" and leave	Questions 10-16 b	lank.
	None		ners or Sedatives iturates, etc.)	☐ Benzos (Valium, Xanax, et	☐ Nicotine	<b></b>
	Alcohol	Hero	oin or other Opiates Ohine, etc.)	Marijuana	Other   Specify	
10. The <u>ir</u> hours		craving, that is,	how much I desire	ed this <b>second</b> dr	ug in the past 24	
	None at all	☐ Slight	☐ Moderate	☐ Considerab	le 🗌 Extre	me

	Site 1	ID:	Subject ID#.	Subjec	Treatment Week 3 et Initials Week
			J		
Date:					
	(mm/de	d/yyyy)			
11. The <u>f</u> hours		ny craving, that is,	how often I desired	this <b>second</b> drug in	the past 24
	Never	☐ Almost never	☐ Several times	☐ Regularly	☐ Almost constantly
12. The <u>le</u>	ength of time I	spent in craving f	or this <b>second</b> drug	during the past 24	hours was:
	None at all	☐ Very short	☐ Short	☐ Somewhat long	☐ Very long
Third D	)rug				
13. A <b>3<sup>rd</sup></b>	craved drug d lark <u>only one</u> of	during the past 24 l	nours was: <sup>3d</sup> craved drug, mark "l	None" and leave questi	ions 14-16 blank.
	None Alcohol	(Barbitu Heroin	urates, etc.) (\)	Benzos /alium, Xanax, etc.) Marijuana	☐ Nicotine ☐ Other Specify
14. The <u>ir</u> hours		craving, that is, he	ow much I desired t	his <b>third</b> drug in the	past 24
	None at all	☐ Slight	☐ Moderate	☐ Considerable	☐ Extreme
15. The <u>fi</u> hours		ny craving, that is,	how often I desired	this <b>third</b> drug in th	e past 24
	Never	☐ Almost never	☐ Several times	B Regularly	☐ Almost constantly
16. The <u>le</u>	ength of time I	spent in craving f	or this third drug du	iring the past 24 hou	urs was:
	None at all	☐ Very short	☐ Short	☐ Somewhat long	☐ Very long
Complete	ed by (Initials):				

### Form 30 - COCAINE SELECTIVE SEVERITY ASSESSMENT

**Treatment Week 3** 

	_	Site ID:		S	Subject II	<b>)</b> #.	_	Subjec	t Initials		Wee
Do	, to:										
Dö	ite:										
		(mm/dd/yyyy)									
iter	ns in lay l estion 4 a	s except 4 and 5 are ass language and the respo nd 5, the subject is aske questions. The rater th	nse is reco d to mark	orded on the appr	a scale of opriate pl	0-7 with ace on th	0 being n e line (on	ormal or ı page 3) tl	no sympto	oms. Fo	r
Da	te of las	t cocaine use:									
					(mm/dd/	yyyy)					
1.	Hyperp	hagia									
		: normal appetite I = eats a lot more than	ueual								
		eats more than twice		ount of fo	ood						
_	11	hania									
<b>Z.</b>	Hypopl	-									
		enormal appetite H = eats less than half o	f normal a	amount o	of food						
	7 =	no appetite at all									
3.	Carboh	nydrate Craving									
-		no craving									
	3-4	1 = strong craving for s									
	/ =	strong craving for swe	ets, cake	s, and co	ookies all	the time					
4.	Cocain	e Craving Intensity									
				Please	use subje	ct intensi	ty rating f	rom pg. 3	of this fo	rm.	
5.	Cocain	e Craving Frequenc	y 🗌								
				Please	use subje	ct freque	ncy rating	from pg.	3 of this f	orm.	
6.	Bradyc	ardia									
-	,			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.	Insomr	nia									
		normal amount of slee									
		l = half of normal amoւ ։ no sleep at all	int of siee	р							
8.	Hypers	omnia									
		normal amount of slee									
		l = could sleep or does sleep or could sleep a			/						

### Form 30 - COCAINE SELECTIVE SEVERITY ASSESSMENT

**Treatment Week 3** 

	Site ID:	Subject ID #.	Subject Initials	Weel
Da	te:		·	
	(mm/dd/yyyy)			
9.	Anxiety			
	0 = usually does not feel and 3-4 = feels anxious half the 7 = feels anxious all the time	time		
10.	Energy Level			
	0 = feels alert and has usual 3-4 = feels tired half the time 7 = feels tired all the time			
11.	Activity Level			
	0 = no change in usual activ 3-4 = participates in half of u 7 = no participation in usual	sual activities		
12.	Tension			
	0-1 = rarely feel tense 3-4 = feels tense half the tin 7 = feels tense most or all th			
13.	Attention			
	0 = able to concentrate on re 3-4 = has difficulty with the a 7 = has difficulty with the ab		l make plans without difficulty	
14.	Paranoid Ideation			
	0 = no evidence of paranoid 3-4 = unable to trust anyone 5 = feels people are out to g 7 = feels a specific person/g			
15	Anhedonia			
10.	0 = ability to enjoy themselve 3-4 = able to enjoy themselve 7 = unable to enjoy themselve	es half of the time		
16.	Depression			
	0 = no feelings related to sa 3-4 = feels sad or depressed 7 = feels depressed all of th	half the time		
17.	Suicidality			
	0 = does not think about bein 3-4 = feels like life is not wo 7 = feels like actually ending	th living		
18.	Irritability			
	0 = feels that most things ar 3-4 = feels that many things	are irritating		
Coi	7 = feels that mostly everyth mpleted by (Initials):	ng is irritating and upsetting		

NIDA-MDS-Mod	af-0001			Form	30 – C	OCA:	INE SE	LECT	TIVE SI			SSESSN ent W	
Date:	ite ID:	·)	]	Sub	ject ID	#.			Subject				eek
CSSA VISUAL ANA	ALOG SC	ALE											
Please do not mark on	upright line	es.											
Please rate the high	est intens	sity of tl	he des	ire for c	ocaine	you	have fe	elt in tl	he last	24 hou	rs:		
	<u> </u>	1 1	<u> </u>			I							
	No Desire at all						Unable t	to Resi	ist				

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

hours:

Form 28 - CLINICAL GLOBAL IMPRESSION - SELF NIDA-MDS-Modaf-0001 **Treatment 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?	

П	No problems
H	
ᆜ	Borderline problems
Ш	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

## Form 29 – CLINICAL GLOBAL IMPRESSION - OBSERVER

Treatment	Wool	- 3
i reatilient	VVEEK	

	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 <u>Severe</u>						Most <u>Severe</u>
Reporte	ed Cocaine Use: (frequency and amount of cocaine used)	1	2	3	4	5	6	7
Cocain	e Seeking: (craving for cocaine, effort to stop, and drug seeking behavior)	1	2	3	4	5	6	7
Reporte	ed Use of Other Drugs: (frequency and amount of non-cocaine drug/alcohol use)	1	2	3	4	5	6	7
Observ	rable Psychiatric Symptoms: (orientation, memory, comprehension, disorganized thinking, rapid/retarded speech, agitation, grooming, hostility, irritability, affective disturbance)	1	2	3	4	5	6	7
Reporte	ed 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
Physica	al/Medical Problems: (those that have emerged or gotten worse after drug use)	1	2	3	4	5	6	7
Malada	aptive Coping in the Family/Social area: (movement away from healthy relationships)	1	2	3	4	5	6	7
Malada	ptive 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

NIDA-MD	S-Modaf-0001	Form 29 - CLINICA	L GLOBAL IMPRESSION - OBSERVER
Date:	Site ID:	Subject ID #.	Subject Initials Week  Week
L	(mm/dd/yyyy) everity of Cocaine De	pendence	
Considering	-	ce with the cocaine depend	lent population, how severe are
	Normal, no symptoms Borderline symptoms Mild symptoms Moderate symptoms Marked symptoms Severe symptoms Most extreme symptoms	possible	
Rate the tot your judgme project, how	ent, it is due entirely to drug	cipant's cocaine dependenc	ce symptoms whether or not, in ne subject's admission to the
	Not assessed, first rating Very much improved Much improved Minimally improved No change Minimally worse Much worse Very much worse		

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 sul	pject		
Doses taken:			
Day of Week:	<u>Date</u> (mm/dd/yyyy)	Time Dose Taken	Dose Not Taken
Comments:	7		
Completed by (Initials):			

	Site ID:		Su	bject ID	#.		Treatme Subject Initials	mt Week 3
Date:	(mm/dd/yyyy)	L						
Did subje	ct receive standardized, mar	nual-gu	uided	individu	ıal psyd	chothe	erapy this week?	
(If No, ple	ease comment below)		Yes	;		No		
If yes, len	gth of psychotherapy sessio	n			minut	es		
	ct require emergency crisis ent sessions this week?		Yes	<b>3</b>		No		
If yes, ho	w many?							
Additional	I comments:							

|--|

	Site ID:	Subject	ID# Subje	Treatment Wee	
	Site ID.	Subject	IDπ. Subje	ect findais Wee.	<u> </u>
Date:	(mm/dd/yyyy)				
<u>Weekly</u>	Vital Signs				
☐ Vital_s	signs not assessed at th	is visit			
Date	(mm/dd/yyyy)		Time Vital Signs taker	(24 hour clock)	
Temperati	ure (oral) s for Temperature	(°F)	NR: 94-100.4	CS□ NCS□	
	essure (sitting)	(mm Hg)	NR: 90-140/50-90	CS □ NCS □	
Comment	s for Blood Pressure:				
Pulse Rat	·	eats/min)	NR: 50-120	CS □ NCS □	
Comment	s for Pulse Rate:				
Respirato	ry Rate (sitting)	(breaths/min)	NR: 8-20	CS □ NCS □	
Comment	s for Respiratory Rate:				
Complete	ed by (Initials):				

## Form 23 - URINE BE SPECIMEN COLLECTION FORM NIDA-MDS-Modaf-0001 **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) ☐ No Was urine temperature within expected range? ☐ Yes Franklin Cup: The temperature must be higher than 96.0 ° F and lower than 104.8 ° F On-

Trak Cup: The temperature must be <u>higher</u> than 90.0 ° F and <u>lower</u> than 99.0 ° F Split Sample Cup: The temperature must be <u>higher</u> than 90.0 ° F and <u>lower</u> than 100.0 ° F

#### Form 23 – URINE BE SPECIMEN COLLECTION FORM

**Treatment Week 4 V2** 

					11 Caunciic VV C		
	Site I	D:	Subject I	D#.	Subject Initials	Week	
Date:							
	(mm/do						
<u>Secono</u>	l Study Visi	t of Week	Urine bar cod	de sticker:			
Date urine	e collected:	(mm/dd/yyy	y)	Urin	e not collected		
FI Ti	ranklin Cup: The rak Cup: The ten	nperature must be	l range? It be <u>higher</u> than 96 I <u>higher</u> than 90.0° I be <u>higher</u> than 90.	F and lower than	99.0° F Split		
Complete	d by (Initials):						

Site ID:

## Form 23 – URINE BE SPECIMEN COLLECTION FORM

Subject ID #.

Subject Initials

Subject Initials

Subject Initials

Week

Date:								
	(mm/de	d/yyyy)						
Third St	tudy Visit (	of Week	Urine bar	code sticke	r:			
Date urine	collected:	(mm/dd/yy		]	Urine not collec	ted [		
Fr Tr	anklin Cup: The ak Cup: The ter	mperature must b	st be <u>higher</u> tha e <u>higher</u> than 9	0.0 ° F and <u>lowe</u>	☐ Yes <u>ower</u> than 104.8° F r_than 99.0° F Spli <u>wer</u> than 100.0° F	On-	0	
Completed	d by (Initials):							

#### Form 24 – SUBSTANCE USE INVENTORY

				Tre	eatment Week	4		
Site	ID:	Subject II	) #	Subject Initials	Week	_		
						j		
Date:								
	ld/yyyy)							
Using timeline follow-back		hothor subject has	on oach day sinco i	the last visit used a	ny amount of the si	ubstances listed be	Now along with the	most common routo
of administration for each	drug. Begin with y	esterday and work	back to the last vis	it. Please be sure th	hat days are contin	uous with last weel	k's form.	most common route
Date of last v	visit:							
	(mm/de	d/yyyy)						
Day of week								
Date								
	Used? ROA	Used? ROA	Used? ROA	Used? ROA	Used? ROA	Used? ROA	Used? ROA	
Cocaine	$\square$ Y/ $\square$ N $\square$	$\square$ Y/ $\square$ N $\square$	$\square$ Y/ $\square$ N					
Alcohol	□Y/ □N	□Y/ □N	□Y/ □N	$\square$ Y/ $\square$ 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 adminis	stration (ROA) codes	s: 1 = oral, 2 = nasa	l, 3 = smoking, 4 = 1	non-intravenous in	jection, 5 = intraver	nous injection		
Completed by (Initials):	:[							
. , ,	1							

	S	ite ID:	S	ubject II	D#.	_	Treatment Week 4 Subject Initials Week		
Date:						-			
	(mr	n/dd/yyyy) Value	Normal A	Abnorma	l* Abnorma Significant		Comments (required for abnormal values)		
1. Specific g	gravity								
2. pH									
3. Glucose									
4. Protein									
5. Ketones									
6. Occult Blo	ood								
7. WBC									
8. RBC									
9. Epithelial	Cells								
*"Ab	bnormal"	is any value outside	the normal l	aborator	ry range.				
For	Glucose,	Protein, Ketones, an	d Occult Blo	od use t	he followir	g scale	to report Values:		
	-1 = Absent 0 = Trace 1 2 3								
For		C, and Epithelial Cel	ls use the fo	llowing s	scale to rep	ort Valu	ves:		
	1 = None (1 - 5) 2 = Few (6 - 10) 3 = Moderate (11 - 50) 4 = Heavy (>50)								
☐ Check I	here if th	nis form is comple	eted for rete	est of pr	evious la	b tests			
Date of	original	lab tests:	(mm/da	d/yyyy)					
Completed b	by (Initia	ls):	•	,					

	Site ID:		S	ubject I	D#.		Treatment Week 4 Subject Initials Week	
				<b>y</b>	·			
<b>.</b>								
Date:	(mm/dd/y	yyy)						
	Value	)	Normal :	Abnorma	al* Abnormal Significant		Comments (required for abnormal values)	
1. Hemogl	obin	g/dL						
2. Hemato	crit	%						
3. RBC		M/uL						
4. Platelet	count	K/uL						
5. WBC		K/uL						
6. Neutrop	hils	%						
7. Lympho	cytes	%						
8. Monocy	tes	%						
9. Eosinop	hils	%						
10. Basop	hils	%						
Please refer to Appendix I of the protocol when determining the significance of abnormal values.   *"Abnormal" is any value outside the normal laboratory range. $million/uL = mil/cumm = mill/mcl = M/cmm = x10^6/cumm$								
						nm		
^	$x \cdot 10^3/uL = thou/cumm = thou/mcl = K/cmm = 1000/uL = x \cdot 10^3/cumm$							
☐ Check	k here if results	on this form are	retest	s of pre	evious lab	tests.		
Date o	of original lab tes	sts:	/m=	n/dd/\n	200			
			(1111)	n/dd/yy	<i>yy)</i>			

									atment Week 4
ī	S	ite ID:	_	Sı	ıbject ID	#.	-	Subject Initials	Week
Date:			<u> </u>				L		
	(m	m/dd/yyyy)							
	(			Niawaa al A	h	\	. Nat	Comments	
		Value		normai A	bnormal* / S	ignificant		Comments (Required for Abnorr	mal values)
1. Sodium			mmol/L						
2. Potassi	um		mmol/L						
3. Chloride	Э		mmol/L						
4. CO2			mmol/L						
5. Glucose	)		mg/dL						
6. Creatini	ne		mg/dL						
7. Albumin	1		g/dL						
8. Total pr	otein		g/dL						
9. SGOT/A	AST		U/L						
10. SGPT	/ALT		U/L						
11. GGT			U/L						
12. Bilirub	in		mg/dL						
13. BUN			mg/dL						
		o Appendix I o is any value o					ficance	of abnormal values.	
	mol/L = mE	-	วนเจเนษ เกษ	nomial i	aburatury	range.			
		ಞ೭ nis form is c	ompleted	for rete	st of pre	vious la	b tests.		
			-		· ·				
Date o	of original	iad tests			(mm/dd/y	ууу)			

								atment W	eek 4
İ	Site ID:	_	Sı	ıbje	et ID#.	Subjec	ct Initials	W	eek
Date:	(mm/dd/yyyy)								
A. ECG o	overall results were:		o <u>rmal</u> normal						
If E	ECG is Normal please skip	to Ques	stion C.						
B. If ECG i	s abnormal, check belov	v for <u>a</u>	<u>ll</u> abnormali	ties.					
	<u>Abn</u>	<u>ormal</u>	Abnormal Significant				<u>Abnormal</u>	Abnormal Significant	
1. Increase	ed QRS voltage			17.	Supraventricular pre	emature b	eat $\square$		
2. Qtc prole	ongation			18.	Ventricular prematu	ire beat			
3. Left atria	al hypertrophy			19.	Supraventricular tad	chycardia			
4. Right atı	rial hypertrophy			20.	Ventricular tachyca	rdia			
5. Left vent	tricular hypertrophy			21.	Atrial fibrillation				
6. Right ve	ntricular hypertrophy			22.	Atrial flutter				
7. Acute in	farction			23.	Other rhythm abnor	malities			
8. Subacut	e infarction			24.	Implanted pacemak	ær			
9. Old infai	rction			25.	1 <sup>st</sup> degree A-V bloc	k			
10. Myoca	rdial ischemia			26.	2 <sup>nd</sup> degree A-V bloc	k			
11. Digitali	s effect			27.	3 <sup>rd</sup> degree A-V bloc	k			
12. Symme	etrical T-wave inversions			28.	LBB block				
13. Poor R	-wave progression			29.	RBB block				
14. Other r	nonspecific ST/T			30.	Pre-excitation synd	rome			
15. Sinus t	achycardia			31.	Other intraventricula	ar conditio	n 🗆		
16. Sinus b	oradycardia			32.	Other, specify				
C. Ventricu	ular rate (bpm)			Ε.	QRS (ms)				
D. PR (ms	)			F.	QTC (ms)				
	nere any abnormal			ove	that preclude the	he subje ∐No		safe entry	y

				nt Week 4
	Site ID:	Subject ID #.	Subject Initials	Week
Date:	(mm/dd/yyyy)			
Comments:				

					Tre	eatment Week 4
	Site	ID:	Subject ID	<u>#.</u>	Subject Initials	Week
Date:						
Date.						
0		ld/yyyy				
<u>Cocaine</u>	_			di i 4b	t O.4 h	
		-	ow much I desire		•	
	None at all	☐ Slight	☐ Moderate	☐ Conside	rable	treme
2. The <u>fre</u>	quency of my	y craving, that is	how often I desir	ed cocaine in th	ne past 24 hours	was:
	Never	☐ Almost never	☐ Several t	imes 🗌 R	egularly $\Box$	Almost constantly
3. The <u>len</u>	gth of time I	spent craving fo	cocaine during th	ne past 24 hour	s was:	
	None at all	☐ Very sho	rt 🔲 Short	☐ Somewl	nat long	Very long
4. Write in	the <u>number</u>	of times you thir	ık you had cravinç	g for cocaine du	ring the past 24	hours:
5. Write ir			cocaine during the	e past 24 nours	:	
	hours	minutes				
6. The <u>wo</u>	<u>rst</u> day: Dur	ing the past wee	k my most intense	e craving occuri	ed on the following	ng day:
	Sunday Thursday	☐ Monday ☐ Friday	☐ Tuesday ☐ Saturday	☐ Wednesday ☐ All days the sa	ame (go to Q. 8)	
	,	,			()	
7. The da	te for that da		(mm/dd/yyyy)			
			(ITIITI/GG/yyyy)			
8. The inte	ensity of my	craving, that is, h	now much I desire	d cocaine on th	at worst day was	<b>S</b> :
	None at all	☐ Slight	☐ Moderate	☐ Conside	rable	treme
<u>Secono</u>	l Drug					
9. A <b>2<sup>nd</sup> c</b> <i>M</i>	raved drug d ark <u>only one</u> o	uring the past 24 fthe following. If n	hours was: o 2 <sup>nd</sup> craved drug, ma	ark "None" and le	ave Questions 10-1	6 blank.
	None		vners or Sedatives	Benzos	☐ Nico	otine
	Alcohol	☐ Her	biturates, etc.) oin or other Opiates phine, etc.)	(Valium, Xanax Marijuana	, etc.) \[ Other \] Spec	
10. The <u>in</u> hours		craving, that is,	how much I desir	ed this <b>second</b>	drug in the past	24
	None at all	☐ Slight	☐ Moderate	☐ Conside	rable	treme

	Site	ID·	Subject ID#.		Subject 1		ent Week 4 Week
	Site	ID.	Subject ID #.		Subject	initials	WCCK
Date:							
	(mm/d	ld/yyyy					
_	requency of m s was:	ny craving, that is,	how often I desire	ed this <b>secor</b>	າ <b>d</b> drug in t	he past 24	
	□ Never	☐ Almost never	☐ Several time	es 🗆 F	Regularly	☐ Almos	t constantly
12. The <u>le</u>	ength of time	spent in craving for	or this <b>second</b> dr	ug during the	e past 24 h	ours was:	
	☐ None at all	☐ Very short	☐ Short	☐ Somew	/hat long	☐ Very lo	ng
Third D	<u> Prug</u>						
13. A <b>3<sup>rd</sup></b>	craved drug o Mark <u>only one</u> of	during the past 24 l	nours was: f <sup>d</sup> craved drug, mark	"None" and le	ave question	ns 14-16 blank.	
	☐ None	(Barbitu	ers or Sedatives urates, etc.) or other Opiates ine, etc.)	Benzos (Valium, Xana: Marijuana	x, etc.)	☐ Nicotine ☐ Other Specify	
	ntensity of my was:	craving, that is, ho	ow much I desired	I this <b>third</b> d	rug in the p	oast 24	
	☐ None at all	☐ Slight	☐ Moderate	☐ Conside	erable	☐ Extreme	
	requency of m was:	ny craving, that is,	how often I desire	ed this <b>third</b> (	drug in the	past 24	
	Never	☐ Almost never	☐ Several time	es 🗆 F	Regularly	☐ Almos	t constantly
16. The <u>le</u>	ength of time	spent in craving f	or this third drug o	during the pa	ast 24 hours	s was:	
	☐ None at all	☐ Very short	☐ Short	☐ Somew	/hat long	☐ Very lo	ng
Complete	ed by (Initials):						

## Form 30 - COCAINE SELECTIVE SEVERITY ASSESSMENT

	Site ID:	S	Subject ID #.	Subje	ct Initials	Week
		<u> </u>				
Da	ate:					
	(mm/dd/yyyy)			<b>-</b>		
ite	l questions except 4 and 5 are asse ms in lay language and the respon estion 4 and 5, the subject is asked the questions. The rater the	se is recorded on I to mark the appr	a scale of 0-7 with opriate place on th	0 being normal or e line (on page 3) t	no symptoms. Fo	or
Da	ate of last cocaine use:		tuo ine response i			
De	ate of last cocalife use.		(mm/dd/yyyy)			
1.	Hyperphagia					
	0 = normal appetite 3-4 = eats a lot more than 7 = eats more than twice u		ood			
2.	Hypophagia					
	0 = normal appetite 3-4 = eats less than half of 7 = no appetite at all	normal amount o	of food			
3.	Carbohydrate Craving					
	0 = no craving 3-4 = strong craving for sw 7 = strong craving for swee					
4.	Cocaine Craving Intensity	Please	use subject intensi	ity rating from pg. :	3 of this form.	
5.	Cocaine Craving Frequenc		use subject freque	ncy rating from pg	. 3 of this form.	
6.	Bradycardia	Please	use scale bel ow.			
	Pulse (BPM)	0 1 >64 64-63	2 3 62-61 60-59	4 5 58-57 56-55	6 7 54-53 <53	
7.	Insomnia					
	0 = normal amount of slee 3-4 = half of normal amount 7 = no sleep at all					
8.	Hypersomnia					
	0 = normal amount of slee 3-4 = could sleep or does 7 = sleep or could sleep a	sleep half the day	y			

## Form 30 - COCAINE SELECTIVE SEVERITY ASSESSMENT

		Site II	D:		Subject ID #.		Subject Initi	als	Week
Da	te:								
0	Anvio	(mm/dd	/уууу)						
9.	<b>Anxie</b> 0	t <b>y</b> = usually does r	not feel anxious						
	3	-4 = feels anxioι	is half the time						
	/	= feels anxious	all the time						
10.	Ener	gy Level							
		= feels alert and -4 = feels tired h		ount of	energy				
	_	= feels tired all							
11.	Activ	rity Level							
	0	= no change in							
		<ul><li>-4 = participates</li><li>= no participation</li></ul>			es				
40	Tens								
12.		-1011 -1 = rarely feel to	ense						
	3	-4 = feels tense	half the time						
	/	= feels tense m	ost or all the til	ne ——	ı				
13.		ntion							
		= able to conce -4 = has difficult			versation, tasks, a he time	and make pl	ans without diffic	ulty	
		= has difficulty							
14.	Para	noid Ideation							
		= no evidence o		ughts					
	5	-4 = unable to tr = feels people a	ire out to get h						
	7	= feels a specifi	c person/group	is plot	ting against him/h	er			
15.	Anhe	edonia							
		= ability to enjoy -4 = able to enjo							
		= unable to enjo			io timo				
16.	Depr	ession							
	0	= no feelings re							
		<ul><li>-4 = feels sad or</li><li>= feels depress</li></ul>			ne				
17	Suic	idality							
17.		idality							
		= does not think -4 = feels like life							
		= feels like actu			ı				
18.	Irrita	bility							
		= feels that mos							
		-4 = feels that m = feels that mos			g ing and upsetting				
C	molete	d by (Initiala):			_				
COI	iihieie	d by (Initials):							

N	ID	$\Delta - \Lambda$	<b>IDS</b>	M	րկո	f_N	<b>00</b> 1
Τ.	w	/ <b>7</b> -11		7 T Y L	vua	T-N	UU.

#### Form 30 - COCAINE SELECTIVE SEVERITY ASSESSMENT

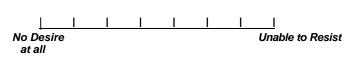
Treatment Week 4

			Heath	iciit vvccis -
	Site ID:	Subject ID #.	Subject Initials	Week
Date:				
	(mm/dd/yyyy)			

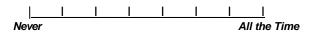
#### CSSA VISUAL ANALOG SCALE

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:



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



NIDA-MDS-Modaf-0001	Form 28 – CLI	NICAL GLOBAL IMPRE	SSION - SELF			
		Treatment Wee				
Site ID:	Subject ID #.	Subject Initials	Week			
Date:						
(mm/dd/yyyy)						
Cocaine Global Severity						
At this time, how would you rate y and cocaine related problems?	ourself overall for cocaine use					
☐ No 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?

Ш	Not assessed
	Very much improved
	Much improved
	Minimally improved
	No change
	Minimally worse
	Much worse
	Very much worse

Completed by (Initials):

			1 reatm	ent week
	Site ID:	Subject ID #.	Subject Initials	Week
Date:				
Date.				
	(mm/dd/yyyy)			

# **Current Severity**

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

		None, Least <u>Severe</u>						Most Severe
Report	red Cocaine Use: (frequency and amount of cocaine used)	1	2	3	4	5	6	7
Cocain	ne Seeking: (craving for cocaine, effort to stop, and drug seeking behavior)	1	2	3	4	5	6	7
Report	red Use of Other Drugs: (frequency and amount of non-cocaine drug/alcohol use)	1	2	3	4	5	6	7
Observ	vable Psychiatric Symptoms: (orientation, memory, comprehension, disorganized thinking, rapid/retarded speech, agitation, grooming, hostility, irritability, affective disturbance)	1	2	3	4	5	6	7
Report	ted Psychiatric Symptoms: (mood disturbance, depression, anxiety,inner restlessness, covert anger, somatic symptoms energy level,motivation, sleep, appetite, libido, anhedonia)	s, 1	2	3	4	5	6	7
Physic	al/Medical Problems: (those that have emerged or gotten worse after drug use)	1	2	3	4	5	6	7
Malada	aptive Coping in the Family/Social area: (movement away from healthy relationships)	1	2	3	4	5	6	7
Malada	aptive 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:	Sub	ject ID#.	Subject Ini	tials	Week
D-4						
Date:						
	(mm/dd/yyyy)					
	(IIIII/GG/yyyy)					
Clobal S	coverity of Coesins	Donandana	•			
<u>Giobal S</u>	Severity of Cocaine	<u>Dependenc</u>	<u>e</u>			
	g your total clinical expe			nt population, ho	w severe are	
this subjec	t's cocaine dependence	symptoms at the	nis time?			
	Normal, no symptoms					
	Borderline symptoms Mild symptoms					
	Moderate symptoms					
	Marked symptoms					
	Severe symptoms  Most extreme symptom	ns possible				
	, ,	·				
Global lı	mprovement of Cod	aine Depen	dence			
	-	-				
	otal improvement in the patent, it is due entirely to					
project, ho	N	3	·	•		
much has	the subject changed?					
	Not assessed, first rat	ng				
	Very much improved Much improved					
	Minimally improved					
	No change					
	Minimally worse Much worse					
	Very much worse					
		7				
Completed	by (Initials):					

## Form 15 – HAMILTON DEPRESSION RATING SCALE

	Site ID:	Subject ID #.	Subject Initials Week
Datas			
Date:			
	(mm/dd/yyyy)		
1. Depres	sed Mood		
	ad, hopeless, helpless, worthles	ss)	
Ļ	0 = Absent	indicated only on avectioning	_
		indicated only on questioning spontaneously reported verb	
		ng states nonverbally – i.e., th	
		ally only these feeling states i	n his/her spontaneous
2. Feeling		communication.	
Z. 1 CCIII19	0 = Absent		
	1 = Self-reproach, feels	s/he has let people down.	
		nation over past errors or sin	
Ļ		ounishment. Delusions of guilt	
L	4 = Hears accusatory or visual hallucinations.	denunciatory voices and/or e	experiences threatening
3. Suicide	)		
	0 = Absent		
L	1 = Feels life is not worth		la danth ta galf
	3 = Suicide ideas or gest	ead or any thoughts of possib	ie death to seii.
		any serious attempt rates 4).	
4. Insomn		, ,	
	0 = No difficulty falling as		
L		onal difficulty falling asleep. (	(i.e., more than ½ hour)
5. Insomn	2 = Complains of nightly	difficulty falling asleep.	
J. 111501111	0 = No difficulty.		
	_	f being restless and disturbed	during the night.
		ght – any getting out of bed r	
6. Insomr	nia Late		
Г	0 = No difficulty.		
	☐ 1 = Waking in early hour	s of the morning but goes ba	ck to sleep.
	2 = Unable to fall asleep	again if gets out of bed.	

## Form 15 – HAMILTON DEPRESSION RATING SCALE

_	Site ID:	Subject ID #.	Subject Initials	Weel
Date:				
	(mm/dd/yyyy)			
7. Work an	d Activities			
	work or hobbies.  2 = Loss of interest in indirect in listlessr work or activities).	activity; hobbies or work – eit ness, indecision and vacillation	weakness related to activities; her directly reported by patient, on (feels s/he has to push self to	or
		al time spent in activities or de because of present illness.	crease in productivity.	
8. Retarda		·		
		at interview	e; decreased motor activity)	
9. Agitation	1			
	0 = None 1 = Fidgetiness 2 = Playing with hanc 3 = Moving about, ca 4 = Hand-wringing, na		lips	
10. Anxiety	/ Psychic			
	<ul><li>0 = No difficulty</li><li>1 = Subjective tension</li><li>2 = Worrying about m</li><li>3 = Apprehensive atti</li><li>4 = Fears expressed</li></ul>	inor matters tude apparent in face or speed	ch	
dia	nysiological concomitants o		al: dry mouth, wind, indigestion, aches. Respiratory: hyperventilation,	
	0 = Absent 1 = Mild 2 = Moderate 3 = Severe 4 = Incapacitating			
12. Somati	c Symptoms Gastrointe	estinal		
	2 = Difficulty eating w		ent. Heavy feelings in abdomen. juires laxatives or medication for	

## Form 15 – HAMILTON DEPRESSION RATING SCALE

_	Site ID:	Subject ID #.	Subject Initials	Week
Date:				
13. Somat	(mm/dd/yyyy) ic Symptoms General 0 = None 1 = Heaviness in limb energy and fatiga 2 = Any clear-cut sym		dache, muscle aches. Loss	; of
14. Genita (sı   	Symptoms  och as loss of libido and me  0 = Absent 1 = Mild 2 = Severe	nstrual disturbances)		
15. Hypoc	hondriasis			
16. Loss o	4 = Hypochondriacal	th health nts, requests for help, etc.		
		oss associated with present illnes ss (according to subject)	SS.	
	virus, need for res 2 = Denies being ill at	ness but attributes cause to bad forther, etc.	ood, climate, overwork,	
	0 = No variation 1 = (Mild) Doubtful or 2 = (Severe) Clear or If answer is 1 or 2		e worse in: O A.M. O P.M.	
	sonalization and Dereali Imptoms such as feelings o	ization f unreality and nihilistic ideas)		
	0 = Absent 1 = Mild 2 = Moderate 3 = Severe 4 = Incapacitating			

## Form 15 – HAMILTON DEPRESSION RATING SCALE

	Site ID:	Subject ID #.	Subject Initials	Weel
Date:				
	(mm/dd/yyyy)			
20. Parano	oid Symptoms			
	0 = None 1 = Suspicious 2 = Ideas of reference 3 = Delusions of reference	e rence and persecution		
21. Obses	sive and Compulsive Sy	mptoms		
	0 = Absent 1 = Mild 2 = Severe			
22. Helple	ssness			
	2 = Subject volunteer 3 = Requires urging, personal hygiene.	is which are elicited only by inquiry s his helpless feelings. guidance and reassurance to accordes not perform necessary chores	mplish chores or	
23. Hopele	essness			
	2 = Consistently feels 3 = Expresses feeling which cannot be of	bts that "things will improve" but ca "hopeless" but accepts reassuran- is of discouragement, despair, pes dispelled. Ind inappropriately perseverates, "I'l	ces. simism about future,	
		esteem, feelings of inferiority, self-depr ness)	eciation (loss of self-esteem) to	o
	2 = Spontaneously in 3 = Different from 2 b etc.	of worthlessness (loss of self este dicates feelings of worthlessness (l y degree: Subject volunteers that s ys of total worthlessness – e.g. "I ar	loss of self esteem). s/he is "no good," "inferior,"	,
Completed	hy (Initials):	¬		

			Treatn	nent Week 4
	Site ID:	Subject ID #.	Subject Initials	Week
Date:				
	(mm/dd/yyyy)			
Date dose	es dispensed ach dose is four tablets	(mm/dd/yyyy)	)	
Kit Numbe	er:			
Bottle Nur	mber:			
Number o	f doses dispensed			
Date unus	sed doses returned	(mm/dd/yyyy)	)	
Number o	of doses returned			
Number o	f doses reported lost by sub	ject		
Doses tak	en:			
	Day of Week:	<u>Date</u>	Time	Dose
		(mm/dd/yyyy)	Dose Taken	Not Taken
Comment	S:			
Complete	d by (Initials):	7		

Γ	Site ID:						ent Wee
		_	Subject ID #	<i>‡</i> .		Subject Initials	Week
Date:							
Lid subject	(mm/dd/yyyy) receive standardized, mar	nual-gu	uided individu	al psyd	chothe	rapy this week?	
(If No, pleas	se comment below)		Yes		No		
lf yes, lengt	h of psychotherapy sessio	n		minu	ites		
	require emergency crisis nt sessions this week?		Yes		No		
If yes, how	many?						
Additional c	comments:						

Completed by (Initials):

## Form – 14 BIRTH CONTROL/PREGNANCY ASSESSMENT

			Treatm	ent Week 4
	Site ID:	Subject ID #.	Subject Initials	Week
Date:				
	(mm/dd/yyyy)	4		
		<u>male subjects only</u> . All fema egative pregnancy test in or		
What me	ethod of birth control is the p	participant currently using (price	or to taking modafinil)?	
	☐ Oral contraceptive			
	☐ Barrier (diaphragm o	or condom plus spermicide)		
	Levonorgestrel impl	ant (Norplant)		
	☐ Intrauterine Contrac	eptive system (IUD)		
	_	ne Acetate Contraceptive inje	ction (Depo-Provera)	
		•		
ļ	Surgical Sterilization	ı - Tubal ligation		
		ostmenopausal, does the sub udy and 30 days after last dos No		able
If yes, m	nark below the acceptable m	ethod selected by the subject	for use:	
	barrier method with	spermicide		
	steroidal contracept in conjunction with a	ive [oral, Implanted, injected] a barrier method	used	
	☐ Contraceptive patch	used in conjunction with a ba	arrier method	
	☐ Intrauterine device [	IUD]		
Was a p	regnancy test performed?	☐ Yes	□ No	
	If yes, date specimen collect		(dd/yyyy)	
	Result: Negative	Positive Unkn	own	
	If no, specify reason:			
Is the su	bject lactating?	Yes 🗆 No		
Commer	nts:			
Complet	ed by (Initials):			

	Site ID: Subject 1		ID# Subi	Treatment We ect Initials Wee	Week 5 Week	
Date:						
	(mm/dd/yyy)	<i>(</i> )				
<u>Weekly</u>	Vital Signs					
☐ Vital s	signs not assessed (mm/dd/yyyy		Time Vital Signs take	n (24 hour clock)		
Temperat	ure (oral)	(°F)	NR: 94-100.4	CS □ NCS □		
	essure (sitting)	(mm Hg)	NR: 90-140/50-90	CS NCS		
	te (sitting)	(beats/min)	NR: 50-120	CS NCS		
	ry Rate (sitting)	(breaths/min)	NR: 8-20	CS NCS		
Complete	ed by (Initials):					

First Study Visit of Week

Date:

## Form 23 – URINE BE SPECIMEN COLLECTION FORM

Site ID:

Subject ID #.

Subject Initials

Week

(mm/dd/yyyy)

Date urine collected:	(mm/dd/yyyy)	Urine not collected	
Franklin Cup: The Trak Cup: The te Sample Cup: The	mperature must be <u>higher</u> than 90. e temperature must be <u>higher</u> than	☐ Yes n 96.0° F and <u>lower</u> than 104.8° F On- .0° F and <u>lower</u> than 99.0° F Split 90.0° F and <u>lower</u> than 100.0° F	□ No
Completed by (Initials):			

Urine bar code sticker:

Completed by (Initials):

#### Form 23 - URINE BE SPECIMEN COLLECTION FORM

**Treatment Week 5 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

# Form 23 – URINE BE SPECIMEN COLLECTION FORM Treatment Week 5 V3

				Treatment	t Week 5 V
Site	ID:	Subject ID	#.	Subject Initials	Week
Date:					
(mm/d	ld/yyyy)				
Third Study Visit	of Week	Urine bar code	sticker:		
Date urine collected:	(mm/dd/yyy	yy)	Urine	not collected	
Trak Cup: The te	ne temperature mus emperature must be	d range? st be <u>higher</u> than 96.0° e <u>higher</u> than 90.0° F a st be <u>higher</u> than 90.0°	and <u>lower</u> than 9	9.0° F Split	
Completed by (Initials)	: []				

#### Form 24 – SUBSTANCE USE INVENTORY

				Tre	eatment Week	5			
Site 1	ID:	Subject II	) #.	Subject Initials	Week	7			
Date:						J			
(mm/de	d/yyyy)								
Ising 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 v	isit:								
	(mm/de	d/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	$\square$ Y/ $\square$ N	□Y/ □N	□Y/ □N	□Y/ □N	□Y/ □N	$\square$ Y/ $\square$ N	□Y/ □N		
Amphetamines	$\square$ Y/ $\square$ N	$\square$ Y/ $\square$ N	□Y/ □N	$\square$ Y/ $\square$ N	$\square$ Y/ $\square$ N	$\square$ Y/ $\square$ 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	$\square$ Y/ $\square$ N	$\square$ Y/ $\square$ N	□Y/ □N	□Y/ □N		
Benzodiazepines	□Y/ □N	□Y/ □N	□Y/ □N	□Y/ □N	$\square$ Y/ $\square$ N $\square$	□Y/ □N	□Y/ □N		
Route of adminis	tration (ROA) codes	s: 1 = oral, 2 = nasa	l, 3 = smoking, 4 = 1	non-intravenous in	jection, 5 = intraver	nous injection			
Completed by (Initials):									
	1								

						Treatme	nt Week
	Site II	D:	Subject ID	) #. <u> </u>	Subject	Initials	Week
_							
Date:							
	(mm/dd	/уууу)					
Cocaine	e						
		aving that is h	ow much I desire	ed cocaine in th	e nast 24	hours was:	
_	_	-				_	
L	None at all	☐ Slight	☐ Moderate	☐ Conside	rable	☐ Extreme	
2. The fre	quency of my	craving, that is,	how often I desi	red cocaine in t	he past 24	4 hours was:	
	Never [	☐ Almost never	☐ Several t	times 🔲 F	Regularly	☐ Almost	constantly
3. The ler	nath of time I s	pent craving for	cocaine during t	he past 24 hou	rs was:		
	_		J	·		□ \/am.la.	
L	None at all	☐ Very shor	t 🗌 Short	☐ Somew	nat long	☐ Very lo	ng
4. Write in	n the <u>number</u> o	f times you thin	k you had cravin	g for cocaine d	uring the p	ast 24 hours:	
5 Write in	— o the total time	spent craving o	ocaine during th	e nast 24 hours	2.		
5. WITE II		Spent craving c	ocame during in	e past 24 flours	<b>).</b>		
	hours	minutes					
6. The wo	orst day: Durin	g the past week	my most intens	e craving occur	red on the	e following day	<b>/</b> :
Г	Sunday	☐ Monday	☐ Tuesday	☐ Wednesday			
	Thursday	Friday	☐ Saturday	All days the s	ame (go to 0	Q. 8)	
7. The da	te for that day						
		(m	m/dd/yyyy)				
8. The <u>int</u>	ensity of my cr	aving, that is, h	ow much I desire	ed cocaine on t	nat worst	day was:	
Г	None at all	☐ Slight	☐ Moderate	☐ Conside	erable	☐ Extreme	
_		_ og			,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		
Second	l Drug						
9. A <b>2<sup>nd</sup></b> c	raved drug dui	ring the past 24	hours was:				
M	lark <u>only one</u> of t	he following. If no	2 <sup>nd</sup> craved drug, m	nark "None" and le	ave Questi	ons 10-16 blank	
	None	☐ Dow	ners or Sedatives	Benzos		☐ Nicotine	
Г	Alcohol		iturates, etc.) in or other Opiates	(Valium, Xana:	x, etc.)	Other	
	1 Alcohol		phine, etc.)	□ Manjuana		Specify	
10. The <u>ir</u>	ntensity of my	craving, that is,	how much I desi	red this <b>second</b>	drug in th	ne past 24	
hours	was:						
Г	None at all	☐ Slight	☐ Moderate	☐ Conside	erable	☐ Extreme	

						Treatme	nt Week 5
	Site	ID:	Subject ID#		Subject In	nitials	Week
Date:							
Date.							
	(mm/d	ld/yyyy)					
	(///////	~, <i>, , , , ,</i>					
11. The fi		ny craving, that is, I	now often I desire	ed this <b>secon</b>	d drug in the	e past 24	
	Never	☐ Almost never	☐ Several tim	nes 🗆 R	Regularly	☐ Almost	constantly
12. The <u>le</u>	ength of time	I spent in craving for	or this <b>second</b> di	rug during the	past 24 ho	urs was:	
	☐ None at all	☐ Very short	☐ Short	☐ Somew	hat long	☐ Very lor	ng
Third D	)rug						
rd							
13. A <b>3</b> <sup>14</sup>	craved drug o flark <u>only one</u> of	during the past 24 h fthe following. If no 3	ours was: <sup>d</sup> craved drug, mar	k "None" and le	ave questions	s 14-16 blank.	
	None		rs or Sedatives	Benzos	. [	Nicotine	
	Alcohol		rates, etc.) or other Opiates	(Valium, Xanax □ Marijuana	t, etc.)	Other	
		(Morphi	ne, etc.)	•		Specify	
14. The <u>ir</u> hours		craving, that is, ho	w much I desire	d this <b>third</b> dr	ug in the pa	st 24	
	☐ None at all	☐ Slight	☐ Moderate	☐ Conside	rable [	☐ Extreme	
15. The <u>fr</u> hours		ny craving, that is, I	now often I desire	ed this <b>third</b> o	Irug in the p	ast 24	
	Never	☐ Almost never	☐ Several tim	nes 🗆 R	egularly	☐ Almost	constantly
16. The le	ength of time	I spent in craving for	or this third drug	during the pa	st 24 hours	was:	
	<del>_</del>	,	J				
L	☐ None at all	☐ Very short	☐ Short	☐ Somew	nat long	☐ Very lo	ıg
Complete	ed by (Initials):	:					

(mm/dd/yyyy)

Date:

#### Form 30 - COCAINE SELECTIVE SEVERITY ASSESSMENT

				Treat	men	t Week 5
Site ID:	_	Subject ID #.	_	Subject Initials		Week
			1		1 [	
			_			

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.

qu	estion 4 and 5, the subject is asked to the questions. The rater then t							at descrii	bes eac
Da	ate of last cocaine use:								
1.	Hyperphagia			(mm/dd/	'YYYY)				
	0 = normal appetite 3-4 = eats a lot more than usu 7 = eats more than twice usua		ount of fo	ood					
2.	Hypophagia								
	0 = normal appetite 3-4 = eats less than half of no 7 = no appetite at all	rmal	amount	of food					
3.	Carbohydrate Craving								
	0 = no craving 3-4 = strong craving for sweet 7 = strong craving for sweets,								
4.	Cocaine Craving Intensity		Please	use subje	ct intensi	ty rating f	rom pg. 3	of this fo	rm.
5.	Cocaine Craving Frequency		Please	use subje	ct freque	ncy rating	from pg.	3 of this f	orm.
6.	Bradycardia		Please	use scale	below.				
	Pulse (BPM) >6	-	1 64-63	2 62-61	3 60-59	4 58-57	5 56-55	6 54-53	7 <53
7.	Insomnia		7						
	0 = normal amount of sleep 3-4 = half of normal amount o 7 = no sleep at all	f slee	⊒ ep						
8.	Hypersomnia		7						
	0 = normal amount of sleep 3-4 = could sleep or does s lee 7 = sleep or could sleep all th			/					

## Form 30 - COCAINE SELECTIVE SEVERITY ASSESSMENT

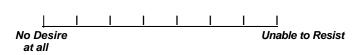
	Site ID:		Subject ID #.	Subject Initials	Week
Date	).				
Daic	<del>.</del>				
	(mm/dd/sss				
	(mm/dd/yyy)	y)			
9. /	Anxiety				
	0 = usually does not fe 3-4 = feels anxious ha				
	7 = feels anxious all th				
10.	Energy Level				
	0 = feels alert and has 3-4 = feels tired half th 7 = feels tired all the ti	ne time	of energy		
11.	Activity Level				
	0 = no change in usua	l activities			
	3-4 = participates in ha 7 = no participation in t		ities		
12.	Tension				
	0-1 = rarely feel tense	ula a di ua a			
	3-4 = feels tense half t 7 = feels tense most o				
12	Attention				
75.		e on reading, co	nversation, tasks, and r	make plans without difficulty	
	3-4 = has difficulty with 7 = has difficulty with t				
	•	ne above an the			
14.	Paranoid Ideation				
	0 = no evidence of par 3-4 = unable to trust a				
	5 = feels people are or 7 = feels a specific per				
	r = leels a specific per	301//group is pi			
15.	Anhedonia	maaluaa ramain	Lunchanged		
	0 = ability to enjoy ther 3-4 = able to enjoy the	mselves half of			
	7 = unable to enjoy the	emselves at all			
16.	Depression				
	0 = no feelings related 3-4 = feels sad or depi				
	7 = feels depressed al		ame		
17.	Suicidality				
	0 = does not think abo				
	3-4 = feels like life is n 7 = feels like actually e	-			
18.	Irritability				
	0 = feels that most thir				
	3-4 = feels that many t 7 = feels that mostly ev				
_		, , ,	5 1 5		
Con	npleted by (Initials): L				

NIDA-MDS-Modaf-0001		Form 30 – COCAINE SELECTIVE SEVERITY ASSESSMENT  Treatment Week 5				
_	Site ID:	Subject ID #.	Subject Initials	Week		
Date:						
	(mm/dd/yyyy)					

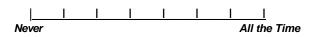
## CSSA VISUAL ANALOG SCALE

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:



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



#### Form 28 - CLINICAL GLOBAL IMPRESSION - SELF

NIDA-MDS-Modaf-0001 **Treatment Week 5** Week Site ID: Subject ID #. **Subject Initials** Date: (mm/dd/yyyy) **Cocaine Global Severity** 

At this time,	how woul	d you r	ate you	rself ov	verall f	or cocai	ne ι	ıse
and cocaine	related p	roblems	s?					

- 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):

			Treatn	nent Week
	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 <u>Severe</u>					-	Most <u>Severe</u>
Report	ed Cocaine Use: (frequency and amount of cocaine used)	1	2	3	4	5	6	7
Cocain	e Seeking: (craving for cocaine, effort to stop, and drug seeking behavior)	1	2	3	4	5	6	7
Report	ed Use of Other Drugs: (frequency and amount of non-cocaine drug/alcohol use)	1	2	3	4	5	6	7
Observ	vable Psychiatric Symptoms: (orientation, memory, comprehension, disorganized thinking, rapid/retarded speech, agitation, grooming, hostility, irritability, affective disturbance)	1	2	3	4	5	6	7
Report	ed Psychiatric Symptoms: (mood disturbance, depression, anxiety,inner restlessness, covert anger, somatic symptoms energy level,motivation, sleep, appetite, libido, anhedonia)	s, 1	2	3	4	5	6	7
Physic	al/Medical Problems: (those that have emerged or gotten worse after drug use)	1	2	3	4	5	6	7
Malada	aptive Coping in the Family/Social area: (movement away from healthy relationships)	1	2	3	4	5	6	7
Malada	aptive 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

			Treatmen	t Week 5
	Site ID:	Subject ID #.	Subject Initials	Week
Date:				
l	(mm/dd/yyyy)			
_				
Global S	Severity of Cocaine	<u>Dependence</u>		
			endent population, how severe are	Э
this subject	ct's cocaine dependence	symptoms at this time?		
	Normal, no symptoms			
	Borderline symptoms Mild symptoms			
	Moderate symptoms			
	Marked symptoms Severe symptoms			
		ns possible		
Global I	mprovement of Cod	caine Dependence		
			dence symptoms whether or not, ir	1
your judgn project, ho		drug treatment. Compared	to the subject's admission to the	
	the subject changed?			
	Not assessed, first rat	ng		
	Very much improved Much improved			
	Minimally improved			
	No change Minimally worse			
	Much worse			
	Very much worse			
Completed	d by (Initials):			

	Site ID:	Subject ID #.	Subject Initials	ent Week Week
	Site ID.	Subject ID #.	Subject linuals	WCCK
Date:				
Į	( (111 )			
	(mm/dd/yyyy)			
Data dasa	- diamanaad			
Ea	s dispensed ach dose is four tablets	(mm/dd/yyyy)		
Kit Numbe	r:			
Bottle Num	nber:			
Number of	doses dispensed			
Date unus	ed doses returned	(mm/dd/yyyy)		
Number of	doses returned			
Number of	doses reported lost by subject			
Doses take	en:			
	Day of Week:	<u>Date</u>	Time	Dose
	•		Dose Taken	Not Taken
		(mm/dd/yyyy)	Taken	Taken
Comments	<u> </u>			
Completes	I by (Initials):			
Completed	i by (IIIIIais).			

## Form 34 - TREATMENT COMPLIANCE - PSYCHOTHERAPY

	Treatm	Treatment Week 5			
Subject ID #.	Subject Initials	Week			
<u> </u>		·			

	Site ID:		Subject ID #.			Subject Initials	Week
Date:	(mm/dd/yyyy)						
Did subjec	ct receive standardized, manu	al-gı	uided individual	psyc	chothe	erapy this week?	
(If No, ple	ase comment below)		Yes		No		
If yes, leng	gth of psychotherapy session		m	inute	S		
Did subjed managem	ct require emergency crisis ent sessions this week?		Yes		No		
If yes, how	v many?						
Additional	comments:						

Completed by (Initials):

				Tre	eatment Week 6
	Site ID:	Subject II	) #	Subject Initials	Week
Date:		<u> </u>			
Date.		l			
	(mm/dd/yyyy)				
	(IIIII/aa/yyyy)				
<u>Weekly</u>	Vital Signs				
☐ Vital s	signs not assessed at this v	isit			
		l	Time Vital Ciana	takan	
Date L	(mm/dd/yyyy)		Time Vital Signs		ur clock)
T		/° <b>୮</b> \	ND: 04400 4		
Temperati		(°F)	NR: 94-100.4	CS 🗆	NCS □
Comment	s for Temperature				
	(101 )				
	ssure (sitting)	(mm Hg)	NR: 90-140/50-9	00 CS ∐	NCS □
Comment	s for Blood Pressure:				
		_			
Pulse Rat	, , , , , , , , , , , , , , , , , , , ,	s/min)	NR: 50-120	cs □	NCS □
Comment	s for Pulse Rate:				
Respirato	ry Rate (sitting) (t	oreaths/min)	NR: 8-20	cs □	NCS □
Comment	s for Respiratory Rate:				
	Г	1			
Complete	ed by (Initials):	r			

Completed by (Initials):

#### Form 23 - URINE BE SPECIMEN COLLECTION FORM

Treatment Week 6 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):

#### Form 23 - URINE BE SPECIMEN COLLECTION FORM

Treatment Week 6 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

#### Form 23 – URINE BE SPECIMEN COLLECTION FORM

### **Treatment Week 6 V3**

			11 Catilicit	MCCK U V
	Site ID:	Subject ID #.	Subject Initials	Week
Date:	(mm/dd/yyyy)			
<u>Third S</u>	Study Visit of Week	Urine bar code stick	ker:	
Date urin	ne collected: (mm/dd/y	<i>yyy)</i>	Urine not collected	
1	ne temperature within expect Franklin Cup: The temperature m Trak Cup: The temperature must Sample Cup: The temperature mu	ust be <u>higher</u> than 96.0° F an be <u>higher</u> than 90.0° F and <u>lo</u>	<u>wer</u> than 99.0° F Split	
Complete	ed by (Initials):			

#### Form 24 – SUBSTANCE USE INVENTORY

				Tre	eatment Week	. 6		
Site	e ID:	Subject II	O#.	Subject Initials	Week	7		
Date:						1		
(mm/	(dd/yyyy)							
Using timeline follow-bac of administration for eac	ck method, record wi h drug. Begin with y	hether subject has esterday and work	on each day since t back to the last vis	the last visit used a sit. Please be sure t	ny amount of the si hat days are contin	ubstances listed be uous with last wee	elow, along with the k's form.	most common route
Date of last								
	(mm/d	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 □	
Route of admin	istration (ROA) code	s: 1 = oral, 2 = nasa	l, 3 = smoking, 4 =	non-intravenous in	jection, 5 = intrave	nous injection		
Completed by (Initials	):							
	1							

						Treatme	
	Site II	): 	Subject ID	) #. 	Subject	Initials	Week
Date:							
	(mm/dd/	<i>'</i> yyyy)					
Cocain	<u>e</u>						
1. The <u>int</u>	ensity of my cra	aving, that is, he	ow much I desire	ed cocaine in the	past 24	hours was:	
Ε	None at all	☐ Slight	☐ Moderate	☐ Consider	able	☐ Extreme	
		craving, that is,  Almost never	how often I desir □ Several t		e past 24 egularly		constantly
	ngth of time I sp None at all	ent craving for  Very shor	cocaine during to	he past 24 hours ☐ Somewh		☐ Very lor	ng
4. Write in	n the <u>number</u> of	times you thinl	k you had craving	g for cocaine du	ring the p	ast 24 hours:	
5. Write ir	n the total time	spent craving c	ocaine during the	e past 24 hours:			
	hours	minutes					
C. The we	aret devu Durin	a the poet week	, mu maat intana		ad an tha	fallowing dov	
o. The <u>wc</u>	_	g trie past week —	my most intense	e craving occur	eu on me	Tollowing day	
	」Sunday ☐ Thursday	<ul><li></li></ul>	☐ Tuesday ☐ Saturday	<ul><li>☐ Wednesday</li><li>☐ All days the sa</li></ul>	me (go to C	0. 8)	
7 The da	ite for that day	was:					
	no ror mar day		nm/dd/yyyy)				
8. The <u>int</u>	ensity of my cra	aving, that is, he	ow much I desire	ed cocaine on the	at worst d	lay was:	
Ε	None at all	☐ Slight	☐ Moderate	☐ Consider	able	☐ Extreme	
Second	d Drug						
9. A <b>2<sup>nd</sup></b> c	raved drug dur <i>lark <u>only</u> one</i> of th	ing the past 24 ne following. If no	hours was: • 2 <sup>nd</sup> craved drug, m	ark "None" and lea	ave Questic	ons 10-16 blank.	
	None		ners or Sedatives iturates, etc.)	☐ Benzos (Valium, Xanax,	etc.)	☐ Nicotine	
	Alcohol	Hero	oin or other Opiates Ohine, etc.)	Marijuana	· · · · /	Other Specify	
10. The <u>ir</u> hours		eraving, that is,	how much I desi	red this second	drug in th	e past 24	
	None at all	☐ Slight	☐ Moderate	☐ Consider	able	☐ Extreme	

	Site	ID:	Subject ID#.		Subject	Treatment Initials	t Week 6
			J				
Date:			L				
	(mm/c	dd/yyyy)					
	frequency of r	ny craving, that is,	how often I desire	ed this <b>seco</b>	<b>1d</b> drug in t	the past 24	
	☐ Never	☐ Almost never	☐ Several tim	es 🗆 F	Regularly	☐ Almost o	constantly
12. The	<u>length</u> of time	I spent in craving f	or this <b>second</b> dr	ug during the	e past 24 h	ours was:	
	☐ None at all	☐ Very short	☐ Short	☐ Somew	hat long	☐ Very Ion	g
<u>Third</u>	<u>Drug</u>						
13. A <b>3</b> '	<sup>rd</sup> craved drug Mark <u>only one</u> o	during the past 24 f	hours was: g <sup>d</sup> craved drug, mark	"None" and le	eave questio	ns 14-16 blank.	
	None		ers or Sedatives	Benzos	v oto)	☐ Nicotine	
	Alcohol	☐ Heroir	urates, etc.) n or other Opiates ine, etc.)	(Valium, Xana ☐ Marijuana	x, etc.)	Other Specify	
	intensity of my	y craving, that is, he	ow much I desired	this <b>third</b> d	rug in the p	past 24	
	☐ None at all	☐ Slight	☐ Moderate	☐ Conside	erable	☐ Extreme	
	frequency of r	my craving, that is,	how often I desire	ed this <b>third</b>	drug in the	past 24	
	☐ Never	☐ Almost never	☐ Several tim	es 🗆 F	Regularly	☐ Almost o	constantly
16. The	<u>length</u> of time	I spent in craving f	or this third drug	during the pa	ast 24 hour	s was:	
	☐ None at all	☐ Very short	☐ Short	☐ Somew	hat long	☐ Very Ion	g
Comple	eted by (Initials)	:					

### Form 30 - COCAINE SELECTIVE SEVERITY ASSESSMENT

**Treatment Week 6** 

	Site ID:	<u></u>	Subject II	) #.	_	Subjec	t Initials		Wee
Da	ite:								
	(mm/dd/yyyy)								
AII	questions except 4 and 5 are ass	sessed by properly	/ trained p	ersonnel.	The subj	ect is ask	ed about e	each of t	the
	ms in lay language and the respo estion 4 and 5, the subject is aske								
	the questions. The rater th								
Da	ate of last cocaine use:								
			(mm/dd/	<i>(yyyy</i> )					
1.	Hyperphagia		,	,					
	0 = normal appetite								
	3-4 = eats a lot more than 7 = eats more than twice		food						
	7 – eats more than twice		1000						
2.	Hypophagia								
	0 = normal appetite								
	3-4 = eats less than half of $7$ = no appetite at all	or normal amount	of 100a						
3.	Carbohydrate Craving								
	0 = no craving	waata aakaa aa	d anakina	half tha ti	ma				
	3-4 = strong craving for s 7 = strong craving for swe								
4.	Cocaine Craving Intensity		use subje	ct intonsi	tv ratina t	rom na 3	of this fo	rm	
		7 10030	. use subje	ot micrisi	ty raung r	rom pg. s	or ans to		
5.	Cocaine Craving Frequence	-		. •		_			
		Please	e use subje	ect treque	ncy rating	j trom pg.	3 OF THIS T	orm.	
6.	Bradycardia								
			use scale			_	0	-	
	Pulse (BPM)	0 1 >64 64-63	2 62-61	3 60-59	4 58-57	5 56-55	6 54-53	7 <53	
	. 3.33 (2)		0_ 0.		00 0.		0.00	100	
7.	Insomnia								
	0 = normal amount of sle								
	3-4 = half of normal amou 7 = no sleep at all	ant of sleep							
	2.30p a. a								
8.	Hypersomnia								
	0 = normal amount of sle								
	3-4 = could sleep or does		ay						

### Form 30 - COCAINE SELECTIVE SEVERITY ASSESSMENT

**Treatment Week 6** 

		Site ID:	Subje	ct ID#.	_	Subject Initials	 Week
Date	e:				L		
		(mm/dd/yyyy)					
9. /	Anxiet	ty					
	3-	= usually does not feel anxious 4 = feels anxious half the tii = feels anxious all the time					
10.	Energ	gy Level					
	3-	= feels alert and has usual a 4 = feels tired half the time = feels tired all the time	amount of energy				
11.	Activ	ity Level					
	3-	<ul><li>no change in usual activiti</li><li>4 = participates in half of us</li><li>no participation in usual a</li></ul>	ual activities				
12.	Tensi	ion					
	3-	1 = rarely feel tense 4 = feels tense half the time = feels tense most or all the					
13.	Atte	ntion					
	3-	<ul><li>able to concentrate on rea</li><li>4 = has difficulty with the ab</li><li>has difficulty with the abo</li></ul>	ove half the time	n, tasks, and	make plai	ns without difficulty	
14.	Parar	noid Ideation					
	3- 5:	<ul><li>no evidence of paranoid the</li><li>4 = unable to trust anyone</li><li>feels people are out to ge</li><li>feels a specific person/group</li></ul>	t him/her	nst him/her			
15.	Anhe	edonia					
	3-	= ability to enjoy themselves 4 = able to enjoy themselve = unable to enjoy themselve	s half of the time	ed			
16.	Depre	ession					
	3-	<ul><li>no feelings related to sade</li><li>4 = feels sad or depressed</li><li>feels depressed all of the</li></ul>	half the time				
17.	Suici	dality					
	0 : 3-	= does not think about being 4 = feels like life is not worth = feels like actually ending l	h living				
18.	Irrital	bility					
	0 : 3-	= feels that most things are 4 = feels that many things a = feels that mostly everythir	re irritating	nsetting			
Con		d by (Initials):		pocialig			

N	NID.	٨	1	m	C	1	/I	A,	٠£	Λ	M	1
ľ	MLD.	А	-1V	w	· •	-17	TO	u	4I -	w	w	J.

#### Form 30 - COCAINE SELECTIVE SEVERITY ASSESSMENT

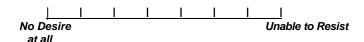
Treatment Week 6

			1 I Cutii	icit vvecit
	Site ID:	Subject ID #.	Subject Initials	Week
D. (				
Date:				
	(mm/dd/yyyy)			

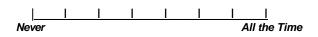
#### CSSA VISUAL ANALOG SCALE

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:



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



Form 28 - CLINICAL GLOBAL IMPRESSION - SELF NIDA-MDS-Modaf-0001 **Treatment Week 6** Site ID: Subject ID #. **Subject Initials** Week Date: (mm/dd/yyyy) **Cocaine Global Severity** 

and cocaine related problems?	
<ul> <li>No problems</li> <li>Borderline problems</li> <li>Mild problems</li> <li>Moderate problems</li> <li>Marked problems</li> <li>Severe symptoms</li> <li>Most extreme problems possible</li> </ul>	

## 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):

			Treatn	nent Week
	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 <u>Severe</u>						Most Severe
Report	red Cocaine Use: (frequency and amount of cocaine used)	1	2	3	4	5	6	7
Cocain	ne Seeking: (craving for cocaine, effort to stop, and drug seeking behavior)	1	2	3	4	5	6	7
Report	ed Use of Other Drugs: (frequency and amount of non-cocaine drug/alcohol use)	1	2	3	4	5	6	7
Observ	vable Psychiatric Symptoms: (orientation, memory, comprehension, disorganized thinking, rapid/retarded speech, agitation, grooming, hostility, irritability, affective disturbance)	1	2	3	4	5	6	7
Report	ted Psychiatric Symptoms: (mood disturbance, depression, anxiety,inner restlessness, covert anger, somatic symptoms energy level,motivation, sleep, appetite, libido, anhedonia)	s, 1	2	3	4	5	6	7
Physic	al/Medical Problems: (those that have emerged or gotten worse after drug use)	1	2	3	4	5	6	7
Malada	aptive Coping in the Family/Social area: (movement away from healthy relationships)	1	2	3	4	5	6	7
Malada	aptive 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  Week
Date:	(mm/dd/yyyy)		
Global S	Severity of Cocaine	<u>Dependence</u>	
	ng your total clinical exper ct's cocaine dependence s	rience with the cocaine dependers	ent population, how severe are
Global	Normal, no symptoms Borderline symptoms Mild symptoms Moderate symptoms Marked symptoms Severe symptoms Most extreme symptom	·	
Rate the to your judgn project, ho	otal improvement in the panent, it is due entirely to d	articipant's cocaine dependenc Irug treatment. Compared to th	
	Not assessed, first ratir Very much improved Much improved Minimally improved No change Minimally worse Much worse Very much worse	ng	
Completed	d by (Initials):		

	Site ID:	Subject ID #.	Subject Initials	Week
ſ	Site 15.	Subject ID II.	Subject initials	Week
Date:				
Date.				
L	(mm/dd/yyyy)			
Date doses	s dispensed <i>ch dose is four tablets</i>	(mm/dd/yyyy)		
Kit Number	r:			
Bottle Num	ber:			
Number of	doses dispensed			
Date unuse	ed doses returned			
	ou docto rotumou	(mm/dd/yyyy)		
Number of	doses returned			
Number of	doses reported lost by subjec	t		
Doses take	en:			
	Day of Week:	<u>Date</u>	Time	Dose
	Day of Week.		Dose	Not
		(mm/dd/yyyy)	Taken	Taken
Comments	:			
Completed	by (Initials):			

					Treatme	nt Week 6
	Site ID:		Subject ID #.	-	Subject Initials	Week
Date:	(mm/dd/yyyy)			_		
Did subjec	ct receive standardized, manu	ıal-gı	uided individual ps	ychothe	erapy this week?	
(If No, ple	ase comment below)		Yes	No		
If yes, len	gth of psychotherapy session		mir	nutes		
	ct require emergency crisis ent sessions this week?		Yes	l No		
If yes, how	w many?					
Additional	comments:					$\neg$

|--|

		_			reatment Week 6
	Site ID:	Su	bject ID #.	Subject Initials	S Week
Date:					
	(mm/dd/yyyy)				
	rm is to be filled out t ning/Baseline and hav	-	-	-	
	nethod of birth control is		-	_	•
	☐ Oral contrace		, , ,	,	
		ragm or condom pl	us spermicide)		
	_	el implant (Norplant			
	☐ Intrauterine C	ontraceptive syster	n (IUD)		
	☐ Medroxyproge	esterone Acetate C	ontraceptive inje	ection (Depo-Provera)	
	☐ Contraceptive	patch			
	☐ Surgical Steril	ization - Hysterecto	omy		
	☐ Surgical Steril	ization - Tubal ligat	ion		
	surgically sterile or 2 y of birth control during	the study and 30 da			cceptable
	☐ Yes	∐ No			
lf yes, r	mark below the accepta	able method selecte	ed by the subjec	t for use:	
	☐ barrier method	d with spermicide			
		raceptive [oral, Imp with a barrier meth		used	
	☐ Contraceptive	patch used in conj	unction with a b	parrier method	
	☐ Intrauterine de	evice [IUD]			
Was a ¡	pregnancy test perform	ed?	□ Y <u>es</u>	□ No	
	If yes, date specimen	collected			
	<b>,</b> ,		(mn	n/dd/yyyy)	
	Result:	egative	ve 🗌 Unk	nown	
	If no, specify reason:				
	ii iio, specily reason.				
ls the s	ubject lactating?	☐ Yes		)	
Comme	ents:				
Comple	eted by (Initials):				

	Site ID:	Subject 1	ID# Su	Treatment	Week 7
Date:		Subject			, cox
	(mm/dd/yyyy)				
<u>Weekly</u>	<u>Vital Signs</u>				
☐ Vital s	(mm/dd/yyyy)	isit ]	Time Vital Signs tal	ken (24 hour clock)	
Temperati	ure (oral)	(°F)	NR: 94-100.4	CS □ NCS □	
Comment	s for Temperature				
	ssure (sitting) s for Blood Pressure:	(mm Hg)	NR: 90-140/50-90	CS□ NCS□	
Pulse Rat	e (sitting) (bear	s/min)	NR: 50-120	CS □ NCS □	
	s for Pulse Rate:	, 			
Respirato	ry Rate (sitting)	oreaths/min)	NR: 8-20	CS□ NCS□	
	s for Respiratory Rate:				

Date:

## Form 23 – URINE BE SPECIMEN COLLECTION FORM

Site ID: Subject ID #. Subject Initials Week

(mm/dd/yyyy)

First Study Visit o	<u>f Week</u>	Urine bar	code sticker:		
Date urine collected:	(mm/dd/yyy)	y)	U	rine not collected	
On-Trak Cup: Th	e temperature mus	t be <u>higher</u> tha t be <u>higher</u> tha	n 90.0 ° F and <u>low</u> e	er than 99.0° F Split	□ No
Completed by (Initials):					

### Form 23 – URINE BE SPECIMEN COLLECTION FORM

Treatment Week 7 V2

Site I	D:	Subject ID	#	Subject Initials	Week
Date:					
(mm/de	d/yyyy)				
<u>Second Study Vis</u>	it of Week	Urine bar code	sticker:		
Date urine collected:	(mm/dd/yyy	у)	Urine	e not collected	
Trak Cup: The ter	e temperature mus mperature must be	d range? st be <u>higher</u> than 96.0 e <u>higher</u> than 90.0° F t be <u>highe</u> r than 90.0°	and <u>lower</u> than	99.0° F Split	No
Completed by (Initials):					

#### Form 23 – URINE BE SPECIMEN COLLECTION FORM

**Treatment Week 7 V3** 

					Treatin	ciit vvcck / v
	Site ID	<b>)</b> :	Subject I	D #.	Subject Initials	Week
Date:	(mm/dd/	(уууу)				
<u>Third S</u>	tudy Visit of	f Week	Urine bar cod	de sticker:		
Date urin	e collected:	(mm/dd/yyy	y)	Urine	e not collected	
F T	rak Cup: The temp	temperature mus perature must be	d range? at be <u>higher</u> than 90 b <u>higher</u> than 90.0° t be <u>higher</u> than 90	Fand lower than	han 104.8° F On- 99.0° F Split	No
Complete	ed by (Initials):					

#### Form 24 – SUBSTANCE USE INVENTORY

				Tre	eatment Week	$\mathcal{I}$		
:	Site ID:	Subject II	) #	Subject Initials	Week	_		
Date:						=		
(m	nm/dd/yyyy)							
Using timeline follow- of administration for e	back method, record wi each drug. Begin with y	hether subject has esterday and work	on each day since t back to the last vis	the last visit used a it. Please be sure ti	ny amount of the su hat days are contin	ubstances listed be uous with last weel	low, along with the k's form.	most common route
Date of la	st visit:							
		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 adr	ministration (ROA) code	s: 1 = oral, 2 = nasa	l, 3 = smoking, 4 =	non-intravenous in	jection, 5 = intraver	nous injection		
Completed by (Initi	als):							

						ent Week 7
	Site	ID:	Subject ID a	#. Su	bject Initials	Week
Date:						
	(mm/c	dd/yyyy)				
	(11111)	, a, y y y y y				
Coca						
1. The	intensity of my	craving, that is, h	ow much I desired	I cocaine in the past	t 24 hours was:	
	☐ None at all	☐ Slight	☐ Moderate	☐ Considerable	☐ Extreme	!
2. The	<u>frequency</u> of m ☐ Never	y craving, that is,  ☐ Almost never	how often I desire	ed cocaine in the pa mes		st constantly
3. The	<u>length</u> of time I	spent craving for	cocaine during the	e past 24 hours was	S:	
	☐ None at all	☐ Very shor	t 🔲 Short	☐ Somewhat lor	ng 🔲 Very I	ong
4. Write	e in the <u>number</u>	of times you thin	k you had craving	for cocaine during t	the past 24 hours	S:
		·	, .	C	·	
5. Write	e in the total <u>tim</u>	ne spent craving o	cocaine during the	past 24 hours:		
	hours	minutes				
6. The	worst day: Dur	ing the past weel	k my most intense	craving occurred or	n the following da	ay:
	Sunday	☐ Monday ☐ Friday	☐ Tuesday	Wednesday	to to O 0)	
	☐ Thursday		☐ Saturday	All days the same (g	(0 t0 Q. 8)	
7. The	date for that da	y was:	(mm/dd/yyyy)			
8. The	intensity of my	craving, that is, h	, , , , , , , , , , , , , , , , , , , ,	I cocaine on that wo	orst day was:	
	☐ None at all	☐ Slight	☐ Moderate	☐ Considerable	☐ Extreme	ı
<u>Seco</u>	nd Drug					
9. A <b>2</b> <sup>n</sup>	<sup>d</sup> craved drug d <i>Mark <u>only one</u> o</i>	uring the past 24 fthe following. If no	hours was: o 2 <sup>nd</sup> craved drug, ma	rk "None" and leave Q	uestions 10-16 blan	ık.
	☐ None		ners or Sedatives	Benzos	☐ Nicotine	
	Alcohol	Hero	oiturates, etc.)  oin or other Opiates  ohine, etc.)	(Valium, Xanax, etc.) ☐ Marijuana	Other Specify	
	e <u>intensity</u> of my urs was:	y craving, that is,	how much I desire	ed this <b>second</b> drug	in the past 24	
	☐ None at all	☐ Slight	☐ Moderate	☐ Considerable	☐ Extreme	<b>:</b>

	Site	ID·	Subject ID	#	Subject		nt Week 7
	Site		Subject ID		Subject		THE STATE OF THE S
Date:							
	(mm/a	dd/yyyy)					
	<u>frequency</u> of n s was:	ny craving, that is, l	how often I desi	red this <b>sec</b>	ond drug in	the past 24	
	☐ Never	☐ Almost never	☐ Several tir	mes $\square$	Regularly	☐ Almost	constantly
12. The	length of time	I spent in craving for	or this <b>second</b> o	Irug during t	he past 24 h	nours was:	
	☐ None at all	☐ Very short	☐ Short	☐ Some	what long	☐ Very lo	ng
Third I	Drug						
13. A <b>3<sup>r</sup></b>	<sup>d</sup> craved drug o <i>Mark <u>only</u> one</i> o	during the past 24 h	nours was: <sup>rd</sup> craved drug, mai	rk "None" and	leave questio	ns 14-16 blank.	
	None		ers or Sedatives	Benzos (Valium, Xar	nav. eta )	☐ Nicotine	
	Alcohol	Heroin	urates, etc.) or other Opiates ine, etc.)	( Validiri, ⊼ai ☐ Marijuana	iax, etc.)	Other Specify	
	intensity of my 's was:	v craving, that is, ho	ow much I desire	ed this third	drug in the p	past 24	
	☐ None at all	☐ Slight	☐ Moderate	☐ Consi	derable	☐ Extreme	
	<u>frequency</u> of n 's was:	ny craving, that is, l	how often I desi	red this <b>thirc</b>	d drug in the	past 24	
	☐ Never	☐ Almost never	☐ Several tir	mes $\square$	Regularly	☐ Almost	constantly
16. The	length of time	I spent in craving for	or this third drug	during the p	oast 24 hour	rs was:	
	☐ None at all	☐ Very short	☐ Short	☐ Some	ewhat long	☐ Very lo	ng
Complet	ted by (Initials)	:					

NIDA-MDS-Modaf-0001 Form 30 - COCAINE SELECTIVE SEVERITY ASSESSMENT **Treatment Week 7** Subject ID #. Site ID: **Subject Initials** Week Date: the or ch of

	(mm/dd/yyyy)								
ite	l questions except 4 and 5 are asses ms in lay language and the respons estion 4 and 5, the subject is asked the questions. The rater the	se is reco	orded on a the appro	a scale of opriate pla	0-7 with o	0 being no e line (on p	ormal or n page 3) th	o sympto	ms. Fo
Da	ate of last cocaine use:			(mm/dd/)	AAA()				
1.	Hyperphagia  0 = normal appetite  3-4 = eats a lot more than to a period of the seats and the seats are the seats		ount of fo		<i>(</i> <b>)                                   </b>				
2.	Hypophagia  0 = normal appetite  3-4 = eats less than half of  7 = no appetite at all	normal a	amount o	f food					
3.	Carbohydrate Craving  0 = no craving  3-4 = strong craving for swee  7 = strong craving for swee					me			
4.	Cocaine Craving Intensity		Please เ	ıse subje	ct intensi	ty rating f	rom pg. 3	of this for	rm.
5.	Cocaine Craving Frequency	′	Please u	ıse subjed	ct frequer	ncy rating	from pg.	3 of this fo	orm.
6.	Bradycardia		Please ı	ıse scale	below.				
	Pulse (BPM)	0 >64	1 64-63	2 62-61	3 60-59	4 58-57	5 56-55	6 54-53	7 <53
7.	Insomnia  0 = normal amount of sleep  3-4 = half of normal amount  7 = no sleep at all		p						
8.	Hypersomnia								
	0 = normal amount of sleep 3-4 = could sleep or doess 7 = sleep or could sleep all	leep hal							

### Form 30 - COCAINE SELECTIVE SEVERITY ASSESSMENT

**Treatment Week 7** 

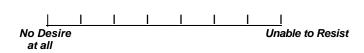
	Site ID:	Subject ID #.	Subject Initials	Wee
Date	2.			
Dan				
	(mm/dd/yyyy	)		
9. /	Anxiety			
	0 = usually does not fee 3-4 = feels anxious half 7 = feels anxious all the	the time		
10.	Energy Level			
	0 = feels alert and has u 3-4 = feels tired half the 7 = feels tired all the tin	time		
11.	Activity Level			
	0 = no change in usual 3-4 = participates in hal 7 = no participation in us	f of usual activities		
12.	Tension			
	0-1 = rarely feel tense 3-4 = feels tense half th 7 = feels tense most or			
13.	Attention			
	0 = able to concentrate 3-4 = has difficulty with 7 = has difficulty with th		make plans without difficulty	
14.	Paranoid Ideation			
	0 = no evidence of para 3-4 = unable to trust an 5 = feels people are out 7 = feels a specific pers	yone		
15.	Anhedonia			
	0 = ability to enjoy them 3-4 = able to enjoy then 7 = unable to enjoy then			
16.	Depression			
	0 = no feelings related t 3-4 = feels sad or depre 7 = feels depressed all			
17.	Suicidality			
	0 = does not think abou 3-4 = feels like life is no 7 = feels like actually er	t worth living		
18.	Irritability			
Con	0 = feels that most thing 3-4 = feels that many th 7 = feels that mostly even npleted by (Initials):			

NIDA-MI	OS-Modaf-0001	Form 30 - COCAINE SELECTIVE SEVERITY ASSESSMENT				
			Treatn	nent Week 7		
_	Site ID:	Subject ID #.	Subject Initials	Week		
Date:						
	(mm/dd/yyyy)					

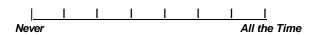
#### CSSA VISUAL ANALOG SCALE

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:



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



# ELF

Treatment Week 7 bject Initials Week
oject illitais — Week

Completed by (Initials):	

			Treatn	nent Week
	Site ID:	Subject ID #.	Subject Initials	Week
Date:				
L	(mm/dd/yyyy)			

# **Current Severity**

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

		None, Least <u>Severe</u>						Most Severe
Report	ed Cocaine Use: (frequency and amount of cocaine used)	1	2	3	4	5	6	7
Cocain	e Seeking: (craving for cocaine, effort to stop, and drug seeking behavior)	1	2	3	4	5	6	7
Reporte	ed Use of Other Drugs: (frequency and amount of non-cocaine drug/alcohol use)	1	2	3	4	5	6	7
Observ	rable Psychiatric Symptoms: (orientation, memory, comprehension, disorganized thinking, rapid/retarded speech, agitation, grooming, hostility, irritability, affective disturbance)	1	2	3	4	5	6	7
Reporte	ed Psychiatric Symptoms: (mood disturbance, depression, anxiety,inner restlessness, covert anger, somatic symptoms energy level,motivation, sleep, appetite, libido, anhedonia)	s, 1	2	3	4	5	6	7
Physica	al/Medical Problems: (those that have emerged or gotten worse after drug use)	1	2	3	4	5	6	7
Malada	aptive Coping in the Family/Social area: (movement away from healthy relationships)	1	2	3	4	5	6	7
Malada	optive 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:		_	
Date.			
	(mana (alali u u u i)		
Global 9	(mm/dd/yyyy) Severity of Cocaine	Donondonoo	
Global	severity or Cocame	<u>Dependence</u>	
	ng your total clinical exper ct's cocaine dependence	rience with the cocaine dependent symptoms at this time?	t population, how severe are
	Normal, no symptoms Borderline symptoms Mild symptoms Moderate symptoms Marked symptoms Severe symptoms Most extreme sympton	ns possible	
<u>Global l</u>	mprovement of Coc	<u>aine Dependence</u>	
your judgr project, ho	nent, it is due entirely to c	articipant's cocaine dependence strug treatment. Compared to the	
	Not assessed, first rating Very much improved Much improved Minimally improved No change Minimally worse Much worse Very much worse	ng	
Completed	d by (Initials):		

Site ID:	Subject ID #.	Subject Initials	ment Week Week
		~ <b>,</b>	]
Date:			
(mm/dd/yyyy)			
Date doses dispensed  Each dose is four tablets	(mm/dd/y		
Kit Number:			
Bottle Number:			
Number of doses dispensed			
Date unused doses returned	(mm/dd/y	yyy)	
Number of doses returned			
Number of doses reported lost by subje	ect		
Doses taken:			
Day of Week:	<u>Date</u>	Time Dose	Dose Not
	(mm/dd/yyyy)	Taken	Taken
Comments:			
Completed by (Initials):			

#### Form 34 - TREATMENT COMPLIANCE - PSYCHOTHERAPY

## 7

Date:  (mm/dd/yyyy)  Did subject receive standardized, manual-guided individual psychotherapy  (If No, please comment below)  Yes  No  If yes, length of psychotherapy session  minutes  Did subject require emergency crisis	Subject Initials Week
(mm/dd/yyyy)  Did subject receive standardized, manual-guided individual psychotherapy  (If No, please comment below)	
(mm/dd/yyyy)  Did subject receive standardized, manual-guided individual psychotherapy  (If No, please comment below)	
Did subject receive standardized, manual-guided individual psychotherapy  (If No, please comment below)	
Did subject receive standardized, manual-guided individual psychotherapy  (If No, please comment below)	
If yes, length of psychotherapy session minutes  Did subject require emergency crisis	this week?
Did subject require emergency crisis	
Did subject require emergency crisis	
management sessions this week?	
If yes, how many?	
Additional comments:	

Completed by (Initials):

	G: ID	g 11	TD 11		nt Week 8
	Site ID:	Subject 1	D#. Su	bject Initials	Week
Date:					
	(mm/dd/yyyy)				
<u>Weekly</u>	Vital Signs				
☐ Vital s	signs not assessed at this	s visit			
Date			Time Vital Signs tak	ken	
	(mm/dd/yyy	<u>/)</u>	3	(24 hour clock	k)
Temperat	ure (oral)	(°F)	NR: 94-100.4	CS□ NCS[	
Comment	s for Temperature				
	essure (sitting)	(mm Hg)	NR: 90-140/50-90	CS□ NCS[	
Pulse Rat	te (sitting) (be	eats/min)	NR: 50-120	CS□ NCS[	<u>_</u>
Respirato	ry Rate (sitting) s for Respiratory Rate:	(breaths/min)	NR: 8-20	CS□ NCS[	
Complete	d by (Initials):				

### Form 23 – URINE BE SPECIMEN COLLECTION FORM

### Treatment Week 8 V1

·	Site 1	ID:	Subject ID #	<u>‡.         </u>	Subject Initials	S	Week
Date:							
<u>First Stu</u>	<u>udy Visit o</u>	<u>f Week</u>	Urine bar code	sticker:			
Date urine	collected:	(mm/dd/yyy	<u>y)</u>	Urin	e not collected		
Was urine	temperature	within expected	l range?		□ Yes □	] No	
Fr. Tr	anklin Cup: The ak Cup: The ter	e temperature mus mperature must be	t be <u>higher</u> than 96.0° <u>higher</u> than 90.0° F a t be <u>higher</u> than 90.0°	nd <u>lower</u> than	han 104.8° F On- 99.0° F Split		
	d bv (Initials):		.be <u>nigner</u> than 90.0	ranu <u>iower</u> u	iali 100.0 F		

### Form 23 – URINE BE SPECIMEN COLLECTION FORM

Treatment Week 8 V2

			11,	Treatment Week o		
Si	te ID:	Subject ID #.	Subject Init	tials Week		
Date:						
(mr	m/dd/yyyy)					
Second Study V	<u>'isit of Week</u>	Urine bar code st	ticker:			
Date urine collected:	(mm/dd/yyyy)		Urine not collected			
Trak Cup: The	The temperature must be temperature must be h	be <u>higher</u> than 96.0° F <u>igher</u> than 90.0° F and	☐ Yes Fand <u>lower</u> than 104.8° F On d <u>lower</u> than 99.0° F Split and <u>lower</u> than 100.0° F	□ No		
Completed by (Initial	s):					

### Form 23 – URINE BE SPECIMEN COLLECTION FORM

Treatment Week 8 V3

			I	reaument v	week o v
_	Site ID:	Subject ID	#. Subject I	nitials	Week
Date:					
Date.					
l	(mm/dd/yyyy)				
<u>Third St</u>	udy Visit of Week	Urine bar cod	e sticker:		
Date urine		(dd/yyyy)	Urine not collecte	ed 🗆	
Fra Tra	ak Cup: The temperature m	e must be <u>higher</u> than 96. ust be <u>higher</u> than 90.0° F	☐ Yes 0° F and <u>lower</u> than 104.8° F C and <u>lower</u> than 99.0° F Split ° F and <u>lower</u> than 100.0° F	□ No <i>On-</i>	
Completed	I by (Initials):				

#### Form 24 – SUBSTANCE USE INVENTORY

					reatment Week 8			
Site 1	ID:	Subject II	) #.	Subject Initials	Week	•		
Date:						J		
(mm/d	d/yyyy)							
Using timeline follow-back of administration for each	method, record wh drug. Begin with ye	nether subject has desterday and work	on each day since t back to the last vis	the last visit used an it. Please be sure th	ny amount of the su hat days are contin	ıbstances listed be uous with last weel	low, along with the k's form.	most common route
Date of last v	isit:							
	(mm/de	d/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	ı
Alcohol	□Y/ □N	□Y/ □N	□Y/ □N	□Y/ □N	□Y/ □N	□Y/ □N	□Y/ □N	
Marijuana	$\square$ Y/ $\square$ N	$\square$ Y/ $\square$ N	$\square$ Y/ $\square$ N	□Y/ □N	$\square$ Y/ $\square$ N	□Y/ □N	□Y/ □N	1
Amphetamines	□Y/ □N	□Y/ □N	□Y/ □N	□Y/ □N	□Y/ □N	□Y/ □N	□Y/ □N	ı
Opiates	□Y/ □N	□Y/ □N	□Y/ □N	□Y/ □N	□Y/ □N	□Y/ □N	□Y/ □N	ı
Barbiturates	$\square$ Y/ $\square$ N $\square$	$\square$ Y/ $\square$ N $\square$	$\square$ Y/ $\square$ N $\square$	$\square$ Y/ $\square$ N $\square$	$\square$ Y/ $\square$ N $\square$	$\square$ Y/ $\square$ N $\square$	□Y/ □N	ı
Benzodiazepines	□Y/□N	□Y/□N	□Y/□N	□Y/□N	□Y/□N	□Y/□N	□Y/ □N	r
Route of administration (ROA) codes: 1 = oral, 2 = nasal, 3 = smoking, 4 = non-intravenous injection, 5 = intravenous injection								
Completed by (Initials):								
	1							

							ment Week 8	
	Site ID:		Subject	ID#.	1 -	Subject Initials	Week	
Date:					J L			
	(mm/dd/yyyy)							
	Value	Norm	al Abnorm	nal* Abnorm Significar		Comments (required for abnormal	values)	
1. Specific	gravity	7 -				(104411041011141		
•				_				
2. pH								
3. Glucose	e							
4. Protein								
5. Ketones	3							
6. Occult E	Blood	] 🗆						
7. WBC		_ ]						
8. RBC								
9. Epitheli	al Cells	] 🗆						
*"	Abnormal" is any value o	outside the norm	al laborat	ory range.				
Fo	or Glucose, Protein, Keto	nes, and Occult	Blood use	e the follow	ing 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):								

		Site ID:		S	ubject I	D#.	ſ	Subject Initials Week  Week
Date:		(magas /alad (m. m. m.)					L	
	(	(mm/dd/yyyy)						
		Value		Normal A	Abnorma	ıl* Abnormal Significant		Comments (required for abnormal values)
1. Hemogl	lobin		g/dL					
2. Hemato	ocrit		%					
3. RBC			M/uL					
4. Platelet	count		K/uL					
5. WBC			K/uL					
6. Neutrop	ohils		%					
7. Lympho	ocytes		%					
8. Monocy	rtes		%					
9. Eosinop	ohils		%					
10. Basop	hils		%					
PI	lease ref	er to Appendix	l of the pro	tocol whe	n detern	ninina the s	significa	nce of abnormal values.
		al" is any value					<b>.</b>	
m	illion/uL	= mil/cumm = i	mill/mcl = N	//cmm = x	:10 <sup>6</sup> /cum	ım		
x	10³/uL =	thou/cumm = t	hou/mcl =	<b>K/cmm</b> = 1	1000/uL :	= x 10³/cum	nm	
☐ Chec	k here i	if results on th	nis form a	re retect	s of nre	evious lah	tests	
		nal lab tests	no ioiiii a	10 101031	.5 or pre	VIOUS IAD	, icoio.	
Date (	origir	เลเ เลม เชอเอ			(mm/dd			

							Treatr	nent Week 8			
	Site ID:		S	ubject II	D #.	_	Subject Initials	Week			
						L					
Date:											
	(mm/dd/yyyy)										
	Value	1	Normal A	Abnormal*	Abnormal*	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 prote	in	g/dL									
9. SGOT/AS	г	U/L									
10. SGPT/AL	т	U/L									
11. GGT		U/L									
12. Bilirubin		mg/dL									
13. BUN		mg/dL									
Pleas	e refer to Appendix I o	of the protoc	ol whe	n determ	ining signi	ificance	of abnormal values.				
* "Ab	normal" is any value o	outside the	normal	laborato	ry range.						
mmol	mmol/L = mEq/L										
	ere if this form is c	ompleted f	or rete	est of pr	evious la	b tests					
Date of o	riginal lab tests										
	<b>9</b>	L	(mm	/dd/yyy	<i>(</i> )						

					Treat	tment Week 8
	Site	ID:	Subject ID	#.	Subject Initials	Week
Date:						
	(mm/c	ld/yyyy)				
Coca	<u>ine</u>					
1. The	intensity of my	craving, that is, ho	w much I desire	d cocaine in the p	ast 24 hours was	<b>S</b> :
	☐ None at all	☐ Slight	☐ Moderate	☐ Consideral	ole 🗆 Extre	me
2. The	frequency of m	y craving, that is, h	now often I desir	ed cocaine in the	past 24 hours wa	as:
	☐ Never	☐ Almost never	☐ Several t	mes 🗌 Reg	ularly 🔲 Alr	most constantly
3. The	<u>length</u> of time I	spent craving for c	cocaine during th	ne past 24 hours	was:	
	☐ None at all	☐ Very short	☐ Short	☐ Somewha	t long	ry long
4. Write	e in the number	of times you think	vou had cravino	ı for cocaine duri	ng the past 24 ho	urs:
		or announce you armin	, , , , , , , , , , , , , , , , , , , ,	,	.ge paet = 1e	<b></b>
= \A/:				1041		
5. Write	e in the total <u>tim</u>	ne spent craving co	caine during the	e past 24 hours:		
	hours	minutes				
6. The	worst day: Dur	ing the past week	my most intense	e craving occurred	d on the following	day:
	<ul><li>☐ Sunday</li><li>☐ Thursday</li></ul>		<ul><li>☐ Tuesday</li><li>☐ Saturday</li></ul>	<ul><li>☐ Wednesday</li><li>☐ All days the sam</li></ul>	e (go to Q. 8)	
	ŕ	, 		, 	,	
7. The	date for that da	y was:	· //// )			
			(mm/dd/yyyy)			
8. The		craving, that is, ho	w much I desire	d cocaine on that	worst day was:	
	☐ None at all	☐ Slight	☐ Moderate	☐ Consideral	ole 🗆 Extrei	me
<u>Seco</u>	nd Drug					
9. A <b>2</b> <sup>n</sup>	d craved drug d	uring the past 24 h	nours was:	ark "Nono" and loav	o Ouostions 10-16 b	lank
	□ None		ers or Sedatives	Benzos	☐ Nicotine	
	_	(Barbit	urates, etc.)	(Valium, Xanax, e	tc.)	; 
	Alcohol		n or other Opiates nine, etc.)		☐ Other Specify	
	intensity of my urs was:	/ craving, that is, h	ow much I desir	ed this <b>second</b> d	rug in the past 24	
	□ None at all	☐ Slight	☐ Moderate	☐ Consideral	ole □ Extrei	me

	Site	ID:	Subject ID#		Subject	Treatment Initials	t Week 8
	2332		2 20 3 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2		a and a control		
Date:							
	(mm/c	dd/yyyy)					
	frequency of r	ny craving, that is,	how often I desire	ed this <b>seco</b>	n <b>d</b> drug in	the past 24	
	☐ Never	☐ Almost never	☐ Several tim	es 🗆 I	Regularly	☐ Almost o	constantly
12. The	<u>length</u> of time	I spent in craving f	or this <b>second</b> dr	ug during th	e past 24 h	nours was:	
	☐ None at all	☐ Very short	☐ Short	☐ Somev	vhat long	☐ Very Ion	g
<u>Third</u>	<u>Drug</u>						
13. A <b>3</b> '	<sup>rd</sup> craved drug Mark <u>only one</u> o	during the past 24 fthe following. If no 3	hours was: g <sup>d</sup> craved drug, mark	c"None" and le	eave questic	ons 14-16 blank.	
	None		ers or Sedatives	Benzos	ata \	☐ Nicotine	
	Alcohol	☐ Heroir	urates, etc.) i or other Opiates  ine, etc.)	(Valium, Xana ☑ Marijuana	x, etc.)	Other Specify	
	intensity of my rs was:	craving, that is, ho	ow much I desired	I this <b>third</b> d	rug in the	past 24	
	☐ None at all	☐ Slight	☐ Moderate	☐ Conside	erable	☐ Extreme	
	frequency of n	ny craving, that is,	how often I desire	ed this <b>third</b>	drug in the	past 24	
	☐ Never	☐ Almost never	☐ Several tim	es 🔲 I	Regularly	☐ Almost o	constantly
16. The	<u>length</u> of time	I spent in craving f	or this third drug	during the pa	ast 24 hou	rs was:	
	☐ None at all	☐ Very short	☐ Short	☐ Somev	vhat long	☐ Very Ion	g
Comple	eted by (Initials)	:					

### Form 30 - COCAINE SELECTIVE SEVERITY ASSESSMENT

		Site ID:		S	Subject II	<b>)</b> #.		Subjec	t Initials		Wee
Da	ıte:						<u> </u>			•	
		(mm/dd/yyyy)									
		ns except 4 and 5 are ass									
		language and the respo and 5, the subject is ask									
7		e questions. The rater ti									
D-	.46	-ti									
Da	ate or las	st cocaine use:			//-I-I	()					
1	Hyper	nhaqia		7	(mm/dd/	yyyy)					
٠.		=									
		= normal appetite 4 = eats a lot more thar	าแรแลโ	_							
	_	= eats more than twice		unt of fo	ood						
				=							
2.	Нурор	hagia									
		= normal appetite		J							
		4 = eats less than half	of normal a	mount	of food						
	7 :	= no appetite at all		1							
3.	Carbo	hydrate Craving									
		= no craving									
		4 = strong craving for s	weets, cak	es, and	cookies	half the ti	me				
	7 :	= strong craving for sw	eets, cakes	s, and c	ookies all	the time					
1	Cocci	no Crovina Intoncitu									
4.	Cocan	ne Craving Intensity		Please	use subje	ct intensi	itv rating f	rom pa. 3	of this fo	rm.	
							.,		0		
5.	Cocair	ne Craving Frequen	су								
				Please	use subje	ct frequei	ncy rating	from pg.	3 of this f	orm.	
6	Brady	cardia									
υ.	Diauy	carura		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.	Insom	nia									
		= normal amount of sle	-	J							
		4 = half of normal amo: = no sleep at all	unt of sieep	)							
	, .	– no sicop at all									
8.	Hypers	somnia		1							
				]							
		= normal amount of sle 4 = could sleep or does		the day	V						
		= sleep or could sleep a			,						

### Form 30 - COCAINE SELECTIVE SEVERITY ASSESSMENT

	-	Site ID:	Subject ID #.	Subject Initials	We
Date	e: [				
		(mm/dd/yyyy)			
9	Anxiet	y			
	3-4	usually does not feel anxious = feels anxious half the time = feels anxious all the time			
10.	Energ	ıy Level			
	3-4	<ul><li>feels alert and has usual amo</li><li>feels tired half the time</li><li>feels tired all the time</li></ul>	ount of energy		
11.	Activi	ity Level			
	3-4	<ul><li>no change in usual activities</li><li>4 = participates in half of usual</li><li>no participation in usual activi</li></ul>			
12.	Tensi	on			
	3-4	1 = rarely feel tense 4 = feels tense half the time = feels tense most or all the tim	ne		
13.	Atter	ntion			
	3-4	<ul> <li>able to concentrate on reading</li> <li>4 = has difficulty with the above</li> <li>has difficulty with the above a</li> </ul>	e half the time	I make plans without difficulty	
14.	Paran	oid Ideation			
	3-4 5 =	= no evidence of paranoid thoug 4 = unable to trust anyone = feels people are out to get hir = feels a specific person/group	m/her		
15.	Anhe	donia			
	3-4	<ul> <li>ability to enjoy themselves rer</li> <li>4 = able to enjoy themselves ha</li> <li>unable to enjoy themselves a</li> </ul>	alf of the time		
16.	Depre	ession			
	3-4	<ul><li>no feelings related to sadness</li><li>4 = feels sad or depressed half</li><li>feels depressed all of the time</li></ul>	f the time		
17.	Suicio	dality			
	3-4	<ul><li>does not think about being de</li><li>feels like life is not worth liv</li><li>feels like actually ending life</li></ul>			
18.	Irritab	•			
	3-4 7 =				
Cor	npietec	l by (Initials):			

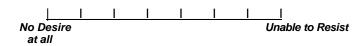
NIDA-M	IDS-Modaf-0001	Form 30 - COCAINE SELECTIVE SEVERITY ASSESSMENT					
				Treatn	nent Week 8		
	Site ID:	Subject ID #.	_	Subject Initials	Week		
Date:							

### CSSA VISUAL ANALOG SCALE

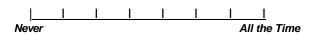
(mm/dd/yyyy)

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:



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



Completed by (Initials):

### F

NIDA-N	IDS-Modaf-0001	Form 28 – CLIN	ICAL GLOBAL IMPRES	
	Site ID:	Subject ID #.	Subject Initials	nent Week 8 Week
Date:	Site ID.	Subject 1D #.	Subject illitials	WEEK
	(mm/dd/yyyy)			
Cocain	e Global Severity			
	ne, how would you rate yours ine related problems?  No problems	self overall for cocaine use		
	Borderline problems Mild problems Moderate problems Marked problems Severe symptoms			
	☐ Most extreme problems p	possible		
<u>Global</u>	Improvement of Cocal	ne Dependence		
	ld you rate yourself for chang roblems since the beginning	ges in cocaine use and cocaine of this study?	)	
	Not assessed Very much improved Much improved Minimally improved No change Minimally worse Much worse Very much worse			

				Treatr	nen	t week
	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 <u>Severe</u>					-	Most Severe
Report	ed Cocaine Use: (frequency and amount of cocaine used)	1	2	3	4	5	6	7
Cocain	ne Seeking: (craving for cocaine, effort to stop, and drug seeking behavior)	1	2	3	4	5	6	7
Report	ed Use of Other Drugs: (frequency and amount of non-cocaine drug/alcohol use)	1	2	3	4	5	6	7
Observ	vable Psychiatric Symptoms: (orientation, memory, comprehension, disorganized thinking, rapid/retarded speech, agitation, grooming, hostility, irritability, affective disturbance)	1	2	3	4	5	6	7
Report	ted 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
Physic	cal/Medical Problems: (those that have emerged or gotten worse after drug use)	1	2	3	4	5	6	7
Malada	aptive Coping in the Family/Social area: (movement away from healthy relationships)	1	2	3	4	5	6	7
Malada	aptive 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
ı	Site ID:	Subject ID #.	Subject Initials Week
Date:			
Dute.			
	(mm/dd/yyyy)		
Global S	Severity of Cocaine	e Dependence	
	,		
		erience with the cocaine depend e symptoms at this time?	ent population, how severe are
uns subjec	or a cocamie dependence	s symptoms at this time:	
	Normal, no symptoms		
	Borderline symptoms Mild symptoms		
	Moderate symptoms		
	Marked symptoms Severe symptoms		
	Most extreme symptor	oms possible	
Global I	mprovement of Cod	caine Dependence	
	-	-	
		participant's cocaine dependenc drug treatment. Compared to the	
project, ho	W	arag treatment. Compared to the	ie subject s dumission to the
much has	the subject changed?		
	Not assessed, first rati	ting	
	Very much improved Much improved		
	Minimally improved		
	No change		
	Minimally worse Much worse		
	Very much worse		
		٦	
Completed	by (Initials):		

### Form 15 – HAMILTON DEPRESSION RATING SCALE

				CIII VVCCI
	Site ID:	Subject ID #.	Subject Initials	Week
Date:		7		
	(mm/dd/yyyy)	_		
	(IIIII/dd/yyyy)			
1. Depres	sed Mood			
•	ad, hopeless, helpless, worthle	ess)		
	0 = Absent			
		s indicated only on questioning		
		s spontaneously reported verba ing states nonverbally – i.e., th		
<u>L</u>	posture, voice, and		Tought lacial expression,	
		ually only these feeling states in	n his/her spontaneous	
	verbal and nonverba		·	
2. Feeling				
	0 = Absent	s/he has let people down.		
		nination over past errors or sinf	iul deeds	
		punishment. Delusions of guilt.		
		r denunciatory voices and/or e		
	visual hallucinations	<b>S.</b>		
3. Suicide	=			
	J 0 = Absent ] 1 = Feels life is not wor	th living		
		lead or any thoughts of possible	e death to self.	
	3 = Suicide ideas or ges	sture.		
		(any serious attempt rates 4).		
4. Insomn		1		
	0 = No difficulty falling a	steep. sional difficulty falling asleep. (i	i e more than ½ hour)	
		y difficulty falling asleep.	i.c., more than 72 hour)	
5. Insomn		, annount raining decop.		
	0 = No difficulty.			
L		of being restless and disturbed		
	J 2 = Waking during the r of voiding).	night – any getting out of bed ra	ates 2 (except for purposes	
6. Insomn	• ,			
J. 11.5011111	3.0			
	0 = No difficulty.			
Ļ		irs of the morning but goes bac	k to sleep.	
	$\angle = Unable$ to fall aslee	o again if gets out of bed.		

### Form 15 – HAMILTON DEPRESSION RATING SCALE

	Site ID:	Subject ID #.	Subject Initials	Week
Date:				
Date.				
L	(mm/dd/nnn)			
7. Work an	(mm/dd/yyyy) d Activities			
	work or hobbies.  2 = Loss of interest in indirect in listlessr work or activities).	activity; hobbies or work – einess, indecision and vacillation	ther directly reported by patient, in (feels s/he has to push self to ecrease in productivity.	or
	4 = Stopped working	because of present illness.		
8. Retardat		ech; impaired ability to concentrat	e: decreased motor activity)	
	0 = Normal speech ar		e, decreased motor delivity)	
	1 = Slight retardation 2 = Obvious retardation 3 = Interview difficult 4 = Complete stupor	at interview		
9. Agitation				
	0 = None 1 = Fidgetiness 2 = Playing with hand 3 = Moving about, cal 4 = Hand-wringing, na		lips	
10. Anxiety	Psychic			
	0 = No difficulty 1 = Subjective tension 2 = Worrying about m 3 = Apprehensive atti 4 = Fears expressed	inor matters tude apparent in face or spee	ch	
11. Anxiety		of amplicate and an Control intention	al during which wind indication	
dia			ar: ary moutn, wind, inalgestion, aches. Respiratory: hyperventilation	ı <b>,</b>
	0 = Absent 1 = Mild 2 = Moderate 3 = Severe 4 = Incapacitating			
12. Somati	c Symptoms Gastrointe	stinal		
	2 = Difficulty eating w		nent. Heavy feelings in abdomen quires laxatives or medication fo	

### Form 15 – HAMILTON DEPRESSION RATING SCALE

	Site ID:	Subject ID #.	Subject Initials	Week
Date:				
	(mm/dd/yyyy)	<u> </u>		
13. Somat	ic Symptoms General  0 = None  1 = Heaviness in limb energy and fatiga  2 = Any clear-cut sym		idache, muscle aches. Loss	of
	ll Symptoms uch as loss of libido and me	enstrual disturbances)		
	0 = Absent 1 = Mild 2 = Severe			
15. Hypod	hondriasis			
16. Loss o	4 = Hypochondriacal	th health nts, requests for help, etc.		
To Insight	2 = Definite weight lo	oss associated with present illnesss (according to subject)	SS.	
			ood, climate, overwork,	
	0 = No variation 1 = (Mild) Doubtful or 2 = (Severe) Clear or If answer is 1 or 2		e worse in: O A.M. O P.M.	
	sonalization and Dereali Symptoms such as feelings o	ization of unreality and nihilistic ideas)		
	0 = Absent 1 = Mild 2 = Moderate 3 = Severe 4 = Incapacitating			

### Form 15 – HAMILTON DEPRESSION RATING SCALE

	Site ID:	Subject ID #.	Subject Initials	Wee
Date:				
20. Parano	(mm/dd/yyyy) oid Symptoms			
	0 = None 1 = Suspicious 2 = Ideas of reference 3 = Delusions of refere	ence and persecution		
21. Obses	sive and Compulsive Sy	mptoms		
	0 = Absent 1 = Mild 2 = Severe			
22. Helple	ssness			
	<ul><li>2 = Subject volunteers</li><li>3 = Requires urging, g</li><li>personal hygiene.</li></ul>	s which are elicited only by inquing his helpless feelings. uidance and reassurance to acted to the second perform necessary chores.	ccomplish chores or	
23. Hopele	essness			
	2 = Consistently feels 3 = Expresses feelings which cannot be di	ts that "things will improve" but "hopeless" but accepts reassur s of discouragement, despair, p spelled. d inappropriately perseverates,	rances. pessimism about future,	
		esteem, feelings of inferiority, self-d ess)	epreciation (loss of self-esteem) to	<b>)</b>
	2 = Spontaneously ind 3 = Different from 2 by etc.	of worthlessness (loss of self elicates feelings of worthlessness degree: Subject volunteers the of total worthlessness – e.g. "	ss (loss of self esteem). at s/he is "no good," "inferior,"	,
Completed	by (Initials):	]		

	Site ID:	Subject ID #.	Subject Initials	Week
Date:				
	(mm/dd/yyyy)			
Date dose	s dispensed ach dose is four tablets	(mm/dd/yyyy)		
Kit Numbe	r:			
Bottle Num	nber:			
Number of	doses dispensed			
Date unus	ed doses returned	(mm/dd/yyyy)		
Number of	doses returned			
Number of	doses reported lost by subject	ct		
Doses take	en:			
	Day of Week:	<u>Date</u>	Time	Dose
	Day of Week.		Dose	Not
		(mm/dd/yyyy)	Taken	Taken
Comments	3:			
Completed	l by (Initials):			

Completed by (Initials):

### PΥ

Trootmont	Wook	Q

NIDA-M	IDS-Modaf-0001	F	Form 34 – TR	EATMI	ENT CO	MPLIANCE	- PSYCHO Treatmer	
	Site ID:		Subject ID	#.	_	Subject Init		Week
Date:								
	(mm/dd/yyyy)							
Did subje	ct receive standardized, man	ual-gı	uided individu	ıal psyd	chothera	apy this week	?	
(If No, ple	ase comment below)		Yes		No			
If yes, len	gth of psychotherapy session	١		minut	es			
	ct require emergency crisis ent sessions this week?		Yes		No			
If yes, how	w many?							
Additional	comments:							

### Form 14 – BIRTH CONTROL / PREGNANCY ASSESSMENT

					Trea	tment Week 8
	Site	ID:	Subject	ID #.	Subject Initials	Week
Date:						
Dute.						
	(mm/a	ld/yyyy)				
	(IIIII/G	(слуууу)				
			-	-	subjects must be tes to be eligible for thi	
What m	nethod of birth o	control is the part	icipant currentl	y using (prior to	taking modafinil)?	
	☐ Oral co	ontraceptive				
	Barrie	r (diaphragm or d	condom plus sp	permicide)		
	Levon	orgestrel implant	(Norplant)			
	☐ Intraut	erine Contracept	ive system (IU	D)		
	☐ Medro	xyprogesterone	Acetate Contra	ceptive injection	(Depo-Provera)	
		aceptive patch				
	_	al Sterilization - I				
	☐ Surgic	al Sterilization -	Tubal ligation			
		e or 2 years post during the study			agree to use an accestudy drug?	eptable
	☐ Yes		lo			
If yes, r	mark below the	acceptable meth	od selected by	the subject for u	use:	
	☐ barrier	method with spe	ermicide			
	steroic	dal contraceptive junction with a ba	[oral, Implante	d, injected] used	d	
		aceptive patch us		ion with a barrie	r method	
	☐ Intraut	erine device [IUD	)]			
Was a p	pregnancy test	performed?		Yes	□ No	
	If yes, date spe	ecimen collected		(mm/dd/yy	<i>yy)</i>	
	Result:	☐ Negative	☐ Positive	☐ Unknown		
	If no, specify re	eason:				
	, <b>,</b> ,					
Is the s	ubject lactating	? <u> </u>	es	□ No		
Comme	ents:					
Comple	l (albitials) hate	•				

	Site ID:	Subject	ID#	<b>Treatm</b> Subject Initials	ent Week 9 Week
	Site 15:	Subject		Subject minus	Week
Date:					
	(mm/dd/yyyy)				
<u>Weekly</u>	Vital Signs				
☐ Vital s	signs not assessed at thi	s visit			1
Date	(mm/dd/yyy	y)	Time Vital Signs	taken (24 hour clo	ck)
Temperate	ure (oral) s for Temperature	(°F)	NR: 94-100.4	CS □ NCS	; <u> </u>
	ssure (sitting)s for Blood Pressure:	(mm Hg)	NR: 90-140/50-9	0 CS□ NCS	
Pulse Rat	e (sitting) (b s for Pulse Rate:	eats/min)	NR: 50-120	CS □ NCS	
	ry Rate (sitting) s for Respiratory Rate:	(breaths/min)	NR: 8-20	CS □ NCS	5 🗆
Complete	d by (Initials):				

# Form 23 - URINE BE SPECIMEN COLLECTION FORM NIDA-MDS-Modaf-0001 **Treatment Week 9 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) ☐ Yes ☐ No Was urine temperature within expected range? Franklin Cup: The temperature must be <u>higher</u> than 96.0° F and <u>lower</u> than 104.8° F On-Trak Cup: The temperature must be <u>higher</u> than 90.0° F and <u>lower</u> 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 9 V2

	Site ID:	Subject ID #	· 	Subject Initials	Week
Date:	(mm/dd/yyyy)				
<u>Second Stud</u>	y Visit of Week	Urine bar code :	sticker:		
Date urine collec	ted: (mm/dd/	(yyyy)	Urine not	t collected	
Franklin C Trak Cup:	The temperature must	ted range? nust be <u>higher</u> than 96.0° be <u>higher</u> than 90.0° Fa ust be <u>higher</u> than 90.0°	F and <u>lower</u> than 1 nd <u>lower</u> than 99.0°	° F Split	
Completed by (In	itials):				

### Form 23 – URINE BE SPECIMEN COLLECTION FORM

### **Treatment Week 9 V3**

	Site ID	):	Subject	ID#.	Subject Initials		Week
Date:						IJ L	
	(mm/dd/	<i>'</i> ( <i>yyyy</i> )					
Third S	tudy Visit o	f Week	Urine bar co	de sticker:			
Date urine	e collected:	(mm/dd/y	/ууу)	Urin	e not collected		
Fi Ti	rak Cup: The tem	temperature m perature must	ed range? ust be <u>higher</u> than 9 be <u>higher</u> than 90.0 ust be <u>higher</u> than 90	° F and <u>lower</u> than	than 104.8° F On- 99.0° F Split	No	
Complete	d by (Initials):						

### Form 24 – SUBSTANCE USE INVENTORY

					eatment Week	9		
Site 1	ID:	Subject ID	) #. 	Subject Initials	Week	1		
Date:						I		
(mm/d	d/yyyy)							
Using timeline follow-back of administration for each	method, record wh drug. Begin with ye	nether subject has c esterday and work	on each day since t back to the last vis	he last visit used ar it. Please be sure th	ny amount of the su nat days are continu	ubstances listed be uous with last week	low, along with the	most common route
Date of last v								
	(mm/a	ld/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			
Alcohol	□Y/□N	□Y/□N	□Y/□N	□Y/□N	□Y/ □N	□Y/□N	□Y/ □N	
Marijuana	$\square$ Y/ $\square$ N $\bigsqcup$	$\square$ Y/ $\square$ N $\bigsqcup$	$\square$ Y/ $\square$ N $\bigsqcup$	$\square$ Y/ $\square$ N $\bigsqcup$	$\square$ Y/ $\square$ N	$\square$ Y/ $\square$ N $\bigsqcup$	$\square$ Y/ $\square$ N $\bigsqcup$	
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 adminis	tration (ROA) codes	s: 1 = oral, 2 = nasal	, 3 = smoking, 4 = 1	non-intravenous inj	iection, 5 = intraver	ous injection		
Completed by (Initials):								

	Site	ID.	Subject ID	#	Subject	Treatmen et Initials	t Week ! Week
	Site	ID.	Subject ID	#.	Subjec	t midais	WEEK
Date:							
	(100,100 (10	let (an ana)					
	(mm/a	ld/yyyy)					
<u>Cocai</u>	<u>ne</u>						
1. The <u>i</u>	ntensity of my o	craving, that is, he	ow much I desire	d cocaine in	the past 24	hours was:	
	☐ None at all	☐ Slight	☐ Moderate	☐ Cons	siderable	☐ Extreme	
2. The <u>f</u>	requency of my	craving, that is,	how often I desir	ed cocaine i	n the past 2	4 hours was:	
	☐ Never	☐ Almost never	☐ Several t	imes [	Regularly	☐ Almost c	onstantly
3. The <u>l</u>	ength of time I	spent craving for	cocaine during tl	ne past 24 h	ours was:		
	☐ None at all	☐ Very shor	t Short	☐ Som	newhat long	☐ Very long	I
4. Write	in the <u>number</u>	of times you thinl	k you had craving	g for cocaine	e during the	past 24 hours:	
5. Write	in the total time	e spent craving c	ocaine during the	e past 24 ho	urs:		
	hours	minutes					
6. The <u>v</u>	worst day: Duri	ng the past week	my most intense	e craving oc	curred on th	e following day:	
	Sunday	Monday	Tuesday	Wednesda	•		
	Thursday	Friday	☐ Saturday	☐ All days th	ne same (go to	Q. 8)	
7. The o	date for that day	y was:	(mm/dd/yyyy)				
8 The i	ntensity of my	craving, that is, he		d cocaine o	n that worst	day was:	
o. me <u>i</u>	_	-	_			_	
	☐ None at all	☐ Slight	☐ Moderate	□ Cons	siderable	☐ Extreme	
<u>Secor</u>	nd Drug						
9. A <b>2<sup>nd</sup></b>		uring the past 24 fthe following. If no		ark "None" ar	nd leave Quest	tions 10-16 blank.	
	None		ners or Sedatives	Benzos	anay ota )	☐ Nicotine	
	Alcohol	Hero	iturates, etc.) in or other Opiates phine, etc.)	(Valium, Xa	ariax, 516.)	Other Specify	
	intensity of my rs was:	craving, that is,	how much I desir	ed this <b>sec</b>	ond drug in	the past 24	
	☐ None at all	☐ Slight	☐ Moderate	☐ Cons	siderable	☐ Extreme	

	Site	ID:	Subject ID#.		Subject		nt Week 9 Week
Date:							
	(mm/c	dd/yyyy)					
	frequency of rrs was:	my craving, that is,	how often I desire	ed this <b>secor</b>	ı <b>d</b> drug in t	he past 24	
	☐ Never	☐ Almost never	☐ Several time	es 🗆 F	Regularly	☐ Almost	constantly
12. The	length of time	I spent in craving for	or this <b>second</b> dr	ug during the	past 24 h	ours was:	
	☐ None at all	☐ Very short	☐ Short	☐ Somew	hat long	☐ Very lor	ng
<u>Third</u>	<u>Drug</u>						
13. A <b>3</b> <sup>r</sup>	<sup>d</sup> craved drug o <i>Mark <u>only one</u> o</i>	during the past 24 h	nours was: r <sup>d</sup> craved drug, mark	"None" and le	ave questio	ns 14-16 blank.	
	None		ers or Sedatives	Benzos (Valium, Xana)	v oto)	☐ Nicotine	
	Alcohol	Heroin	or other Opiates [ine, etc.)	Marijuana	t, etc.)	Other Specify	
	intensity of myrs was:	y craving, that is, ho	ow much I desired	I this <b>third</b> di	ug in the p	oast 24	
	☐ None at all	☐ Slight	☐ Moderate	☐ Conside	rable	☐ Extreme	
	frequency of rrs was:	my craving, that is,	how often I desire	ed this <b>third</b> (	drug in the	past 24	
	☐ Never	☐ Almost never	☐ Several time	es 🗆 F	Regularly	☐ Almost	constantly
16. The	length of time	I spent in craving for	or this third drug	during the pa	st 24 hours	s was:	
	☐ None at all	☐ Very short	☐ Short	☐ Somew	hat long	☐ Very lor	ng
Comple	ted by (Initials)	:					

### Form 30 - COCAINE SELECTIVE SEVERITY ASSESSMENT

**Treatment Week 9 Subject Initials** Week Site ID: Subject ID #. Date: the h of

	(mm/dd/yyyy)								
ite	questions except 4 and 5 are asse ms in lay language and the respon estion 4 and 5, the subject is asked the questions. The rater the	se is reco	orded on the appr	a scale of opriate pl	f 0-7 with ace on the	0 being n e line (on	ormal or i page 3) th	no sympto	ms. Fo
Da	ate of last cocaine use:			/ ///	, , , , , , , , , , , , , , , , , , ,				
1.	Hyperphagia  0 = normal appetite  3-4 = eats a lot more than  7 = eats more than twice u		ount of fo	(mm/dd/	Уууу)				
2.	Hypophagia  0 = normal appetite  3-4 = eats less than half of 7 = no appetite at all	f normal	amount o	of food					
3.	Carbohydrate Craving  0 = no craving  3-4 = strong craving for sweet  7 = strong craving for sweet					me			
4.	Cocaine Craving Intensity		Please (	use subje	ct intensi	ty rating f	rom pg. 3	of this fo	rm.
5.	Cocaine Craving Frequenc	у	Please (	use subje	ct frequer	ncy rating	from pg.	3 of this f	orm.
6.	Bradycardia		Please (	use scale	below.				
	Pulse (BPM)	0 >64	1 64-63	2 62-61	3 60-59	4 58-57	5 56-55	6 54-53	7 <53
7.	Insomnia  0 = normal amount of slee  3-4 = half of normal amount  7 = no sleep at all		ep						
8.	Hypersomnia								

0 = normal amount of sleep 3-4 = could sleep or does s leep half the day

7 = sleep or could sleep all the time

### Form 30 - COCAINE SELECTIVE SEVERITY ASSESSMENT

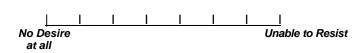
		Site ID:	Subject ID #.		Subject Initials	Wee
Б.			_			
Date	<b>):</b>					
		(mm/dd/yyyy)				
0	A micia 4	••				
9. /	Anxiet					
		= usually does not feel anxic 4 = feels anxious half the tir				
		= feels anxious all the time				
10.	Energ	gy Level				
		= feels alert and has usual a 4 = feels tired half the time	amount of energy			
		= feels tired all the time				
11	Activ	ity Level				
• • • •		= no change in usual activiti	es			
	3-	4 = participates in half of us	ual activities			
	/ =	= no participation in usual ac	ctivities			
12.	Tensi	ion				
		1 = rarely feel tense 4 = feels tense half the time				
		= feels tense most or all the				
13.	Atter	ntion				
70.			ding, conversation, tasks, and r	nake pl	ans without difficulty	
	3-	4 = has difficulty with the ab	ove half the time	•	,	
	/ =	= has difficulty with the abov	/e all the time			
14.	Parar	noid Ideation				
		= no evidence of paranoid th 4 = unable to trust anyone	noughts			
	5 =	= feels people are out to get				
	7 =	= feels a specific person/gro	oup is plotting against him/her			
15.	Anhe	donia				
		= ability to enjoy themselves				
		4 = able to enjoy themselve = unable to enjoy themselve				
		, ,				
16.	-	ession				
		= no feelings related to sadr 4 = feels sad or depressed l				
	7 =	= feels depressed all of the	time			
17.	Suici	dality				
	0 =	= does not think about being				
		4 = feels like life is not worth = feels like actually ending li	_			
18.	Irritak	•				
		= feels that most things are 4 = feels that many things a				
_	7 =	= feels that mostly everythin				
Con	npieted	d by (Initials):				

NIDA-MDS-Modaf-0001		Form 30 - COCAINE S	SELECTIVE SEVERITY A	ASSESSMENT	
			<b>Treatment Week</b>		
_	Site ID:	Subject ID #.	Subject Initials	Week	
Date:					
_	(mm/dd/yyyy)				

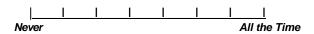
### CSSA VISUAL ANALOG SCALE

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:



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



### Form 28 - CLINICAL GLOBAL IMPRESSION - SELF

NIDA-MDS-Modaf-0001 **Treatment Week 9** 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):

			Treatr	nent Week !
	Site ID:	Subject ID #.	Subject Initials	Week
Date:				·
<u> </u>	(mm/dd/yyyy)			

# **Current Severity**

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

		None, Least <u>Severe</u>						Most <u>Severe</u>
Report	red Cocaine Use: (frequency and amount of cocaine used)	1	2	3	4	5	6	7
Cocain	ne Seeking: (craving for cocaine, effort to stop, and drug seeking behavior)	1	2	3	4	5	6	7
Report	ed Use of Other Drugs: (frequency and amount of non-cocaine drug/alcohol use)	1	2	3	4	5	6	7
Observ	vable Psychiatric Symptoms: (orientation, memory, comprehension, disorganized thinking, rapid/retarded speech, agitation, grooming, hostility, irritability, affective disturbance)	1	2	3	4	5	6	7
Report	ted Psychiatric Symptoms: (mood disturbance, depression, anxiety,inner restlessness, covert anger, somatic symptoms energy level,motivation, sleep, appetite, libido, anhedonia)	i, 1	2	3	4	5	6	7
Physic	al/Medical Problems: (those that have emerged or gotten worse after drug use)	1	2	3	4	5	6	7
Malada	aptive Coping in the Family/Social area: (movement away from healthy relationships)	1	2	3	4	5	6	7
Malada	aptive 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:		7	
	(mm/dd/yyyy)		
<u>Global</u>	Severity of Cocaine I	<u>Dependence</u>	
	ng your total clinical exper	ience with the cocaine dependent symptoms at this time?	population, how severe are
	Normal, no symptoms		
	Borderline symptoms		
	<ul><li>Mild symptoms</li><li>Moderate symptoms</li></ul>		
	Marked symptoms		
	<ul><li>Severe symptoms</li><li>Most extreme symptom</li></ul>	s possible	
<u>Global</u>	Improvement of Coc	aine Dependence	
your judg project, h	ment, it is due entirely to d	articipant's cocaine dependence s rug treatment. Compared to the s	
	_		
	<ul><li>Not assessed, first ratir</li><li>Very much improved</li></ul>	9	
	☐ Much improved		
	☐ Minimally improved ☐ No change		
	Minimally worse		
	<ul><li>J Much worse</li><li>J Very much worse</li></ul>		
	-		
Complete	d by (Initials):		

	Site ID:	Subject ID #.	Subject Initials	Week
Date:				
	(mm/dd/yyyy)			
Date dose	s dispensed ach dose is four tablets	(mm/dd/yyyy)		
Kit Numbe	r:			
Bottle Nun	nber:			
Number of	doses dispensed			
Date unus	ed doses returned			
Number of	doses returned	(mm/dd/yyyy)		
	doses reported lost by subje	ct		
Doses take	en:			
	Day of Week:	<u>Date</u>	Time	Dose
	·	(mm/dd/yyyy)	Dose Taken	Not Taken
Comments	5:			
55	-			
Completed	d by (Initials):			

NIDA-MDS-Modal-0001		FORM 54 - IREATMENT C			11 00	Treatment Wee		
	Site ID:		Subject ID #	<b>‡</b> .	_	Subject Initials	Week	
Date:		<u>L</u>			L		J <u>L </u>	
	(mm/dd/yyyy)							
Did subjed	ct receive standardized, ma	nual-g	uided individu	al psych	other	apy this week?		
(If No, ple	ase comment below)		Yes		No			
If yes, len	gth of psychotherapy session	on		minute	es			
	ct require emergency crisis ent sessions this week?		Yes		No			
If yes, how	w many?							
Additional	comments:							

Completed by (Initials):

	Site ID: Subject	et ID #. Subjec	Treatment Week 10 t Initials Week
Date:			
<u>Weekly</u>	v Vital Signs		
☐ Vital Date	signs not assessed at this visit  (mm/dd/yyyy)	Time Vital Signs taken	(24 hour clock)
	ture (oral) (°F) ts for Temperature	NR: 94-100.4	CS NCS
	essure (sitting) (mm Hg) ts for Blood Pressure:	NR: 90-140/50-90	CS   NCS
	te (sitting) (beats/min)	NR: 50-120	CS □ NCS □
Respirato	ts for Pulse Rate:  ory Rate (sitting) (breaths/min) ts for Respiratory Rate:	NR: 8-20	CS NCS
Complete	ed by (Initials):		

### Form 23 - URINE BE SPECIMEN COLLECTION FORM

# Treatment Week 10 V1 Site ID: Subject ID #. Subject Initials Week [mm/dd/yyyy) | First Study Visit of Week | Urine bar code sticker: | Urine not collected | |

Was urine temperature within expected range? 

Franklin Cup: The temperature must be higher than 96.0° F and lower than 104.8° F OnTrak 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

(mm/dd/yyyy)

Completed by (Initials):

Site ID:

### Form 23 – URINE BE SPECIMEN COLLECTION FORM

# Subject ID #. Subject Initials Week Subject Initials Week

Date:						
	(mm/d	d/yyyy)				
<u>Second</u>	Study Vis	it of Week	Urine bar	code sticker:		
Date urine	collected:	(mm/dd/yy	vyy)	]	Jrine not collected	
Fra Tra Sa	anklin Cup: The	mperature must k temperature mu	ust be <u>higher</u> tha be <u>higher</u> than 90		☐ Yes <u>rer</u> than 104.8° F On- han 99.0° F Split <u>er</u> than 100.0° F	□ No

### Form 23 – URINE BE SPECIMEN COLLECTION FORM

Treatment Week 10 V3

			Treatment week to v			
	Site ID:	Subje	ct ID#.	Subject Initials	Week	
Date:	(mm/dd/yyyy	)				
<u>Third St</u>	udy Visit of We	<u>eek</u> Urine bar	code sticker:			
Date urine	collected:	(mm/dd/yyyy)	Urin	e not collected		
Fra Tra	nk Cup: The temperate	expected range? erature must be <u>higher</u> tha ure must be <u>higher</u> than 90 rature must be <u>higher</u> than	.0 ° F and <u>lower</u> than	99.0° F Split		
Completed	by (Initials):					

### Form 24 – SUBSTANCE USE INVENTORY

					tment Week 1	10		
Site I	ID:	Subject ID	)#	Subject Initials	Week	•		
Date:								
Date.								
(mm/de	d/yyyy)							
Using timeline follow-back of administration for each	method, record wh drug. Begin with ye	ether subject has c esterday and work	on each day since t back to the last vis	he last visit used ar it. Please be sure th	ny amount of the su nat days are continu	ubstances listed be uous with last week	low, along with the 's form.	most common route
Date of last vi	isit:							
	(mm/a	ld/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	$\square$ Y/ $\square$ 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 administ	tration (ROA) codes	s: 1 = oral, 2 = nasal	, 3 = smoking, 4 = 1	non-intravenous inj	ection, 5 = intraven	ous injection		
Completed by (Initials):								

	a.	ID.	C.L' (ID	ш	0.11	Treatment V	
	Site	טו:	Subject ID	#.	Subjec	et Initials	Week
Date:							
	(mm/a	ld/yyyy)					
<u>Cocai</u>	<u>ne</u>						
1. The <u>ii</u>	ntensity of my	craving, that is, h	ow much I desire	d cocaine in	the past 24	hours was:	
	☐ None at all	☐ Slight	☐ Moderate	☐ Cons	derable	☐ Extreme	
2. The <u>f</u>	requency of my	y craving, that is,	how often I desir	ed cocaine ir	the past 2	24 hours was:	
	☐ Never	☐ Almost never	☐ Several t	imes $\Box$	Regularly	☐ Almost co	nstantly
3. The <u>l</u> e	ength of time I	spent craving for	cocaine during the	ne past 24 ho	ours was:		
	☐ None at all	☐ Very shor	t 🗆 Short	☐ Some	ewhat long	☐ Very long	
4. Write	in the <u>number</u>	of times you thin	k you had cravin	g for cocaine	during the	past 24 hours:	
5. Write	in the total <u>tim</u>	e spent craving of minutes	cocaine during the	e past 24 hou	ırs:		
6. The <u>v</u>	<u>vorst</u> day: Duri	ing the past weel	c my most intense	e craving occ	urred on th	e following day:	
	Sunday	Monday	Tuesday	Wednesda			
	Thursday	☐ Friday	☐ Saturday	☐ All days th	e same (go to	Q. 8)	
7. The c	date for that day	y was:					
8. The <u>i</u>	ntensity of my	craving, that is, h	(mm/dd/yyyy) ow much I desire	d cocaine or	that worst	day was:	
	☐ None at all	☐ Slight	☐ Moderate	☐ Cons	derable	☐ Extreme	
<u>Secor</u>	nd Drug						
9. A <b>2<sup>nd</sup></b>	craved drug d Mark <u>only one</u> or	uring the past 24 fthe following. If no	hours was: o 2 <sup>nd</sup> craved drug, m	ark "None" and	d leave Ques	tions 10-16 blank.	
	None		ners or Sedatives biturates, etc.)	Benzos (Valium, Xa	nav etc)	☐ Nicotine	
	Alcohol	Hero	oin or other Opiates ohine, etc.)	☐ Marijuana	ian, 010. <i>j</i>	Other Specify	
	intensity of myrs was:	craving, that is,	how much I desir	ed this <b>seco</b>	<b>nd</b> drug in	the past 24	
	☐ None at all	☐ Slight	☐ Moderate	☐ Consi	derable	☐ Extreme	

	Site	ID:	Subject ID#.		Subject In	Treatment	Week 10 Week
_							
Date:							
	(mm/c	ld/yyyy)					
	frequency of nrs was:	ny craving, that is, l	now often I desire	d this <b>secon</b>	<b>d</b> drug in th	e past 24	
	☐ Never	☐ Almost never	☐ Several time	es 🗆 R	egularly	☐ Almost o	constantly
12. The	<u>length</u> of time	I spent in craving for	or this <b>second</b> dru	ug during the	past 24 ho	urs was:	
	☐ None at all	☐ Very short	☐ Short	☐ Somew	hat long	☐ Very Ion	g
<u>Third</u>	<u>Drug</u>						
13. A <b>3</b> <sup>r</sup>	<sup>d</sup> craved drug o <i>Mark <u>only one</u> o</i>	during the past 24 h	nours was: <sup>rd</sup> craved drug, mark	"None" and le	ave question:	s 14-16 blank.	
	None		ers or Sedatives	Benzos	[	Nicotine	
	Alcohol	Heroin	or other Opiates ne, etc.)	(Valium, Xanax ] Marijuana	:, etc.)	Other Specify	
	intensity of myrs was:	y craving, that is, ho	ow much I desired	this <b>third</b> dr	ug in the pa	ast 24	
	☐ None at all	☐ Slight	☐ Moderate	☐ Conside	rable	☐ Extreme	
	frequency of r rs was:	ny craving, that is, l	now often I desire	d this <b>third</b> o	Irug in the p	oast 24	
	☐ Never	☐ Almost never	☐ Several time	es 🗌 R	egularly	☐ Almost o	constantly
16. The	length of time	I spent in craving for	or this third drug o	luring the pa	st 24 hours	was:	
	☐ None at all	☐ Very short	☐ Short	☐ Somew	hat long	☐ Very Ion	g
Comple	ted by (Initials)	:					

## Form 30 - COCAINE SELECTIVE SEVERITY ASSESSMENT

**Treatment Week 10** 

		Site ID:	Subject ID	#	Subject Initials	Week
Da	te:					
		(mm/dd/yyyy)				
AII	questio	ns except 4 and 5 are assesse	d by properly trained pe	rsonnel. The subj	ect is asked about each	of the
		language and the response is and 5, the subject is asked to				
•		e questions. The rater then tr				
Da	te of las	st cocaine use:				
			(mm/dd/y	yyy)		
1.	Hyper	phagia				
		= normal appetite				
		4 = eats a lot more than usua				
	7	= eats more than twice usua	amount of food			
2.	Нурор	hagia				
	0 :	= normal appetite				
	3-	4 = eats less than half of nor	mal amount of food			
	7	= no appetite at all				
3.	Carbo	hydrate Craving				
	0 :	= no craving				
	3-	4 = strong craving for sweets				
	7 :	= strong craving for sweets,	cakes, and cookies all	the time		
4.	Cocaii	ne Craving Intensity				
			Please use subject	ct intensity rating f	from pg. 3 of this form.	
5.	Cocaii	ne Craving Frequency				
			Please use subjec	ct frequency rating	from pg. 3 of this form.	
6.	Brady	cardia				
•	,	<b></b>	Please use scale l	below.		
		0	1 2	3 4	5 6 7	
		Pulse (BPM) >64		60-59 58-57	56-55 54-53 <5	3
7.	Insom	nia				
	0 :	= normal amount of sleep				
	3-	4 = half of normal amount of	sleep			
	7	= no sleep at all				
8.	Hyper	somnia				
		= normal amount of sleep				
	3-	4 = could sleep or does slee				
	7	= sleep or could sleep all the	e time			

## Form 30 - COCAINE SELECTIVE SEVERITY ASSESSMENT

**Treatment Week 10** 

	Site ID:	Subject ID #.	Subject Initials	Weel
Date	<u> </u>	<u> </u>		
	(mm/dd/yyyy)			
9.	Anxiety			
	0 = usually does not feel and 3-4 = feels anxious half the 7 = feels anxious all the time	time		
10.	Energy Level			
	0 = feels alert and has usua 3-4 = feels tired half the time 7 = feels tired all the time			
11.	Activity Level			
	0 = no change in usual activ 3-4 = participates in half of u 7 = no participation in usual	sual activities		
12.	Tension			
	0-1 = rarely feel tense 3-4 = feels tense half the tin 7 = feels tense most or all th			
13.	Attention			
	0 = able to concentrate on re 3-4 = has difficulty with the a 7 = has difficulty with the ab		make plans without difficulty	
14.	Paranoid Ideation			
	0 = no evidence of paranoid 3-4 = unable to trust anyone 5 = feels people are out to g 7 = feels a specific person/g	_		
15.	Anhedonia			
	0 = ability to enjoy themselv 3-4 = able to enjoy themselv 7 = unable to enjoy themsel	es half of the time		
16.	Depression			
	0 = no feelings related to sa 3-4 = feels sad or depressed 7 = feels depressed all of th	I half the time		
17.	Suicidality			
	0 = does not think about bein 3-4 = feels like life is not wor 7 = feels like actually ending	th living		
18.	Irritability			
	0 = feels that most things are 3-4 = feels that many things 7 = feels that mostly everyth	are irritating		
Cor	noleted by (Initials):			

### Form 30 - COCAINE SELECTIVE SEVERITY ASSESSMENT

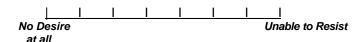
**Treatment Week 10** 

				Ticati			
	Site ID:		Subject ID #.		Subject Initials	_	Week
Date:		7					
	(mm/dd/yyyy)	_					

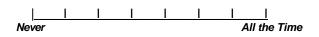
#### CSSA VISUAL ANALOG SCALE

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:



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



## N

NIDA_M	IDS-Modaf-0001	Form 28 - CLIN	ICAL GLOBAL IMPRE	SSION - SFLI
NIDA-W	1D5-W10ua1-0001	roim 20 – CEIIV		ent Week 10
	Site ID:	Subject ID #.	Subject Initials	Week
Date:		<del>-</del>		
	(mm/dd/yyyy)			
Cocain	e Global Severity			
	ne, how would you rate yourse ine related problems?	If overall for cocaine use		
_	_			

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):	

NIDA-MDS-Modaf-0001		Form 29 - CLINICAL GLOBAL IMPRESSION - OBSERVER			
				Screening/Basel	ine 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 <u>Severe</u>
Report	red Cocaine Use: (frequency and amount of cocaine used)	1	2	3	4	5	6	7
Cocair	ne Seeking: (craving for cocaine, effort to stop, and drug seeking behavior)	1	2	3	4	5	6	7
Report	ed Use of Other Drugs: (frequency and amount of non-cocaine drug/alcohol use)	1	2	3	4	5	6	7
Observ	vable Psychiatric Symptoms: (orientation, memory, comprehension, disorganized thinking, rapid/retarded speech, agitation, grooming, hostility, irritability, affective disturbance)	1	2	3	4	5	6	7
Report	red 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
Physic	al/Medical Problems: (those that have emerged or gotten worse after drug use)	1	2	3	4	5	6	7
Malada	aptive Coping in the Family/Social area: (movement away from healthy relationships)	1	2	3	4	5	6	7
Malada	aptive 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

				Treatmen	t Week 10
	Site ID:	Subject ID #.	Sub	eject Initials	Week
Date:					
	(mm/dd/yyyy)				
Global S	Severity of Cocaine D	<u>ependence</u>			
	ng your total clinical experient's cocaine dependence sy		ependent populati	on, how severe a	are
ino odbjet		mptomo at uno umo.			
	Normal, no symptoms				
	Borderline symptoms Mild symptoms				
	Moderate symptoms				
	Marked symptoms				
	Severe symptoms  Most extreme symptoms	nossiblo			
<u> </u>	i wost extreme symptoms	s possible			
Global I	mprovement of Coca	<u>ine Dependence</u>			
Rate the to	otal improvement in the par	ticinant's cocaine dene	ndence symptom	s whether or not	in
	nent, it is due entirely to dr				
project, ho					
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	d by (Initials):				

_	Site ID:	Subject ID #.	Subject Initials	ent Week I Week
Date:		]		
	(mm/dd/yyyy)	J		
Date doses	s dispensed ch dose is four tablets	(mm/dd/yy	yy)	
Kit Number	r:			
Bottle Num	ber:			
Number of	doses dispensed			
Date unuse	ed doses returned	(mm/dd/yy	yy)	
Number of	doses returned			
Number of	doses reported lost by su	ubject		
Doses take	en:			
	Day of Week:	<u>Date</u>	Time Dose	Dose Not
		(mm/dd/yyyy)	Taken	Taken
Comments	:			
Completed	by (Initials):	_		

Completed by (Initials):

# PY

. (22)	IDS-Modaf-0001					OMPLIANCE - PS` Trea		Week 10
	Site ID:	_	Subject ID	#.	ı	Subject Initials	_	Week
Date:								
	(mm/dd/yyyy)							
Did subje	ct receive standardized, manu	ıal-g	uided individ	ual psy	chother	apy this week?		
(If No, please comment below)			Yes		No			
If yes, ler	ngth of psychotherapy session			minute	es			
	ect require emergency crisis nent sessions this week?		Yes		No			
If yes, ho	w many?							
Additiona	Il comments:							

## Form 14 – BIRTH CONTROL / PREGNANCY ASSESSMENT

				Treatm	ient Week 1
	Site ID:		Subject ID #.	Subject Initials	Week
Date:		_			<u> </u>
	( (11/				

	(mm/dd/yyyy)
	is to be filled out for <u>female subjects only</u> . All female subjects must be tested at //Baseline and have a negative pregnancy test in order to be eligible for this study.
What meth	nod 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 - Tubal ligation
	gically sterile or 2 years postmenopausal, does the subject agree to use an acceptable birth control during the study and 30 days after last dose of study drug?
	Yes
If yes, mar	k 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 pre	gnancy test performed?
lf y	yes, date specimen collected (mm/dd/yyyy)
Re	esult:
lf ı	no, specify reason:
Is the subj	ect lactating?
Comments	
Completed	by (Initials):

	Site ID:	Subject	ID#.	Treatme Subject Initials	ent Week 10 Week
Date:					
	(mm/dd/yyyy)				
<u>Weekly</u>	Vital Signs				
☐ Vital s	signs not assessed at thi	s visit			7
Date	(mm/dd/yyy	y)	Time Vital Signs	taken (24 hour clo	_ ock)
Temperate	ure (oral) s for Temperature	(°F)	NR: 94-100.4	CS □ NC	s 🗆
	ssure (sitting) s for Blood Pressure:	(mm Hg)	NR: 90-140/50-9	90 CS 🗆 NCS	S 🗆
Pulse Rat	re (sitting) (b s for Pulse Rate:	eats/min)	NR: 50-120	CS □ NCS	 3 □
	ry Rate (sitting) s for Respiratory Rate:	(breaths/min)	NR: 8-20	CS 🗆 NCS	S □
Complete	d by (Initials):	]			

Completed by (Initials):

#### Form 23 - URINE BE SPECIMEN COLLECTION FORM

# **Treatment Week 11 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):

#### 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: 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

## Form 23 – URINE BE SPECIMEN COLLECTION FORM

Treatment Week 11 V3

				reaument	week 11 v
F	Site ID:	Subject ID	#. Sı	bject Initials	Week
Date:					
	(mm/dd/yyyy)				
Third Stu	udy Visit of Week	Urine bar code	sticker:		
	ady viole of viole	omio bar oode	Chonor:		
Date urine			Urine not c	ollected $\square$	
	(mm/da	Vyyyy)			
Was urine	temperature within expe	cted range?		Yes □ No	
Fra	nklin Cup: The temperature k Cup: The temperature mus	must be <u>higher</u> than 96.0	° F and <u>lower</u> than 104	l.8° F On-	
	mple Cup: The temperature in				
Completed	by (Initials):	7			
		<b></b>			

### Form 24 – SUBSTANCE USE INVENTORY

				<b>Treatment Week 11</b>					
Site 1	ID:	Subject II	O #.	Subject Initials	Week	1			
Date:						1			
(mm/de	d/yyyy)								
Using timeline follow-back of administration for each	method, record wh drug. Begin with y	hether subject has esterday and work	on each day since t back to the last vis	the last visit used a it. Please be sure tl	ny amount of the su hat days are continu	ubstances listed be uous with last week	low, along with the a's form.	most common route	
Date of last v									
	(mm/c	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	$\square$ Y/ $\square$ N $\square$	□Y/ □N	□Y/ □N	□Y/ □N	$\square Y / \square N$	$\square Y / \square N$	□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 adminis	tration (ROA) codes	s: 1 = oral, 2 = nasa	l, 3 = smoking, 4 = 1	non-intravenous in	jection, 5 = intraver	nous injection			
Completed by (Initials):									
	1								

	Site	ID:	Subject II	<b>)</b> #.	Subjec	et Initials	nt Week 11 Week
Date:							
	(100 100 /						
	(11111/)	dd/yyyy)					
Cocain							
_	_	-	how much I desire		·		
	None at all	☐ Slight	☐ Moderate	☐ Consi	derable	☐ Extreme	
	<u>equency</u> of m □ Never	y craving, that is ☐ Almost never	s, how often I desi		the past 2 Regularly		st constantly
3. The <u>le</u>	ngth of time I	spent craving fo	or cocaine during	the past 24 ho	ours was:		
	☐ None at all	☐ Very sho	ort 🗌 Short	☐ Some	what long	☐ Very I	ong
4. Write i	in the <u>number</u>	of times you thi	nk you had cravir	g for cocaine	during the	past 24 hours	s:
5. Write i	n the total tim	ne spent craving	cocaine during th	e past 24 hou	ırs:		
	hours	minutes	_	•			
6 Tho w				o orovina ooo	urrad on th	o following de	
o. The <u>wi</u>	_	_	ek my most intens	_		le following da	ay.
	<ul><li>Sunday</li><li>Thursday</li></ul>	<ul><li></li></ul>	☐ Tuesday ☐ Saturday	<ul><li>☐ Wednesday</li><li>☐ All days the</li></ul>	/ e same (go to	Q. 8)	
7. The da	ate for that da		nm/dd/yyyy)				
8. The <u>in</u>	tensity of my	craving, that is,	how much I desire	ed cocaine on	that worst	day was:	
	☐ None at all	☐ Slight	☐ Moderate	☐ Consi	derable	☐ Extreme	
Secon	d Drug						
9. A <b>2<sup>nd</sup></b> (	craved drug d <i>Mark <u>only one</u> o</i>	luring the past 24 of the following. If i	4 hours was: n <b>o 2<sup>nd</sup> craved drug, r</b>	nark "None" and	d leave Ques	tions 10-16 blan	k.
	None		wners or Sedatives	Benzos		☐ Nicotine	
	Alcohol	□ He	rbiturates, etc.) roin or other Opiates	(Valium, Xar □ Marijuana	nax, etc.)	Other	
		,	orphine, etc.)			Specify	
	<u>ntensity</u> of my s was:	y craving, that is	, how much I desi	red this <b>seco</b>	<b>nd</b> drug in	the past 24	
Г	□ None at all	□ Cliabt	□ Moderate	□ Consi	doroblo	□ Evtrome	

					Treatment Week			
	Site	ID:	Subject ID #	·.	Subject	Initials	Week	
			J					
Date:								
	(mm/a	ld/yyyy)						
11. The <u>fr</u> hours		ny craving, that is,	how often I desire	ed this <b>seco</b> r	<b>ıd</b> drug in t	he past 24		
	Never	☐ Almost never	☐ Several tim	nes 🗆 F	Regularly	☐ Almos	t constantly	
12. The <u>le</u>	ength of time	I spent in craving f	or this <b>second</b> di	rug during the	past 24 h	ours was:		
	None at all	☐ Very short	☐ Short	☐ Somew	hat long	☐ Very lo	ong	
Third D	rug							
13. A <b>3<sup>rd</sup></b>	craved drug o lark <u>only one</u> o	during the past 24 fthe following. If no	hours was: 3 <sup>d</sup> craved drug, mar	k "None" and le	ave question	ns 14-16 blank		
	None		ers or Sedatives	Benzos		☐ Nicotine		
	Alcohol	Heroir	urates, etc.) n or other Opiates [ nine, etc.)	(Valium, Xana: ☐ Marijuana	k, etc.)	Other Specify		
14. The <u>in</u> hours		craving, that is, h	ow much I desire	d this <b>third</b> di	rug in the p	oast 24		
	None at all	☐ Slight	☐ Moderate	☐ Conside	erable	☐ Extreme		
15. The <u>fr</u> hours		ny craving, that is,	how often I desire	ed this <b>third</b> (	drug in the	past 24		
	] Never	☐ Almost never	☐ Several tim	nes 🗆 F	Regularly	☐ Almos	t constantly	
16. The <u>le</u>	ength of time	I spent in craving f	or this third drug	during the pa	ıst 24 hour	s was:		
	None at all	☐ Very short	☐ Short	☐ Somew	hat long	☐ Very lo	ong	
Complete	d by (Initials):	:						

## Form 30 - COCAINE SELECTIVE SEVERITY ASSESSMENT

**Treatment Week 11** 

	Site	ID:		Subject II	<b>)</b> #.		Subjec	t Initials		Wee
Da	ite:									
	(mm/c	ld/yyyy)								
ite	l questions except 4 and ms in lay language and lestion 4 and 5, the subj the questions. 7	the response is rec	orded on the appr	a scale of opriate pl	f 0-7 with ace on the	0 being n e line (on	ormal or r page 3) th	no sympto	ms. Fo	r
Da	ate of last cocaine us	e:								
				(mm/dd/	yyyy)					
1.	Hyperphagia									
	0 = normal appe	etite								
		more than usual nan twice usual amo	ount of fo	nod						
	7 – eats more ti	ian twice usuai anii		oou						
2.	Hypophagia									
	0 = normal appe 3-4 = eats less t 7 = no appetite	han half of normal	amount o	of food						
3.	Carbohydrate Cra	ving								
		ving for sweets, ca ng for sweets, cake								
4.	Cocaine Craving I	ntensity	Please	use subje	ct intensi	ty rating f	rom pg. 3	of this fo	rm.	
5.	Cocaine Craving I	Frequency	Please	use subje	ct frequei	ncy rating	from pg.	3 of this f	orm.	
6.	Bradycardia									
	•			use scale	below.	_	_		_	
	Pulse (	0 BPM) >64	1 64-63	2 62-61	3 60-59	4 58-57	5 56-55	6 54-53	7 <53	
7.	Insomnia									
	0 = normal amo 3-4 = half of nor 7 = no sleep at a	mal amount of slee	ep							
8.	Hypersomnia									
		unt of sleep op or does sleep ha ald sleep all the time		/						

## Form 30 - COCAINE SELECTIVE SEVERITY ASSESSMENT

**Treatment Week 11** 

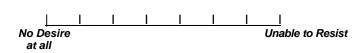
		Site ID:	Subject ID #.	Subject Initials	Weel
Date	٠.				
Dun					
		(mm/dd/yyyy)			
9	Anxiet	y [			
	3-	usually does not feel anxion  4 = feels anxious half the tire feels anxious all the time			
10.	Energ	gy Level			
	3-	= feels alert and has usual a 4 = feels tired half the time = feels tired all the time	amount of energy		
11.	Activ	ity Level			
	3-	<ul><li>no change in usual activiti</li><li>4 = participates in half of use</li><li>no participation in usual ac</li></ul>	ual activities		
12.	Tensi	ion			
	3-	1 = rarely feel tense 4 = feels tense half the time = feels tense most or all the			
13.	Atter	ntion			
	3-	<ul><li>able to concentrate on rea</li><li>4 = has difficulty with the above</li><li>has difficulty with the above</li></ul>		nake plans without difficulty	
14.	Parai	noid Ideation			
	3- 5:	<ul><li>no evidence of paranoid the</li><li>4 = unable to trust anyone</li><li>feels people are out to get</li><li>feels a specific person/group</li></ul>	-		
15.	Anhe	edonia			
	3-	<ul><li>ability to enjoy themselves</li><li>4 = able to enjoy themselve</li><li>unable to enjoy themselve</li></ul>	s half of the time		
16.	-	ession			
	3-	<ul><li>no feelings related to sadr</li><li>feels sad or depressed t</li><li>feels depressed all of the</li></ul>	half the time		
17.	Suici	dality			
		= does not think about being 4 = feels like life is not worth			
		= feels like actually ending li			
18.	Irrital	bility			
-	0 :	= feels that most things are			
		4 = feels that many things a = feels that mostly everythin			
Con		d by (Initials):			

NIDA-MDS-Modaf-0001		Form 30 - COCAIN	Form 30 - COCAINE SELECTIVE SEVERITY ASSESSMENT			
			Treatme	ent Week 11		
_	Site ID:	Subject ID #.	Subject Initials	Week		
Date:						
	(mm/dd/yyyy)					
CCCA VIC	UAL ANALOC SCALE					

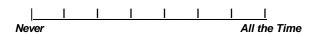
#### CSSA VISUAL ANALOG SCALE

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:



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



NIDA-MDS-Modaf-0001		Form 28 – CLINICAL GLOBAL IMPRESSION				
	Site ID:	Subject ID #.	Subject Initials	ent Week 11 Week		
Date:						
	(mm/dd/yyyy)					
<u>Cocain</u>	<u>e Global Severity</u>					
	ne, how would you rate you ine related problems?	rself overall for cocaine use				
[] [] [] []	No problems Borderline problems Mild problems Moderate problems Marked problems Severe symptoms Most extreme problems	s possible				
	Improvement of Coca	aine Dependence  nges in cocaine use and cocaine	Э			
related pi	roblems since the beginnin	g of this study?				
	Not assessed Very much improved Much improved Minimally improved No change Minimally worse Much worse Very much worse					

				Treatm	ient	Week I
<u></u>	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 <u>Severe</u>						Most Severe
Report	ed Cocaine Use: (frequency and amount of cocaine used)	1	2	3	4	5	6	7
Cocain	e Seeking: (craving for cocaine, effort to stop, and drug seeking behavior)	1	2	3	4	5	6	7
Reporte	ed Use of Other Drugs: (frequency and amount of non-cocaine drug/alcohol use)	1	2	3	4	5	6	7
Observ	rable Psychiatric Symptoms: (orientation, memory, comprehension, disorganized thinking, rapid/retarded speech, agitation, grooming, hostility, irritability, affective disturbance)	1	2	3	4	5	6	7
Report	ed Psychiatric Symptoms: (mood disturbance, depression, anxiety,inner restlessness, covert anger, somatic symptoms energy level,motivation, sleep, appetite, libido, anhedonia)	s, 1	2	3	4	5	6	7
Physica	al/Medical Problems: (those that have emerged or gotten worse after drug use)	1	2	3	4	5	6	7
Malada	aptive Coping in the Family/Social area: (movement away from healthy relationships)	1	2	3	4	5	6	7
Malada	optive 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:		1	
Date.			
	(mm/dd/yyyy)	I	
<u>Globa</u>	I Severity of Cocaine L	<u>Dependence</u>	
	ring your total clinical experi ject's cocaine dependence s	ence with the cocaine dependent ymptoms at this time?	population, how severe are
	☐ Normal, no symptoms		
	☐ Borderline symptoms		
	<ul><li>Mild symptoms</li><li>Moderate symptoms</li></ul>		
	☐ Marked symptoms		
	<ul><li>Severe symptoms</li><li>Most extreme symptom</li></ul>	s possible	
	•	•	
<u>Globa</u>	I Improvement of Coca	<u>aine Dependence</u>	
	gment, it is due entirely to di	rticipant's cocaine dependence s rug treatment. Compared to the s	
	as the subject changed?		
	☐ Not assessed, first ratin	α	
	☐ Very much improved	J	
	<ul><li>☐ Much improved</li><li>☐ Minimally improved</li></ul>		
	☐ No change		
	<ul><li>☐ Minimally worse</li><li>☐ Much worse</li></ul>		
	☐ Very much worse		
Complet	ted by (Initials):		

	a'. TD	0.11 . TD //		ent Week 11
	Site ID:	Subject ID #.	Subject Initials	Week
D				
Date:				
l	(mm/dd/yyyy)			
Date dose	s dispensed och dose is four tablets	(mm/dd/yyy	y)	
Kit Numbe	r:			
Bottle Num	nber:			
Number of	doses dispensed			
Date unus	ed doses returned	(mm/dd/yyy	y)	
Number of	doses returned			
Number of	doses reported lost by subje	ect		
Doses take	en:			
	Day of Week:	<u>Date</u> (mm/dd/yyyy)	Time Dose Taken	Dose Not Taken
Comments	S:			
Completed	I by (Initials):			

## N

# Y

NIDA-MDS-Modaf-0001		Form 34 – TREATMENT COMPLIANCE - PSYCHOTHERAPY				
	Site ID:	Subject I	D#.	Subject Initials	ent Week 11 Week	
Date:	(mm/dd/yyyy)					
Did subje	ct receive standardized, manu	al-guided indivi	idual psychothe	rapy this week?		
(If No, ple	ease comment below)	☐ Yes	□ No			
If yes, len	ngth of psychotherapy session		minutes			

Did subject require emergency crisis management sessions this week? ☐ Yes ☐ No If yes, how many? Additional comments:

Completed by (Initials):

				Treatme	nt Week 12
_	Site ID:	Subjec	t ID #.	Subject Initials	Week
Date:					
	(mm/dd/yyyy)				
Weekly V	<u>/ital Signs</u>				
☐ Vital_sig	gns not assessed a	t this visit			_
Date			Time Vital Signs	taken	
Date	(mm/dd/	′уууу)	Time vital digita	(24 hour clo	ck)
Temperatur	e (oral)	(°F)	NR: 94-100.4	CS □ NCS	
	for Temperature	,			
				_	_
	sure (sitting)	(mm Hg)	NR: 90-140/50-9	0 CS 🗆 NCS	; <u> </u>
Comments	for Blood Pressure	:			
Pulse Rate	(sitting)	(beats/min)	NR: 50-120	CS □ NCS	 :
	for Pulse Rate:	_ (			_
Respiratory	Rate (sitting)	(breaths/min)	NR: 8-20	CS □ NCS	
Comments	for Respiratory Rat	e:			
Completed	by (Initials):				
Completed	by (IIIIIais).				

### Form 23 – URINE BE SPECIMEN COLLECTION FORM

**Treatment Week 12 V1** 

	Site ID:	Subject ID #.		Week
Date:	(mm/dd/yyyy)			
	(11111111111111111111111111111111111111			
<u>First St</u>	udy Visit of Week	Urine bar code s	ticker:	
Date urine	e collected: (mm/dd	(уууу)	Urine not collected	
Fr Tr	temperature within expectantlin Cup: The temperature related to the temperature must the temperature must ample Cup: The temperature m	nust be <u>higher</u> than 96.0° l t be <u>higher</u> than 90.0° F an		No
Completed	d by (Initials):	]		

## Form 23 – URINE BE SPECIMEN COLLECTION FORM

**Treatment Week 12 V2** 

	Site I	D:	Subject II	) #.	Subject Initials	3	Week
Date:							
Date.	(mm/do	<del>(</del> ///////					
	(mm/ac	" <i>"</i> "					
<u>Second</u>	Study Visi	it of Week	Urine bar cod	e sticker:			
Date urine	collected:	(mm/dd/yy)	/y)	Urine	e not collected		
Fr Tr	anklin Cup: The ak Cup: The ten	nperature must be	d range? st be <u>higher</u> than 96. e <u>higher</u> than 90.0° I t be <u>higher</u> than 90.0	and <u>lower</u> than	99.0° F Split	] No	
Completed	d by (Initials):						

## Form 23 – URINE BE SPECIMEN COLLECTION FORM

## Treatment Week 12 V3

Site	ID:	Subject II	) #.	Subject Initials	Week
Date: (mm/c	dd/yyyy)				
Third Study Visit	of Week	Urine bar cod	e sticker:		
Date urine collected:	(mm/dd/y	()()()	Urine	e not collected	]
Trak Cup: The te	he temperature m emperature must	ed range? ust be <u>higher</u> than 96. be <u>higher</u> than 90.0° l ust be <u>higher</u> than 90.0	Fand lower than	99.0° F Split	
Completed by (Initials)	:				

### Form 24 – SUBSTANCE USE INVENTORY

				Trea	tment Week 1	12		
Site 1	ID:	Subject II	) #.	Subject Initials	Week	7		
Date:								
(mm/d	d/yyyy)							
Using timeline follow-back of administration for each	method, record wh drug. Begin with yo	nether subject has esterday and work	on each day since t back to the last vis	he last visit used an it. Please be sure th	ny amount of the su nat days are continu	ubstances listed be uous with last week	low, along with the 's form.	most common route
Date of last v	isit:							
	(mm/de	d/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	$\square$ Y/ $\square$ N	□Y/ □N	$\square$ Y/ $\square$ 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	$\square$ Y/ $\square$ N	□Y/ □N	□Y/ □N	$\square$ Y/ $\square$ N	□Y/ □N	□Y/ □N	□Y/ □N	
Benzodiazepines	$\square$ Y/ $\square$ N $\square$	□Y/ □N	□Y/ □N	$\square$ Y/ $\square$ N $\square$	□Y/ □N	□Y/ □N	□Y/ □N	
Route of adminis	tration (ROA) codes	s: 1 = oral, 2 = nasa	l, 3 = smoking, 4 = 1	non-intravenous in	iection, 5 = intraver	nous injection		
Completed by (Initials):								
	1 1							

Site ID:		S	ubject ]	ID#.		Treatment Week 12 Subject Initials Week	
Date:						L	
l	(mm/dd,	(1000)					
		Value	Normal .	Abnorma	al* Abnorma Significant		Comments (required for abnormal values)
1. Specific	gravity						
2. pH							
3. Glucose	)						
4. Protein							
5. Ketones							
6. Occult E	Blood						
7. WBC							
8. RBC							
9. Epithelia	al Cells						
*",	Abnormal" is an	y value outside	the normal l	aborato	ory range.		
Fo	r Glucose, Prote	ein, Ketones, ar	nd Occult Blo	od use	the followin	ng scale t	to report Values:
	-1 = Abse 0 = Trace 1 2 3 4						
Fo	r WBC, RBC, an	d Epithelial Ce	lls use the fo	llowing	scale to rep	oort Value	es:
	1 = None 2 = Few ( 3 = Mode 4 = Heav	(6 – 10) erate (11 – 50)					
☐ Check	c here if this fo	orm is comple	eted for rete	est of p	revious la	ıb tests.	
Date o	f original lab to	ests	(n	nm/dd/	<i></i>		
Completed	I by (Initials):		•				

		Site ID:		S	ubject II	D #.		Treatment Week 12 Subject Initials Week	
Date:	(1	mm/dd/yyyy	)						
		Value		Normal A		l* Abnormal Significant		Comments (required for abnormal values)	
1. Hemog	lobin		g/dL						
2. Hemato	ocrit		%						
3. RBC			M/uL						
4. Platelet	count		K/uL						
5. WBC			K/uL						
6. Neutrop	ohils		%						
7. Lympho	ocytes		%						
8. Monocy	/tes		%						
9. Eosinop	ohils		%						
10. Basop	hils		%						
Please refer to Appendix I of the protocol when determining the significance of abnormal values.  *"Abnormal" is any value outside the normal laboratory range.									
		= mil/cumm = thou/cumm =					ım		
$x  ext{ } 10^3/\text{uL} = \text{thou/cumm} = \text{thou/mcl} = \text{K/cmm} = 1000/\text{uL} = x  ext{ } 10^3/\text{cumm}$									
☐ Chec	k here i	f results on	his form ar	e retest	s of pre	evious lab	tests.		
Date of original lab tests					(mm/c	ld/yyyy)			

	Site ID:		S	ubject l	ID#.		Treatme Subject Initials	ent Week 12 Week	
				<u> </u>					
Date:						<u> </u>			
	(mm/dd/yyyy) Value		Normal A	Abnorma	l* Abnorma Significan		Comments (Required for Abnormal	values)	
1. Sodium		mmol/L							
2. Potassiu	ım	mmol/L							
3. Chloride		mmol/L							
4. CO2		mmol/L							
5. Glucose		mg/dL							
6. Creatinir	ne	mg/dL							
7. Albumin		g/dL							
8. Total pro	otein	g/dL							
9. SGOT/A	ST	U/L							
10. SGPT/	ALT	U/L							
11. GGT		U/L							
12. Bilirubii	n	mg/dL							
13. BUN		mg/dL							
Ple * " <i>j</i>	Please refer to Appendix I of the protocol when determining significance of abnormal values.  * "Abnormal" is any value outside the normal laboratory range.								
mn	mol/L = mEq/L								
☐ Check	here if this form is o	ompleted	for rete	est of p	revious la	ab tests	<b>S.</b>		
Date of			(mm/da	d/yyyy)					

	ar. ID		~	.1. '	-4 ID # C 1 1		tment Week 12
	Site ID:	7	St	ibje	et ID #. Subj	ject Initials	Week
ъ.							
Date:							
	(mm/dd/yyyy)						
A. ECG	overall results were:		e <u>rmal</u> normal				
lf	ECG is Normal please	skip 1	to Question	n C.			
B. If ECG i	is abnormal, check belov	v for <u>al</u>	<u>l</u> abnormalit	ies.			
	<u>Abn</u>	<u>ormal</u>	Abnormal Significant			<u>Abnormal</u>	Abnormal Significant
1. Increase	ed QRS voltage			17.	Supraventricular premature	beat $\square$	
2. Qtc prol	ongation			18.	Ventricular premature beat		
3. Left atria	al hypertrophy			19.	Supraventricular tachycardi	а 🗆	
4. Right at	rial hypertrophy			20.	Ventricular tachycardia		
5. Left ven	tricular hypertrophy			21.	Atrial fibrillation		
6. Right ve	entricular hypertrophy			22.	Atrial flutter		
7. Acute in	nfarction			23.	Other rhythm abnormalities		
8. Subacut	te infarction			24.	Implanted pacemaker		
9. Old infa	rction			25.	1 <sup>st</sup> degree A-V block		
10. Myoca	rdial ischemia			26.	2 <sup>nd</sup> degree A-V block		
11. Digitali	is effect			27.	3 <sup>rd</sup> degree A-V block		
12. Symmo	etrical T-wave inversions			28.	LBB block		
13. Poor R	-wave progression			29.	RBB block		
14. Other r	nonspecific ST/T			30.	Pre-excitation syndrome		
15. Sinus t	tachycardia			31.	Other intraventricular condit	ion 🗌	
16. Sinus l	oradycardia			32.	Other, specify		
C. Ventrice	ular rate (bpm)			Ε.	QRS (ms)		
D. PR (ms	3)			F.	QTC (ms)		
	here any abnormal ontinuation in the s			ove	that preclude the sub	-	safe entry

# Form 13 - ELECTROCARDIOGRAM

			Treatme	ent Week L
	Site ID:	Subject ID #.	Subject Initials	Week
Date:				
	(mm/dd/yyyy)			
Comments:				

							Treatment Week 12
Ī	Site ID:		S	ubject I	D#.	_	Subject Initials Week
Date:							
l	(mm/dd/yyyy)						
1. Height	inc	hes					
2. Weight	po	unds					
			A. Normal	B. Abnorma	C. al Abnormal Significant	D. Not Done	E. Comments (required for abnormal values)
3. Oral (mo	uth)						
4. Head an	d Neck						
5. Eyes, ea	rs, nose/throat						
6. Cardiova	scular						
7. Chest							
8. Lungs							
9. Abdomei	n (include liver/spleen)						
10. Extremi	ties						
11. Skin, ha	air, nails						
12. Neurop	sychiatric mental status						
13. Neurop	sychiatric sensory/motor						
14. Musculo	oskeletal						
15. Genera	l appearance						
16. Rectal							
17. Prostate	Э						
18. Breast							

Site ID:  Date:  (mm/dd/yyyy)	;	Subject II	O #.	[	Subject Initials Week  Week
	A. Norma	B. I 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					

	<b>~</b> :	TD.	a	. 11		ent Week 12
	Site	ID:	Subject ID	) #. 	Subject Initials	Week
Date:						
	(mm/c	dd/yyyy)				
<u>Cocain</u>	•					
1. The <u>in</u>	tensity of my	craving, that is,	how much I desire	ed cocaine in the	past 24 hours was:	
	☐ None at all	☐ Slight	☐ Moderate	☐ Consider	able 🔲 Extrem	е
2. The <u>fre</u>	<u>equency</u> of m	y craving, that is	s, how often I desir	ed cocaine in th	e past 24 hours was	<b>:</b> :
	□ Never	☐ Almost neve	r 🔲 Several t	imes 🗌 Re	gularly	ost constantly
3. The <u>le</u>	ngth of time I	spent craving for	or cocaine during t	he past 24 hours	was:	
	☐ None at all	☐ Very sh	ort   Short	☐ Somewh	at long	long
1 Writa i	n the number	of times you th	ink you had craving	n for cocaine du	ing the past 24 hou	re·
4. Wille i	Ti tile <u>ildiliber</u>	or times you tri	ilik you liau clavili	g for cocame du	ing the past 24 hou	13.
 5. Write i	n the total tim	ne spent craving	cocaine during the	e past 24 hours:		
	hours	minutes	_	•		
6 The w				e craving occurr	ed on the following o	lav <sup>.</sup>
о. тпо <u>т</u>	_	_	_	_	od on the following c	auy.
[	<ul><li>☐ Sunday</li><li>☐ Thursday</li></ul>	<ul><li>☐ Monday</li><li>☐ Friday</li></ul>	☐ Tuesday ☐ Saturday	<ul><li>☐ Wednesday</li><li>☐ All days the sa</li></ul>	me (go to Q. 8)	
7. The da	ate for that da	y was:	(mm/dd/yyyy)			
8. The <u>in</u>	tensity of my	craving, that is,	how much I desire	ed cocaine on the	at worst day was:	
	☐ None at all	☐ Slight	☐ Moderate	☐ Consider	able 🔲 Extrem	e
Secon	d Drug					
		uring the past 2 f the following. If		ark "None" and lea	ve Questions 10-16 bla	nk.
	None		owners or Sedatives	Benzos	☐ Nicotine	
[	Alcohol	He	arbiturates, etc.) eroin or other Opiates orphine, etc.)	(Valium, Xanax, Marijuana	etc.)  Other Specify	
	ntensity of my s was:	craving, that is	s, how much I desir	red this <b>second</b>	drug in the past 24	
[	☐ None at all	☐ Slight	☐ Moderate	☐ Consider	able 🔲 Extrem	e

	Site	ID:	Subject ID#		Subject	Treatment	Week 12 Week
Date:							
	(mm/c	dd/yyyy)					
	frequency of n	ny craving, that is, I	now often I desire	ed this <b>seco</b>	nd drug in	the past 24	
	☐ Never	☐ Almost never	☐ Several tim	es 🗆	Regularly	☐ Almost	constantly
12. The	length of time	I spent in craving for	or this <b>second</b> dr	ug during th	e past 24 h	nours was:	
	☐ None at all	☐ Very short	☐ Short	☐ Some	vhat long	☐ Very Ion	g
Third	<u>Drug</u>						
13. A <b>3</b>	rd craved drug o Mark <u>only one</u> o	during the past 24 h	nours was: <sup>d</sup> craved drug, mark	c"None" and l	eave questio	ons 14-16 blank.	
	None		rs or Sedatives [rates, etc.)	Benzos (Valium, Xana	uv etc.)	☐ Nicotine	
	Alcohol	Heroin	or other Opiates ne, etc.)	∫ Marijuana	ix, 610.)	Other Specify	
	intensity of my irs was:	/ craving, that is, ho	ow much I desired	d this <b>third</b> d	rug in the p	past 24	
	☐ None at all	☐ Slight	☐ Moderate	☐ Consid	erable	☐ Extreme	
	frequency of n	ny craving, that is, I	now often I desire	ed this <b>third</b>	drug in the	past 24	
	□ Never	☐ Almost never	☐ Several tim	es 🔲	Regularly	☐ Almost	constantly
16. The	length of time	I spent in craving for	or this third drug	during the pa	ast 24 hour	rs was:	
	☐ None at all	☐ Very short	☐ Short	☐ Some	vhat long	☐ Very Ion	g
Comple	eted by (Initials)	:					

# Form 30 - COCAINE SELECTIVE SEVERITY ASSESSMENT

**Treatment Week 12** 

		Site ID:	<u></u>	Subject ID	)#		Subjec	t Initials		Week
D-4									L	
Dat	te:									
		( ( ( ( ) )								
ΔΙΙ	auestion	(mm/dd/yyyy) ns except 4 and 5 are asse	ssed by properly	trained no	rsonnal	The subi	ort is ask	ed ahout i	each of the	
iter	ns in lay estion 4 a	l language and the respon and 5, the subject is asked e questions. The rater the	se is recorded or to mark the app	n a scale of ropriate pla	0-7 with ace on the	0 being n e line (on	ormal or r page 3) th	no sympto	oms. For	
Da	te of las	st cocaine use:		(mm/dd/)	(MAAA)					
1.	Hyper	phagia		(mm/aa/)	· <b>yyy</b> /					
	3-	= normal appetite 4 = eats a lot more than = eats more than twice u		ood						
2.	Нурор	phagia								
	3-	= normal appetite 4 = eats less than half of = no appetite at all	normal amount	of food						
3.	Carbo	hydrate Craving								
	3-	= no craving 4 = strong craving for sw = strong craving for swee								
4.	Cocaiı	ne Craving Intensity	Please	use subje	ct intensi	ity rating f	rom pg. 3	of this fo	rm.	
5.	Cocaiı	ne Craving Frequenc		use subje	ctfrequer	ncy rating	from pg.	3 of this f	orm.	
6.	Brady	cardia	Please	use scale	below.					
		Pulse (BPM)	0 1 >64 64-63	2 62-61	3 60-59	4 58-57	5 56-55	6 54-53	7 <53	
7.	Insom	nia								
	3-	= normal amount of slee 4 = half of normal amour = no sleep at all								
8.	Hyper	somnia								
	3-	= normal amount of slee 4 = could sleep or does = sleep or could sleep al	leep half the da	у						

# Form 30 - COCAINE SELECTIVE SEVERITY ASSESSMENT

**Treatment Week 12** 

		Site ID:	Subjec	et ID#.	Subject Initials	Wee
Date	۵۰.		, <u>L</u>			
Date	J.					
		(mana (alal (m. m. r.)				
		(mm/dd/yyyy)				
9	Anxiet	у				
		= usually does not feel anxio				
		4 = feels anxious half the tin = feels anxious all the time	ie			
10.	Energ	gy Level				
	0 :	= feels alert and has usual a	mount of energy			
	3-	4 = feels tired half the time = feels tired all the time	o,			
	7 :	= reers thed all the time				
11.		ity Level				
		= no change in usual activition = 4 = participates in half of usu				
	7 :	= no participation in usual ac	tivities			
12.	Tensi	ion				
		1 = rarely feel tense 4 = feels tense half the time				
		= feels tense most or all the	time			
13	Atter	ntion				
.0.	0 :	= able to concentrate on rea		tasks, and make	plans without difficulty	
		4 = has difficulty with the ab = has difficulty with the abov				
		•				
14.		<b>noid Ideation</b> = no evidence of paranoid th	oughts			
	3-	4 = unable to trust anyone	-			
		<ul><li>feels people are out to get</li><li>feels a specific person/gro</li></ul>		st him/her		
1-						
15.	Anhe	donia = ability to enjoy themselves	remains unchange	ed.		
	3-	4 = able to enjoy themselves	half of the time	-		
	7 :	= unable to enjoy themselve	s at all			
16.	-	ession				
		= no feelings related to sadn 4 = feels sad or depressed h				
		= feels depressed all of the				
17.	Suici	dality				
		= does not think about being				
		4 = feels like life is not worth = feels like actually ending li				
19	Irrital	hility				
10.		= feels that most things are r	not irritating			
	3-	4 = feels that many things a	e irritating	eatting		
Con		= feels that mostly everything by (Initials):	, io irritating and uβ ¬	ostung		

N	ID	$\Delta - \Lambda$	<b>IDS</b>	M	րկո	f_N	<b>00</b> 1
Τ.	w	/ <b>7</b> -11		7 T Y L	vua	T-N	UU.

#### Form 30 - COCAINE SELECTIVE SEVERITY ASSESSMENT

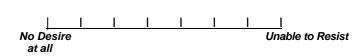
**Treatment Week 12** 

				Heati	icit	WCCK 1
	Site ID:	Subject ID #.	_	Subject Initials	_	Week
Date:						
	L (mm/dd/yyyy)					

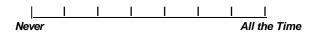
### CSSA VISUAL ANALOG SCALE

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:



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



Form 28 - CLINICAL GLOBAL IMPRESSION - SELF NIDA-MDS-Modaf-0001 **Treatment Week 12** Subject ID #. **Subject Initials** Week Site ID: 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

# **Global Improvement of Cocaine Dependence**

Most extreme problems possible

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

Moderate problems Marked problems Severe symptoms

Completed by (Initials):

				Treatn	ient	Week I
<u></u>	Site ID:	Subject ID #.	_	Subject Initials	_	Week
Date:			L		] [	
	(mm/dd/yyyy)					

# **Current Severity**

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

		None, Least <u>Severe</u>						Most Severe
Report	ed Cocaine Use: (frequency and amount of cocaine used)	1	2	3	4	5	6	7
Cocain	e Seeking: (craving for cocaine, effort to stop, and drug seeking behavior)	1	2	3	4	5	6	7
Reporte	ed Use of Other Drugs: (frequency and amount of non-cocaine drug/alcohol use)	1	2	3	4	5	6	7
Observ	rable Psychiatric Symptoms: (orientation, memory, comprehension, disorganized thinking, rapid/retarded speech, agitation, grooming, hostility, irritability, affective disturbance)	1	2	3	4	5	6	7
Report	ed Psychiatric Symptoms: (mood disturbance, depression, anxiety,inner restlessness, covert anger, somatic symptoms energy level,motivation, sleep, appetite, libido, anhedonia)	s, 1	2	3	4	5	6	7
Physica	al/Medical Problems: (those that have emerged or gotten worse after drug use)	1	2	3	4	5	6	7
Malada	aptive Coping in the Family/Social area: (movement away from healthy relationships)	1	2	3	4	5	6	7
Malada	eptive 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 S	Severity of Cocaine	<u>Dependence</u>	
	-	-	
	ng your total clinical expe ct's cocaine dependence	rience with the cocaine dependen symptoms at this time?	t population, how severe are
		cymptome at the time.	
	Normal, no symptoms Borderline symptoms		
	Mild symptoms		
	Moderate symptoms  Marked symptoms		
	Severe symptoms		
	Most extreme symptor	ns possible	
Global I	mprovement of Cod	caine Dependence	
	<del>-</del>	participant's cocaine dependence	symptoms whather or not in
		drug treatment. Compared to the	
project, ho	w the subject changed?		
much nas	the subject changeu?		
	Not assessed, first rati Very much improved	ng	
	Much improved		
	Minimally improved		
	No change Minimally worse		
	Much worse		
<u> </u>	Very much worse		
Completed	d by (Initials):		

				Treatn	nent	Week 1
_	Site ID:		Subject ID #.	Subject Initials	_	Week
Date:		7			J	
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 <u>RIGHT NOW</u> as you are filling out the questionnaire.

	Strong <u>Disagre</u>						rongly 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	e 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 cocain	ne. 1	2	3	4	5	6	7
18. Even if it were possible, I probably would not use cocained	е						
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

			Treatme	ent Week 12
	Site ID:	Subject ID #.	Subject Initials	Week
Date:				
_	(mm/dd/vvvv)			

(mm/dd/yyyy)							
s	strongl	у	Strongly				
	Disagre						ree
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 tim	e. 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 usin	ng						
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 n	ot						
use it.	1	2	3	4	5	6	7
Completed by (Initials):							

			Treatme	ent Week 12
	Site ID:	Subject ID #.	Subject Initials	Week
Date:				
Date.				
	(			
1. Depres	(mm/dd/yyyy)			
	ad, hopeless, helpless, worth	nless)		
	2 = These feeling stat 3 = Communicates fee posture, voice, and	es indicated only on questioning. es spontaneously reported verbal eling states nonverbally – i.e., thro d tendency to weep.	ough facial expression,	
		tually only these feeling states in bal communication.	nis/ner spontaneous	
2. Feeling				
	2 = Ideas of guilt or ru 3 = Present illness is	Is s/he has let people down. Imination over past errors or sinfula a punishment. Delusions of guilt. or denunciatory voices and/or exp		
3. Suicide				
	3 = Suicide ideas or g	dead or any thoughts of possible	death to self.	
4. Insomn	ia Early			
		asleep. asional difficulty falling asleep. (i.e tly difficulty falling asleep.	e., more than ½ hour)	
5. Insomn	ia Middle			
		s of being restless and disturbed on night – any getting out of bed rat		:
6. Insomn	ia Late			
		ours of the morning but goes back ep again if gets out of bed.	to sleep.	

	a: 15	0.11 175 //			ent	Week 12
	Site ID:	Subject ID #.	Г	Subject Initials	1 [	Week
Date:						_
7 Mork 6	(mm/dd/yyyy) and Activities					
7. WOIK a	☐ 0 = No difficulty					
		elings of incapacity, fatigue, or	weakne	ss related to activitie	es;	
		n activity; hobbies or work – eit ness, indecision and vacillation				or
	3 = Decrease in actu	al time spent in activities or de because of present illness.	ecrease i	n productivity.		
8. Retard		eech; impaired ability to concentrate	e; decrea:	sed motor activity)		
[ ] [ ]	0 = Normal speech a 1 = Slight retardation 2 = Obvious retardati 3 = Interview difficult 4 = Complete stupor	at interview on at interview				
9. Agitatio	on					
[] [] [] []	0 = None 1 = Fidgetiness 2 = Playing with hand 3 = Moving about, ca 4 = Hand-wringing, no		lips			
10. Anxie	ty Psychic					
[ [ [ [	0 = No difficulty 1 = Subjective tensio 2 = Worrying about m 3 = Apprehensive att 4 = Fears expressed	ninor matters itude apparent in face or speed	ch			
(I		of anxiety such as: Gastrointestina cular: palpitations, headaches. Re .)				hea,
[] [] []	0 = Absent 1 = Mild 2 = Moderate 3 = Severe 4 = Incapacitating					
12. Soma	tic Symptoms Gastrointe	estinal				
	0 = None					
		but eating without encouragem vithout urging. Requests or req				

					Treatn	nent We	ek 12
	_	Site ID:	Subject ID #.		Subject Initials	We	eek
Date:	Ļ		<u> </u>				
24.0.							
		(mm/dd/yyyy)					
12 50	matia	bowels or medica Symptoms General	tion for G.I. symptoms.				
13. 301	auc	Symptoms General					
		0 = None 1 = Heaviness in limb energy and fatiga 2 = Any clear-cut syn		es, headad	che, muscle aches. L	oss of	
14. Ge		Symptoms ch as loss of libido and me	enstrual disturbances)				
		0 = Absent					
		1 = Mild 2 = Severe					
	Ш						
15. Hy <sub>l</sub>	poch	ondriasis					
		0 = Not present					
	H	1 = Self-absorption (I 2 = Preoccupation w					
		3 = Frequent compla	ints, requests for help, etc				
	Ш	4 = Hypochondriacal	delusions				
16. Los	ss of	Weight					
		0 = No weight loss					
	H		loss associated with prese ess (according to subject)	nt illness.			
47 1	٠١.٠	Z = Bomillo Wolghi lo	do (docording to cabject)				
17. Insi	ignt						
			eing depressed and ill. ness but attributes cause t	n had food	d climate overwork		
		virus, need for re	st, etc.	.o bad 1000	a, ciiriate, overwork,		
	Ш	2 = Denies being ill a	t all				
18. Diu	ırnal	Variation					
		0 = No variation					
	H	1 = (Mild) Doubtful or 2 = (Severe) Clear or					
		, ,	2, note whether the sympto	oms are we	orse in: O A.M. O F	P.M.	
19. De	perso	onalization and Dereal	ization of unreality and nihilistic ideas	)			
		0 = Absent					
		1 = Mild					
	_	2 = Moderate 3 = Severe					
		4 = Incapacitating					

Completed by (Initials):

					$\mathbf{T}$	reatment	Week 12
	Site ID:		Subject ID#.		Subject Initia	als	Week
D-4		_ L					
Date:							
	(mm/dd/yyyy)						
20. Paran	oid Symptoms						
	0 = None 1 = Suspicious 2 = Ideas of reference 3 = Delusions of refer		d persecution				
21. Obses	ssive and Compulsive Sy	mptoms					
	0 = Absent 1 = Mild 2 = Severe						
22. Helple	essness						
	<ul> <li>0 = Not present</li> <li>1 = Subjective feeling</li> <li>2 = Subject volunteers</li> <li>3 = Requires urging, opersonal hygiene.</li> <li>4 = Despite urging, do</li> </ul>	his help Juidance	oless feelings. and reassurance to	accom		ene.	
23. Hopel	essness						
	0 = Not present 1 = Intermittently doul 2 = Consistently feels 3 = Expresses feeling which cannot be of 4 = Spontaneously ar equivalent	"hopeles s of disc ispelled.	ss" but accepts reas ouragement, despa	ssurance ir, pessi	es. mism about futu		
	lessness anges from mild loss of self elusion notions of worthlessi		elings of inferiority, se	elf-deprec	iation (loss of sel	f-esteem) to	
	0 = Not present 1 = Indicates feelings 2 = Spontaneously ind 3 = Different from 2 b etc. 4 = Expresses feeling equivalent	licates fe / degree	eelings of worthlessi : Subject volunteers	ness (lo: s that s/h	ss of self esteerne is "no good,"	m). "inferior,"	

					Treatm	ent Week 12
	Site 1	ID:	Subject ID	#.	Subject Initials	Week
Date:						
	(mm/de	d/yyyy)				
<u>Genera</u>	al Informatio	<u>on</u>				
G4. Dat	e of admission	1				
G8. Cla		☐ Intake	☐ Follo	<i>(mm/dd/yyyy)</i> ow-up		
G9. Cor	ntact code	☐ In person	☐ Tele	phone	☐ Mail	
G10. Ger	nder	☐ Male	☐ Fem	ale		
G12. Spe	ecial	☐ Terminated	d □ Refu	ısed	☐ Unable to resp	ond
G14. Hov	w long have yo	ou lived at your	current address?	Years	Months	
G16. Date	e of birth:					
				(mm/dd	(/yyyy)	
	what race do y nsider yourself	?	hite (not Hispanic) ack (not Hispanic) nerican Indian askan Native sian/Pacific Islande		☐ Hispanic - Mexi☐ Hispanic - Pue☐ Hispanic - Cuba☐ Hispanic - Othe	rto Rican an
G18. Do	you have a re	ligious preferen	ce?		☐ Islamic ☐ Other ☐ None	
control	ou been in a lled environme at 30 days?	_		☐ Ps	edical treatment ychiatric treatment her	
How m	nany days?					
<u>MEDIC</u>	AL STATUS	<u>s</u>				
How ma	ny times in yo	ur life have you	been hospitalized	for medical pr	oblems?	
M3. Do y	you have any	chronic medical	problem(s) which	continue to int	erfere with your life?	
li	f "Yes", please s	pecify in 'Comme		∟ INC	,	
		rescribed medic	cation on a regular	basis for a phy	sical problem?	
"	. 100 , pieuse s	poony in Comme	∏ Yes	☐ No	)	

				Treatmen	t Week 12
	Site ID:	Subject ID #.	Sub	oject Initials	Week
Date:					
	(mm/dd/yyyy)	_			
Do y	ou receive a pension for a ph	Ĺ Yes	le psychiatric dis ☐ No	abilities.)	$\neg$
How	many days have you experie	nced medical problems i	n the past 30 day	/s?	
How	For #M7 and M8 please ask the stroubled or bothered have yo 0 = Not at all 1 = Slightly	u been by these medical			ly
How	important to you now is treatr  ☐ 0 = Not at all ☐ 1 = Slightly	ment for these medical p	roblems? 3 = Considerably	y	ly
	dence Ratings e above information <u>significan</u>	tly distorted by:			
	Subject's misrepresentation	?	☐ Yes	☐ No	
	Subject's inability to underst	and?	☐ Yes	□ No	
Com	ments:				
Emn	loyment/Support Status	•			
<u> </u>	<u>oymeny Support Status</u>	<u>-</u>			
Edu	cation completed (GED = 12 y	vears):	Years	Months	
Trai	ning or technical education co	empleted:	Months		
Do	you have a valid driver's licens	se?	Yes 🗆 1	No	
Do	you have an automobile availa Answer "no" if no valid driver's		Yes 🗆 1	No	
E6. Ho	ow long was your longest full-t	ime job?	Years	Months	
Usu	al (or last) occupation:				
1 = High 2 = Man 3 = Adm floris 4 = Cler 5 = Skill mac 6 = Sem welc 7 = Uns 8 = Hom 9 = Stuc	dent, disabled, no occupation	rs of large businesses purses, opticians, pharmacists, pers/proprietors of small busine gent) er, bookkeeper, clerk, draftsper ing (baker, barber, brakeperscer, repairperson, tailor, welder, nder, bus driver, cutter, cook, on helper, unspecified labor, porter	sses (bakery, car de son, timekeeper, sec n, chef, electrician, fi policeperson, plumb Irill press, garage gua	alership, engraving bu retary reperson, lineperson, er) ard, checker, waiter, s	usiness, spot
Doe Doe	s someone contribute the ma	jority of your support?		Yes □ N	0

				Treatment Wee	ek 12
	Site ID:	Subject ID #.	Subjec	t Initials We	eek
Date:					
Date.					
	(mm/dd/yyyy)				
E10. Us	ual employment pattern, past	t 3 years.			
	☐ 1 = full time (35+ h	ırs/week)	5 = military		
	☐ 2 = part time (regul☐ 3 = part time (irregul☐ 3		$\Box$ 6 = retired/c $\Box$ 7 = unempto		
	4 = student			olled environment	
E11 How ma	any days were you paid for w	orking in the past 30 days	s?		
How muc	h money did you receive from	n the following sources in	the past 30 days	;?	
Employ	rment (net income)		\$		
			•		
Unemp	loyment compensation		\$		
Welfare	<b>;</b>		\$		
Pension	n, benefits or social security		\$		
	i, benefits of social scounty				
Mate, f	amily or friends (money for pe	ersonal expenses)	\$		
Illegal			\$		
How m	any people depend on you fo	r the majority of their food	, shelter, etc.?		
How m	any days have you experienc	ed employment problems	in the past 30 da	ays?	
For Quest	ions E20 and E21 please ask the s	subject to use the subject ratir	ng scale.		
	oubled or bothered have you labeled or bothered have you labeled 0 = Not at all 1 = Slightly		nt problems in the 3 = Considerably	e past 30 days?   4 = Extremely	
How im	portant to you now is counse 0 = Not at all		t problems? 3 = Considerably	☐ 4 = Extremely	
Confider	nce Ratings				
Is the abo	ove information significantly d	listorted by:			
Subje	ct's misrepresentation?	☐ Yes	s □ No		
Subje	ct's inability to understand?	☐ Yes	s □ No		
Comn	nents:				

						Treatm	ent W	eek 12
		Site ID:	Subject	ID #.	Sub	ject Initials	<u>  W</u>	Veek
Ι	Date:				<u> </u>			
	D/A	(mm/dd/yyyy)						
<u>4</u>	<u>Drug/Al</u>	<u>lcohol Abuse</u>	Days in Past	Lifetime	Rout	e of Administr	ration	
	7		30 Days	<u>Years</u>	(1 = 0) 3 = sr	oral, 2 = nasal, noking, 4 = non iv	/ inj.	
	Alcohol	I – any use at all			5 = iv	-	,	
	Alcohol	I – to intoxication						
	Heroin							
	Methad	done						
	Other of	opiates/analgesics						Ī
	Barbitu	rates						
	Other s	sedatives/hypnotics/tranquilizers	3					Ī
	Cocain	е						Ī
	Amphe	tamines						1
	Cannal							Ī
	Hallucir							1
	Inhalan	_						1
	_	nan one substance per day						_
		ng alcohol)						
D17	How m	any times have you had alcoho	ol DTs?					
	How mar	ny times in your life have you be	een treated for	r:				
D19*	Alcoho	I abuse						
D20*	Drug a	buse						
	How man	ny times of these were detox on	ıly?					
D21	Alcoho	ol						
D22	Drugs							
	⊐ Enter "Ni	N" if answers to Question D19	9 or D20 = "0	 00"				
		h money would you say you you			on:			
	] A	Icohol		\$				
	D	rugs		\$				
	J							
		many days have you been treat cohol or drugs in the past 30 da						

	ar. Th	0.11		ent Week
	Site ID:	Subject ID #.	Subject Initials	Week
Date:				
	(mm/dd/yyyy)			
How many	y days in the past 30 days	have you experienced:		
A	Icohol problems			
D	rug problems			
		k the subject to use the subject rating the subject ration in the past 30 days by the		
	ol problems   0 = Not at all     1 = Slightly	2 = Moderately	Considerably	mely
	roblems   0 = Not at all     1 = Slightly	2 = Moderately	Considerably	mely
How impo	rtant to you now is treatme	nt for these:		
	ol problems   0 = Not at all	2 = Moderately	Considerably	mely
	oroblems   0 = Not at all     1 = Slightly	2 = Moderately	Considerably	mely
	ce Ratings ve information significantly	distorted by:		
s	ubject's misrepresentation?	☐ Yes	☐ No	
s	ubject's inability to understa	and?	☐ No	
 Comment	s:			
<u>Legal S</u>	tatus			
		suggested by the criminal justi	00	
	n (judge, probation/parole o		☐ Yes ☐	No
Are yo	ou on probation or parole?		☐ Yes ☐	No
How many	v times in vour life have vo	u been arrested and charged w	ith the followina:	
	fting/vandalism			
	_			
	/probation violation(s)			
	charge(s)			
Forger	у			
Weapo	ons offense			
Burgla	ry, larceny, breaking and e	ntering		

				Treatmen	
F	Site ID:	Subject ID #.	Subje	ect Initials	Week
Date:			J		
	(mm/dd/yyyy)				
Assault					
Arson					
Rape					
Homicid	de, manslaughter				
Prostitu	tion				
Contem	pt of court				
Other, s	specify:				
How ma	any of these charges resulted	d in conviction?			
	ter "NN" if no arrests or charges.				
How many	times in your life have you b	een charged with the fo	ollowing:		
Disorde	erly conduct, vagrancy, publi	c intoxication?			
Driving	while intoxicated?				
Major o	driving violations (reckless dr	iving, speeding, no licer	nse, etc.)?		
L21* How m	any months were you incarc	erated in your life?		Months	
Are you	u presently awaiting charges	, trial or sentence?	☐ Yes	□ No	
What fo	or?				
lf multiple	e charges, use the number of the	most severe from above(L3	B-L16), or use the fo	ollowing codes: 18	=disorderly
conduct,	19=driving while intoxicated, 20=	major driving violation.		_	
L26 How man	ny days in the past 30 were y	ou detained or incarce	rated?		
How man	ny days in the past 30 have y	ou engaged in illegal a	ctivities for profit?	?	
For	Questions L28 and L29 please a	sk the subject to use the s	ubject rating scale.		
	ous do you feel your present 0 = Not at all		3 = Considerably	☐ 4 = Extreme	elv
	ortant to you now is counsel	·	·		.,
	0 = Not at all  1 = Slightly		3 = Considerably	4 = Extreme	ly
Confidenc Is the abov	e Ratings e information significantly dis	storted by:			
Subject	's misrepresentation?	☐ Yes	□ No		
Subject	t's inability to understand?	☐ Yes	☐ No		
Comments	:				

							Treatm	ent '	Week 1
Site	D:		S	ubject ID#.	r	Subje	ect Initials	1 6	Week
Date:					L			J L	
(mm/	dd/yyyy)								
<u>Family/Social Re</u>	<u>lations</u>	<u>hips</u>							
Marital status		arried eparated		☐ Remarried ☐ Divorced			idowed ever Married		
Are you satisfied w	ith this s	situation	?	☐ Yes ☐	No	□ In	different		
Usual living arrang	gements	(past thr	ee years)						
1 = with sexual pa						= alone			
☐ 2 = with sexual pa ☐ 3 = with children a		ne		with family with friends			lled environm ble arrangem		
Are you satisfied w	ith these	living a	rangeme	nts?	□ No		Indifferent		
Do you live with an			rangomo				ao.o		
Has a current alco	hol prob	lem?		☐ Yes	□ No	)			
Uses non-prescrib	ed drugs	?		☐ Yes	□ No	)			
With whom do you	spend r	nost of y	our free ti	me?	☐ Fa	ımily [	Friends	] Alo	ne
Are you satisfied	with sper	nding yo	ur free tim	ne this way?	☐ Ye	es 🗆 N	lo 🗌 Indiffer	ent	
				-					
Have you had any sig	nificant p	periods i	n which y	ou have experie	nced se	erious pr	oblems gettii	ng	
along with:	In the	e past 30	) days			<u>Lifetime</u>			
	Yes	No	N/A		Yes	No	N/A		
Mother									
Father	Ш		Ш		Ш	Ш	Ш		
Siblings									
Sexual partner/ Spouse									
Children									
	_								
Other significant family									
Please specify	if "Yes":								
Close friends									
Neighbors			П				П		
Co-workers			_		_	_	_		
L.O.WOTKATS	1 1	1 1	1 1		1 1	1 1	1 1		

				Treatment	Week 12
	Site ID:	Subject ID #.	Subjec	et Initials	Week
Dat					
Dat	e.				
	(mm/dd/yyyy)				
Did	I anyone abuse you?				
F	Physically (caused you physical harm) In the past 30 days	□ No	Lifetime	☐ Yes ☐	No
	Sexually (forced sexual advances or sometimes in the past 30 days ☐ Yes	sexual acts)	Lifetime	☐ Yes ☐	No
Ho	w many days in the past 30 have you	had serious conflicts?			
	With your family:				
	With other people excluding fam	ily:			
	Questions F32-35 please ask the subject to w troubled or bothered have you been				
	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	,
Ho	w important to you now is treatment or	r counseling for these:			
	Family problems  ☐ 0 = Not at all ☐ 1 = Slightly	☐ 2 = Moderately ☐	3 = Considerably	☐ 4 = Extremely	,
		_ Z = Woderately	0 - Considerably	L + - Extromoly	
	Social problems  0 = Not at all 1 = Slightly	☐ 2 = Moderately ☐	3 = Considerably	4 = Extremely	,
<u>Co</u>	nfidence Ratings				
ls t	he above information significantly dist	orted by:			
	Subject's misrepresentation?	☐ Yes	□ No		
	Subject's inability to understand?	☐ Yes	□ No		
Co	omments:				
	sychiatric Status	for any nevertal agical	or amational arch	lom(s)?	
ПО	w many times have you been treated	ior arry psychological (	л етнопонаї ргов	ıcııı(ə) !	
	In a hospital or inpatient setting				
	As an outpatient or private patient				
	Do you receive a pension for a psyc	chiatric disability?	☐ Ye	s 🗆 No	)

		g: 1D						Treatment Week 12			
		Site ID:		Г	Sub	ject ID#.		Subject Init	tials	1	eek
Ι	Date:										
		(mm/dd/yy				P		/	. ,.,	ı	
	have yo	ou had a significa	int period (th	at wa	as not	a direct re	suit of aru	g/aiconoi use)	in which	n you	
				<u>In</u>	the pa	st 30 days			Lifetir	<u>ne</u>	
P4	depres hopele	enced serious sion (sadness, ssness, loss of t, difficulty with									
	-	inctioning)?			Yes		No		Yes		No
P5	anxiety unreas	enced serious /tension (uptight, onably worried,									
	inability	to feel relaxed)?		Ш	Yes	Ш	No	Ц	Yes		No
P6	(saw th	enced hallucinatio nings or heard voicere not there)?			Yes		No		Yes		No
P7	unders	enced trouble tanding, concentra embering?	ating,		Yes		No		Yes		No
,	For Questic	ons P8-10, Subject o	an have been	unde	r the int	fluence of a	cohol/druas.				
P8	Experie	enced trouble ling violent behavi		_	Yes		No		Yes		No
P9	Experie of suici	enced serious thou ide?	ughts		Yes		No		Yes		No
P10	Attemp	ted suicide?			Yes		No		Yes		No
P11	for any	rescribed medicat psychological or nal problem?	ion		Yes	П	No		Yes		No
P12	1	any days in the pa	st 30 have yo								140
	J	or Questions P13 ar	-	-		•					
	1 How muc	ch have you been t	_		_		-	_	ms		
P13	in the pa	st 30 days? │ 0 = Not at all ☐	1 = Slightly		2 = Mo	oderately		☐ 3 = Consider	ably $\Box$	4 = Ext	emely
P14	How imp	ortant to you now i 0 = Not at all □					oroblems?	☐ 3 = Consider	ably 🗆	] 4 = Ext	remely
<u>(</u>	<u>Confide</u> n	ce Ratings									
		e information signi	ficantly distort	ed by	<b>'</b> :						
P22	Subject'	s misrepresentation	on?		Yes		No				
P23	Subject's	s inability to under	stand?		Yes		No				
	Comr	nents:									
(	Completed	d by (Initials:									

			Treatme	ent Week 12
	Site ID:	Subject ID #.	Subject Initials	Week
			J	
D .				
Date:				
	(mana (dali na na)			
	(mm/dd/yyyy)			
	Ask subject to read each of the ite	ems and choose only one answer fo	ar each question	
Drug U		enis and choose only one answer to	r each question	
Drug C	<u> </u>			
1 How m	any times have you hit up (i.e. ir	njected any drugs) in the last mon	th?	
]	I haven't hit up	njested drij druge) in tre last men		
	If you have not injected	drugs in the last month, go to Ques	stion 7.	
Į	Once a week or less			
l I	More than once a week but I	less than once a day		
	☐ Once a day ☐ 23 times a day			
[	☐ More than three times a day	,		
2. How m	any times in the last month have	e you used a needle after someon	e else had alreadv	
used it		,		
	No times			
[	One time			
[ 	Two times			
l I	☐ 3-5 times ☐ 6-10 times			
[	☐ More than 10 times			
ں How m		a needle before you in the past mo	onth?	
	☐ None	a needle belefe yearn are paer me	o	
[	One person			
[	Two people			
Į	3-5 people			
l I	6-10 people			
l 4. How m	☐ More than 10 people	someone used a needle after you	12	
	☐ No times	someone used a needle arter you	ı <b>:</b>	
	One time			
[	☐ Two times			
[	3-5 times			
Į	6-10 times			
		cleaned needles before re-using	thom?	
	len, in the last month, have you ☐ I do not re-use	cleaned needles before re-using	mem?	
	☐ Every time			
	Often			
[	Sometimes			
	Rarely			
	Never			
б. Before г	using needles again, how often ☐ I do not re-use	in the past month did you use ble	each to clean them?	
	☐ Foo not re-use ☐ Every time			
[	☐ Often			
[	☐ Sometimes			
[	☐ Rarely			
	□ Never			

			Treatmer	nt Week 12
	Site ID:	Subject ID #.	Subject Initials	Week
Date:		<u> </u>		
	(mm/dd/yyyy)			
<u>Sexual</u>	<u>Behavior</u>			
		s, have you had sex with in the last mont	:h?	
	None	say in the last month skin to Overtion 12		
	One If you have not had	sex in the last month, skip to Question 12.	,	
	Two			
L	3-5 people			
	6-10 people More than 10 people			
8. How ofte		s when having sex with your regular part	tner(s) in the last	
month?	-		(-)	
L	No regular partner/no pe	enetrative sex		
<u> </u>	l Every time l Often			
	Sometimes			
	Rarely			
0.11	Never	and an experience be all a second to a second an extension	-0	
9. How ofte	en nave you used condom I No casual partner/no pe	s when you had sex with casual partners	<b>3</b> ?	
	Every time	siletiative sex		
	Often			
	Sometimes			
	l Rarely l Never			
10. How of		ns when you have been paid for sex in th	ne last month?	
	No paid partner/no pene	etrative sex		
	Every time			
	Often Sometimes			
	Rarely			
	Never			
11. How <u>m</u>	any times have you had ar	nal sex in the last month?		
	No times One time			
	Two times			
	3-5 times			
Ļ	6-10 times			
E <sub>1</sub>	More than 10 times veryone should answer Que	estion 12		
	ou had an HIV test come b			
	Yes			
	l No l Don't know			
	I DOLLKIIOM			
Complete	d by (Initials):			
F. 12.10	, ( / .			

	Site ID:	Subject ID #.	Subject Initials	ient Week J Week
Date:		_ <b></b>		] [
D ( )	(mm/dd/yyyy)			
Date doses (	n dose is four tablets	(mm/dd/y	<i>(УУУУ)</i>	
Kit Number:				
Bottle Number	er:			
Number of d	oses dispensed			
Date unused	l doses returned	(mm/dd/		
Number of d	oses returned			
Number of d	oses reported lost by su	ubject		
Doses taken	:			
	Day of Week:	<u>Date</u>	Time Dose	Dose Not
		(mm/dd/yyyy)	Taken	Taken
		(		
Comments:				
Completed b	y (Initials):			

# Form 34 - TREATMENT COMPLIANCE - PSYCHOTHERAPY

12

1 (12)11 1(1	Nioual VVVI					Treatment	
	Site ID:		Subject ID	#.		Subject Initials	Week
Date:							
	(mm/dd/yyyy)						
Did subject	ct receive standardized, manu	ıal-gı	uided individ	ual psyd	chothe	rapy this week?	
(If No, ple	ase comment below)		Yes		No		
If yes, len	gth of psychotherapy session			minut	es		
	ct require emergency crisis ent sessions this week?		Yes		No		
If yes, how	w many?						
Additional	comments:						<b>-</b>

Completed by (Initials):

# Form 14 - BIRTH CONTROL / PREGNANCY ASSESSMENT

						Treati	ment Week 12				
	Site ID:		Subjec	t ID#.	S	ubject Initials	Week				
Date:											
Date.											
	(mm/dd/yyyy)										
This form	n is to be filled out t	for fom al	o subjects o	alv. All for	mala subjec	ote must be too	stad at				
	ng/Baseline and hav		-	-	-						
What met	thod of birth control is	s the parti	cipant current	tly using (p	orior to taking	g modafinil)?					
_	☐ Oral contrace	•			·	,					
	Barrier (diaph		ondom plus s	permicide)	)						
	_	•	•	. ,							
	_	Levonorgestrel implant (Norplant) Intrauterine Contraceptive system (IUD)									
	☐ Medroxyproge	Medroxyprogesterone Acetate Contraceptive injection (Depo-Provera)									
	☐ Contraceptive	Contraceptive patch									
	Surgical Steril	Surgical Sterilization - Hysterectomy									
	Surgical Steril	ization - 7	Γubal ligation								
	urgically sterile or 2 y f birth control during						eptable				
	Yes	□ N	0								
If yes, ma	ark below the accepta	ble metho	od selected by	the subje	ct for use:						
Г	barrier method	d with spe	rmicide	•							
	steroidal conti	•		ed, injecte	d] used						
	in conjunction	•									
	☐ Contraceptive	patch us	ed in conjunct	tion with a	barrier meth	nod					
	Intrauterine de	evice [IUD	]								
Was a pr	egnancy test perform	ed?		Yes		No					
If	yes, date specimen	collected									
	, ee, date ep eee			(m	m/dd/yyyy)						
R	Result: Ne	gative	☐ Positive	☐ Unl	known						
1f	no, specify reason:										
"	no, specify reason.										
Is the sub	ject lactating?	☐ Ye	es .		lo						
Commen	ts:										
0	al has diagrams.										
Complete	ed by (Initials):										

				Treatm	ent Week 12
	Site ID:	Subject I	D#.	Subject Initials	Week
Date:					
	(mm/dd/yyyy)	_			
Did Subje	ct receive HIV Counseling	at Week 12?			
(If No, ple	ase comment below)	☐ Yes	☐ No		
Additional	comments:				
Complete	d by (Initials):				

Weekly Study Visit

Date urine collected:

Completed by (Initials):

Date:

Site ID:

(mm/dd/yyyy)

Trak Cup: The temperature must be <u>higher</u> than 90.0 ° F and <u>lower</u> than 99.0 ° F Split Sample Cup: The temperature must be <u>higher</u> than 90.0 ° F and <u>lower</u> than 100.0 ° F

#### Form 23 - URINE BE SPECIMEN COLLECTION FORM

# **Treatment Week 16** Subject ID #. **Subject Initials** Week Urine bar code sticker: Urine not collected (mm/dd/yyyy) Was urine temperature within expected range? ☐ No Yes Franklin Cup: The temperature must be higher than 96.0° F and lower than 104.8° F On-

### Form 24 – SUBSTANCE USE INVENTORY

				Trea	ntment Week 1	13		
Site 1	ID:	Subject II	) #.	Subject Initials	Week	7		
Date:						ı		
(mm/de								
Using timeline follow-back	method, record wh	ether subject has	on each day since t	the last visit used a	ny amount of the su	ubstances listed be	low, along with the	most common route
of administration for each		esterday and work	DACK TO THE IAST VIS	it. Please be sure ti	nat days are contini	uous with last weel	CS TORM.	
Date of last v		d/yyyy)						
<b>.</b>	(11111)	<i></i>						
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	$\square$ Y/ $\square$ N $\square$	$\square$ Y/ $\square$ N $\square$	$\square$ Y/ $\square$ N $\square$	□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	$\square$ Y/ $\square$ N	$\square$ Y/ $\square$ 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 adminis	tration (ROA) codes	:: 1 = oral, 2 = nasa	l, 3 = smoking, 4 = I	non-intravenous in	jection, 5 = intraver	nous injection		
Completed by (Initials):								

### Form 24 – SUBSTANCE USE INVENTORY

		Subject ID #.			itment Week I						
Site ID:				Subject Initials Week		1					
Date:						ı					
(mm/d	d/yyyy)										
Using timeline follow-back of administration for each	method, record wh	nether subject has o	on each day since t	he last visit used ar	ny amount of the su	ıbstances listed be	low, along with the i	nost common route			
		esterday and work	back to the last visi	ii. I lease be sule ii	iai days are contin	uous wiiii iast weer	K 3 IOIIII.				
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	$\square$ Y/ $\square$ 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	$\square$ Y/ $\square$ N	□Y/ □N	□Y/ □N	□Y/ □N	□Y/ □N	$\square$ Y/ $\square$ 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 adminis	tration (ROA) codes	s: 1 = oral. 2 = nasa	l. 3 = smokina. 4 = ı	non-intravenous ini	ection. 5 = intraver	nous injection					
		,	, : · · · · · · · · · · · · · · · · ·		<del></del>	<b>y</b>					
Completed by (Initials):											

### Form 24 – SUBSTANCE USE INVENTORY

				Trea	atment Week 1	15			
Site ID:		Subject ID #.		Subject Initials	Week	Week			
Date:						ı			
( <i>mm/d</i> e	d/vvvv)								
Using timeline follow-back	method, record wh	nether subject has	on each day since	the last visit used a	ny amount of the s	ubstances listed be	elow, along with the	most common route	
of administration for each		esterday and work	DACK TO THE IAST VIS	it. Piease de sure ti	nat days are contin	uous with last weel	K S TOTTII.		
Date of last vi		d/yyyy)							
	(11111/40	<i></i>							
Day of week									
Date									
	Used? ROA	Used? ROA	Used? ROA	Used? ROA	Used? ROA	Used? ROA	Used? ROA		
Cocaine	$\square$ Y/ $\square$ N	□Y/ □N	□Y/ □N	$\square$ Y/ $\square$ 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	$\square$ Y/ $\square$ N $\square$	□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):									

#### Form 24 – SUBSTANCE USE INVENTORY

				Trea	atment Week 1	16		
Site 1	ID:	Subject II	) #.	Subject Initials	Week	•		
Date:								
(mm/de	d/yyyy)							
Using timeline follow-back of administration for each	method, record wh drug. Begin with ye	ether subject has e esterday and work	on each day since t back to the last vis	he last visit used a it. Please be sure tl	ny amount of the ຣເ hat days are contini	ubstances listed be uous with last week	low, along with the i a's form.	nost common route
Date of last vi					•			
	(mm/do	d/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 adminis	tration (ROA) codes	s: 1 = oral, 2 = nasa	l, 3 = smoking, 4 = 1	non-intravenous in	jection, 5 = intraver	nous injection		
Completed by (Initials):								

			Treatme	nt Week 16
	Site ID:	Subject ID #.	Subject Initials	Week
Date:				
Date.				
	(mm/dd/yyyy)			
		ems and choose only one answer for	r each question	
Drug U	-			
<u> Drag C</u>				
1. How m	any times have you hit up (i.e. i	njected any drugs) in the last mont	h?	
	☐ I haven't hit up			
Г		drugs in the last month, go to Quest	tion 7.	
[	<ul><li>☐ Once a week or less</li><li>☐ More than once a week but</li></ul>	less than once a day		
	Once a day	less than once a day		
	23 times a day			
	☐ More than three times a day	/		
		e you used a needle after someone	e else had already	
used it?				
L	☐ No times ☐ One time			
<u> </u>	Two times			
Ī	☐ 3-5 times			
	☐ 6-10 times			
	☐ More than 10 times			
3. How m		a needle before you in the past mo	onth?	
L	」 None □ One person			
[	☐ Two people			
	☐ 3-5 people			
	6-10 people			
[	☐ More than 10 people		_	
4. How m	any times in the last month has □ No times	someone used a needle after you?	?	
L T	☐ No times ☐ One time			
	Two times			
	3-5 times			
	6-10 times			
[	☐ More than 10 times			
5. How of	ten, in the last month, have you □ I do not re-use	ı cleaned needles before re-using t	hem?	
L	☐ Every time			
	☐ Often			
	Sometimes			
	Rarely			
	Never			
	using needles again, how ofter  I do not re-use	n in the past month did you use blea	ach to clean them?	
	☐ Full Hot re-use			
ŗ	☐ Often			
Ī	Sometimes			
	Rarely			
	Never			

			Treatme	nt Week 16
	Site ID:	Subject ID #.	Subject Initials	Week
Date:				
	(mm/dd/yyyy)			
Sexual	<u>Behavior</u>			
		s, have you had sex with in the last	month?	
	None	,, ,		
_		sex in the last month, skip to Questi	ion 12.	
F	」One ]Two			
F	3 -5 people			
F	6-10 people			
Ē	More than 10 people			
8. How ofte		s when having sex with your regula	ar partner(s) in the last	
month?	•	3 , 3		
	No regular partner/no pe	netrative sex		
L	Every time			
Ļ	Often			
F	Sometimes			
F	Rarely Never			
9. How oft	=	s when you had sex with casual pa	rtners?	
	No casual partner/no per			
	Every time			
	Often			
<u> </u>	Sometimes			
Ļ	Rarely			
_ 10 How o	Never	ns when you have been paid for se	ev in the last month?	
TO. FIOW O	No paid partner/no pene		X III tile last month:	
Ē	Every time	nanvo oox		
	Often			
	Sometimes			
	Rarely			
	Never			
11. How m	any times have you had an	ial sex in the last month?		
F	」No times ]One time			
F	Two times			
	3-5 times			
	6-10 times			
	More than 10 times			
. E	veryone should answer Que	stion 12.		
	ou had an HIV test come b ] Yes	eack positive?		
F	l Yes No			
F	Don't know			
_				
Complete	d by (Initials):			

## Form 14 – BIRTH CONTROL / PREGNANCY ASSESSMENT

				Г	<b>Treatment Week 16</b>					
	Site ID:	Su	bject ID#.	Subject Init	ials Week					
Date:										
	(mm/dd/yyyy)									
	is to be filled out t g/Baseline and hav									
What met	hod of birth control is	the participant cu	rrently using (pric	or to taking modafin	il)?					
	Oral contrace	otive								
	Barrier (diaph	Barrier (diaphragm or condom plus spermicide)								
	Levonorgestre	el implant (Norplan	t)							
	Intrauterine C	ontraceptive syster	n (IUD)							
	,, ,	esterone Acetate C	ontraceptive inje	ction (Depo-Prover	a)					
	•	patch								
	_	ization - Hysterecto	•							
	Surgical Steril	ization - Tubal liga	tion							
	rgically sterile or 2 y birth control during Yes				n acceptable					
If yes, ma	rk below the accepta	ible method selecte	ed by the subject	for use:						
, ,	_	d with spermicide	,							
	steroidal cont	aceptive [oral, Imp with a barrier metl		used						
	_	patch used in con		arrier method						
	Intrauterine de	evice [IUD]								
Was a pre	egnancy test perform	ed?	☐ Yes	□ No						
If	yes, date specimen	collected	(mm	/dd/yyyy)						
R	esult:	egative	ive 🗌 Unkn	own						
If	no, specify reason:									
Is the sub	ject lactating?	☐ Yes	☐ No							
Comment										
Complete	d by (Initials):									

				Treatm	ent Week 16
	Site ID:	Subject I	D#.	Subject Initials	Week
Date:					
	(mm/dd/yyyy)	1			
Did Subje	ect receive HIV Counseling	at Follow up?			
(If No, ple	ease comment below)	☐ Yes	□ No		
Additiona	Il comments:				
Complete	ed by (Initials):				

# NIDA-MDS-Modaf-0001

# Form 37 – FOLLOW UP Treatment Week 16

Site 1	ID:	Subjec	t ID#.	, ,	Subject In	itials	Week
Date:							
·	ld/yyyy)						
Has contact been ma	ade with the subjec	t? L	Yes		No		
If Yes, date of		mm/dd/s s s s s		If No, s	skip to ques	tion #7.	
2. Does the subject rep alcohol abuse/deper	oort currently receivindence?				☐ Yes	☐ No	
<ul><li>3. Does the subject rep if it were generally a</li><li>4. Have any adverse ev</li></ul>	vailable for substan	take the st nce abuse t	udy drug a reatment?	again	☐ Yes ☐ Yes	□ No	Unknown
If 'Yes', an Adver	rse Event CRF form mu		eted.		□ Yes	□ No	
	s Adverse Event report	t must be file					
<ol><li>If subject does not of since last clinic visit? (</li></ol>			ise of any	of the fol	lowing and	if so, for h	ow many days
		Days <u>Used</u>					
☐ Co	ocaine						
□ м	ethamphetamines						
☐ Ar	mphetamines						
□ Ве	enzodiazepines						
□ AI	Icohol						
☐ M:	arijuana						
□ Se	edatives						
□ Ni	icotine						
□ O <sub>I</sub>	piates						
□ Ва	arbiturates						
□ No	one						
□ Ot	ther						
	ade with someone ong to the contact:					] Yes	□ No
8. Is the subject living?	If the subject has died	l, a Serious A	dverse Even			☐ Unkn	OWII
<ul><li>9. Is the subject curren</li><li>10. Additional commen</li></ul>				☐ Yes	s □ No	□ Unkn	own
Completed by (Initials):							

(mm/dd/yyyy)

# End of Trial

	_	Site	ID:		Subject II	) #.		Subject	Initials	Week
Da	te:									J L
Th	is form	•	ld/yyyy)	, ovorv oc	ncontod a	ubios	.4			
			ompleted fo	or every co	nisentea s	иојес	; t.			
1. [	Date of la	st clinic visit				(mm	/dd/yyyy)			
2. [	Date of la	st study drug	dispensed			(mm/	/dd/yyyy)			
3. \	If "I	•	below reason	(s) not rando			No			
	If "	Yes", indicate	e below reaso	n(s) subject	is no longer	in stua	ly.			
Re		ubject's parti r <i>k all that app</i>	icipation has	ended:						
		completed s	•							
□ me		failed to mee	t Inclusion/E	xclusion crit	eria. <i>Entry C</i>	riteria	form must	indicate wh	ich criteria w	ere/were not
	Subject	declined to p	participate (de	uring Screer	ning).					
	Subject	requested to	withdraw fro	om study						
		Subject rep	orts drug not	working	☐ Otl	ner <i>Pl</i>	ease spec	ify below.		
	Subject	developed s	ensitivity to s	tudy drug oi	experience	d inter	current illr	ness, unrela	ted medical	condition,
or	If s	ubject experie	dverse event enced advers se specify wh	e event(s), al	n Adverse Ev	ent Ca	se Report			nination.
		terminated fo	or administra mments.	tive reasons	. Include pro	otocolı	non-comp	liance in this	:	
	Subject	transferred t	o another tre	atment prog	ram (select	type)				
		/lethadone	□LAAM	□ Dr	rug Free	☐ Inp	oatient Deto	x or Treatme	ent	
	П	herapeutic Co	mmunity	□ O1	her, specify					
	Subject Subject Subject	did not returr	area. n to study/clir lled environn							
4. (	Comment	s:								
			g this form, ve been rev				with my	supervisio	n and mana	agement,
		vestigator:	_				Date			

# Form 16 – ADVERSE EVENTS All Visits

Site ID:	S	ubject ID #.	Subject	Initials					
Has the subject h	ad any Adverse Event	s during the time	period evaluated	d? ☐ Yes		] No	(If yes, p	lease list l	below).
D: Severity	E: Relationship	F: Action <u>Regardin</u>	Taken g Study Drug	G: Other Action Tal	ken <u>H</u>	: Outcome o	of AE		I: Serious?
1 = Mild 2 = Moderate 3 = Severe	1 = Definitely 2 = Probably 3 = Possibly 4 = Remotely 5 = Definitely Not 6 = Unknown		sed Dose	1 = None 2 = Pharmacologic TI 3 = Nonpharm. Thera 4 = Hospitalization	nerapy 2 py 3 4 5 6	<ul><li>Still presen</li><li>Residual ef</li></ul>	no sequelae t, no treatment t, being treate fects, no treatr ffects, being tre	: d ment	1 = Yes 0 = No (If yes, comple SAE Form)
Adver	A se Event	B Start Date	C <b>Stop Date</b>	D Severity	E Related	F Action	G Other Act.	H Outcome	l e <b>SA</b> E

# NIDA-MDS-Modaf-0001

# Form 16 – ADVERSE EVENTS All Visits

_	Site ID:	Subject ID #.	Subject Initi	als					
las the sub	oject had any Adverse Events	during the time period evalua	ated?	Vac	□ No	(If ve	es, please list	halow)	
D: Severity	E: Relationship	F: Action Taken Regarding Study Drug	G: Other Acti		H: Outcome		o, picase nse	I: Serious?	
= 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 = Pharmacol 3 = Nonpharm 4 = Hospitaliza	ogic Therapy . Therapy	1 = Resolved, 2 = Still prese 3 = Still prese 4 = Residual 6 5 = Residual 6 6 = Death 7 = Unknown	nt, no treatnent, being treeffects, no treeffects, bein	nent eated reatment	1 = Yes 0 = No (If yes, complete SAE Form)	
	A Adverse Event	B <b>Start Date</b>	C Stop Date	D <b>Severity</b>	E Related	F Action	G Other Act.	H Outcome	l Sae

# NIDA-MDS-Modaf-0001

# Form 16 – ADVERSE EVENTS All Visits

	Site ID:	Subject ID #.	Subject Init	ials					
Has the subj	ect had any Adverse Events o	during the time period evalu	ated?	Yes	□ No	(If ye	es, please list	below).	
D: Severity	E: Relationship	F: Action Taken Regarding Study Drug	G: Other Act	tion Taken	H: Outcome	of AE		I: Serious?	
1 = Mild 1 = Definitely 1 = None 2 = Moderate 2 = Probably 2 = Discontinued Perm. 3 = Severe 3 = Possibly 3 = Discontinued Temp 4 = Remotely 4 = Reduced Dose 5 = Definitely Not 5 = Increased Dose 6 = Unknown 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 <b>Stop Date</b>	D <b>S</b> everity	E Related	F Action	G Other Act.	H Outcome	l SAE?

	Site ID:	Subject ID #.	7	Subject Initials	All Visits Week
Date:	(mm/dd/yyyy)		_   _		
<u>Demogr</u>	aphic Information				
Date of Co	onsent: (mm/dd/yyyy)	Gender: [	☐ Male	☐ Female	
Date of Bi	rth: (mm/dd/yyyy)	Height:	in	Weight:	lb
Ethnicity (	regardless of race):				
☐ Hispan	ic or Latino spanic or Latino				
Race (indi	icate which single major ra	ce applies):			
☐ White ☐ Americ ☐ Other,	an India <u>n or Alaska Native</u>		Asian Native Hawai Unknown	ian or Other Pac	ific Islander
☐ Particip	pant chooses not to answe	r race/ethnicity question	ns.		
<u>Serious</u>	Adverse Event				
Type of e	vent				
	Death Immediately Life-threaten	ing event	Persistent/Sig Congenital ar	gnificant Disabilit	у
	Hospitalization/prolonged		Other, specify		
If patient of	lied, Date of death	(mm/dd/yy)	yy)		
Caus	e of Death	_			
Autop	osy Report Requested?	☐ Yes ☐	No Reason:		
Descriptio Form):	n of the Serious Adverse E	Event (make sure the de	escription and	date are consiste	ent with the AE
Onset date		Severity Gr	rade: Mild	☐ Moderate	☐ Severe
Reported t	(mm/dd/yyyy) to IRB by:		Date:	(mm/dd/yyyy)	

	Site ID:	Subject	: ID #.	Subject Initials	All Visits Week
Date:					<u> </u>
	(mm (dd)( a a a s)				
	(mm/dd/yyyy)				
Reported	to Sponsor (NIDA) by:			Date:	
Type of R	eport:  Initial Report	☐ Follow-up	Report	(mm/da	VYYYY)
Was the S	SAE related to the investigat	ional agent?			
	Definitely Probably	☐ Possibly	Remotely	☐ Definitely Not	Unknown
Action Ta	aken regarding <u>investigation</u> None Discontinued permanently	☐ Discontin	ued temporarily dose	☐ Increased dos	e
Other act	tions taken:				
	] None ] Remedial therapy – pharm		Remedial therapy Hospitalization -ne	<ul> <li>non-pharmacologic</li> <li>or prolonged</li> </ul>	
Outcome				1 10	
	<ul><li>☐ Resolved; no sequelae</li><li>☐ Not yet resolved, but imp</li><li>☐ Not yet resolved, no char</li><li>☐ Not yet resolved, worseni</li></ul>	nge		hronic condition, or permanent disabilit	у
Date of S	AE Resolution:		☐ continuing		
Concomi	mm/d) tant medications: (both le				
Relevant	tests/laboratory data, incl	uding dates:			
	acceptance and y acceptance, and	aug uudoo.			
	history including pre-exis g., allergies, pregnancy, smokin			nction, etc.	

PCH = patch

Date:	Site ID:	Subject ID #.	Subject I	nitials Week
	(mm/dd/yyyy)			
<u>Investigation</u>	onal Agent Adminis	<u>stration</u>		
Is the investiga	ational agent information	known?	es 🗆 No	
If yes, investig	ational agent name		Lot number:	
Expiration date	e: ( <i>mm/dd/yyyy</i> )			
Quantity: Codes	Units:	Frequency:	Route of Adminis	stration:
Start date:	(mm/dd/yyyy)	Stop	date: (mm/dd/y	yyyy)
Comments:				
Unit of Medic	ation	Frequency	Route of Admin	istration
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	ONCE = one dose QD = once daily BID = twice daily TID = 3 times/day QID = 4 times/day QOD = every other day PRN = as needed	TD = transdermal / INH = inhaled   IM = intramuscular   IV = intravenous   IV = INTAVENOUS   IV = INTA	SL = sublingual AUR = auricular A = intra-articular NAS = nasal O = intraocular JNK = unknown

	Site ID:	Subject ID #	<u>ŧ.</u>	Subject Initials	All Visits Week
Date:	(mm/dd/yyyy)				
<u>Demogr</u>	aphic Information				
Date of Co	onsent: (mm/dd/yyyy)	Gender:	☐ Male	☐ Female	
Date of Bi	rth: (mm/dd/yyyy)	Height:	in	Weight:	lb
Ethnicity (	regardless of race):				
	ic or Latino spanic or Latino				
Race (indi	icate which single major ra	ce applies):			
☐ White ☐ Americ ☐ Other,	an India <u>n or Alaska Native</u>	African American [	☐ Asian ☐ Native Hawa ☐ Unknown	iian or Other Pac	sific Islander
☐ Particip	pant chooses not to answe	r race/ethnicity quest	ions.		
<u>Serious</u>	Adverse Event				
Type of e	vent				
	Death Immediately Life-threaten	ing event	<ul><li>☐ Persistent/Si</li><li>☐ Congenital a</li></ul>	gnificant Disabilit	У
	Hospitalization/prolonged		Other, specif		
If patient d	lied, Date of death	(mm/dd/	yyyy)		
Caus	e of Death				
Autop	osy Report Requested?	☐ Yes [	☐ No Reason	:	
Description Form):	n of the Serious Adverse E	Event (make sure the	description and	date are consist	ent with the AE
Onset date		Severity	Grade:   Mild	☐ Moderate	☐ Severe
Reported t	(mm/dd/yyyy) to IRB by:		Date:	(mm/dd/yyyy)	

	Site ID:	Subject II	D#	Subject Initials	All Visits Week
Date:					,
	(mm/dd/yyyy)				
Reported	to Sponsor (NIDA) by:			Date:	
Type of R	eport:  Initial Report	☐ Follow-up F	Report	(mm/dd.	<i>'</i> yyyy)
Was the S	SAE related to the investiga	ational agent?			
	Definitely Probably	☐ Possibly	☐ Remotely	☐ Definitely Not	☐ Unknown
Action Ta	aken regarding <u>investigat</u> ] None ] Discontinued permanentl	Discontinue	ed temporarily ose	☐ Increased dose	Э
Other act	<b>tions taken:</b> ] None ] Remedial therapy – phari		medial therapy - spitalization -ne	– non-pharmacologic w or prolonged	;
	to date:  Resolved; no sequelae  Not yet resolved, but im  Not yet resolved, no cha  Not yet resolved, worsel	proving ange [		hronic condition, r permanent disabilit	y
Date of S	AE Resolution:	dd/yyyy)	continuing		
Concomi	tant medications: (both le	,			
Relevant	tests/laboratory data, inc	luding dates:			
	history including pre-exi g., allergies, pregnancy, smoki			nction, etc.	

Date:	Site ID:  (mm/dd/yyyy)	Subject ID #.	Subjec	t Initials	All Visits Week
<u>Investigation</u>	onal Agent Adminis	<u>tration</u>			
Is the investiga	ational agent information	known?	s 🗆 No		
If yes, investiga	ational agent name		Lot number:		
Expiration date	: ( <i>mm/dd/yyyy</i> )				
Quantity:	Units:	Frequency:	Route of Admir	nistration:	
Codes	listed below.				
Start date:	(mm/dd/yyyy)	Stop d	late: (mm/do	1/уууу)	
Comments:					
			D. M. (Alle)		
Unit of Medica	ation	Frequency	Route of Adm	inistration	
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	ONCE = one dose QD = once daily BID = twice daily TID = 3 times/day QID = 4 times/day QOD = every other day PRN = as needed	PO = oral TD = transdermal INH = inhaled IM = intramuscular IV = intravenous REC = rectal VAG = vaginal SQ = subcutaneou	IO = intraocular UNK = unknown	r

Date:	Site ID: Subject ID #. Subject Initials Week  (mm/dd/yyyy)
<u>Demogr</u>	aphic Information
Date of Co	onsent: Gender: Male Female  (mm/dd/yyyy)
Date of Bir	th: Height: in Weight: Ib
Ethnicity (r	regardless of race):
	c or Latino panic or Latino
Race (indi	cate which single major race applies):
☐ White ☐ America ☐ Other, s	☐ Black or African American ☐ Asian ☐ Native Hawaiian or Other Pacific Islander ☐ Unknown
☐ Particip	pant chooses not to answer race/ethnicity questions.
Serious	Adverse Event
Type of ev	
If patient d	ied, Date of death (mm/dd/yyyy)
Cause	e of Death
Autop	osy Report Requested?
Description Form):	n of the Serious Adverse Event (make sure the description and date are consistent with the AE
Onset date	
Reported t	(mm/dd/yyyy) To IRB by: Date: (mm/dd/yyyy)

	Site ID:	Subject	: ID #.	Subject Initials	All Visits Week
				J	
Date:					
	(mm (old/s as a s)				
	(mm/dd/yyyy)				
Reported	to Sponsor (NIDA) by:			Date:	
Type of R	eport:  Initial Report	☐ Follow-up	Report	(mm/da	<i>(</i> / <i>y</i> / <i>y</i> / <i>y</i> /
Was the S	SAE related to the investigat	ional agent?			
	Definitely Probably	☐ Possibly	Remotely	☐ Definitely Not	Unknown
Action Ta	aken regarding <u>investigation</u> None Discontinued permanently	☐ Discontin	ued temporarily dose	☐ Increased dos ☐ Delayed dose	e
Other act	tions taken:				
	] None ] Remedial therapy – pharm		Remedial therapy Hospitalization -ne	<ul> <li>non-pharmacologic</li> <li>or prolonged</li> </ul>	
Outcome			□ <b>p</b>	I Por	
	<ul><li>☐ Resolved; no sequelae</li><li>☐ Not yet resolved, but imp</li><li>☐ Not yet resolved, no char</li><li>☐ Not yet resolved, worsen</li></ul>	nge		chronic condition, or permanent disabilit	у
Date of S	AE Resolution:	d/yyyy)	☐ continuing		
Concomi	tant medications: (both le	,			
Relevant	tests/laboratory data, incl	uding dates:			
	•				
	history including pre-exis g., allergies, pregnancy, smoking			nction, etc.	

Date:	Site ID:  (mm/dd/yyyy)	Subject ID #.	Subject Initials	All Visits Week
<u>Investiga</u>	tional Agent Admin	istration		
Is the invest	igational agent informatio	n known?	s 🗆 No	
If yes, inves	tigational agent name		Lot number:	
Expiration d	ate: ( <i>mm/dd/yyyy</i> )			
Quantity:	Units:	Frequency:	Route of Administration:	
Start date:	(mm/dd/yyyy)	Stop o	date: (mm/dd/yyyy)	
Comments:				
Unit of Med	lication	Frequency	Route of Administration	
CAP = capsule g = gram GR = grain GTT = drop ug = microgram uL = microliter mg = milligram mL = milliliter PCH = patch	PUF = puff SPY = spray/squirt SUP = suppository  TSP = teaspoon TBS = tablespoon	ONCE = one dose QD = once daily BID = twice daily TID = 3 times/day QID = 4 times/day QOD = every other day PRN = as needed	PO = oral SL = subling TD = transdermal INH = inhaled IM = intramuscular IV = intravenous REC = rectal VAG = vaginal SQ = subcutaneous  SL = subling AUR = auric IA = intra-art NAS = nasal IO = intraocu UNK = unkn VAG = vaginal	ular ticular I ular

## Form 18 - CONCOMITANT MEDICATIONS

**All Visits** 

	Site ID:		Sub	ject ID #.	Subject I	nitials			
Has the subje	ect taken any o	concomitant	medication	ns during this s	tudy?	]Yes □No	(If yes, p	lease complete tabl	e)
CAP = capsule g = gram GR = grain GTT = drop ug = microgram uL = microliter	Unit of Medic mg = milligrar mL = milliliter oz = ounce PUF = puff SPY = spray/s PCH = Patch	n SUP = s TSP = te TBS = ta TAB = ta	ablespoon ablet	ONCE = 0 QD = onc BID = twic TID = 3 tir	ce daily PRN = as r	ery other day	PO = oral TD = transdermal INH = inhaled IM = intramuscular	VAG = vaginal NAS SQ = subcutaneous IO =	intra-articular = nasal intraocular <= unknown
Medication	n	Dose	Units	Frequency	Route of Administration	Start Date	Stop Date	Continuing? (check if yes)	Indication

# Form 18 - CONCOMITANT MEDICATIONS

**All Visits** 

	Site ID:		Subj	ect ID #.	Subject I	nitials			
Has the subject  CAP = capsule  g = gram	Unit of Medi mg = milligra mL = millilite	cation nm SUP = r TSP =	suppository teaspoon	ONCE = 0 QD = once	Frequency one dose QID = 4 time e daily QOD = eve	ry other day	Route of a PO = oral TD = transdermal	VAG = vaginal NAS	intra-articular = nasal
GR = grain GTT = drop ug = microgram uL = microliter	oz = ounce PUF = puff SPY = spray PCH = Patch	= TAB -squirt UNK	tablespoon tablet unknown	BID = twic TID = 3 tir	mes/day	needed	IM = intramuscular	AUR = auricular	i = unknown
Medication		Dose	Units	Frequency	Route of Administration	Start Date	Stop Date	Continuing? (check if yes)	Indication

## Form 18 - CONCOMITANT MEDICATIONS

**All Visits** 

	Site ID:		Subject ID #.	Subject	nitials			
Has the subject  CAP = capsule g = gram GR = grain GTT = drop ug = microgram uL = microliter	Unit of Medicatio mg = milligram mL = milliliter oz = ounce PUF = puff	son SUP = suppositor TSP = teaspoon TBS = tablespoon TAB = tablet rt UNK = unknown	y ONCE QD = 0 BID =	Frequency E = one dose QID = 4 tir	ery other day	Route of Admi PO = oral REC TD = transdermal VAG INH = inhaled SQ = IM = intramuscular SL =	= rectal IA = = vaginal NAS subcutaneous IO =	intra-articular = nasal
Medication	Do	ose Units	Frequenc	Route of cy Administration	Start Date	Stop Date	Continuing? (check if yes)	Indication
							7 0	
			<b>-</b>				7 0	
			<b>_</b>				<b>7</b>	

					Retest Week	
	Site ID: Subject ID #.		ID#. Subje	Subject Initials		
Date:						
<b>D</b> = 4 = = 4	4					
Retest	<u>1</u>					
Date	/ / -l -l /-		Time Vital Signs taken		٠)	
	(mm/dd/y	/yyy) 		(24 hour clock	<b>(</b> )	
Temperate	ure (oral)	(°F)	NR: 94-100.4	CS□ NCS[		
Comment	s for Temperature					
Blood Pre	ssure (sitting)	(mm Hg)	NR: 90-140/50-90	CS□ NCS[		
Comment	s for Blood Pressure:					
Pulse Rat	e (sitting)	(beats/min)	NR: 50-120	CS □ NCS [		
	s for Pulse Rate:	(353.3,)	55 5			
Pospirato	ry Rate (sitting)	(breaths/min)	NR: 8-20	CS 🗆 NCS [	 ¬	
			NIX. 0-20	C3 🗀 NC3 L		
Comment	s for Respiratory Rate	<del>)</del> :				
Complete	d by (Initials):					

	G. TD	g 1: ,	ID "	C 1: . I	1	Retest
	Site ID:	Subject	ID #.	Subject In	iitiais	Week
Date:						
Date.		٦				
		_				
Retest 2	2					
				Г		1
Date			Time Vital Signs		24 5 5 1 5 1 5	
	(mm/dd/yyy			(2	24 hour clo	OCK)
Temperati		(°F)	NR: 94-100.4	C	S NCS	S 🗆
Comment	s for Temperature					
Blood Pre	ssure (sitting)	 (mm Hg)	NR: 90-140/50-9	90 C	S □ NCS	S 🗆
	s for Blood Pressure:	( 3)				_
Pulse Rat	e (sitting) (be	eats/min)	NR: 50-120	C	S NCS	S 🗆
Comment	s for Pulse Rate:					
Pospirato	ry Rate (sitting)	(breaths/min)	NR: 8-20		S □ NCS	
	s for Respiratory Rate:	(breatils/IIIII)	NIX. 0-20	C	S LI NOC	, 🗆
Comment	3 for Respiratory Rate.					
	Г	 1				
Complete	d by (Initials):					

	Site ID:	Subject I	D#.	Subjec	t Initials	V	Retest Veek
				~		$\neg \vdash$	
Date:		]					
Retest 3	<u>!</u>						
Date	(mm/dd/yyyy		Time Vital Sig	ns taken	(24 hou	ur clock)	
Temperatu	ure (oral) s for Temperature	」(°F)	NR: 94-100.4		cs□	NCS □	
	ssure (sitting) s for Blood Pressure:	(mm Hg)	NR: 90-140/50	0-90	cs 🗆	NCS □	
Pulse Rate Comments	e (sitting) (be	ats/min)	NR: 50-120		cs 🗆	NCS 🗆	
	ry Rate (sitting) s for Respiratory Rate:	(breaths/min)	NR: 8-20		CS 🗆	NCS 🗆	
Completed	d by (Initials):						

Completed by (Initials):

-	Site ID:	Subject	ID#. Subjec	t Initials	Retest Week
Date:		7			
		J			
Retest 4	<u>!</u>				
_		$\neg$			
Date L	(mm/dd/yyy	y)	Time Vital Signs taken	(24 hour clock)	
Temperatu		(°F)	NR: 94-100.4	CS □ NCS □	
Comments	s for Temperature				
	ssure (sitting) s for Blood Pressure:	(mm Hg)	NR: 90-140/50-90	CS□ NCS□	
Pulse Rate	e (sitting) (be	eats/min)	NR: 50-120	CS □ NCS □	
Comments	s for Pulse Rate:				
	ry Rate (sitting)	(breaths/min)	NR: 8-20	CS □ NCS □	

## Form 14 – BIRTH CONTROL / PREGNANCY ASSESSMENT

						Unscheduled
ı	Site ID:	Sub	ject ID#.		Subject Initials	Week
Date:				Ĺ		
Date.						
This form	(mm/dd/yyyy)  is to be filled out f	or fomalo subjects	anly All for	mala ci	ubicate must be too	stad at
	g/Baseline and have	_	-		-	
What meth	hod of birth control is	the participant curr	entlv usina (p	rior to t	aking modafinil)?	·
	Oral contrace		3 (1		,	
	_	agm or condom plu	ıs spermicide)	)		
		l implant (Norplant)				
		ontraceptive system				
	_	sterone Acetate Co	` ,	iection	(Depo-Provera)	
			na doopavo m	,000.011	(2000 1 1010.0)	
		zation - Hysterector	mv			
	_	zation - Tubal ligation	•			
	3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3	<b>3</b>				
	rgically sterile or 2 ye					eptable
method of	birth control during t		ys after last d	ose of s	study drug?	
	Yes	∐ No				
If yes, mai	rk below the accepta	ble method selected	d by the subje	ct for us	se:	
	barrier method	with spermicide				
	_	aceptive [oral, Impla	anted, injected	d] used		
		with a barrier method	•	-		
	Contraceptive	patch used in conju	unction with a	barrier	method	
	Intrauterine de	vice [IUD]				
Was a pre	gnancy test perform	ed?	Yes		□ No	
If	yes, date specimen of	collected				
"	yes, date speciment	ooncolod	(mi	m/dd/yyy	y)	
Re	esult:	gative   Positive	⁄e □ Unl	known		
If	no, specify reason:					
ls the subj	ject lactating?	☐ Yes		lo		
Comments	e.					
Comment	S.					
Completed	d by (Initials):					

									Unscheduled 1
ı	S	Site ID:		S	ubject I	D#.		Subject Initials	Week
Date:			<u></u> _						
Date.									
	(mm/i	dd/yyyy)							
	(///////								
		Value		Normal /	Abnorma	ll* Abnorma Significant		Comments (required for abno	ormal values)
1. Hemogl	obin		g/dL						
2. Hemato	ocrit		%						
3. RBC			M/uL						
4. Platelet	count		K/uL						
5. WBC			K/uL						
6. Neutrop	hils		%						
7. Lympho	ocytes		%						
8. Monocy	rtes		%						
9. Eosinop	ohils		%						
10. Basop	hils		%						
Please refer to Appendix I of the protocol when determining the significance of abnormal values.  *"Abnormal" is any value outside the normal laboratory range.									
m	illion/uL =	mil/cumm = n	nill/mcl = l	M/cmm = x	10 <sup>6</sup> /cum	m			
x	$10^3/uL = th$	ou/cumm = th	ou/mcl = l	K/cmm = 1	1000/uL :	= x 10³/cun	nm		
☐ Checl	k here if r	esults on th	is form a	re retest	s of pre	evious lat	tests.		
Date o	of original	lab tests			(mm/da	d/yyyy)			

							Unscheduled 2		
	Site ID:		S	ubject I	D#.	_	Subject Initials Week		
Date:									
	(mm/dd/yyyy)								
	Value		Normal	Abnorma	al* Abnormal Significant		Comments (required for abnormal values)		
1. Hemogl	lobin	g/dL							
2. Hemato	ocrit	%							
3. RBC		M/uL							
4. Platelet	count	K/uL							
5. WBC		K/uL							
6. Neutrop	phils	%							
7. Lympho	ocytes	%							
8. Monocy	rtes	%							
9. Eosinop	phils	%							
10. Basop	hils	%							
Please refer to Appendix I of the protocol when determining the significance of abnormal values.  *"Abnormal" is any value outside the normal laboratory range.									
m	illion/uL = mil/cumm	= mill/mcl = M	/cmm = x	10 <sup>6</sup> /cum	nm				
x	10 <sup>3</sup> /uL = thou/cumm :	= thou/mcl = K	/cmm = 1	1000/uL	= x 10³/cum	nm			
□ Chaol	k here if results on	this form or	o rotoot	c of pr	avious lab	tosto			
□ Crieci	k nere ii resuits on	uns ioiin ar	e retest	s or bre	evious iab	iesis.			
Date o	of original lab tests			(mm/da	d/yyyy)				

								<b>Unscheduled 1</b>		
	Site ID:	7	S	ubject I	D#.	Ī	Subject Initials	Week		
Date:		<b>-</b>				•				
(r	<i>nm/dd/yyyy)</i> Value		Normal A	hnormal	I* Abnormal	* Not	Comments			
	Value		Normai F	Diloinia	Significant		(Required for Abnor	rmal 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 = m  Check here if		mpleted	for rete	est of p	revious la	ab tests	s.			
Date of origina				•						
J. J. J. J. J										

(mm/dd/yyyy)

			_				Unscheduled 2
\$	Site ID:		S	ubject l	ID #.	Г	Subject Initials Week
Date:		_				•	
(m	n <i>m/dd/yyyy)</i> Value		Normal A	Abnorma	ıl* Abnormal Significant		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					
	to Appendix I o " is any value o					ificance	e of abnormal values.
mmol/L = mE	Eq/L						
☐ Check here if t	his form is co	ompleted_	for rete	st of p	revious la	ıb tests	3.
Date of original	lab tests						

(mm/dd/yyyy)

ſ	Site ID	: 	S	ubject l	ID#.	Γ	Subject Initials Week
Date:						Ĺ	
L	(mm/dd,						
		Value	Normal /	Abnorma	al* Abnormal Significant		Comments (required for abnormal values)
1. Specific	gravity						
2. pH							
3. Glucose							
4. Protein							
5. Ketones							
6. Occult E	Blood						
7. WBC							
8. RBC							
9. Epithelia	al Cells						
*",	Abnormal" is any	value outside th	ne normal l	aborato	ory range.		
Fo	r Glucose, Protei	in, Ketones, and	Occult Blo	od use	the followin	g scale	to report Values:
	-1 = Abse. 0 = Trace 1 2 3 4	nt					
Fo	r WBC, RBC, and	l Epithelial Cells	use the fol	llowing	scale to rep	ort Valu	ves:
	1 = None ( 2 = Few (6 3 = Moder 4 = Heavy	6 – 10) rate (11 – 50)					
☐ Check	here if this for	m is complete	d for rete	st of p	revious la	b tests	
Date o	f original lab te	ests		(mm/	dd/yyyy)		
Completed	by (Initials):			(,	···		

	Site ID	:	S	ubject II	O#.	Г	Subject Initials Week
Date:							
	(mm/dd,	/vvvv)					
	•	,,,,,					
	,	√alue	Normal		* Abnorma Significant		Comments (required for abnormal values)
1. Specific	gravity						
2. pH							
3. Glucose	e						
4. Protein							
5. Ketones	<u> </u>						
6. Occult I	Blood						
7. WBC							
8. RBC							
9. Epithelia	al Cells						
*55	Abnormal" is any	value outside th	ne normal l	aborator	y range.		
Fo	or Glucose, Prote	in, Ketones, and	Occult Blo	ood use t	he followir	ng scale t	o report Values:
Fo	-1 = Abse 0 = Trace 1 2 3 4 or WBC, RBC, and		use the fo	llowing s	cale to rep	oort Value	9S:
	1 = None ( 2 = Few (6 3 = Moder 4 = Heavy	6 – 10) rate (11 – 50)					
☐ Chec	k here if this fo	rm is complete	d for rete	est of pr	evious la	b tests.	
Date o	of original lab te	ests		(mm/d	ld/yyyy)		
Completed	d by (Initials):						

	Site ID:	$\neg$	S	ubject ID #.	Subject In	itials	Unscheduled 1 Week
Date:							
	(mm/dd/yyyy)						
A. ECG	G overall results were:		ormal				
			normal				
	If ECG is Normal please skip	to Ques	stion C.				
B. If EC	G is abnormal, check belo	w for <u>a</u>	<u>II</u> abnormali	ties.			
	<u>Ab</u>	<u>normal</u>	Abnormal Significant		<u>Abr</u>	normal	Abnormal Significant
1. Increa	ased QRS voltage			17. Supraventric	cular premature beat		
2. Qtc p	rolongation			18. Ventricular p	remature beat		
3. Left a	trial hypertrophy			19. Supraventrio	cular tachycardia		
4. Right	atrial hypertrophy			20. Ventricular ta	achycardia		
5. Left v	entricular hypertrophy			21. Atrial fibrillat	ion		
6. Right	ventricular hypertrophy			22. Atrial flutter			
7. Acute	e infarction			23. Other rhythn	n abnormalities		
8. Suba	cute infarction			24. Implanted pa	acemaker		
9. Old in	farction			25. 1 <sup>st</sup> degree A	-V block		
10. Myo	cardial ischemia			26. 2 <sup>nd</sup> degree A	-V block		
11. Digit	alis effect			27. 3 <sup>rd</sup> degree A	-V block		
12. Sym	metrical T-wave inversion	s 🗆		28. LBB block			
13. Pooi	r R-wave progression			29. RBB block			
14. Othe	er nonspecific ST/T			30. Pre-excitation	n syndrome		
15. Sinu	s tachycardia			31. Other intrave	entricular condition		
16. Sinu	s bradycardia			32. Other, specif	fy		
	ricular rate (bpm)			E. QRS (ms)			
D. PR (r	ms)			F. QTC (ms)			

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

## Form 13 - ELECTROCARDIOGRAM

	Site ID:	Subject ID #.	Subject Initials	Unscheduled 1 Week
Date:				
	(mm/dd/yyyy)			
Comments	S:			

							Unscheduled 2
	Site ID:	_	Sı	ubjec	t ID #. Subjec	t Initials	Week
Date:							
	( ( ( ) )						
	(mm/dd/yyyy)						
A. ECG	overall results were:		o <u>rmal</u> normal				
lf I	ECG is Normal please skip	to Ques	tion C.				
B. If ECG i	s abnormal, check belo	w for <u>al</u>	<u>l</u> abnormali	ties.			
	<u>Abı</u>	<u>normal</u>	Abnormal Significant		<u> </u>	<u>Abnormal</u>	Abnormal Significant
1. Increase	ed QRS voltage			17.	Supraventricular premature be	at 🗌	
2. Qtc prol	ongation			18.	Ventricular premature beat		
3. Left atria	al hypertrophy			19.	Supraventricular tachycardia		
4. Right at	rial hypertrophy			20.	Ventricular tachycardia		
5. Left ven	tricular hypertrophy			21.	Atrial fibrillation		
6. Right ve	entricular hypertrophy			22.	Atrial flutter		
7. Acute in	farction			23.	Other rhythm abnormalities		
8. Subacut	te infarction			24.	Implanted pacemaker		
9. Old infa	rction			25.	1 <sup>st</sup> degree A-V block		
10. Myoca	rdial ischemia			26.	2 <sup>nd</sup> degree A-V block		
11. Digitali	s effect			27.	3 <sup>rd</sup> degree A-V block		
12. Symmo	etrical T-wave inversions	s 🗆		28.	LBB block		
13. Poor R	-wave progression			29.	RBB block		
14. Other r	nonspecific ST/T			30.	Pre-excitation syndrome		
15. Sinus t	achycardia			31.	Other intraventricular condition	n 🗆	
16. Sinus b	oradycardia			32.	Other, specify		
C. Ventrice	ular rate (bpm)			E.	QRS (ms)		
D. PR (ms	;)			F.	QTC (ms)		
	here any abnorma ontinuation in the			ove	that preclude the subjection ☐ Yes ☐ No	ct from	safe entry

## Form 13 - ELECTROCARDIOGRAM

	Site ID:	Subject ID #.	Subject Initials	Unscheduled 2 Week
Date:				
Comments	(mm/dd/yyyy) s:			